I, Dr. Elizabete Stahl, as Medical Director of the Federal Bureau of Prisons, certify under penalty of perjury that the enclosed documents are originals, or copies thereof, from the records of the U.S. Federal Bureau of Prisons. The enclosed index and documents constitute the administrative record to be filed in *Kingdom v. Trump, et al.*, U.S. District Court for the District of Columbia, Case No. 1:25-cv-00691 (D.D.C.)

The attached index is a true and accurate list of the contents of the administrative record for the development of the February 19, 2026, policy implemented by the Federal Bureau of Prisons to comply with the following:

(i) Section 4(c) of Executive Order 14168, "Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government" (the "Executive Order"), signed by President Trump on January 20, 2025, which directed the Federal Bureau of Prisons to revise its policies concerning medical care to be consistent with the Executive Order and ensure that no Federal funds are expended for any medical procedure, treatment, or drug for the purpose of conforming an inmate's appearance to that of the opposite sex.

Sincerely,

ELIZABETE STAHL Digitally signed by ELIZABETE STAHL
Date: 2026.03.12 15:22:41 -04'00'

Federal Bureau of Prisons

Dated: 03/12/2026

Index of Administrative Record
Kingdom v. Trump, et al.,
Civil Action No. 1:25-cv-00691-RCL
U.S. District Court for the District of Columbia

A. Compliance with Section 4(c) of Executive Order 14168

Date	Document Type	Description	Bates Number
		Administrative Record Summary	AR-000001-AR-000004
		Memorandum on Program Statement 5260.01, Management of Inmates with Gender Dysphoria (Feb. 19, 2026)	AR-000005-AR-000047
04/10/2024	Study	The Cass Review, Independent Review of Gender Identity Services for Children and Young People	AR-000048 - AR-000435
9/1/2009	Clinical Guideline	The Endocrine Society's Clinical Guidelines. Endocrine Treatment of Transsexual Persons.	AR-000436-AR-000468
8/27/2012	Standards of Care	World Professional Association for Transgender Health: Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People.	AR-000469-AR-000588
3/17/2025	Exhibit	Declaration of Dr. Cathy Thompson	AR-000589-AR-000683
6/17/2017	Clinical Guidelines	University of California, San Francisco Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People.	AR-000684-AR-000882
8/24/2017	Clinical Guidelines	Endocrine Society Clinical Practice Guideline: Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons.	AR-000883-AR-000917
12/1/2016	Clinical Guidance	Federal Bureau of Prisons Medical Management of Transgender Inmates. Clinical Guidance	AR-000918-AR-000957

Date	Document Type	Description	Bates Number
5/17/2024	Journal Article	World Professional Association for Transgender Health, WPATH and USPATH Comment on the Cass Review.	AR-000958-AR-000960
06//27/2024	Journal Article	The Economist: Research into trans medicine has been manipulated. https://www.economist.com/united-states/2024/06/27/research-into-trans-medicine-has-been-manipulated	AR-000961 AR-000964
11/12/2025	Medical Resource	Coalition of Correctional Healthcare Authorities (CCHA), Correctional Health Policy Priorities.	AR-000965
6/11/2024	Journal Article	Risk of Suicide and Self-Harm Following Gender-Affirmation Surgery.	AR-000966 AR-000974
11/28/2024	Journal Article	Defining a danger zone for iatrogenic long thoracic nerve injury in gender-affirming mastectomy.	AR-000975-AR-000986
2/4/2025	Study	Examining gender-specific mental health risks after gender-affirming surgery: a national database study.	AR-000987-AR-000993
9/10/2021	Study	Thematic Analysis of Lived Experience in Patients With Adult Acquired Buried Penis.	AR-000994 AR-000995
9/6/2023	Study	Gender-affirming treatment and mental health diagnoses in Danish transgender persons: a nationwide register-based cohort study.	AR-000996-AR-001006
11/13/2017	Study	Cohort profile: Study of Transition, Outcomes and Gender (STRONG) to assess health status of transgender people.	AR-001007-AR-001019
11/19/2025	Study	Treatment for pediatric gender dysphoria: Review of evidence and best practices. U.S. Department of Health and Human Services.	AR-001020-AR-001429
4/1/2017	Study	Varied reports of adult transgender suicidality: Synthesizing and describing the peer-reviewed and gray literature.	AR-001430-AR-001445

Date	Document Type	Description	Bates Number
6/1/2023	Journal Article	Gender-affirming care, incarceration, and the Eighth Amendment.	AR-001446-AR-001452
5/1/2025	New Article	AAP speaks out against HHS report on gender dysphoria, medical organizations' statements	AR-001453-AR-001454
9/1/2025	Medical Manual	Diagnostic and statistical manual of mental disorders (5-TR).	AR-001455-AR-001464
12/1/2015	Clinical Guidelines	Guidelines for psychological practice with transgender and gender nonconforming people.	AR-001465-AR-001497
1/1/2017	Code of Conduct	Ethical principles of psychologists and code of conduct	AR-001498-AR-001539
2/1/2024	Policy Statement	APA policy statement on affirming evidence-based inclusive care for transgender, gender-diverse, and nonbinary individuals, addressing misinformation, and the role of psychological practice and science.	AR-001540-AR-001543
9/23/2022	Journal Article	Gender dysphoria and its non-surgical and surgical treatments.	AR-001544-AR-001551
4/1/2021	Study	Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review.	AR-001552-AR-001567
11/6/2023	Study	Gender differences in risks of suicide and suicidal behaviors in the USA: A Narrative Review.	AR-001568-AR-001586
9/15/2022	Standard of Care	Standards of care for the health of transgender and gender diverse people, version 8.	AR-001587-AR-001844
11/26/2014	BOP Policy	Transgender Clinical Care Consultant Team	AR-001845-AR-001846

Date	Document Type	Description	Bates Number
11/01/2014	BOP Policy	BOP Transgender resource guide	AR-001847-AR-001856
12/1/2016	BOP Policy	BOP Medical Management of Transgender Inmates	AR-001857-AR-001896
5/3/2018	Journal Article	Suicidal ideation and suicide attempts in persons with gender dysphoria.	AR-001897-AR-001902
9/1/2021	Study	Fact Sheet: Suicide Risk and Prevention for Transgender People: Summary of Research Findings.	AR-001903-AR-001905
9/20/2019	Journal Article	Deficiencies in scientific evidence for medical management of gender dysphoria.	AR-001906-AR-001914
3/20/2023	Study	Suicide-related outcomes following gender-affirming treatment: A review.	AR-001915-AR-001930
5/2/2025	News Article	Researchers slam HHS report on gender-affirming care for youth.	AR-001931-AR-001936
8/19/2024	Study	Discontinuing hormonal gender reassignment: A nationwide register study.	AR-001937-AR-001945
8/5/2023	Journal Article	Prevalence of suicidal thoughts and attempts in the transgender population of the world: A systematic review and meta-analysis.	AR-001946-AR-001959
10/03/2002	Report	World report on violence and health. World Health Organization.	AR-001960-AR-002319
7/1/2022	Study	Health care experiences of patients discontinuing or reversing prior gender-affirming treatments.	AR-002320-AR-002330

Date	Document Type	Description	Bates Number
11/1/2022	Report	SB 132 the Transgender Respect, Agency, and Dignity Act implementation review report.	AR-002331-AR-002367
10/1/2022	Resource Guide	Resource guide to improve safety in carceral housing for transgender people.	AR-002368-AR-002501
9/1/2020	Report	OIG special report: The California Department of Corrections and Rehabilitation has taken thoughtful and important steps to address the difficult conditions of confinement for incarcerated transgender, nonbinary, and intersex individuals.	AR-002502-AR-002588
2/1/2024	Journal Article	The public health crisis state of transgender health care and policy.	AR-002589-AR-002591
8/18/2022	Journal Article	Continuation of gender-affirming hormones among transgender adolescents and adults.	AR-002592-AR-002598
9/19/2025	Declaration	Declaration of Kristopher E. Kaliebe, M.D.	AR-002599-AR-002673
6/4/2024	Journal Article	The present state of housing and treatment of transgender incarcerated persons.	AR-002674-AR-002683
3/12/2020	Journal Article	Trends in suicide death risk in transgender people: Results from the Amsterdam Cohort of Gender Dysphoria study	AR-002684-AR-002689
11/19/2025	Study	HHS Releases Peer-Reviewed Report Discrediting Pediatric Sex-Rejecting Procedures	AR-002690-AR-002693
7/16/2016	Journal Article	A case report of first-onset psychosis in transgendered female, Gynecological Endocrinology	AR-002694-AR-002697

Date	Document Type	Description	Bates Number
5/1/2010	Journal Article	Tapering vs. Cold Turkey: Symptoms vs. Successful Discontinuation of Menopausal Hormone Therapy.	AR-002698-AR-0026700
8/1/2018	Journal Article	The Perioperative Care of the Transgender Patient	AR-002701-AR-002718
8/4/2016	Journal Article	The effect of cross-sex hormonal treatment on gender dysphoria individuals' mental health: a systematic review	AR-002719-AR-002732
5/1/2021	News Article	Reducing Transgender Surgery Side Effects, Endocrine Society	AR-002733-AR-002736
7/26/2005	Journal Article	Patient-Reported Complications and Functional Outcomes of Male-to-Female Sex Reassignment Surgery	AR-002737-AR-002748
10/7/2015	Journal Article	Treatment of Symptoms of the Menopause: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism	AR-002749-AR-002785
1/17/2023	Journal Article	Timing of testosterone discontinuation and assisted reproductive technology outcomes in transgender patients: a cohort study	AR-002786-AR-002791
10/30/2024	Journal Article	Dispute arises over World Professional Association for Transgender health's involvement in WHO's trans health guideline	AR-002792-AR-002795
3/7/2002	Journal Article	Hierarchy of evidence: a framework for ranking evidence evaluating healthcare interventions.	AR-002796-AR-002803
1/1/2015	Journal Article	Gender Dysphoria: Definition and Evolution Through the Years.	AR-002804-AR-002816
9/15/2023	News Article	Randomized controlled trials are the 'gold standard' of research—but a difficult fit for trans care	AR-002817-AR-002821

Date	Document Type	Description	Bates Number
12/13/2024	News Article	Several countries have restricted the use of puberty blockers, citing insufficient evidence on their benefits for gender-questioning youth and potential long-term effects.	AR-002822-AR-002828
8/29/2016	Journal Article	Cross-sex hormone therapy in transgender persons affects total body weight, body fat and lean body mass: a meta-analysis.	AR-002829-AR-002839
6/1/2003	Journal Article	Weighing risks and benefits in treating the individual patient. Clinics in Perinatology	AR-002840-AR-002851
3/19/2021	Journal Article	Standardization vs customization: finding the right balance. Annals of Family Medicine	AR-002852-AR-002858
3/15/2020	Medical Study	Effects of gender-affirming hormone therapy on insulin resistance and body composition in transgender individuals: A systematic review.	AR-002859-AR-002871
1/9/2024	Medical Study	Hormone therapy and cancer risks in transgender people: a systematic review.	AR-002872-AR-002884
2/8/2023	Journal Article	The effect of gender-affirming hormones on gender dysphoria, quality of life, and psychological functioning in transgender individuals:	AR-002885-AR-002900
2/1/2024	Medical Study	Cardiovascular disease in transgender people: a systematic review and meta-analysis.	AR-002901-AR-002912
1/13/2016	Medical Study	A systematic review of the effects of hormone therapy on psychological functioning and quality of life in transgender individuals.	AR-002913-AR-2923
2/1/2011	Article	Self-directed violence surveillance: Uniform definitions and recommended data elements, version 1.0.	AR-002924-AR-003019
4/1/2018	Article	Correctional Policy and Attempted Suicide Among Transgender Individuals	AR-003020-AR-003031

Date	Document Type	Description	Bates Number
2/22/2011	Article	Long-term Follow-up of Persons Undergoing Sex Reassignment Surgery	AR-003032-AR-003039
5/1/2015	Care Guide	California Correctional Health Services Care Guide Gender Dysphoria	AR-003040 AR-003051
10/1/2025	Care Guide	California Correctional Health Care Services Care Guide on Transgender	AR-003052-AR-003091
1/31/2023	Policy	Minnesota Department of Corrections Management and Placement of Incarcerated People Who Are Transgender, Gender Diverse, Intersex, or Nonbinary	AR-003092-AR-003100
5/20/2020	Policy	Kentucky Corrections Policies and Procedures: Lesbian, Gay, Bisexual, Transgender, and Intersex	AR-003101-AR-003110
12/21/2022	Policy	Oklahoma Department of Corrections Determination and Management of Inmates with Gender Dysphoria	AR-003111-AR-003117
09/30/2024	Policy	Florida Department of Corrections Office of Health Services. Bulletin 15.05.23. Mental Health Treatment for Gender Dysphoria	AR-003118-AR-003125
2/18/2025	Policy	BOP Policy: Sexually Abusive Behavior Prevention	AR-003126-AR-003190
6/1/2023	Policy	California Correctional Health Care Services Referral for Consideration of Gender Affirming Surgery	AR-003191-AR-003193
3/17/2025	Exhibit	Declaration of Dr. Dan H. Karasic	AR-003194-AR-003244
4/4/2025	Exhibit	Second Declaration of Dr. Dan H. Karasic	AR-003245-AR-003251

ADMINISTRATIVE RECORD

The goal of the Bureau of Prisons (BOP) is to deliver medically necessary health care to inmates effectively in accordance with proven standards of care without compromising public safety concerns inherent to BOP's overall mission. *See* Program Statement 6010.05.

BOP's clinical guidance is aimed to reflect the evolving nature of treatment, based on what is considered the "community standard," while translating it to a carceral environment. No single source is used in writing clinical guidance. Robust clinical guidance is ideally built on high-quality research, such as randomized controlled trials, systematic reviews, and well-designed observational studies. But not every diagnostic tool, condition, or treatment plan is well understood. Medical providers are therefore reliant on expert opinions, peer reviewed sources, and medical societies or organizations. As this administrative record will show, treatment of gender dysphoria is an evolving science; involves a field of medicine that is continuously shaped by advances in psychology, ethics, and public health; and implicates sensitive safety, security, and prison-administration concerns.

BOP is tasked with providing essential medical, dental, and mental health (psychiatric) services in a manner consistent with accepted community standards that are supported by reliable evidence for a correctional environment. Providing medically necessary care, which is informed by the community standard of care as translated into the carceral setting, is an important tenet of correctional health care and must be viewed in light of the correctional environment's unique safety, security, and administration concerns. But within this context, challenges exist in defining appropriate clinical guidance for patients who are diagnosed with gender dysphoria in a carceral setting.

On January 20, 2025, President Trump issued Executive Order 14,168, *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, 90 Fed. Reg. 8, 615 (Jan. 30, 2025). Section 4(c) of the Executive Order provided, "The Attorney General shall ensure that the Bureau of Prisons (BOP) revises its policies concerning medical care to be consistent with this order and shall ensure that no Federal funds are expended for any medical procedure, treatment, or drug for the purpose of conforming an inmate's appearance to that of the opposite sex." "This Order shall be implemented consistent with applicable law[.]" *Id.* § 8(b).

In evaluating its medical policies, BOP considered the relevant issues, factors, information, and sources, including conducting extensive reviews of existing research, medical expert opinions, medical journals, national media reports, recent medical studies, state correctional policies, BOP's prior policies, and pertinent case law.

As a result of this research and as further explained in the accompanying memorandum to the Administrative Record, BOP has revised its policy to reflect treatment for gender dysphoria that is more aligned with the latest scientific information and consistent with BOP's longstanding policy of providing medical care that is tailored to the unique needs of the inmate. *See* Program Statement 5260.01, *Management of Inmates with Gender Dysphoria*, Federal Bureau of Prisons (Feb. 19, 2026). For example, BOP's reviews found, based on the best reliance evidence, that

providing hormones to inmates diagnosed with gender dysphoria is generally not medically necessary to address gender dysphoria. The reliable evidence base for the care of gender dysphoria with hormone interventions is limited. Existing studies are small in sample size, short in duration, observational rather than randomized, and focused on narrowly defined populations. For all these reasons, it is not possible to draw evidence-based conclusions about long-term outcomes of hormone use in persons diagnosed with gender dysphoria while there is well documented side effects and downsides flowing from hormone use. Providing hormone interventions in a carceral setting is further complicated because of heightened security risks and other prison-administration concerns. It is therefore appropriate to focus treatment for gender dysphoria in a carceral setting on non-hormone modalities that generally are available to those in the custody of the BOP, such as psychotherapy. Further, the tapering of hormones for inmates currently receiving hormone therapy is feasible if performed through the appropriate process and closely monitored by health and mental health providers, as required by Program Statement 5260.01.

Providing inmates with hormones to address gender dysphoria creates safety, security, and prison-administration concerns for both the inmate receiving hormones and for correctional staff. For example, the physical changes that may occur as a result of cross-sex hormones, such as the growth of breasts and the feminization of their faces and voices, increases the risk of victimization by other inmates. BOP incarcerates sexual predators and other violent individuals who have a tendency to prey upon inmates who appear feminine, including due to hormones or social accommodations, requiring BOP staff to devote more attention and time to keeping these inmates safe. For instance, BOP staff spend a significant amount of time ensuring these inmates have appropriate cellmates and often use additional resources managing these inmates in protective custody. Staff members' personal safety is also at an increased risk when they must intervene to stop fights between inmates or predatory behavior.

Similarly, providing or allowing access to social accommodations to some inmates and not to others causes animosity between inmates, which creates additional safety, security, and prison-administration concerns. Inmates who do not receive social accommodations may feel resentful for not being able to receive additional items from the commissary. Historically, providing certain items to one group of inmates and not another creates conflict within BOP facilities. Further, allowing inmates to use social accommodations, such as wearing makeup and feminine undergarments, increases the risk that those inmates will be targeted. Allowing inmates to have these social accommodations also requires BOP staff to spend more time and resources ensuring the safety of these inmates. Finally, providing social accommodations increases the risk of inmates concealing contraband and escaping from facilities and can hinder investigation of intra-prison incidents.

Finally, inmates have also threatened self-harm and suicide to obtain sex trait modification interventions, such as hormones and social accommodations. The availability of cross-sex hormones and social accommodations can create improper incentives for inmates to harm themselves.

Providing sex trait modification surgeries also jeopardizes the safety, security, and administration of BOP facilities because inmates receiving these surgeries are at higher risk of harassment due to their appearance. This increased risk results in BOP expending additional time and resources to

ensure the protection of these inmates. Transferring such inmates to opposite-sex facilities is not an acceptable way to mitigate these safety, security, and prison-administration concerns as it would then create security, safety, and privacy issues for the inmates of the opposite sex. For example, the presence of a male in close quarters with female inmates may harm the emotional and physical well-being of some female inmates, particularly those who have suffered from sexual abuse.

Based on a review of the practice of housing males in female facilities, BOP has decided to discontinue this practice. The previous practice potentially increases the risk of violence and sexual assault for women housed in the female facilities. Housing female inmates with men also compromises the female inmates' privacy. This is especially true when women are forced to sleep and shower in spaces with men.

Research of State Policies

Florida
Florida Department of Corrections Office of Health Services, Bulletin No. 15.05.23 titled Mental Health Treatment of Inmates with Gender Dysphoria.

California
- California Correctional Health Care Services, Care Guide on Gender Dysphoria. (2015)
- California Correctional Health Care Services Referral for Consideration of Gender Affirming Surgery. (2023)
- California Correctional Health Care Services, Care Guide on Transgender (2025)

Kentucky
Kentucky Corrections Policies and Procedures on Lesbian, Gay, Bisexual, Transgender and Intersex Offenders.

Oklahoma
Oklahoma Department of Corrections Policies on Determination and Management of Inmates with Gender Dysphoria.

Minnesota
Department of Corrections Management and Placement of Incarcerated People Who are Transgender, Gender Diverse, Intersex, or Nonbinary

Review of Case Studies

As further explained in the accompanying memorandum to the Administrative Record, the study of gender dysphoria in the carceral community is relatively new, which hampers the ability to reference a community standard of care. Compared with other illnesses or conditions, Gender dysphoria has had a newer, more rapidly evolving clinical landscape (Fraser, L., 2015). A recent and swift evolution of community clinical guidance makes it more difficult to determine where the standard of care currently lies. For example, the World Professional Association for Transgender Health's (WPATH) initial guidance recommended as recently as 1990 a treatment model for gender dysphoria with strict eligibility requirements for diagnosis, evaluations from separate mental

health providers, and required psychotherapy. This stands in contrast with later versions of the WPATH guidance, which reduced or eliminated these requirements (Fraser, L., 2015 & Coleman, E., et al., 2022).

Moreover, recent investigations have called into question WPATH's current recommendations, making determining the community standard even more challenging (Block, J., 2024). Other nations such as Sweden, Denmark, France, and the United Kingdom have distanced themselves from the stance of U.S. organizations such as WPATH, particularly related to care of minors and young adults, due to concerns about the body of research and potential research bias, among other things (Galvin, G., 2024). The recent divergence in global recommendations on proper care for this population leads to challenges in determining a set community standard, especially in the carceral setting. Other leading community organizations are similarly reevaluating their clinical guidance for patients diagnosed with gender dysphoria, in light of recent information. For example, the University of California at San Francisco, long known for its clinical guidance in this area, is currently undergoing a revision of its recommendations for this population (UCSF, n.d.).

A 2020 systematic review of available studies "found insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition"—it concluded that "[t]he evidence is very incomplete, demonstrating a gap between current clinical practice and clinical research." Haupt et al., *Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women*, 11 Cochrane Database of Systematic Reviews, Art. No. CD013138, at 2, 11 (2020). Another systematic review of studies concluded that it was "impossible to draw conclusions about the effects of hormone therapy on death by suicide" because of the "low" "strength of evidence." Kellan E. Baker, et al., *Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review*, 5 J. Endocrine Soc. 1, 12-13 (2021).

BOP reviewed recent studies that indicated that there are significant risks accompanying hormone interventions used to address gender dysphoria. For example, evidence showed that males who are treated with estrogen have twenty-two times the likelihood to develop breast cancer. *See* Rakesh R. Gurrala et al., *The Impact of Exogenous Testosterone on Breast Cancer Risk in Transmasculine Individuals*, 90(1) Annals of Plastic Surgery 96 (2023).

BOP also concluded that hormone-based interventions for gender dysphoria are fraught with serious risks. There are non-surgical, non-hormone related interventions that have been shown to address gender dysphoria effectively—specifically, "[s]ocial support and psychotherapy are widely recognized approaches." *K.C. v. Individual Members of the Med. Licensing Bd. of Ind.*, 121 F.4th 604, 610-11 (7th Cir. 2024) (citing Danyon Anderson et al., *Gender Dysphoria and Its Non-Surgical and Surgical Treatments*, 10 Health Psych. Rsch., 4 (2022)).

For additional details and cites, please see attached memorandum.

Memorandum on Program Statement 5260.01, Management of Inmates with Gender Dysphoria (Feb. 19, 2026)

I. Introduction

On January 20, 2025, the President issued Executive Order 14,168, *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, 90 Fed. Reg. 8,615 (Jan. 30, 2025), which prohibited the Bureau of Prisons (BOP) from expending federal funds for "any medical procedure, treatment, or drug for the purpose of conforming an inmate's appearance to that of the opposite sex" "to the extent consistent with applicable law." *Id.* at 8,617-18. In light of Executive Order 14,168 and BOP's own independent judgment, BOP has reevaluated its policies regarding inmates and gender dysphoria.

BOP's general policy is to "deliver medically necessary health care to inmates effectively in accordance with proven standards of care without compromising public safety concerns inherent to the Bureau's overall mission." BOP Program Statement (PS) 6010.05 §1, Health Services Administration. Though BOP considers community standards of care, BOP must consider such standards in light of the unique nature of the carceral environment. In evaluating its policies on gender dysphoria, BOP considered the relevant issues, factors, information, and sources, including conducting extensive reviews of existing research, medical expert opinions, medical journals, national media reports, recent medical studies, state correctional policies, BOP's prior policies, and pertinent case law.

For example, BOP has considered the standards of care issued by the World Professional Association for Transgender Health (WPATH) and other organizations, such as the Endocrine Society. BOP has determined that WPATH's standards of care and other guidelines issued by similar organizations are not reliable or at a minimum, show that medical interventions to address gender dysphoria are highly controversial, medically disputed, and insufficiently proven by appropriate evidence. In addition, the recent debate regarding WPATH's standards and other organizations' guidelines support reevaluation of policies regarding gender dysphoria, particularly in the correctional context.

WPATH has recently been characterized as not "political neutral," *Gibson v. Collier*, 920 F.3d 212, 221 (5th Cir. 2019), and as an "advocacy organization," whose "lodestar is ideology, not science," *Eknes-Tucker v. Governor of Alabama*, 114 F.4th 1241, 1261 (11th Cir. 2024) (Lagoa, J., concurring); *see, e.g.*, *United States v. Skrmetti*, 605 U.S. 495, 543 (2025) (Thomas, J., concurring) ("Recent revelations suggest that WPATH, long considered a standard bearer in treating pediatric gender dysphoria, bases its guidance on insufficient evidence and allows politics to influence its medical conclusions." (citation omitted)); *Edmo v. Corizon, Inc.*, 949 F.3d 489, 497 (9th Cir. 2020) (O'Scannlain, J., opinion respecting the denial of reh'g en banc) ("The WPATH Standards are merely criteria promulgated by a controversial private organization with a declared point of view."); Expert Report of Kristopher E. Kaliebe, M.D., ¶63 (Sept. 19, 2025) (hereinafter "Kaliebe Decl.") ("WPATH's internal documents clearly show that WPATH is an advocacy organization and not a scientific one."); *Nondiscrimination in Health & Health Education Programs or Activities*, 85 Fed. Reg. 37,160, 37,186-98 (June 19, 2020) (calling WPATH "an advocacy group" and explaining that the U.S. Department of Health and Human

Services did not consider WPATH's guidelines to be based on "independent scientific fact-finding"); *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices*, U.S. Dep't Health and Human Services, 170 (Nov. 19, 2025) ("This combination of poorly managed COIs [conflicts of interests] and restrictive membership practices significantly undermines the credibility and scientific integrity of SOC-8 as a clinical practice guideline. The GDG's [guideline development group's] handling of … evidence WPATH commissioned for development of SOC-8 further highlights the serious threat to clinical integrity that plagued the guideline development process."); Executive Order 14,187, *Protecting Children from Chemical and Surgical Mutilation*, 90 Fed. Reg. 8,771, 8,771 (Feb. 3, 2025) (finding that WPATH "lacks scientific integrity"). And WPATH's standards have been described as being based on "self-referencing consensus rather than evidence-based research" and "built … on concededly weak evidence." *See, e.g.*, *Skrmetti*, 605 U.S. at 544 (Thomas, J., concurring) ("WPATH appears to rest [its conclusions] on self-referencing consensus rather than evidence-based research."); *id.* at 547 (WPATH and other "prominent medical professionals … have built their medical determinations on concededly weak evidence" and "have surreptitiously compromised their medical recommendations to achieve political ends."); *K.C. v. Individual Members of Med. Licensing Bd. of Indiana*, 121 F.4th 604, 611 (7th Cir. 2024) ("Some have expressed doubt about whether WPATH's guidelines actually reflect medical consensus as to treatments for gender dysphoria."); Kaliebe Decl. ¶¶60-82.

An expert has persuasively opined that "WPATH has violated many principles underpinning medical ethics and research and contributed to widespread publication bias in gender medicine," Kaliebe Decl. ¶63, and that "WPATH openly engages in ideologically-based political advocacy, systematically misrepresents evidence, and often bases its recommendations, no matter how impactful for the patient, on low-quality supporting evidence," Kaliebe Decl. ¶60. Countries that once looked to WPATH and other organizations in the United States have begun to backtrack and distance themselves from WPATH and these other organizations. *See, e.g.*, Gabriela Galvin, *The UK is the latest country to ban puberty blockers for trans kids. Why is Europe restricting them?*, Euro News (Dec. 13, 2024); *Skrmetti*, 605 U.S. at 537-38 (Thomas, J., concurring). Other organizations are similarly reevaluating their clinical guidance for patients suffering from gender dysphoria, in light of recent debate. For example, the University of California at San Francisco, known for its clinical guidance in this area, is currently undergoing a revision of its recommendations for this population. *See Gender Affirming Health Program*, University of California San Francisco, https://transcare.ucsf.edu/guidelines.

WPATH's standards are particularly unreliable when it comes to prisoners. *See, e.g.*, Kaliebe Decl. ¶60. WPATH recommended that sex-trait-modification interventions, including surgery, hormones, and social accommodations, should be provided to inmates in correctional facilities before a meaningful number of inmates had such interventions. *See, e.g.*, *Edmo*, 949 F.3d at 497-98 (O'Scannlain, J., opinion respecting the denial of reh'g en banc). In fact, when WPATH published the current version of the standards, a small number of inmates in the United States had ever received sex-trait-modification interventions, there were no reliable studies on such interventions in the correctional context, and WPATH failed to adequately consider or address the

special challenges of the inmate population. *See, e.g.*, *id.* (O'Scannlain, J., opinion respecting the denial of reh'g en banc); Kaliebe Decl. ¶79.

Guidelines from other organizations are similarly unpersuasive as WPATH's. The Endocrine Society, for example, has received similar criticism to WPATH. *See, e.g.*, *K.C.*, 121 F.4th at 611 ("But the most influential voices in this group have been two professional organizations—the Endocrine Society and the World Professional Association for Transgender Health…. But these organizations have not evaded criticism."); *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices*, U.S. Dep't Health and Human Services, 14 (Nov. 19, 2025). This is unsurprising given that WPATH and the Endocrine Society collaborated on their guidelines. *See* Kaliebe Decl. ¶74 ("the WPATH and Endocrine Society collaborated, meaning a very small, interconnected group of WPATH members led to the creation of multiple guidelines among multiple medical organizations"). And WPATH's guidelines have also influenced other organization guidelines, making those guidelines similarly unpersuasive. *See* Kaliebe Decl. ¶75 ("WPATH's unreliable and low-quality recommendations have infected other guidelines, causing a systematic distortion of clinical guidance.").

In sum, BOP does not find WPATH's or other organizations' similar standards or guidelines persuasive. *See* Kaliebe Decl. ¶60 ("WPATH and other affirmative guidelines regarding the care of people with Gender Dysphoria should neither be treated as authoritative nor be used to determine care for Gender Dysphoria."). If anything, recent discussions show that the appropriateness of sex-trait-modification interventions to address gender dysphoria is subject to "fierce scientific and policy debates about the[ir] safety, efficacy, and propriety," and filled with "sincere concerns" with "profound" implications, *Skrmetti*, 605 U.S. at 525; *see, e.g.*, *Gibson*, 920 F.3d at 221 ("the WPATH Standards of Care [and the guidelines of other organizations] reflect not consensus, but merely one side in a sharply contested medical debate"); *Haverkamp v. Linthicum*, 152 F.4th 618, 625 n.7 (5th Cir. 2025) (same); *Clark v. Valletta*, 157 F.4th 201, 206 (2d Cir. 2025) ("how to treat that disorder [*i.e.*, gender dysphoria] is not settled in the scientific and medical community"); *id.* at 216 ("as the record reflects, medical experts disagree about how to treat gender dysphoria").

For at least these reasons and the others discussed in this memorandum, it was prudent for BOP to reevaluate its policies regarding gender dysphoria, as those policies unreasonably relied on these organizations, these organizations' guidelines, and other biased sources regarding interventions to address gender dysphoria. After considering the relevant issues and factors and weighing the relevant considerations, BOP has revised its policy to reflect treatment for gender dysphoria that is more aligned with the latest scientific information, that is consistent with BOP's longstanding policy of providing medical care that is tailored to the unique needs of the inmate, and that accounts for the complex security and administration concerns in the correctional environment. *See* Program Statement 5260.01, *Management of Inmates with Gender Dysphoria*, Federal Bureau of Prisons (Feb. 19, 2026).

As further explained below, BOP has adopted Program Statement 5260.01. That policy requires an individualized treatment plan for each inmate that is diagnosed with gender dysphoria.

The individualized treatment plan may include psychotherapy, group counseling, psychiatric services, and psychotropic medications.

BOP will not provide sex trait modification surgeries to address gender dysphoria, but BOP will provide care necessary to address any complications or resulting conditions from such surgeries, such as urethral stricture and pelvic infections.

BOP will not provide social accommodations to address gender dysphoria and when practicable, will remove or confiscate social accommodations.

If an inmate is diagnosed with gender dysphoria but is not currently receiving hormones to address gender dysphoria, BOP will not provide hormones to address the inmate's gender dysphoria. If an inmate is previously and currently diagnosed with gender dysphoria and is currently receiving hormones to address gender dysphoria, BOP will develop a tapering plan for each inmate after consideration of appropriate factors. For inmates that have recently begun receiving hormones to address gender dysphoria, the tapering plan will include a rapid discontinuation of the hormone intervention. For inmates that have been receiving hormones to address gender dysphoria for an extended period of time, the tapering plan will generally include an appropriately paced discontinuation of the hormone intervention. For inmates who (1) are post sex trait modification surgery or (2) have been receiving hormones to address gender dysphoria for an extended period of time and develop severe physiological and psychological withdrawal effects from tapering, it may not be appropriate in all cases for the initial tapering plan to include cessation of hormones.

Nothing in Program Statement 5260.01 prevents a prison official from providing care required by federal law, including the Eighth Amendment to the U.S. Constitution. And under Program Statement 5260.01 and other BOP policies, BOP will ensure that all inmates diagnosed with gender dysphoria receive care in accordance with federal law, including the Eighth Amendment to the U.S. Constitution.

II. Program Statement 5260.01, Management of Inmates with Gender Dysphoria (Feb. 19, 2026)

A. Sex Trait Modification Surgeries

After considering the relevant issues and factors and weighing the relevant considerations, BOP adopts a policy prohibiting sex trait modification surgeries to address gender dysphoria, but for inmates who have had sex trait modification surgery, medical care will be provided as necessary to address any complications or resulting conditions, such as urethral stricture and pelvic infections. Sex trait modification surgeries are not medically necessary to address gender dysphoria. Sex trait modification surgeries are highly controversial, medically disputed, and unproven by appropriate evidence; or at the very least, there is reasonable debate about the efficacy of sex trait modification surgeries to address gender dysphoria. To the extent there is uncertainty about the efficacy of sex trait modification surgeries to address gender dysphoria, that uncertainty counsels against providing such controversial interventions when there are other more established treatments, such as psychotherapy, available. Even assuming sex trait modification surgeries are

medically necessary or appropriate to address gender dysphoria, BOP concludes that sex trait modification surgeries in the secure prison environment raise numerous security and prison-administration concerns, and each concern, whether considered separately, cumulatively, or in any combination, outweighs any costs from Program Statement 5260.01, any reliance interests, and any benefits from providing sex trait modification surgeries. In BOP's judgment, and after considering the relevant issues and factors and weighing the relevant considerations, prohibiting sex trait modification surgeries is reasonable and appropriate to provide adequate care to inmates diagnosed with gender dysphoria; is reasonable and appropriate to maintain internal order, discipline, and institutional security of the correctional environment; and outweighs any asserted benefit, costs, or interests from allowing sex trait modification surgeries.

1. Sex trait modification surgeries are not medically necessary to address gender dysphoria.

BOP's general policy is to "deliver medically necessary health care to inmates effectively in accordance with proven standards of care without compromising public safety concerns inherent to the Bureau's overall mission." PS 6010.05 §1, Health Services Administration. BOP also provides inmates with gender dysphoria care to address the condition, including individualized treatment plans that may include psychotherapy, group counseling, psychiatric services, and psychotropic medications.

After considering the relevant issues and factors and weighing the relevant considerations, BOP concludes that sex trait modification surgeries are not medically necessary to address gender dysphoria, especially in the correctional context. Sex trait modification surgeries are highly controversial, medically disputed, and unproven by appropriate evidence. Medical professionals, at the very least, reasonably disagree on the efficacy of sex trait modification surgeries to address gender dysphoria, particularly in the correctional context. Sex trait modification surgeries are not "medically necessary" or "in accordance with proven standards of care." PS 6010.05 §1, Health Services Administration. It is reasonable for BOP to not provide medically disputed or insufficiently proven interventions to inmates, especially when those interventions may result in irreversible effects or harms.

Medical professionals have persuasively explained that sex trait modification surgeries are not medically necessary. *See, e.g.*, Kaliebe Decl. ¶21 ("Cross-sex surgeries are not medically necessary and should not be made available in correctional environments."); *id.* ¶155 (same); *id.* ¶118 ("Cross-sex surgeries have not been shown to be medically necessary."). At the very least, sex trait modification surgeries are highly controversial and subject to reasonable medical disagreement. *See, e.g.*, *Gibson*, 920 F.3d at 216 ("For it is indisputable that the necessity and efficacy of sex reassignment surgery is a matter of significant disagreement within the medical community."); *id.* at 221 ("sex reassignment surgery is medically controversial"); *id.* at 226 ("sex reassignment surgery remains an issue of deep division among medical experts"); *id.* ("the undisputed medical controversy over sex reassignment surgery"); *Haverkamp*, 152 F.4th at 625 ("there remains 'significant disagreement within the medical community' about whether sex-reassignment surgery is an 'effective treatment for gender dysphoria'"); *Kosilek v. Spencer*, 774 F.3d 63 (1st Cir. 2014) (en banc). There is little (if any) reliable evidence showing that sex trait

modification surgeries treat gender dysphoria. *See, e.g.*, Kaliebe Decl. ¶¶118-30. In any event, there is no reliable evidence showing that sex trait modification surgeries treat gender dysphoria in the correctional environment. *See, e.g.*, Kaliebe Decl. ¶118 ("These surgeries have substantial risks, and there is little, if any, reliable data supporting that such surgeries cause meaningful long-term benefits in improving mental health or reducing suicide risks. This is particularly true in prison settings. Indeed, there are no controlled studies, high-quality evidence, or reliable evidence on sex-trait modification, such as through cross-sex surgery, of inmates with Gender Dysphoria in the carceral setting."). Sex trait modification surgery can prolong symptoms of gender dysphoria, undermine other treatments to address gender dysphoria, worsen symptoms of gender dysphoria, and cause other physical and psychological harms. *See, e.g.*, Kaliebe Decl. ¶¶118-30; *id.* ¶129 ("Cross-sex surgeries can have serious complications, some of which are lifelong…."); *id.* ¶130 ("As such, with the known harms to healthy tissue, potential increased risk of psychiatric decompensation, technical issues such as wound care, potential surgical complications, potential life-long health complications, and unclear mental health benefits, cross-sex surgeries within the correctional environment are not medical necessary."). To the extent that sex trait modification surgeries might have short-term benefits to addressing gender dysphoria in the correctional context, they are outweighed by the potential long-term harm. *See, e.g.*, Kaliebe Decl. ¶¶118-30. In any event, BOP determines that it is reasonable to not provide sex trait modification surgeries given the uncertainty in long-term benefit and its potential irreversibility.

Even if there is some reliable evidence that sex trait modification surgeries address gender dysphoria when the individual is in society at large, the evidence does not sufficiently support that sex trait modification surgeries address gender dysphoria in the correctional environment. What a person may want or need to address gender dysphoria outside prison says little (if anything) about what that person should have access to in a secure prison environment. *See, e.g.*, Kaliebe Decl. ¶142 ("The concept of social transitioning through social accommodations, hormones, or surgery is out of place in the correctional context because an inmate does not live in society at large but a secure prison environment."); *id.* ¶118. That is especially true given that inmates often present unique backgrounds not readily present in individuals in society at large. *See, e.g.*, Kaliebe Decl. ¶¶127, 141-43.

Again, BOP provides inmates with gender dysphoria with individualized treatment plans with well-established treatment methods for gender dysphoria, such as psychotherapy, group counseling, psychiatric services, and psychotropic medications. Sex trait modification surgeries are not medically necessary or at a minimum, there is reasonable disagreement as to their efficacy, such that it is reasonable for BOP to not provide the intervention. In BOP's judgment, it is reasonable and appropriate to provide these individual treatment plans without the prospect of providing or allowing access to sex trait modification surgeries to address gender dysphoria.

2. Security and prison-administration concerns support Program Statement 5260.01's prohibition on sex trait modification surgeries.

BOP's general policy is to "deliver medically necessary health care to inmates effectively in accordance with proven standards of care *without compromising public safety concerns inherent to the Bureau's overall mission*." PS 6010.05 §1, Health Services Administration (emphasis

added). BOP is responsible for "the safekeeping, care, and subsistence of all persons charged with or convicted of offenses against the United States." 18 U.S.C. §4042(a). Providing sex trait modification surgeries to inmates, including to address gender dysphoria, raises serious security and prison-administration concerns. These security and prison-administration concerns independently support BOP's adoption of a prohibition on providing inmates sex trait modification surgeries to address gender dysphoria. The security and prison-administration concerns, when considered separately, cumulatively, or in any combination, outweigh the benefits (medical or otherwise) from providing sex trait modification surgeries. Thus, even if sex trait modification surgeries address gender dysphoria, BOP, after considering the relevant issues and factors and weighing the relevant considerations, determines that it is reasonable and appropriate to not provide or allow access to sex trait modification surgeries to address gender dysphoria.

Sex trait modification surgeries jeopardize the security, safety, and prison administration of correctional facilities in at least three ways. First, the inmate receiving sex trait modification surgery will experience increased risk of the inmate becoming a target for attacks, which increases harm to the targeted inmate and the prison officials tasked with protecting the inmate. Second, special treatments, such as providing or allowing access to sex trait modification surgeries to address gender dysphoria, raise fairness concerns and can breed resentment among other inmates, which can lead to violence. Third, granting sex trait modification surgeries conflicts with a reasonable practice of refusing to reward threats of self-harm and may even increase self-harm. Each of BOP's security and prison-administration concerns, whether considered cumulatively, separately, or in any combination, outweighs any asserted benefits from providing or allowing access to sex trait modification surgeries to address gender dysphoria.

First, prohibiting sex trait modification surgeries reduces the chance of an inmate being targeted by other inmates. "Recognizing that reasonable concerns would arise regarding a post-operative, male-to-female transsexual being housed with male prisoners takes no great stretch of the imagination." *Kosilek*, 774 F.3d at 93. The inmate would inevitably become a target for abuse in the male facility. *Cf., e.g.*, *Keohane v. Fla. Dep't of Corr. Sec'y*, 952 F.3d 1257, 1275 (11th Cir. 2020) (noting the "obvious[]" consequence of permitting a male inmate to dress and be groomed as a female "would inevitably become a target for abuse in an all-male prison"). And based on BOP's experience and expertise, these same concerns also apply to women's correctional facilities, which also experience meaningful amounts of harassment and violence. *See, e.g.*, Emily Buehler, *Substantiated Incidents of Sexual Victimization Reported by Adult Correctional Authorities*, 2016-2018, U.S. Dep't of Justice, 18 (2023) (noting that 31% of the recorded incidents of inmate-on-inmate sexual harassment occurred in female correctional facilities).

Sex trait modification surgeries not only put the inmate at additional risk of assault or harassment but also endanger "the prison employees who would have to step in to protect" the inmate and will require expending already limited resources to address these risks. *Keohane*, 952 F.3d at 1263. Preventing such attacks would require prison officials to be more vigilant in protecting the inmates from assault or harassment, despite BOP's limited resources.

It is insufficient to point to transfer to mitigate these security and prison-administration complications from sex trait modification surgeries. For example, a transfer of a post-operative

male to a female facility will increase the risk of harm of female inmates. *See* Kaliebe Decl. ¶139 ("[H]ighly relevant is the fact that the presence of a biological male in close quarters in a female prison could significantly harm the emotional and physical well-being of certain female prisoners, such as female victims of sexual abuse. This concern is particularly acute since female prisoners suffer from extremely high rates of sexual trauma. Placing these vulnerable female inmates with biological males could have meaningful negative effects on female inmates."); *see also, e.g.*, *Cruel and Unusual Punishment: Stopping the Dangerous Policies Putting Men in Women's Prisons*, Independent Women's Forum (Dec. 20, 2024). And based on BOP's experience and expertise, similar concerns exist for transfer of a female inmate to a male facility, as the female inmate would be a target by other male prisoners and implicate the privacy interests of male inmates.

Second, based on BOP's experience and expertise, fairness concerns counsel against providing or allowing access to sex trait modification surgeries. When inmates receive special treatment within a correctional environment, other inmates may begin to resent those receiving special treatment, which can increase the risk of retaliation against the inmate receiving special treatment and cause ripple effects throughout the correctional institution and disrupting the delicate prison environment. Fairness concerns are particularly present if such special treatment is provided to one type of facilities (*e.g.*, female facilities) and not another (*e.g.*, male facilities).

Finally, BOP has considered the issue of self-harm and has determined that a policy prohibiting sex trait modification surgeries avoids rewarding threats of self-harm and may reduce overall self-harm. Inmates frequently use threats of self-harm and suicide to try to obtain concessions from prison officials. *See, e.g.*, Kaliebe Decl. ¶148 ("In my experience working in correctional facilities and treating adult and juvenile inmates, including those diagnosed with Gender Dysphoria, inmates frequently use threats of self-harm and suicide to try to obtain concessions from prison officials."); *Kosilek*, 774 F.3d at 94 ("Such threats are not uncommon in prison settings …."). But providing sex trait modification surgeries, especially in response to threats of self-harm or suicide, could increase self-harm. *See, e.g.*, Kaliebe Decl. ¶149 ("In corrections, rewarding self-injury or threats of self-injury tends to increase overall self-harm, both for the individual patient and also within the system."). Granting such requests may establish an "unacceptable precedent," forcing "prison authorities to comply with the prisoners' particular demands." *Kosilek*, 774 F.3d at 94. Consequently, it is reasonable for prison administrators to have rules against providing inmates benefits in response to self-harm or suicide to discourage threats. *See* Kaliebe Decl. ¶150 ("Simple and clear institutional policies, such as no social transitions or no initiation of new hormone treatments, are likely to lead to the lowest level of self-harm and the least overall harm to inmates because when prisoners know the interventions they desire are not available, they are less likely to self-harm to obtain them. In other words, it is reasonable for prison administrators to have outright prohibitions of providing inmates benefits, such as unproven surgeries, special-order items, and housing placements, in response to self-harm or suicide threats to discourage false threats."); *Kosilek*, 774 F.3d at 94 (noting that such threats must be "firm[ly] reject[ed] by the authorities, who must be given ample discretion in the dealing with such situations"). BOP determines that a clear rule against sex trait modification surgeries is the most reasonable way to handle this complex issue. BOP takes threats of self-harm seriously and has protocols in place to handle these complex situations.

After considering the relevant issues and factors and weighing the relevant considerations, BOP determines that each of its security and prison-administration concerns, whether considered separately, cumulatively, or in any combination, outweighs any asserted benefits of providing sex trait modification surgeries. In addition, after considering the relevant issues and factors and weighing the relevant considerations, BOP determines that the medical concerns discussed above when considered with any of its security or prison-administration concerns—separately, cumulatively, or in any combination—outweighs any asserted benefits of providing sex trait modification surgeries.

3. Other considerations do not outweigh the benefits from Program Statement 5260.01.

a. Reliance Interests and Costs

BOP has also considered potential reliance interests, but the potential reliance interests are either illegitimate or outweighed by the benefits of Program Statement 5260.01. Indeed, after considering the relevant issues and factors and weighing the relevant considerations, BOP determines that each of its medical, security, and prison-administration concerns, whether considered separately, cumulatively, or in any combination, outweighs the asserted benefits, interests, or costs of providing or allowing access to sex trait modification surgeries.

As an initial matter, the policy prohibits future sex trait modification surgeries, and an inmate has no reasonable reliance interest in the future possibility of obtaining such surgeries. That is all the more true if sex trait modification surgeries are not medically necessary or in accordance with proven standards of care.

Even if an inmate has a currently scheduled sex trait modification surgery, the inmate still does not have legitimate reliance interests. Sex trait modification surgeries are not medically necessary or in accordance with proven standards of care. An inmate has no legitimate reliance interest in an unproven surgical intervention. Nor does an inmate have a legitimate reliance interest in a surgical intervention that is, at a minimum, subject to reasonable debate in the medical community.

In any event, even if the prospect of sex trait modification surgeries created legitimate reliance interests, the interests are not weighty. Providing sex trait modification surgeries has not been a longstanding, formal policy of BOP, and access to medical interventions has always been subject to security concerns. *See, e.g.*, PS 6010.05 §1, Health Services Administration; PS 5538.08, Escorted Trips. Further, the policy has always been subject to change, including based on security and prison-administration concerns. And the reliance interests are even smaller given, again, that sex trait modification surgeries are not medically necessary, unproven, or medically disputed.

Moreover, implementing Program Statement 5260.01 will incur, at most, *de minimis* costs and will likely lead to savings. Program Statement 5260.01 will mitigate security and prison-administration concerns, which will reduce costs. Program Statement 5260.01 will also reduce expenditures on medical interventions that are not medically necessary or are medically disputed and on medical procedures to address potential complications from sex trait modification surgeries.

Expenditures on care for inmates diagnosed with gender dysphoria are unlikely to meaningfully increase. In general, BOP officials would monitor an inmate diagnosed with gender dysphoria and provide the patient with an individualized treatment plan, which would generally have care in addition to the provision of surgery. To the extent that Program Statement 5260.01 would result in increased costs, it is outweighed by other considerations or the savings from the unavailability of sex trait modification surgeries.

In sum, after considering the relevant issues and factors and weighing the relevant considerations, BOP determines that each of its medical, security, and prison-administration concerns, whether considered separately, cumulatively, or in any combination, significantly outweigh any costs, any reliance interests created by a former policy of providing or allowing access to sex trait modification surgeries, and any benefits from providing or allowing access to sex trait modification surgeries. In BOP's judgment and after considering the relevant issues and factors and weighing the relevant considerations, BOP determines that prohibiting sex trait modification surgeries is reasonable and in the best interest of the agency, its officials, and those in its custody.

b. Alternatives

BOP has considered alternatives and has determined that Program Statement 5260.01 is more reasonable than and preferable to potential alternatives.

For example, BOP has considered the option of allowing sex trait modification surgeries only for inmates that have already undergone a different sex trait modification surgery. Although Program Statement 5260.01 permits procedures to address complications with past sex trait modification surgeries, BOP does not think it is prudent to allow further surgeries that do not address complications of past surgeries. Sex trait modification surgeries are not medically necessary, are unproven, or are medically controversial; can harm the inmate; and can have long-term irreversible effects. BOP does not find it prudent to provide additional potentially harmful interventions because the inmate has already had an intervention. Even if sex trait modification surgeries are medically beneficial to address gender dysphoria, further surgeries still raise the above security and prison-administration concerns, and each of these concerns outweighs the benefits of providing or allowing access to sex trait modification surgeries in this context. In BOP's judgment, Program Statement 5260.01's handling of sex trait modification surgeries is more reasonable than and preferable to this alternative approach.

BOP has considered the option of allowing sex trait modification surgeries only for inmates that have undergone hormones to address gender dysphoria. But sex trait modification surgeries are not medically necessary, are unproven, or are medically controversial; can harm the inmate; and can have long-term irreversible effects. BOP does not find it prudent to provide this medically disputed and potentially harmful intervention because the inmate is undergoing hormones, even if the inmate has received hormones for an extended period of time. Even if sex trait modification surgeries are medically beneficial to address gender dysphoria, such surgeries still raise the above security and prison-administration concerns, including those in addition to the security and prison-administration concerns that hormones may raise. The security and prison-administration concerns outweigh the benefits of providing sex trait modification surgeries in this circumstance. In BOP's

judgment, Program Statement 5260.01's handling of sex trait modification surgeries is more reasonable than and preferable to this alternative approach.

BOP has considered a policy that would allow sex trait modification surgeries based on an inmate's individual security profile. But the inmate's security profile does not change that sex trait modification surgeries are not medically necessary, unproven, or medically controversial; can harm the inmate; and can have long-term irreversible effects. BOP does not find it prudent to provide this medically disputed and potentially harmful intervention when the inmate's security profile may be low risk. Even if sex trait modification surgeries are medically beneficial to address gender dysphoria, surgeries still raise security and prison-administration concerns: An inmate with a low-risk security profile does not sufficiently mitigate that sex trait modification surgeries increase the risk that the inmate will become a target from attacks, which increases the risk of harm to the targeted inmate and prison officials tasked with protecting the inmate. Nor does it mitigate the fairness or self-harm concerns. In BOP's judgment, Program Statement 5260.01's handling of sex trait modification surgeries is more reasonable than and preferable to this alternative approach.

BOP has considered allowing sex trait modification surgeries based on the type of custody the inmate is in. But this alternative does not change that sex trait modification surgeries are not medically necessary or at the very least, controversial and disputed. Even if sex trait modification surgeries are medically beneficial to address gender dysphoria, the above prison-administration and safety concerns persist regardless of the type of custody the inmate is in. For example, providing sex trait modification surgeries to inmates in administrative segregations or protective custody does not negate all the above security and prison-administration concerns. And even if the inmate is in more limited custody now, such as administrative segregation, the inmate likely will not always be in such custody. In BOP's judgment, Program Statement 5260.01's handling of sex trait modification surgeries is more reasonable than and preferable this alternative approach.

BOP has also considered and rejected an alternative that allows inmates to pay for sex trait modification surgeries. Such an alternative does not sufficiently mitigate the medical, security, or prison-administration concerns of allowing sex trait modification surgeries. In BOP's judgment, Program Statement 5260.01's handling of sex trait modification surgeries is more reasonable than and preferable to this alternative approach.

Finally, BOP has considered other alternatives, including a combination of the above alternatives, but BOP has determined that Program Statement 5260.01's handling of sex trait modification surgeries is better than alternative approaches and is the most reasonable approach for addressing this issue.

* * *

In sum, BOP issues Program Statement 5260.01 independent of Executive Order 14,168 and after considering the relevant issues and factors and weighing the relevant considerations. Program Statement 5260.01's handling of sex trait modification surgeries is justified by the medical concerns of the intervention alone. Security and prison-administration concerns bolster that determination. Further, even assuming there are medical benefits to inmates from sex trait modification surgery, Program Statement 5260.01's handling of sex trait modification surgeries is justified by security and prison-administration concerns, as each of those concerns, whether

considered separately, cumulatively, or in any combination, outweigh any costs of Program Statement 5260.01, any reliance interests, and any benefits sex trait modification surgeries provide. BOP also concludes that Program Statement 5260.01's handling of sex trait modification surgeries is more reasonable than and preferable to potential alternatives. After considering the relevant issues and factors and weighing the relevant considerations, BOP determines that Program Statement 5260.01's handling of sex trait modification surgeries is reasonable and appropriate.

B. Social Accommodations

After considering the relevant issues and factors and weighing the relevant considerations, BOP adopts a policy prohibiting social accommodations, including to address gender dysphoria. Social accommodations are not medically necessary to address gender dysphoria. Social accommodations are highly controversial, medically disputed, and unproven by appropriate evidence; or at the very least, there is reasonable debate about the efficacy of social accommodations to address gender dysphoria. Even assuming social accommodations are medically necessary or beneficial to treat gender dysphoria, BOP concludes that social accommodations in the secure prison environment raise numerous security and prison-administration concerns that separately, cumulatively, or in a combination outweigh any medical benefits to an inmate. In BOP's judgment, and after considering the relevant issues and factors and weighing the relevant considerations, prohibiting access to social accommodations is reasonable and appropriate to provide adequate care to inmates diagnosed with gender dysphoria; to maintain internal order, discipline, and institutional security of the correctional environment; and outweighs any asserted benefit from allowing social accommodations.

1. Social accommodations are not medically necessary to address gender dysphoria.

BOP's general policy is to "deliver medically necessary health care to inmates effectively in accordance with proven standards of care without compromising public safety concerns inherent to the Bureau's overall mission." PS 6010.05 §1, Health Services Administration. BOP also provides inmates with gender dysphoria care to address the condition, including individualized treatment plans that may include psychotherapy, group counseling, psychiatric services, and psychotropic medications.

Based on BOP's review of the record and after considering the relevant issues and factors and weighing the relevant considerations, BOP concludes that social accommodations are not medically necessary to address gender dysphoria, especially in the correctional context. Social accommodations are highly controversial, medically disputed, and unproven by appropriate evidence. Medical professionals, at the very least, reasonably disagree on the efficacy of social accommodations to address gender dysphoria, particularly in the correctional context. Social accommodations are not "medically necessary" or "in accordance with proven standards of care." PS 6010.05 §1, Health Services Administration. It is reasonable for BOP to not provide medically disputed or insufficiently proven accommodations to inmates.

Medical professionals have persuasively explained that social accommodations are at most psychologically pleasing, not medically necessary. *See, e.g.*, Kaliebe Decl. ¶22 ("'Social

accommodation' is not medically necessary in the correctional setting."); *id.* ¶156 (same); *id.* ¶136 ("The fact that some social-transitioning items are psychologically pleasing to inmates with Gender Dysphoria does not mean that such interventions are medically necessary."); *Keohane*, 952 F.3d at 1274; *Bayse v. Ward*, 147 F.4th 1304, 1313 (11th Cir. 2025); *cf., e.g.*, *Fisher v. Fed. Bureau of Prisons*, 484 F. Supp. 3d 521, 534 (N.D. Ohio 2020) ("cosmetic products are not among the minimal civilized measures of life's necessities" (brackets omitted)). There is limited to no reliable evidence showing that access to social accommodations treats gender dysphoria. *See, e.g.*, Kaliebe Decl. ¶136 ("There is limited evidence suggesting that allowing cosmetic and clothing items, such binders, undergarments, makeup, wigs, and other accessories and items stereotypically associated with the opposite sex, would improve or resolve symptoms associated with Gender Dysphoria. And there is no evidence-based study or reliable evidence showing that access to such items improves or resolves symptoms in inmates with Gender Dysphoria, regardless of whether the inmate is in a facility that aligns with the inmate's biological sex or gender identity."). Social accommodations "can prolong the symptoms [of gender dysphoria] and undermine psychotherapy, and there is no clear evidence of medical benefit." Kaliebe Decl. ¶136. To the extent that social accommodations might have short-term benefits to addressing gender dysphoria in the correctional context, they are outweighed by the potential long-term harm. *See, e.g.*, Kaliebe Decl. ¶140 ("[W]hile social transition might decrease inmate-patients' discomfort in the short term, it ultimately may cause long-term harm, such as continuation of Gender Dysphoria."). In any event, BOP determines that it is reasonable to no longer provide access to social accommodations given the uncertainty in long-term benefit.

Even if there is some reliable evidence that social accommodations address gender dysphoria when the individual is in society at large, the evidence does not support that social accommodations address gender dysphoria in the correctional environment. The concept of access to social accommodations is out of place in the correctional context because an inmate does not live in society at large but rather a secure prison environment. What a person may want or need to socially transition outside prison says little (if anything) about what that person should have access to in a secure prison environment. *See, e.g.*, Kaliebe Decl. ¶142 ("The concept of social transitioning through social accommodations, hormones, or surgery is out of place in the correctional context because an inmate does not live in society at large but a secure prison environment.").

Again, BOP provides inmates with gender dysphoria with individualized treatment plans with well-established treatment methods for gender dysphoria, such as psychotherapy, group counseling, psychiatric services, and psychotropic medications. Social accommodations are not medically necessary or at a minimum, there is reasonable disagreement as to their efficacy, such that it is reasonable for BOP to not provide social accommodations. In BOP's judgment, it is reasonable and appropriate to provide these individual treatment plans without the prospect of providing or allowing access to social accommodations to address gender dysphoria.

2. Security and prison-administration concerns support Program Statement 5260.01's prohibition on social accommodations.

BOP's general policy is to "deliver medically necessary health care to inmates effectively in accordance with proven standards of care *without compromising public safety concerns inherent to the Bureau's overall mission*." PS 6010.05 §1, Health Services Administration (emphasis added). BOP is responsible for "the safekeeping, care, and subsistence of all persons charged with or convicted of offenses against the United States." 18 U.S.C. §4042(a). Providing social accommodations to inmates, including to address gender dysphoria, raises serious security and prison-administration concerns. These security and prison-administration concerns not only support the medical concerns for BOP's adoption of a prohibition on providing inmates social accommodations but also independently support BOP's adoption of such a prohibition. At a minimum, the security and prison-administration concerns, when considered separately or cumulatively or in any combination, outweigh the benefits (medical or otherwise) from providing social accommodations. Thus, even if social accommodations address gender dysphoria, BOP, after considering the relevant issues and factors and weighing the relevant considerations, determines that it is reasonable and appropriate to not provide or allow access to social accommodations, including to address gender dysphoria.

Social accommodations jeopardize the security, safety, and prison administration of correctional facilities in at least four ways. First, providing social accommodations heightens the risk of inmates concealing dangerous contraband or escaping and may hinder the prison's ability to investigate intra-prison crimes. Second, providing social accommodations disrupts the uniform appearance among inmates, increasing the risk the accommodated inmate becomes a target for attacks, which increases the risk of harm to the targeted inmate and prison officials tasked with protecting the inmate. Third, special accommodations designed to change an inmate's outward appearance raise fairness concerns and can breed resentment among other inmates, which can lead to violence. Fourth, granting social accommodations conflicts with a reasonable practice of refusing to reward threats of self-harm and may even increase self-harm.

First, certain social accommodations, such as wigs, breast pads, buttock pads, and chest binders, can enable an inmate to hide contraband or other items without easy detection. *See, e.g.*, *Keohane*, 952 F.3d at 1263 ("the [Florida Department of Corrections] FDC concluded that there are clear advantages to maintaining uniformity in a prison setting, including the ability to more readily detect contraband"); *Keohane v. Fla. Dep't of Corr. Sec'y*, 981 F.3d 994, 998 (11th Cir. 2020) (Newsom, J., concurring in denial of reh'g en banc); *cf. Green v. Polunsky*, 229 F.3d 486, 490 (5th Cir. 2000) ("contraband such as drugs and weapons can be hidden in long hair"). A uniform dress code enables prison officials to more readily detect contraband. *See Keohane*, 952 F.3d at 1263. In addition to the harm from contraband going undetected, BOP would have to expend additional time and expense to administer the facility and ensure its security and safety.

Providing access to certain social accommodations also increases risk of escape by the inmate and may hinder the prison's ability to investigate intra-prison crimes because these items can be used to obfuscate or conceal an inmate's identity. Inmates would be able to change their appearances with ease by removing their social accommodations, such as wigs, chest binders, or

breast padding. *See, e.g.*, *Green*, 229 F.3d at 490. By prohibiting these items, Program Statement 5260.01 decreases the risk of fleeing inmates from avoiding detection or delaying detection and helps ensure the prison can adequately investigate intra-prison crimes.

Second, prohibiting social accommodations reduces the chance of an inmate being targeted by other inmates. For example, allowing a male inmate to obtain items designed to make him appear more feminine may entice other male inmates to disturb the orderly operation of the facility and can lead to increased incidents of assault or harassment on the accommodated inmate. Indeed, an inmate dressed or groomed as a female, such as via social accommodations, would increase the risk of the inmate becoming a target for abuse in a male prison. *See, e.g.*, *Keohane*, 952 F.3d at 1275 (noting the "obvious[]" consequence of permitting a male inmate to dress and be groomed as a female "would inevitably become a target for abuse in an all-male prison"); *Keohane*, 981 F.3d at 997-98 (Newsom, J., concurring in denial of reh'g en banc). And based on BOP's experience and expertise, these same concerns apply to both male and female correctional facilities, as female facilities also experience meaningful amounts of harassment and violence. *See, e.g.*, Emily Buehler, *Substantiated Incidents of Sexual Victimization Reported by Adult Correctional Authorities*, 2016-2018, U.S. Dep't of Justice, 18 (2023) (noting that 31% of the recorded incidents of inmate-on-inmate sexual harassment occurred in female correctional facilities).

Social accommodations not only put the inmate at additional risk of assault or harassment but also endanger "the prison employees who would have to step in to protect" the inmate and will require expending already limited resources to address these risks. *Keohane*, 952 F.3d at 1263. Preventing such attacks would require prison officials to be more vigilant in protecting the accommodated inmates from assault or harassment, despite BOP's limited resources.

And obviously, transfer to an opposite-sex facility is not an appropriate recourse in an attempt to mitigate these security and prison-administration complications from social-accommodations. Transfer would not sufficiently mitigate all the security and prison-administration concerns from providing social accommodations; in fact, transfer would create new grave security and prison-administration concerns. *See, e.g.*, Kaliebe Decl. ¶139 ("[H]ighly relevant is the fact that the presence of a biological male in close quarters in a female prison could significantly harm the emotional and physical well-being of certain female prisoners, such as female victims of sexual abuse. This concern is particularly acute since female prisoners suffer from extremely high rates of sexual trauma. Placing these vulnerable female inmates with biological males could have meaningful negative effects on female inmates."); *Cruel and Unusual Punishment: Stopping the Dangerous Policies Putting Men in Women's Prisons*, Independent Women's Forum (Dec. 20, 2024). And transfer is not medically necessary or appropriate to address gender dysphoria. *See, e.g.*, Kaliebe Decl. ¶¶23, 157. Transfer to address gender dysphoria is unproven, medically disputed, and controversial. *See* Kaliebe Decl. ¶139 ("There is no reliable study or high-quality evidence suggesting that an inmate being housed in a facility in line with the inmate's gender identity rather than the inmate's biological sex has any meaningful benefits (let alone long-term benefits) to the inmate's Gender Dysphoria symptoms."). It is reasonable for BOP to not provide a transfer to an inmate diagnosed with gender dysphoria, given the security, prison-administration, and medical issues.

Third, based on BOP's experience and expertise, fairness concerns counsel against providing access to social accommodations. When inmates receive special treatment within a correctional environment, other inmates may begin to resent those receiving special treatment, which can increase the risk of retaliation against the inmate receiving special treatment and cause ripple effects throughout the correctional institution and disrupting the delicate prison environment. Moreover, in general, correctional environments aim to be uniform in their approach to access to items because once a facility grants access to one thing for an inmate, it often makes it difficult to refuse granting special items to everyone else. Fairness concerns are particularly present if such special treatment is provided to one type of facilities (*e.g.*, female facilities) and not another (*e.g.*, male facilities).

Finally, BOP has considered the issue of self-harm and has determined that a policy prohibiting social accommodations avoids rewarding threats of self-harm and may reduce overall self-harm. Inmates frequently use threats of self-harm and suicide to try to obtain concessions from prison officials. *See, e.g.*, Kaliebe Decl. ¶148 ("In my experience working in correctional facilities and treating adult and juvenile inmates, including those diagnosed with Gender Dysphoria, inmates frequently use threats of self-harm and suicide to try to obtain concessions from prison officials."); *Kosilek*, 774 F.3d at 94 ("Such threats are not uncommon in prison settings …."). But providing access to social accommodations, especially in response to threats of self-harm or suicide, could increase self-harm. *See, e.g.*, Kaliebe Decl. ¶149 ("In corrections, rewarding self-injury or threats of self-injury tends to increase overall self-harm, both for the individual patient and also within the system."). Granting such requests may establish an "unacceptable precedent," forcing "prison authorities to comply with the prisoners' particular demands." *Kosilek*, 774 F.3d at 94. Consequently, it is reasonable for prison administrators to have rules against providing inmates benefits in response to self-harm or suicide to discourage threats. *See* Kaliebe Decl. ¶150 ("Simple and clear institutional policies, such as no social transitions or no initiation of new hormone treatments, are likely to lead to the lowest level of self-harm and the least overall harm to inmates because when prisoners know the interventions they desire are not available, they are less likely to self-harm to obtain them. In other words, it is reasonable for prison administrators to have outright prohibitions of providing inmates benefits, such as unproven surgeries, special-order items, and housing placements, in response to self-harm or suicide threats to discourage false threats."); *Kosilek*, 774 F.3d at 94 (noting that such threats must be "firm[ly] reject[ed] by the authorities, who must be given ample discretion in the dealing with such situations"). BOP determines that a clear rule against social accommodations is the most reasonable way to handle this complex issue. BOP takes threats of self-harm seriously and has protocols in place to handle these complex situations.

After considering the relevant issues and factors and weighing the relevant considerations, BOP determines that each of its security and prison-administration concerns, whether considered separately, cumulatively, or in any combination, outweighs any asserted benefits of providing social accommodations. In addition, after considering the relevant issues and factors and weighing the relevant considerations, BOP determines that the medical concerns discussed above when considered with any of its security and prison-administration concerns—separately, cumulatively, or in any combination—outweighs any asserted benefits of providing social accommodations.

3. Other considerations do not outweigh the benefits from Program Statement 5260.01.

a. Reliance Interests and Costs

BOP has also considered potential reliance interests, but the potential reliance interests are either illegitimate or outweighed by the benefits of the policy. Indeed, after considering the relevant issues and factors and weighing the relevant considerations, BOP determines that each of its medical, security, and prison-administration concerns, whether considered separately, cumulatively, or in any combination, outweighs the asserted benefits, interests, or costs of providing or allowing access to social accommodations.

As an initial matter, an inmate that currently does not have social accommodations has no legitimate reliance interest in the future possibility of obtaining access to social accommodations. That is especially true because social accommodations are not medically necessary or in accordance with proven standards of care.

Inmates currently in possession of social accommodations do not have legitimate reliance interests either. Social accommodations are not medically necessary or in accordance with proven standards of care. A policy that produces, at most, psychologically pleasing effects does not create legitimate reliance interests. That is all the more true given that social accommodations can prolong symptoms of gender dysphoria, may lead to long-term harm, and can undermine psychotherapy.

In any event, even if social accommodations create legitimate reliance interests, the interests are not weighty. Providing social accommodations has not been a longstanding, formal policy of BOP, and access to social accommodations has always been subject to security concerns. *See, e.g.*, PS 6010.05 §1, Health Services Administration; PS 5521.06, Housing Units, Inmates, and Inmate Work Areas; PS 5580.08, Inmate Personal Property ("Staff may not allow an inmate to accumulate materials to the point where the materials become a fire, sanitation, security, or housekeeping hazard."). Moreover, BOP policy has always been subject to change, including based on security and prison-administration concerns. Further, inmates that have had social accommodations for a short period of time have limited reliance interests. And the weight of this reliance varies among inmates due to, in part, the length of their prison sentence, among other things. Inmates that are in possession of social accommodations with little time left have a smaller interest than those with a longer remaining prison sentence.

Moreover, implementing Program Statement 5260.01 will incur, at most, *de minimis* costs and will likely lead to savings. Program Statement 5260.01 will mitigate security and prison-administration concerns, which will reduce costs. Program Statement 5260.01 will also reduce expenditures on interventions that are not medically necessary or medically disputed. Expenditures on care for inmates diagnosed with gender dysphoria are unlikely to meaningfully increase. In general, BOP officials would monitor an inmate diagnosed with gender dysphoria and provide the inmate with an individualized treatment plan, which would generally have care in addition to the provision of social accommodations. To the extent that Program Statement 5260.01 would result

in increased costs, it is outweighed by other considerations or the savings from reduced availability of social accommodations.

In sum, after considering the relevant issues and factors and weighing the relevant considerations, BOP determines that each of its medical, security, and prison-administration concerns, whether considered separately, cumulatively, or in any combination, significantly outweigh any costs of Program Statement 5260.01, any reliance interests created by a former policy of providing access to social accommodations, and any benefits from providing social accommodations. In BOP's judgment, prohibiting social accommodations is reasonable, appropriate, and in the best interest of the agency, its officials, and those in its custody.

b. Alternatives

BOP has considered alternatives and has determined that Program Statement 5260.01 is more reasonable than and preferable to potential alternatives.

For example, BOP has considered the option of denying future requests for social accommodations but allowing inmates who were previously given social accommodations to maintain access to social accommodations. Such an approach is not warranted because of BOP's medical concerns. Even if there are benefits to the more limited course as to social accommodations, BOP has determined that such a limitation would not adequately minimize the above security and prison-administration concerns to justify the alternative. In BOP's judgment, Program Statement 5260.01's handling of social accommodations is more reasonable than and preferable to this alternative approach.

BOP has considered a policy that would allow social accommodations based on an inmate's individual security profile. Such an approach is not warranted because of BOP's medical concerns. Even if there are benefits to this alternative approach to social accommodations, case-by-case determinations would not sufficiently mitigate the increased security and prison-administration concerns from social accommodations. For example, it would not sufficiently minimize the risks associated with the inmate becoming a target by other inmates, the risk to prison officials to deal with the increased risk of the inmate becoming a target, the risk from non-uniformity in the prison environment, or the risks related to threats of self-harm. Moreover, BOP's security profile is predictive, so the risk associated with contraband, escape, and intra-prison crime is still increased. In BOP's judgment, Program Statement 5260.01's handling of social accommodations is more reasonable than and preferable to this alternative approach.

BOP has considered allowing social accommodations based on the type of custody the inmate is in. Such an approach is not warranted because of BOP's medical concerns. Even if there are benefits to this alternative approach to social accommodations, the above prison-administration and safety concerns persist regardless of the type of custody the inmate is in, such as administrative segregations or general population. For example, providing social accommodations to inmates in administrative segregation still raises contraband-detection concerns, increases the risk of the inmate being targeted by other inmates, and raises the risk related to threats of self-harm. In any event, even if the inmate is in more limited custody now, such as administrative segregation, the inmate likely will not always be in such custody. Providing access to the items to inmates in such

custody to only take it away when the inmate leaves that custody is not prudent and risks further disruptions in the prison environment and potentially further self-harm threats by the inmate. In BOP's judgment, Program Statement 5260.01's handling of social accommodations is more reasonable than and preferable to this alternative approach.

BOP has considered and rejected a policy that removes all gendered clothing and hygiene products individually marketed to a particular sex. Though this option would foster uniformity for inmate dresswear, it also has significant drawbacks that render it a less desirable policy than the one selected. Implementing such a policy would be significantly costly and disruptive as it would require BOP to redesign its longstanding dress-code policy. This alternative policy would also entail the prison staff to remove newly classified contraband from all inmates, requiring BOP to expend even more resources than the selected policy as the latter involves removing contraband from a small percentage of the prison population. Moreover, this option would not be considered satisfactory by those who seek social accommodations to address gender dysphoria. In short, this alternative's defects significantly outweigh any purported advantages; in BOP's judgment, Program Statement 5260.01's handling of social accommodations is more reasonable than and preferable to this alternative approach.

BOP has also considered and rejected an alternative that allows inmates to pay for social accommodations to address gender dysphoria. Such an alternative does not sufficiently mitigate the medical, security, or prison-administration concerns of allowing social accommodations. In BOP's judgment, Program Statement 5260.01's approach to social accommodations is more reasonable than and preferable to this alternative approach.

Finally, BOP has considered other alternatives, including a combination of the above alternatives, but BOP has determined that Program Statement 5260.01's handling of social accommodations is better than and preferable to alternative approaches and is the most reasonable approach for addressing this issue.

* * *

In sum, BOP issues Program Statement 5260.01 independent of Executive Order 14,168 and after considering the relevant issues and factors and weighing the relevant considerations. Program Statement 5260.01's handling of social accommodations is justified by the medical concerns of the intervention. Security and prison-administration concerns bolster that determination. Further, even assuming there are medical benefits to inmates from providing social accommodations, Program Statement 5260.01's handling of social accommodations is justified by security and prison-administration concerns, as each of those interests, whether considered separately, cumulatively, or in any combination, outweighs any costs of Program Statement 5260.01, any reliance interests, and any benefits with respect to social accommodations. BOP also concludes that Program Statement 5260.01's handling of social accommodations is more reasonable than and preferable to potential alternatives. After considering the relevant issues and factors and weighing the relevant considerations, BOP determines that Program Statement 5260.01's handling of social accommodations is reasonable.

C. Hormones

After considering the relevant issues and factors and weighing the relevant considerations, BOP adopts Program Statement 5260.01's approach regarding hormones to address gender dysphoria. Under Program Statement 5260.01, if an inmate is diagnosed with gender dysphoria but is not currently receiving hormones to address gender dysphoria, BOP will not provide hormones to address the inmate's gender dysphoria. Hormonal interventions for inmates who are not currently receiving hormones to address gender dysphoria are not medically necessary or at a minimum, are highly controversial, medically disputed, and unproven by appropriate evidence. To the extent there is uncertainty about the efficacy of hormones to address gender dysphoria, that uncertainty counsels against providing such controversial interventions to inmates who are not currently receiving hormones when there are other more established treatments, such as psychotherapy, available. Even assuming hormones are beneficial to address gender dysphoria, BOP concludes that hormones in the secure prison environment raise numerous security and prison-administration concerns, and each concern, whether considered separately, cumulatively, or in any combination, outweigh any costs from Program Statement 5260.01, any reliance interests, and any benefits from providing hormones to inmates diagnosed with gender dysphoria who are not currently receiving hormones.

Under Program Statement 5260.01, if an inmate is previously and currently diagnosed with gender dysphoria and is currently receiving hormones to address gender dysphoria, BOP will develop a tapering plan for each inmate after consideration of appropriate factors. For inmates that have recently begun receiving hormones to address gender dysphoria, the tapering plan will include a rapid discontinuation of the hormone intervention. For inmates that have been receiving hormones to address gender dysphoria for an extended period of time, the tapering plan will generally include an appropriately paced discontinuation of the hormone intervention. For inmates who (1) are post sex trait modification surgery or (2) have been receiving hormones to address gender dysphoria for an extended period of time and develop severe physiological and psychological withdrawal effects from tapering, it may not be appropriate in all cases for the initial tapering plan to include cessation of hormones.

Even for inmates currently receiving hormones to address gender dysphoria, such hormonal interventions are medically controversial and disputed. There are little (if any) reliable evidence on the benefits of hormonal interventions to address gender dysphoria, especially in the correctional environment. There are also indications that hormonal interventions can prolong symptoms of gender dysphoria, undermine other treatments to address gender dysphoria, worsen symptoms of gender dysphoria, and cause physical and psychological harm. But given that inmates currently receiving hormones involve a more complex case in light of the reality that removing medical interventions can cause stress or other side effects, BOP determines that it is reasonable to take the above approach with respect to inmates who are currently receiving hormones to address gender dysphoria, which balances the medical, security, and prison-administration concerns to deal with this more complex situation.

In BOP's judgment, and after considering the relevant issues and factors and weighing the relevant considerations, Program Statement 5260.01's approach as to hormones is reasonable, and

appropriate to provide adequate care to inmates diagnosed with gender dysphoria; is reasonable and appropriate to maintain internal order, discipline, and institutional security of the correctional environment; and outweighs any asserted benefit from alternative policies regarding hormones to address gender dysphoria.

1. In general, hormones are not medically necessary to address gender dysphoria.

a. Inmates Not Currently Receiving Hormones to Address Gender Dysphoria

After considering the relevant issues and factors and weighing the relevant considerations, BOP concludes that hormones are not medically necessary to address gender dysphoria for individuals not currently receiving hormones to address gender dysphoria, especially in the correctional context. Hormonal interventions to address gender dysphoria are highly controversial, medically disputed, and unproven by appropriate evidence. Medical professionals, at the very least, reasonably disagree on the efficacy of hormones to address gender dysphoria for individuals not currently receiving hormones to address gender dysphoria, particularly in the correctional context. Hormones are not "medically necessary" or "in accordance with proven standards of care" for inmates not currently receiving hormones to address gender dysphoria. PS 6010.05 §1, Health Services Administration. It is reasonable for BOP to not provide medically disputed or insufficiently proven interventions to inmates who are not currently receiving the intervention.

An expert has persuasively explained that hormones are not medically necessary to address gender dysphoria when that inmate is not currently receiving hormones to address gender dysphoria. *See, e.g.*, Kaliebe Decl. ¶20 ("it is not medically necessary to provide hormone therapy to inmates who are diagnosed with Gender Dysphoria but not currently receiving hormone therapy"); *id.* ¶154 (same); *id.* ¶112 ("it is appropriate to not initiate hormone therapy on inmates who are not currently subject to hormonal therapy"). At the very least, providing hormones to address gender dysphoria is highly controversial, insufficiently proven, or subject to reasonable medical disagreement. Indeed, hormones to address gender dysphoria "is unproven" and "experimental." *See, e.g.*, Kaliebe Decl. ¶20 ("Hormone therapy is unproven and experimental treatment for Gender Dysphoria that generally should not be available to those in the custody of the Federal Bureau of Prisons."); *id.* ¶154 (same). Providing hormonal interventions to address gender dysphoria "is not based on guidelines using best practice or systematic reviews of evidence." Kaliebe Decl. ¶83. There is little (if any) reliable evidence showing that hormones address gender dysphoria. *See, e.g.*, Kaliebe Decl. ¶83; Haupt et al., *Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women*, 11 Cochrane Database of Systematic Reviews, Art. No. CD013138, at 2, 11 (2020); Kellan E. Baker, et al., *Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review*, 5 J. Endocrine Soc. 1, 12-13 (2021); *Marcum v. Crews*, No. 5:25-CV-00238-GFVT, 2025 WL 2630922, at *7 (E.D. Ky. Sept. 12, 2025) ("The problem in making this analogy is that the Plaintiff is assuming that HRT is a well-settled area of medicine. When, in fact, the record indicates that there remains significant disagreement about whether the side effects and the negative consequences of HRT outweigh the positive benefits. And, further, there is medical evidence

suggesting that even if HRT is not provided, there are other ways to care for an individual diagnosed with Gender Dysphoria, absent using HRT."); *Marcum v. Crews*, No. 25-5840, Dkt. 26 at 6 (6th Cir. Oct. 23, 2025) ("The existing record thus suggests that the medical community has not reached a consensus on the role hormone therapy should play in treating gender dysphoria."). In any event, there is no reliable evidence showing that hormones address gender dysphoria in the correctional environment. To the contrary, recent research has raised significant concerns on the safety, efficacy, and prudence of hormonal interventions to address gender dysphoria. *See, e.g.*, Kaliebe Decl. ¶86 ("Recent large reviews and research into harms from hormone treatment for Gender Dysphoria raise increased concerns regarding the safety, efficacy, and prudence of this practice.").

There are also indications that hormonal interventions can prolong symptoms of gender dysphoria, undermine other treatments to address gender dysphoria, worsen symptoms of gender dysphoria, and cause "[s]ubstantial [h]ealth risks" and "[m]edical harms." *See, e.g.*, Kaliebe Decl. ¶¶96-111; Rakesh R. Gurrala et al., *The Impact of Exogenous Testosterone on Breast Cancer Risk in Transmasculine Individuals*, 90(1) Annals of Plastic Surgery 96 (2023) (explaining that evidence showed that males who are treated with estrogen have twenty-two times the likelihood to develop breast cancer). Some of the effects of hormonal interventions also might not be reversible. *See, e.g.*, Kaliebe Decl. ¶109. To the extent that hormonal interventions might have short-term benefits to addressing gender dysphoria in the correctional context, they may be placebo effects, *see, e.g.*, Kaliebe Decl. ¶¶90-91, or in any event, outweighed by the potential long-term risks or harms. At any rate, BOP determines that it is reasonable to not provide hormones to inmates not currently receiving hormones given the uncertainty in benefits, the potential harms, and the potential irreversibility of some effects of the intervention.

Again, BOP provides inmates with gender dysphoria with individualized treatment plans with well-established treatment methods for gender dysphoria, such as psychotherapy, group counseling, psychiatric services, and psychotropic medications. Hormonal interventions for inmates not currently receiving the intervention to address gender dysphoria are not medically necessary or at a minimum, there is reasonable disagreement as to their efficacy, such that it is reasonable for BOP to not provide the intervention. In BOP's judgment, it is reasonable and necessary and appropriate to provide these individual treatment plans to inmates who are not currently hormones without the prospect of receiving hormones to address gender dysphoria.

b. Inmates Currently Receiving Hormones to Address Gender Dysphoria

Though the medical concerns explained above are still present for inmates currently receiving hormones, BOP has determined that a different approach is warranted as to inmates that are already receiving hormones to address gender dysphoria. These inmates involve a more complex situation, reflecting the reality that removing medical interventions can cause stress or other side effects. *See* Kaliebe Decl. ¶114.

Under Program Statement 5260.01, inmates who are previously and currently diagnosed with gender dysphoria and are currently receiving hormones to address gender dysphoria will receive tapering plans based on the appropriate factors, such as the duration the inmate has been

receiving hormones to address gender dysphoria, the initial rationale for receiving the hormone intervention, the response by the inmate to the intervention, and whether the inmate has undergone sex trait modification surgery. But BOP determines that it is appropriate to generally divide these inmates based on the length of time the inmate has received hormones to address gender dysphoria. *See* Kaliebe Decl. ¶114 ("it is reasonable for dysphoric patients to be divided into different patient populations with different clinical approaches").

For inmates that recently started receiving hormones to address gender dysphoria, BOP determines that such inmates will receive a tapering plan that includes a rapid discontinuation of hormones. *See* Kaliebe Decl. ¶114 ("A rapid discontinuation is appropriate for those who recently started treatment."). Given the medical concerns with respect to hormones, the short-term side-effects to discontinuing hormones when hormones have only been recently provided to the inmate, and the other measures BOP has in place to monitor and receive requests from inmate patients, among other relevant considerations, BOP determines that a tapering plan that includes a rapid discontinuation of hormones is reasonable for inmates who have only recently begun receiving hormones to address gender dysphoria.

For inmates that have been receiving hormones to address gender dysphoria for an extended period of time, the inmates will receive a tapering plan based on the appropriate factors. In general, the tapering plan will include an appropriately paced discontinuation of the hormone intervention. *See* Kaliebe Decl. ¶114 ("A rapid discontinuation is appropriate for those who recently started treatment, but a slow withdrawal could be appropriate for others ….). For inmates who (1) are post sex trait modification surgery or (2) have been receiving hormones to address gender dysphoria for an extended period of time and develop severe physiological and psychological withdrawal effects from tapering, it may not be appropriate in all cases for the initial tapering plan to include cessation of hormones. But given "the unproven medical benefits of continued hormone[s]," "the potential negative effects of hormone[s]," and that "it is likely rare that an inmate should continue hormone therapy indefinitely," Kaliebe Decl. ¶116, tapering plans should be reevaluated regularly with respect to cessation of hormones, including during the inmate's chronic care clinic appointments.

All inmates who are tapering and were receiving mental health treatment before tapering will continue to receive counseling and pharmacological treatment as appropriate as part of the inmate's individualized treatment plan. Tapering plans may be adjusted as necessary based on monitoring and follow-up evaluations, but the adjusted tapering plans must still be consistent with the purpose of Program Statement 5260.01 and based on all relevant factors, including security and prison-administration concerns. And inmate patients may submit a request for additional medical or mental health care or evaluation if they have acute concerns during the tapering process.

In BOP's judgment, the above approach reasonably balances the medical concerns presented by hormones for inmates that are currently receiving hormones to address gender dysphoria.

2. Security and prison-administration concerns support Program Statement 5260.01's approach to hormones to address gender dysphoria.

BOP's general policy is to "deliver medically necessary health care to inmates effectively in accordance with proven standards of care *without compromising public safety concerns inherent to the Bureau's overall mission*." PS 6010.05 §1, Health Services Administration (emphasis added). BOP is responsible for "the safekeeping, care, and subsistence of all persons charged with or convicted of offenses against the United States." 18 U.S.C. §4042(a). Providing hormonal interventions to inmates to address gender dysphoria raises serious security and prison-administration concerns. These security and prison-administration concerns independently support Program Statement 5260.01's handling of hormones. At a minimum, the security and prison-administration concerns, when considered separately, cumulatively, or in any combination, outweigh the benefits from a policy handling hormones differently, such as allowing more access to hormones to address gender dysphoria. Thus, after considering the relevant issues and factors and weighing the relevant considerations, BOP determines that it is reasonable and appropriate to adopt Program Statement 5260.01's approach to hormonal interventions to address gender dysphoria.

Using hormonal interventions to address gender dysphoria jeopardizes the security, safety, and prison administration of correctional facilities in at least three ways. First, the inmate receiving hormones will have increased risk of the inmate becoming a target for attacks, which increases harm to the targeted inmate and prison officials tasked with protecting the inmate. Second, special treatments raise fairness concerns and can breed resentment among other inmates, which can lead to violence. Third, granting hormones conflicts with a reasonable practice of refusing to reward threats of self-harm and may even increase self-harm. Each of BOP's security and prison-administration concerns, whether considered cumulatively, separately, or in any combination, outweighs any asserted benefits from a different approach to hormones than the one adopted in Program Statement 5260.01.

First, limiting the availability of hormonal interventions to address gender dysphoria reduces the chance of an inmate being targeted by other inmates. The inmate would inevitably become a target for abuse in the male facility. *Cf., e.g.*, *Keohane*, 952 F.3d at 1275 (noting the "obvious[]" consequence of permitting an inmate to dress and be groomed as a female "would inevitably become a target for abuse in an all-male prison"); *Kosilek*, 774 F.3d at 93 ("Recognizing that reasonable concerns would arise regarding a post-operative, male-to-female transsexual being housed with male prisoners takes no great stretch of the imagination."). And based on BOP's experience and expertise, these same concerns also apply to women's correctional facilities, which also experience meaningful amounts of harassment and violence. *See, e.g.*, Emily Buehler, *Substantiated Incidents of Sexual Victimization Reported by Adult Correctional Authorities*, 2016-2018, U.S. Dep't of Justice, 18 (2023) (noting that 31% of the recorded incidents of inmate-on-inmate sexual harassment occurred in female correctional facilities).

Hormonal interventions not only put the inmate at additional risk of assault or harassment but also endanger "the prison employees who would have to step in to protect" the inmate and will require expending already limited resources to address these risks. *Keohane*, 952 F.3d at 1263.

Preventing such attacks would require prison officials to be more vigilant in protecting the inmates from assault or harassment, despite BOP's limited resources.

It is insufficient to point to transfer to mitigate these security and prison-administration complications from providing hormones to address gender dysphoria. For example, a transfer of a male (who is receiving hormones to address gender dysphoria) to a female facility will increase the risk of harm of female inmates. *See* Kaliebe Decl. ¶139 ("[H]ighly relevant is the fact that the presence of a biological male in close quarters in a female prison could significantly harm the emotional and physical well-being of certain female prisoners, such as female victims of sexual abuse. This concern is particularly acute since female prisoners suffer from extremely high rates of sexual trauma. Placing these vulnerable female inmates with biological males could have meaningful negative effects on female inmates."); *see also, e.g.*, *Cruel and Unusual Punishment: Stopping the Dangerous Policies Putting Men in Women's Prisons*, Independent Women's Forum (Dec. 20, 2024). And based on BOP's experience and expertise, similar concerns exist for transfer of a female inmate to a male facility, as the female inmate would be a target by other male prisoners. Moreover, transfer is not medically necessary to address gender dysphoria. *See, e.g.*, Kaliebe Decl. ¶¶23, 157. Transfer to address gender dysphoria is unproven, medically disputed, and controversial. *See* Kaliebe Decl. ¶139 ("There is no reliable study or high-quality evidence suggesting that an inmate being housed in a facility in line with the inmate's gender identity rather than the inmate's biological sex has any meaningful benefits (let alone long-term benefits) to the inmate's Gender Dysphoria symptoms."). It is reasonable for BOP to not provide a transfer to an inmate diagnosed with gender dysphoria (including those receiving hormones), given the security, prison-administration, and medical concerns.

Second, based on BOP's experience and expertise, fairness concerns counsel against broader availability of hormones to address gender dysphoria. When inmates receive special treatment within a correctional environment, other inmates may begin to resent those receiving special treatment, which can increase the risk of retaliation against the inmate receiving special treatment and cause ripple effects throughout the correctional institution and disrupting the delicate prison environment. Fairness concerns are particularly present if such special treatment is provided to one type of facilities (*e.g.*, female facilities) and not another (*e.g.*, male facilities).

Finally, BOP has considered the issue of self-harm and has determined that Program Statement 5260.01's handling of hormones to address gender dysphoria reduces rewarding threats of self-harm and may reduce overall self-harm. Inmates frequently use threats of self-harm and suicide to try to obtain concessions from prison officials. *See, e.g.*, Kaliebe Decl. ¶148 ("In my experience working in correctional facilities and treating adult and juvenile inmates, including those diagnosed with Gender Dysphoria, inmates frequently use threats of self-harm and suicide to try to obtain concessions from prison officials."); *Kosilek*, 774 F.3d at 94 ("Such threats are not uncommon in prison settings …."). But providing more access to hormones, especially in response to threats of self-harm or suicide, could increase self-harm. *See, e.g.*, Kaliebe Decl. ¶149 ("In corrections, rewarding self-injury or threats of self-injury tends to increase overall self-harm, both for the individual patient and also within the system."). Granting such requests may establish an "unacceptable precedent," forcing "prison authorities to comply with the prisoners' particular demands." *Kosilek*, 774 F.3d at 94. Consequently, it is reasonable for prison administrators to have

rules against providing inmates benefits in response to self-harm or suicide to discourage threats. *See* Kaliebe Decl. ¶150 ("Simple and clear institutional policies, such as no social transitions or no initiation of new hormone treatments, are likely to lead to the lowest level of self-harm and the least overall harm to inmates because when prisoners know the interventions they desire are not available, they are less likely to self-harm to obtain them. In other words, it is reasonable for prison administrators to have outright prohibitions of providing inmates benefits, such as unproven surgeries, special-order items, and housing placements, in response to self-harm or suicide threats to discourage false threats."); *Kosilek*, 774 F.3d at 94 (noting that such threats must be "firm[ly] reject[ed] by the authorities, who must be given ample discretion in the dealing with such situations"). BOP determines that Program Statement 5260.01's approach as to hormones is the most reasonable way to handle this complex issue. BOP takes threats of self-harm seriously and has protocols in place to handle these complex situations.

After considering the relevant issues and factors and weighing the relevant considerations, BOP determines that each of its security and prison-administration concerns, whether considered separately, cumulatively, or in any combination, outweighs any asserted benefits of providing hormones in a broader way that differs from the approach adopted by Program Statement 5260.01. Specifically, each of the above security and prison-administration concerns, whether considered separately, cumulatively, or in any combination, support not providing hormones to address gender dysphoria to an inmate who is not currently receiving hormones. Each of the above security and prison-administration concerns, whether considered separately, cumulatively, or in any combination, also support providing tapering plans that include a rapid discontinuation of hormones for inmates who recently begun receiving hormones to address gender dysphoria. These concerns further support providing tapering plans that include an appropriately paced discontinuation of hormones for inmates who have been receiving hormones to address gender dysphoria for an extended period of time. And these concerns support the approach with respect to inmates who are post sex trait modification surgery or have been receiving hormones to address gender dysphoria for an extended period of time and develop severe physiological and psychological withdrawal effects from tapering. BOP has determined that it is reasonable to tolerate some of these security and prison-administration concerns for inmates that present the complex situation described above in the way that Program Statement 5260.01 handles hormones for these inmates. In addition, after considering the relevant issues and factors and weighing the relevant considerations, BOP determines that the medical concerns discussed above when considered with any of its security and prison-administration concerns—separately, cumulatively, or in any combination—outweighs any asserted benefits of providing hormones in a way that differs from the approach adopted by Program Statement 5260.01.

3. Other considerations do not outweigh the benefits from Program Statement 5260.01.

a. Reliance Interests and Costs

BOP has also considered potential reliance interests, but the potential reliance interests are either illegitimate or outweighed by the benefits of Program Statement 5260.01. Indeed, after considering the relevant issues and factors and weighing the relevant considerations, BOP

determines that each of its medical, security, and prison-administration concerns, whether considered separately, cumulatively, or in any combination, outweighs the asserted benefits, interests, or costs of providing hormones to address gender dysphoria in a way that differs from the approach adopted in Program Statement 5260.01.

As an initial matter, Program Statement 5260.01 prohibits providing hormones to inmates who are not currently receiving hormones to address gender dysphoria, and an inmate has no reasonable reliance interest in the future possibility of obtaining hormones. That is especially true because hormones are not medically necessary or at a minimum, controversial or medically disputed. It is reasonable for BOP to not provide medically disputed or insufficiently proven interventions to inmates who are not currently receiving the medically disputed intervention.

As for inmates currently receiving hormones to address gender dysphoria, these inmates' reliance interests are at best in the provision of "medically necessary health care to inmates effectively in accordance with proven standards of care without compromising public safety concerns inherent to the Bureau's overall mission." PS 6010.05 §1, Health Services Administration. In BOP's judgment, Program Statement 5260.01 is designed to provide such care.

In any event, even if the availability of hormones to address gender dysphoria create legitimate reliance interests, the interests are not sufficiently weighty to outweigh the benefits of Program Statement 5260.01. Access to hormones has always been subject to security concerns. *See, e.g.*, PS 6010.05 § 1, Health Services Administration. Moreover, BOP policies have always been subject to change, including based on new medical studies, security concerns, and prison-administration concerns.

Moreover, implementing Program Statement 5260.01 will incur, at most, *de minimis* costs and will likely lead to savings. Program Statement 5260.01 will mitigate security and prison-administration concerns, which will reduce costs. Program Statement 5260.01 will also reduce expenditures on medical interventions that are not medically necessary or medically disputed. Expenditures on care for inmates diagnosed with gender dysphoria are unlikely to meaningfully increase. In general, even if an inmate is receiving hormones, BOP officials would monitor the inmate patient and provide the inmate patient with an individualized treatment plan, which would generally have care in addition to the provision of hormones. To the extent that Program Statement 5260.01 would result in increased costs, it is outweighed by other considerations or the savings from reduced availability of hormones.

In sum, after considering the relevant issues and factors and weighing the relevant considerations, each of BOP's medical, security, and prison-administration concerns, whether considered separately, cumulatively, or in any combination, significantly outweigh any reliance interests created by a former policy that provided more access to hormones than the approach adopted in Program Statement 5260.01. In BOP's judgment, Program Statement 5260.01's handling of hormones to address gender dysphoria is reasonable and in the best interest of the agency, its officials, and those in its custody.

b. Alternatives

BOP has considered alternatives and has determined that Program Statement 5260.01 is more reasonable than and preferable to potential alternatives.

For example, BOP has considered a policy allowing hormones to inmates diagnosed with gender dysphoria but are not currently receiving hormones to address gender dysphoria, such as on a case-by-case basis. Such an approach is not warranted because of BOP's medical concerns. Even if there are benefits to the alternative approach as to hormones for inmates currently not receiving hormones, BOP has determined that the alternative approach would not adequately minimize the above security and prison-administration concerns to justify the alternative. In BOP's judgment, Program Statement 5260.01's approach to hormones for inmates not currently receiving hormones is preferable to this alternative approach.

BOP has considered a policy allowing case-by-case determinations on whether to adopt tapering plans for inmates who have recently begun receiving hormones. Such an approach is not warranted because of BOP's medical concerns. In BOP's judgment, any effects from tapering, including a rapid discontinuation of hormones, for inmates who recently began receiving hormones are outweighed by the benefits of not providing a medically disputed medical intervention that can prolong symptoms of gender dysphoria, undermine other treatments to address gender dysphoria, worsen symptoms of gender dysphoria, and cause physical and psychological harm, including harm that is potentially irreversible. Even if there are benefits to the alternative approach as to hormones for inmates who recently began receiving hormones, BOP has determined that the alternative approach would not adequately minimize the above security and prison-administration concerns to justify the alternative. In BOP's judgment, Program Statement 5260.01's approach to hormones for inmates who recently begun receiving hormones is preferable to this alternative approach.

BOP has considered an alternative that allows case-by-case determinations on whether to adopt tapering plans for inmates who have been receiving hormones for an extended period of time. Such an approach is not warranted because of BOP's medical concerns. In BOP's judgment, any effects from tapering for inmates have been receiving hormones for an extended period of time are outweighed by the benefits of not continuing to provide a medically disputed medical intervention that can prolong symptoms of gender dysphoria, undermine other treatments to address gender dysphoria, worsen symptoms of gender dysphoria, and cause physical and psychological harm, including harm that is potentially irreversible. The potential harm is further minimized by Program Statement 5260.01's approach to cessation of hormones for inmates who (1) are post sex trait modification surgery or (2) have been receiving hormones to address gender dysphoria for an extended period of time and develop severe physiological and psychological withdrawal effects from tapering. And the potential harm is even further minimized by the ability of inmate patients under Program Statement 5260.01 to request additional medical or mental health care or evaluation if they have acute concerns during the tapering process. Moreover, even if there are benefits to the alternative approach as to hormones for inmates who have been receiving hormones for an extended period of time, BOP has determined that this alternative approach would not adequately minimize the above concerns to justify the alternative. In BOP's judgment, Program

Statement 5260.01's approach to hormones for inmates who have been receiving hormones more an extended period of time is preferable to this alternative approach.

BOP has also considered and rejected an alternative that allows inmates to pay for hormones to address gender dysphoria when BOP would not provide such hormones. Such an alternative does not sufficiently mitigate the medical, security, or prison-administration concerns of allowing hormones when BOP would not provide such hormones. In BOP's judgment, Program Statement 5260.01's approach to hormones is preferable to this alternative approach.

Finally, BOP has considered other alternatives, including a combination of the above alternatives, but BOP has determined that Program Statement 5260.01's approach to hormones is preferable to alternative approaches and is the most reasonable approach for addressing this issue.

* * *

In sum, BOP issues Program Statement 5260.01 independent of Executive Order 14,168 and after considering the relevant issues and factors and weighing the relevant considerations. Program Statement 5260.01's approach to hormones is justified by the medical concerns of the intervention. Security and prison-administration concerns bolster that determination. Further, even assuming there are medical benefits to inmates from hormones, Program Statement 5260.01's handling of hormones is justified by security and prison-administration concerns, as each of those interests, whether considered separately, cumulatively, or in any combination, outweigh any costs of Program Statement 5260.01, any reliance interests, and any benefits from broader availability of hormones. BOP also concludes that Program Statement 5260.01's handling of hormones is preferable to and more reasonable than potential alternatives. After considering the relevant issues and factors and weighing the relevant considerations, BOP determines that Program Statement 5260.01's approach to hormones is reasonable.

D. Other Aspects of Program Statement 5260.01

After considering the relevant issues and factors and weighing the relevant considerations, including reliance interests, costs, and potential alternatives, BOP adopts the other aspects of Program Statement 5260.01.

For example, under Program Statement 5260.01, identified medical and psychiatric comorbidities, which can complicate treatment for gender dysphoria, should generally be addressed before treatment for gender dysphoria proceeds. *See, e.g.*, Kaliebe Decl. ¶¶55-57; Florida Dep't of Corrections, Policy 15.05.23, 3-4 (Sept. 30, 2024) ("All medical and psychiatric comorbidities must be identified as these comorbidities can complicate the treatment of Gender Dysphoria."). As appropriate, medical and psychiatric comorbidities should be addressed through psychotherapy, psychotropic medication, or other appropriate medically accepted interventions. *See, e.g.*, Kaliebe Decl. ¶¶55-59. When comorbidities are addressed before gender dysphoria, further treatment for gender dysphoria may be necessary and may proceed once these medical and psychiatric comorbidities are resolved or ruled out as the potential cause of gender dysphoria.

Moreover, psychotherapy should be prioritized. Psychotherapy is a well-known and well-established treatment for gender dysphoria and helps patients while avoiding the use of potentially

irreversible medical interventions. *See, e.g.*, Kaliebe Decl. at page 14 ("Psychotherapy is the preferred treatment approach for Gender Dysphoria, particularly within correctional environments."); *see also, e.g.*, Kaliebe Decl. ¶¶43-59; *K.C.*, 121 F.4th at 610-11 ("Social support and psychotherapy are widely recognized approaches" to treating gender dysphoria. (citing Danyon Anderson et al., *Gender Dysphoria and Its Non-Surgical and Surgical Treatments*, 10 Health Psych. Rsch., at 4 (2022))).

Again, BOP provides individualized treatment plans to address gender dysphoria, which may include psychotherapy, group counseling, psychiatric services, and psychotropic medications. Nothing in Program Statement 5260.01 prevents a prison official from providing care required by federal law, including the Eighth Amendment to the U.S. Constitution. And Program Statement 5260.01 requires BOP to ensure that all inmates diagnosed with gender dysphoria receive care in accordance with federal law, including the Eighth Amendment to the U.S. Constitution. In BOP's judgment, the other aspects of Program Statement 5260.01 are preferable to potential alternatives and reasonable in light of the relevant issues and factors. The costs for these other aspects of Program Statement 5260.01 are *de minimis* and outweighed by their benefits. Any reliance interests are outweighed by the benefits of these other aspects of Program Statement 5260.01 and Program Statement 5260.01 as a whole. After considering the relevant issues and factors and weighing the relevant considerations, BOP determines that the other aspects of Program Statement 5260.01 is reasonable.

III. Severability

Each of the provisions of Program Statement 5260.01 serve an important, related, but distinct purpose. BOP also confirms that each of the provisions in Program Statement 5260.01 is intended to operate independently of each other and that the potential invalidity of one provision should not affect the other provisions. Accordingly, if any provision of Program Statement 5260.01, or the application of any provision of Program Statement 5260.01 to any individual or circumstance, is held to be invalid, the remainder of Program Statement 5260.01 and the application of its provisions to any other individuals or circumstances shall not be affected.

For example, if a court concludes that the aspect or any aspect of Program Statement 5260.01 regarding hormones or social accommodations is unlawful, BOP would still prohibit sex trait modification surgeries. Program Statement 5260.01's prohibition on sex trait modification surgeries, even without the provisions on hormones or social accommodations, would still reasonably address the applicable medical, security, and prison-administration concerns; outweigh any costs, reliance interests, and countervailing benefits; and be more reasonable than and preferable to potential alternatives.

If a court concludes that the aspect of Program Statement 5260.01 regarding hormones or sex trait modification surgeries is unlawful, BOP would still prohibit social accommodations. Program Statement 5260.01's prohibition on social accommodations, even without the provisions on hormones or sex trait modification surgeries, would still reasonably address the applicable medical, security, and prison-administration concerns; outweigh any costs, reliance interests, and countervailing benefits; and be more reasonable than and preferable to potential alternatives.

If a court concludes that the aspect of Program Statement 5260.01 regarding hormones is unlawful, BOP would still prohibit sex trait modification surgeries and social accommodations. Program Statement 5260.01's prohibition on sex trait modification surgeries and social accommodations, even without the provisions on hormones, would still reasonably address the applicable medical, security, and prison-administration concerns; outweigh any costs, reliance interests, and countervailing benefits; and be more reasonable than and preferable to potential alternatives.

If a court concludes that any part of Program Statement 5260.01 regarding hormones is unlawful, BOP would still adopt the other aspects of Program Statement 5260.01 with respect to hormones. For instance, Program Statement 5260.01's prohibition on hormones for inmates with gender dysphoria who are not current receiving hormones, even without the other provisions on hormones, would still reasonably address the applicable medical, security, and prison-administration concerns; outweigh any costs, reliance interests, and countervailing benefits; and be more reasonable than and preferable to potential alternatives. Program Statement 5260.01's provision on hormones for inmates with gender dysphoria who recently begun receiving hormones, even without the provisions on hormones for inmates who have been receiving hormones for an extended period of time, would still reasonably address the applicable medical, security, and prison-administration concerns; outweigh any costs, reliance interests, and countervailing benefits; and be more reasonable than and preferable to potential alternatives.

To give another example, if a court concludes that Program Statement 5260.01 cannot be retroactive to remove already issued social accommodations, then BOP would apply that aspect of Program Statement 5260.01 prospectively, such that no social accommodations will be provided in the future. Although continuing to allow accommodations already granted may lead to medical, security, and prison-administration harms that Program Statement 5260.01 seeks to avoid, the benefits from a prohibition on future social accommodations would still outweigh any costs, reliance interests, and countervailing benefits and be preferable to a policy allowing more access to social accommodations.

To be sure, BOP has determined that every provision of Program Statement 5260.01 is legally supportable, individually and in the aggregate, but include this discussion to remove any doubt that it would have adopted the remaining provisions of Program Statement 5260.01 without any of the other provisions, should any of them or any application of them be deemed unlawful by a court. The intent of Program Statement 5260.01 is for federal funds to not be expended for any medical procedure, treatment, or drug for the purpose of conforming an inmate's appearance to that of the opposite sex to the maximum extent permitted by law, including the Eighth Amendment to the U.S. Constitution. Nothing in Program Statement 5260.01 shall prevent a prison official from providing care required by federal law, including the Eighth Amendment to the U.S. Constitution. BOP shall ensure that all inmates diagnosed with gender dysphoria receive care in accordance with federal law, including the Eighth Amendment to the U.S. Constitution. And nothing in Program Statement 5260.01 is intended, nor shall it be construed, to create a private cause of action.

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- Oklahoma
    - Oklahoma Department of Corrections Policies on Determination and Management of Inmates with Gender Dysphoria.
- Minnesota
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The Cass Review

Independent review of gender identity services for children and young people



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Foreword from the Chair

"Medicine's ground state is uncertainty. Wisdom - for both the patients and doctors - is defined by how one copes with it."

Atul Gawande, Complications (2002)



Dr Hilary Cass

This Review is not about defining what it means to be trans, nor is it about undermining the validity of trans identities, challenging the right of people to express themselves, or rolling back on people's rights to healthcare. It is about what the healthcare approach should be, and how best to help the growing number of children and young people who are looking for support from the NHS in relation to their gender identity.

The Review has not been conducted in a vacuum. There have been many moving parts and a significant, often challenging public debate. I have been buffeted by different issues along the way but have tried to remain focused on my remit.

One of the great pleasures of the Review has been getting to meet and talk to so many interesting people. I want to thank all those who have generously given their time to share their stories, experiences and perspectives. I have spoken to transgender adults who are leading positive and successful lives, and feeling empowered by having made the decision to transition. I have spoken to people who have detransitioned, some of whom deeply regret their earlier decisions. I have spoken to many parents, with very different perspectives. Some have fought to get their children onto a medical pathway and have spoken about how frustrated they have felt to have to battle to get support. Others have felt a medical pathway

was entirely the wrong decision for their child and have described their dismay about actions taken without their consent and in ignorance of the various other difficulties their child may have been through, such as loss of a parent, traumatic illness, diagnosis of neurodiversity and isolation or bullying in school.

As well as hearing from those with lived experience, I have spoken to a very wide range of clinicians and academics. Clinicians who have spent many years working in gender clinics have drawn very different conclusions from their clinical experience about the best way to support young people with gender-related distress. Some feel strongly that a majority of those presenting to gender services will go on to have a long-term trans identity and should be supported to access a medical pathway at an early stage. Others feel that we are medicalising children and young people whose multiple other difficulties are manifesting through gender confusion and gender-related distress.

One thing unites all these people; they all believe passionately in what they have told me, and those with either parental or clinical responsibility for children and young people are trying their very best to do what they feel is the right thing to support them.

Despite the best intentions of everyone with a stake in this complex issue, the toxicity of the debate is exceptional. I have faced criticism for engaging with groups and individuals who take a social justice approach and advocate for gender affirmation, and have equally been criticised for involving groups and individuals who urge more caution. The knowledge and expertise of experienced clinicians who have reached different conclusions about the best approach to care are sometimes dismissed and invalidated.

There are few other areas of healthcare where professionals are so afraid to openly discuss their views, where people are vilified on social media, and where name-calling echoes the worst bullying behaviour. This must stop.

Polarisation and stifling of debate do nothing to help the young people caught in the middle of a stormy social discourse, and in the long run will also hamper the research that is essential to finding the best way of supporting them to thrive.

This is an area of remarkably weak evidence, and yet results of studies are exaggerated or misrepresented by people on all sides of the debate to support their viewpoint. The reality is that we have no good evidence on the long-term outcomes of interventions to manage gender-related distress.

It often takes many years before strongly positive research findings are incorporated into practice. There are many reasons for this. One is that doctors can be cautious in implementing new findings, particularly when their own clinical experience is telling them the current approach they have used over many years is the right one for their patients. Quite the reverse happened in the field of gender care for children. Based on a single Dutch study, which suggested that puberty blockers may improve psychological wellbeing for a narrowly defined group of children with gender incongruence, the practice spread at pace to other countries. This was closely followed by a greater readiness to start masculinising/feminising hormones in mid-teens, and the extension of this approach to a wider group of adolescents who would not have met the inclusion criteria for the original Dutch study. Some practitioners abandoned normal clinical approaches to holistic assessment, which has meant that this group of young people have been exceptionalised compared to other young people with similarly complex presentations. They deserve very much better.

On a personal note, I would like to talk through this foreword to the children and young people at the heart of this Review. I have decided not to write to you separately because it is important that everyone hears the same message. Some of you have been really clear that you want much better advice on the options available to you and the risks and benefits of different courses of action and will be pleased by what you will read in this report. Others of you have said you just want access to puberty blockers and hormones as quickly as possible, and may be upset that I am not recommending this. I have been very mindful that you may be disappointed by this. However, what I want to be sure about is that you are getting the best combination of treatments, and this means putting in place a research programme to look at all possible options, and to work out which ones give the best results. There are some important reasons for this decision.

Firstly, you must have the same standards of care as everyone else in the NHS, and that means basing treatments on good evidence. I have been disappointed by the lack of evidence on the long-term impact of taking hormones from an early age; research has let us all down, most importantly you. However, we cannot expect you to make life-changing decisions in a vacuum without being able to weigh their risks and benefits now and in the long-term, and we have to build the evidence-base with good studies going forward. That is why I am asking you to join any research studies that look at the longer-term outcomes of these interventions so you can help all those coming behind you. We have to show that the treatments are safe and produce the positive outcomes you want from them. People in research studies often do better than people who are on regular treatment because they get the chance to try new approaches, as well as getting much closer follow-up and support.

Secondly, medication is binary, but the fastest growing group identifying under the trans umbrella is non-binary, and we know even less about the outcomes for this group. Some of you will also become more fluid in your gender identity as you grow older. We do not know the ‘sweet spot’ when someone becomes settled in their sense of self, nor which people are most likely to benefit from medical transition. When making life-changing decisions, what is the correct balance between keeping options as flexible and open as possible as you move into adulthood, and responding to how you feel right now?

Finally, I know you need more than medical intervention, but services are really stretched, and you are not getting the wider support you need in managing any mental health problems, arranging fertility preservation, getting help with any challenges relating to neurodiversity, or even getting counselling to work through questions and issues you may have. We need to look at all the elements that are needed in a package of care that will help you thrive and fulfil your broader life goals.

The first step for the NHS is to expand capacity, offer wider interventions, upskill the broader workforce, take an individualised, personal approach to care, and put in place the mechanisms to collect the data needed for quality improvement and research.

Expanding capacity at all levels of the system will not only allow for more timely care and space to explore, but also free-up the specialist services for those who need them most. I know there are many who have waited too long already and will continue to do so, and that like me, colleagues across the NHS are deeply concerned about this. We can't fix everything overnight, but we must make a start.

I would also like to share some thoughts with all my clinical colleagues. We have to start from the understanding that this group of children and young people are just that; children and young people first and foremost, not individuals solely defined by their gender incongruence or gender-related distress. We have to cut through the noise and polarisation to recognise that they need the same standards of high-quality care to meet their needs as any other child or young person. When you talk to these young people and their parents/carers, they want the same things as everyone else: the chance to be heard, respected and believed; to have their questions answered; and to access help and advice. It is only when they have been on very long waiting lists, and sidelined from usual care in local services, that they are forced to do their own research and may come to a single medical answer to their problems.

As experienced clinicians, you are familiar with dealing with complexity in presentation, but for this group of young people expertise has been concentrated in a small group of people, which has served to gatekeep the knowledge. We have heard many clinical staff question their capacity and capability and this has made them nervous about working within this population. I know you just need the appropriate training, support and most importantly the confidence to do what you have been trained to do and treat this population as you would any other young person in distress.

In conducting this Review I have had to make recommendations based on the currently available information. I am very aware that this is a point in time and as new evidence is gathered different insights might emerge. I have recommended a service model that has inbuilt mechanisms to be able to evolve and adapt with the emerging research overseen by appropriate governance structures both within individual NHS organisations and at a national level.

It is not just children and young people with gender-related distress who are facing emotional and social challenges, but the wider population of adolescents. We can only do our job by being ambitious for all children and young people and prioritising development of services to meet their broader needs.



Dr Hilary Cass, OBE

About this report

The Independent Review of Gender Identity Services for Children and Young People was commissioned by NHS England to make recommendations on the questions relating to the provision of these services as set out in the terms of reference (Appendix 1).

The Review has been forward looking. Its role was to consider how the current clinical approach and service model should be improved. In order to do this, it has been necessary to understand the current landscape and why change is needed, so that any future model addresses existing challenges.

This report is primarily for the commissioners and providers of services for children and young people needing support around their gender. However, because of the wide interest in this topic, effort has been made to make it as accessible as possible, while also representing the data which are sometimes detailed and complex.

The Review is cognisant of the broader cultural and societal debates relating to the rights of transgender people. It is not the role of the Review to take any position on the beliefs that underpin these debates. Rather, this Review is strictly focused on the clinical services provided to children and young people who seek help from the NHS to resolve their gender-related distress.

1. Approach

2. Context

3. Understanding the patient cohort

4. Clinical approach and clinical management

5. Service model

The report has five parts:

Throughout, the Review has focused on hearing a wide range of perspectives to better understand the challenges within the current system and aspirations for how these could be addressed. This report does not contain all that we have heard but summarises consistent themes, using direct quotes to illustrate points made, where appropriate.

The report includes findings from the systematic reviews commissioned from the University of York to inform the work. The full peer reviewed papers are available with open access at **https://adc.bmj.com/pages/gender-identity-service-series**.

The report represents a point in time and draws conclusions and makes recommendations based on the evidence that is currently available.

The Review is independent of the NHS and Government and neither required nor sought approval or sign-off of this report's contents prior to publication.

Language

Labels can be confusing; young people sometimes find them helpful and sometimes find them stigmatising. There is no consensus on the best language to use around this subject. The language surrounding this area has also changed rapidly and young people have developed varied ways of describing their experiences using different terms and constructs that are relevant to them.

The Review tries as far as possible to use language and terms that are respectful and acknowledge diversity, but that also accurately describe the complexity of what we are trying to articulate.

The terms used may not always feel right to some; nevertheless, it is important to emphasise that the language used is not an indication of a position being taken by the Review. A glossary of terms is included. Key definitions are:

Gender incongruence is the term used in the International Classification of Diseases Eleventh Revision (ICD-11) (World Health Organization, 2022) to describe "a marked and persistent incongruence between an individual's experienced gender and the assigned sex". It has been moved out of the "Mental and behavioural disorders" chapter and into the "Conditions related to sexual health" chapter so that it is not perceived as a mental health disorder. It does not include references to dysphoria or dysfunction.

Gender dysphoria is the term used in Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR) (American Psychiatric Association, 2022). In the DSM-5-TR definition gender incongruence has to be associated with clinically significant distress or impairment of function. Younger children with gender incongruence may not experience dysphoria, but it commonly arises or increases as they enter puberty.

Gender dysphoria is the more commonly used term in research publications, as well as clinical settings. It is also most likely to be familiar to the lay public since it has been used widely in mainstream and social media. Like depression, it is a label that is used colloquially to describe feelings, as well as being a formal diagnosis.

Within the report, we use the term gender incongruence as defined above, and gender-related distress to describe the feelings that commonly arise or intensify during puberty and lead to a young person seeking help from the NHS.

The term child is used to refer to pre-pubertal children and young people to refer to under 18s who have entered puberty. The report also refers to adolescents when discussing the stages of brain development, and both adolescents and youth where the study being described uses these terms. Young adults refers to those between the ages of 18 and 30.

During the lifetime of the Review, the term trans has moved from being a quite narrow definition to being applied as an umbrella term to a broader spectrum of gender diversity. This report uses ‘transgender’ to describe binary transgender individuals and ‘non-binary’ for those who do not have a traditional gender binary of male or female. The term ‘gender non-conforming’ is used to describe those individuals who do not choose to conform to traditional gender norms and ‘gender-questioning’ as a broader term that might describe children and young people who are in a process of understanding their gender identity. The term ‘trans’ is used as the umbrella term.

The terms patient and service user are also used throughout the report. Although these have been used interchangeably, we have used service user when someone has used the service but may no longer be a patient under the service.

This report also includes citations from many other sources. It is important to note that these citations may use language and terminology that the Review would not choose. As a general rule, the report retains the language of the referenced papers. Any adaptation of a citation to provide clarity is represented by square brackets.

The Review was commissioned by and is for the NHS in England, however throughout the report we use the terms NHSE, NHS and UK. This is usually to align with the papers and research being discussed.

Summary and recommendations

1. The aim of this Review is to make recommendations that ensure that children and young people who are questioning their gender identity or experiencing gender dysphoria receive a high standard of care. Care that meets their needs, is safe, holistic and effective. At its heart are vulnerable children and young people and an NHS service unable to cope with the demand.

2. Yet from the start, the Review stepped into an arena where there were strong and widely divergent opinions unsupported by adequate evidence. The surrounding noise and increasingly toxic, ideological and polarised public debate has made the work of the Review significantly harder and does nothing to serve the children and young people who may already be subject to significant minority stress.

3. Within this context the Review set out to understand the reasons for the growth in referrals and the changing epidemiology, and to identify the clinical approach and service model that would best serve this population.

4. There are conflicting views about the clinical approach, with expectation at times being far from usual clinical practice. This has made some clinicians fearful of working with gender-questioning young people, despite their presentation being similar to many children and young people presenting to other NHS services.

5. Although some think the clinical approach should be based on a social justice model, the NHS works in an evidence-based way. Whilst navigating a way through the surrounding 'culture war', the Review has been acutely and increasingly aware of the need for evidence to support its thinking and ultimately the final recommendations made in this report.

6. When the Review started, the evidence base, particularly in relation to the use of puberty blockers and masculinising/feminising hormones, had already been shown to be weak. There was, and remains, a lot of misinformation easily accessible online, with opposing sides of the debate pointing to research to justify a position, regardless of the quality of the studies.

7. To understand the best way to support children and young people, the Review's ambition was therefore not only to understand the existing evidence, but also to improve the evidence base so that young people, their families and carers, and the clinicians working with them have the best information upon which to form their decisions.

8. To scrutinise the existing evidence the Review commissioned a robust and independent evidence review and research programme from the University of York to inform its recommendations and remained cautious in its advice whilst awaiting the findings.

9. The University of York's programme of work has shown that there continues to be a lack of high-quality evidence in this area and disappointingly, as will become clear in this report, attempts to improve the evidence base have been thwarted by a lack of cooperation from the adult gender services.

10. The Review has therefore had to base its recommendations on the currently available evidence, supplemented by its own extensive programme of engagement.

11. Hearing directly from people with lived experience and clinicians has provided valuable insight into the ways in which services are currently delivered and experienced. This has contributed to the Review's understanding of the positive experiences of living as a trans or gender diverse person, as well the uncertainties, complexities and challenges faced by children, young people, their families and carers, and those working in and around services trying to support them.

12. This report is organised into five parts:

- **Part 1** - Approach describes the Review's approach to the work undertaken.
- **Part 2** - Context explores the history of services for children and young people with gender dysphoria, highlighting the changing demographic and the rise in referral rate.
- **Part 3** - Understanding the patient cohort sets out what we have learnt about the characteristics of children and young people who are seeking NHS support for gender incongruence and considers what may be driving the rise in referrals and the change in the case-mix.
- **Part 4** - Clinical approach and clinical management looks at what we need to do to help children and young people to thrive: the purpose, expected benefits and outcomes of clinical interventions in the pathway, including the use of hormones and how to support complex presentations.
- **Part 5** - Service model considers the gender service delivery model, workforce requirements, pathways of care into this specialist service, further development of the evidence base and how to embed continuous clinical improvement and research.

13. At the end of this Review, while there is still uncertainty, the following remains true:

- There are children and young people, families and carers all trying to make sense of their individual situations, often dealing with considerable challenges and upheaval.
- The length of the waiting list to access gender services has significant implications for this population and NHS service delivery.
- Generalisations about children and young people questioning their gender identity or experiencing gender dysphoria are unhelpful. People are individuals.
- Young people's sense of identity is not always fixed and may evolve over time. There should be no hierarchy of gender identity or how this is expressed, be that socially or medically. Nobody should feel the need to invalidate their own experience for fear it reflects badly on other identities and choices.
- Whilst some young people may feel an urgency to transition, young adults looking back at their younger selves would often advise slowing down.
- For some, the best outcome will be transition, whereas others may resolve their distress in other ways. Some may transition and then de/retransition and/or experience regret. The NHS needs to care for all those seeking support.
- The care of this population needs to be holistic and personal. It may comprise a wide range of interventions and services, some of which can be delivered outside NHS specialist services.

- There remains diversity of opinion as to how best to treat these children and young people. The evidence is weak and clinicians have told us they are unable to determine with any certainty which children and young people will go on to have an enduring trans identity.
- Many primary and secondary care clinicians have concerns about their capacity and competence to work with this population and some are fearful of doing so given the surrounding social debate.
- Our current understanding of the long-term health impacts of hormone interventions is limited and needs to be better understood.
- Young people become particularly vulnerable at the point of transfer to adult services.

14. Whatever your views on gender identity, there is no denying there are increasing numbers of children and young people seeking support from the NHS for gender-related distress. They should receive the same quality of care as other children and young people experiencing distress.

15. A compassionate and kind society remembers that there are real children, young people, families, carers and clinicians behind the headlines. The Review believes that each individual child and young person seeking help from the NHS should receive the support they need to thrive.

Key points and recommendations

16. In considering the key questions outlined in the terms of reference, this Report can only set out what is known and unknown and think about how the NHS can respond safely, effectively and compassionately, leaving some issues for wider societal debate. However, in order to gain as broad an understanding as possible the Review drew on several sources of information (see Figure 1), underpinned by basic scientific and clinical principles.

Figure 1: What has informed the Review?



Evidence

- Series of systematic reviews
- Qualitative research
- Quantitative research
- GIDS discharge summary audit



Lived Experience

- Weekly listening sessions with individual service users & parents
- Focus groups with young people & young adults
- Regular meetings with support & advocacy groups
- Existing documented insights into lived experience
- Personal narratives





Professional Input

- Listening sessions with clinicans & other professionals
- Focus groups with GIDS staff
- Programme of thematic roundtables
- Professional panel & online survey
- Clinical Expert Group
- Workshops & discussions with frontline staff, professional bodies, national organisations & system leaders

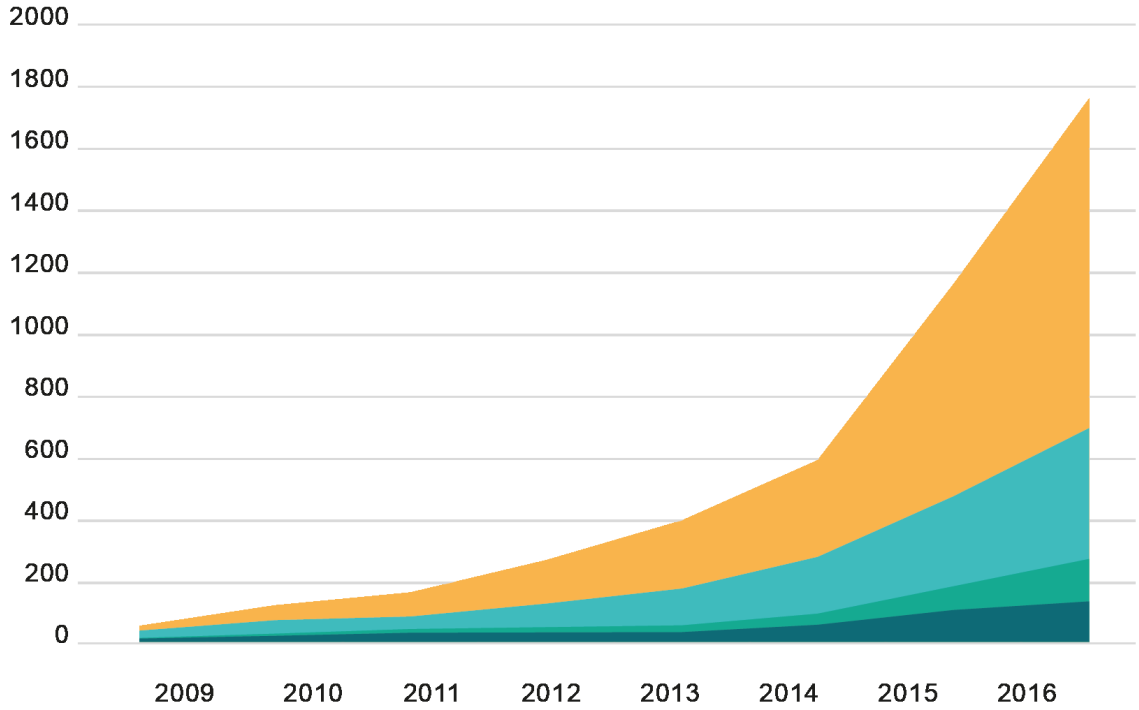


International Sources

- Guideline appraisal
- International survey
- Meetings with international clinicians & policy makers

17. The numbers of children and young people presenting to the UK NHS Gender Identity Service (GIDS) has been increasing year on year since 2009, with an exponential rise in 2014.

Figure 2: Sex ratio in children and adolescents referred to GIDS in the UK (2009-16)



	2009	2010	2011	2012	2013	2014	2015	2016
Adolescents F	15	48*	78*	141*	221*	314*	689*	1071*
Adolescents M	24	44*	41	77*	120*	185*	293*	426*
Children F	2	7	12	17	22	36	77*	138*
Children M	10	19	29	30	31	55*	103*	131

AFAB = Assigned female at birth

AMAB = Assigned male at birth

*Indicates p< .05 which shows a significant increase of referrals compared to previous year

Source: Figure adapted from de Graaf, N. M., Giovanardi, G., Zitz, C., & Carmichael, P. (2018). Sex ratio in children and adolescents referred to the Gender Identity Development Service in the UK (2009-2016). Archives of Sexual Behavior, 47(5), 1301-1304. https://doi.org/10.1007/s10508-018-1204-9, with permission from Springer Nature.

18. Prior to 2009, GIDS did not attract significant attention. At that time, the service saw fewer than 50 children per year, with even fewer receiving medical treatment. However, unprecedented demand and a change in the demographic of young people accessing gender services has generated a series of unresolved issues, a long waiting list and an unsustainable service model, one that was not set up to manage the new population.

19. The Review has focused on future provision and has not scrutinised previous provision, but it is necessary to look back to fully appreciate the context leading to the current circumstances and to learn lessons relating to previous and current clinical management and understand why change is needed.

20. GIDS was established in 1989. At that time, the service saw fewer than 10 children a year, predominantly pre-pubertal birth-registered males, and the main focus was therapeutic, with only a small proportion referred for hormone treatment by around age 16.

21. The approach to treatment changed with the emergence of 'the Dutch Protocol' which involved the use of puberty blockers from early puberty. In 2011, the UK trialled the use of puberty blockers in the 'early intervention study.'

22. Preliminary results from the early intervention study in 2015-2016 did not demonstrate benefit. The results of the study were not formally published until 2020, at which time it showed there was a lack of any positive measurable outcomes. Despite this, from 2014 puberty blockers moved from a research-only protocol to being available in routine clinical practice and were given to a broader group of patients who would not have met the inclusion criteria of the original protocol.

23. The adoption of a treatment with uncertain benefits without further scrutiny is a significant departure from established practice. This, in combination with the long delay in publication of the results of the study, has had significant consequences in terms of patient expectations of intended benefits and demand for treatment.

24. A planned update of the service specification by NHS England in 2019, examined the published evidence on medical interventions in this area and found it to be weak. In the absence of a clear evidence base on how best to support the growing numbers of gender-questioning children and young people seeking help from the NHS this Independent Review was commissioned by NHS England in autumn 2020.

Interim report

25. In 2022, the Review published an interim report, which provided some initial advice. It set out the importance of evidence-based service development and highlighted major gaps and weaknesses in the research base underpinning the clinical management of children and young people with gender incongruence and gender dysphoria, including the appropriate approaches to assessment and treatment. Critically, the interim report highlighted that little is known about the medium- and longer-term outcomes for children and young people receiving NHS support and/or treatment.

26. This lack of evidence placed limitations on the advice that could be given by the Review. An independent research programme was commissioned with the aim of providing the Review with the best available collation of published evidence, as well as qualitative and quantitative research to fill knowledge gaps.

27. The research programme, led by the University of York, comprised appraisal of the published evidence and guidelines, an international survey and quantitative and qualitative research. A Clinical Expert Group (CEG) was established by the Review to help interpret the findings.

28. This final report provides full details of the research approach and methodology used by the research team and a synthesis of the findings alongside interpretation of what they mean for the Review. The peer reviewed systematic reviews have been published alongside this report.

29. In addition to formal research, an extensive programme of engagement has informed the Review. A mixed-methods approach was taken that prioritised input from people with relevant lived experience and organisations working with LGBTQ+ youth or children and young people generally, and clinicians and other professionals with responsibility for providing care and support to children and young people within specialist gender services and beyond.

Understanding the patient cohort

30. The Review explored the reasons for the increase in referrals and why this increase has disproportionately been seen in birth-registered females presenting in adolescence, and the implications of this for the service.

31. This is a different cohort from that looked at by earlier studies. Among referrals there is a greater complexity of presentation with high levels of neurodiversity and/or co-occurring mental health issues and a higher prevalence than in the general population of adverse childhood experiences and looked after children. The increase in referrals and change in case-mix is also being seen internationally.

32. Understanding who is accessing services informs an appropriate clinical approach. Therefore, to gain a complete understanding, the Review examined what is known about the nature and causes of gender incongruence and dysphoria. This goes to the heart of some of the core controversies in this area.

33. A failure to consider or debate the underlying reasons for the change in the patient population has led to people taking different positions about how to respond to the children and young people at the centre of the debate, without reasoned discussion about what has led to their gender experience and distress.

34. There is broad agreement that gender incongruence, like many other human characteristics, arises from a combination of biological, psychological, social and cultural factors.

35. A common explanation put forward is that the increase in presentation is because of greater acceptance. While it certainly seems to be the case that there is much greater acceptance of trans identities, particularly among younger generations, which may account for some of the increase in numbers, the exponential change in referrals over a particularly short five-year timeframe is very much faster than would be expected for normal evolution of acceptance of a minority group. This also does not adequately explain the switch from birth-registered males to birth-registered females, which is unlike trans presentations in any prior historical period.

36. There are different issues involved in considering gender care for children and young people than for adults. Children and young people are on a developmental trajectory that continues to their mid-20s and this needs to be considered when thinking about the determinants of gender incongruence. An understanding of brain development and the usual developmental tasks of adolescence is

essential in understanding how development of gender identity relates to the other aspects of adolescent development.

37. This group of young people should also be considered in the context of a wider group of adolescents with complex presentations seeking help from the NHS. There has been a substantial increase in rates of mental health problems in children and adolescents across the UK over the past decade, with increased anxiety and depression being most evident in teenage girls and a rise in young people presenting with other bodily manifestations of distress; for example, eating disorders, tics and body dysmorphic disorder.

38. Research suggests gender expression is likely determined by a variable mix of factors such as biological predisposition, early childhood experiences, sexuality and expectations of puberty. For some, mental health difficulties are hard to disentangle. The impact of a variety of contemporary societal influences and stressors (including online experience) remains unclear. Peer influence is also very powerful during adolescence as are different generational perspectives.

39. Pragmatically the above explanations for the observed changes in the population are all likely to be true to a greater or lesser extent, but for any individual a different mix of factors will apply.

40. This is a heterogenous group, with broad ranging presentations often including complex needs that extend beyond gender-related distress and this needs to be reflected in the services offered to them by the NHS.

41. Too often this cohort are considered a homogenous group for whom there is a single driving cause and an optimum treatment approach, but this is an over-simplification of the situation. Being gender-questioning or having a trans identity means different things to different people. Among those being referred to children and young people's gender services, some may benefit from medical intervention and some may not. The clinical approach must reflect this.

42. Working through this multi-layered developmental process takes time, and the role of the clinical team is to help the young person address some of these issues so that they can better understand their gender identity and evaluate the options available to them.

Clinical approach and management

43. Clinicians have a range of viewpoints on the care and treatment of gender-questioning children and young people, with many left confused as to what the best approach might be. There are mixed views on what young people want and need; for example, young people have told us they need space and time to explore, but also that questioning feels intrusive. Some parents feel less questioning is needed, whilst others think the process is not thorough enough.

44. The Review sought to better understand the different clinical approaches and management, including through a standardised procedure for appraising international clinical guidelines (carried out by the research team at the University of York).

45. The findings raise questions about the quality of currently available guidelines. Most guidelines have not followed the international standards for guideline development, and because of this the research team could only recommend two guidelines for practice - the Finnish guideline published in 2020 and the Swedish guideline published in 2022.

46. However, even these guidelines lack clear recommendations regarding certain aspects of practice and would be of benefit if they provided more detailed guidance on how to implement recommendations.

47. The World Professional Association of Transgender Healthcare (WPATH) has been highly influential in directing international practice, although its guidelines were found by the University of York appraisal process to lack developmental rigour.

48. Early versions of two international guidelines - the Endocrine Society 2009 and WPATH 7 - influenced nearly all the other guidelines, except for the recent Nordic guidelines.

49. Given the lack of evidence-based guidelines, it is imperative that staff working within NHS gender services are cognisant of the limitations in relation to the evidence base and fully understand the knowns and the unknowns.

Assessment

50. The interim report advised that a developmentally informed assessment framework is needed to guard against inconsistencies and gaps in the assessment process, with clear responsibility and guidance for the different components of the process at primary, secondary and tertiary level.

51. Despite the agreement within the international guidelines on the need for a multi-disciplinary team, and some commonalities between them in the areas explored during the assessment process, the most striking problem is the lack of any consensus on the purpose of the assessment process.

52. In response to these findings, the Review asked its CEG to develop a consensus on the purpose of and approach to assessment.

53. Cognisant of the inconsistency in the published research and the complexity of presentations, the CEG worked to develop a holistic needs assessment framework. Its purpose is to derive a multi-level formulation leading to an individual care plan that supports the development of the child/young person's broader wellbeing and functioning. This is consistent with approaches for adolescents with other complex multi-faceted presentations.

54. When conducting an assessment, it will be important that clinicians are mindful that presentations, pathways and outcomes for this cohort are very individual, and the focus needs to be on helping each person to find the best pathway for them. Assessments should be respectful of the individual's experience and be developmentally informed.

Recommendation 1:

Given the complexity of this population, these services must operate to the same standards as other services seeing children and young people with complex presentations and/or additional risk factors. There should be a nominated medical practitioner (paediatrician/child psychiatrist) who takes overall clinical responsibility for patient safety within the service.

Recommendation 2:

Clinicians should apply the assessment framework developed by the Review's Clinical Expert Group, to ensure children/ young people referred to NHS gender services receive a holistic assessment of their needs to inform an individualised care plan. This should include screening for neurodevelopmental conditions, including autism spectrum disorder, and a mental health assessment. The framework should be kept under review and evolve to reflect emerging evidence.

Diagnosis

55. The Review has heard mixed views about how young people perceive the value of a diagnosis of gender dysphoria. Many young people do not see themselves as having a medical condition and some may feel it undermines their autonomy and right to self-determination. Others see diagnosis as validating, and important when looking to access hormone treatment.

56. Some service users and advocates view an extensive exploration of other conditions and diagnoses as an attempt to find 'any other reason' for the person's distress other than them being trans.

57. There are several reasons why listing all relevant formal diagnoses is important for this group of children and young people:

- To provide the best evidence-based care, it is important that the clinician considers all possible (sometimes multiple) diagnoses that may be hindering the young person's wellbeing and ability to thrive.
- The clinician carries responsibility for the assessment, subsequent treatment recommendations and any harm that might be caused to a patient under their care. They need to define as clearly and reproducibly as they can exactly what condition they are treating to be accountable for their decisions on the options offered to the patient. If they are offering potentially irreversible medical treatments to a patient, it is important to specify whether the patient meets formal diagnostic criteria for gender dysphoria or any other conditions.
- Finally, the Review's commissioned systematic review demonstrated that other diagnoses within the group were not consistently documented, and in order to better understand and support these young people it is essential that all diagnoses are systematically recorded for clinical and research purposes.

58. Although a diagnosis of gender dysphoria has been seen as necessary for initiating medical treatment, it is not reliably predictive of whether that young person will have longstanding gender incongruence in the future, or whether medical intervention will be the best option for them. Understanding how the gender-related distress has evolved in a particular individual, what other factors may be contributing, and the individual's needs and preferences for treatment are equally important.

59. It is also important to ensure that there is a focus on functioning, general well-being and resilience, to ensure the child/young person is able to make considered decisions about their future pathway.

Individualised care plan

60. Historically, the model of care for children and young people presenting with gender incongruence or distress was entirely based on a psychosocial model, with medical interventions being introduced more recently. Most clinical teams would still see psychosocial interventions as the starting point in a care pathway.

61. The controversy surrounding the use of medical treatments has taken focus away from what an individual's care and treatment plan is intended to achieve, both for individual children and young people and for the overall population.

62. The Review has kept at its heart the concern that clinicians are dealing with a group of children and young people who frequently, albeit not always, will be in a state of considerable distress by the time they present to the NHS, and will often have multiple unmet needs.

63. There should be a tiered approach to any intervention package which:

- addresses urgent risk;
- reduces distress and associated mental health issues and psychosocial stressors, so that the young person is able to function and make complex decisions;
- co-develops a plan for addressing the gender issues, which may involve any combination of social, psychological and physical interventions.

64. There should be a distinction for the approach taken to pre- and post-pubertal children when considering the most appropriate interventions. This is of particular importance in relation to social transition, which may not be thought of as an intervention or treatment because it is something that generally happens at home, online or in school and not within health services.

65. The central aim is to help young people to thrive and achieve their life goals. The immediate goal of the care and treatment plan must be to address distress, if this is part of the child/young person's presentation, and any barriers to participation in everyday life (for example, school community or social activities).

66. For the majority of young people, a medical pathway may not be the best way to achieve this. For those young people for whom a medical pathway is clinically indicated, it is not enough to provide this without also addressing wider mental health and/or psychosocially challenging problems such as family breakdown, barriers to participation in school life or social activities, bullying and minority stress.

Psychological interventions

67. The systematic review of psychosocial interventions found that the low quality of the studies, the poor reporting of the intervention details, and the wide variation in the types of interventions investigated, meant it was not possible to determine how effective different interventions were for children and young people experiencing gender distress.

68. Despite this, we know that many psychological therapies have a good evidence base for the treatment in the general population of conditions that are common in this group, such as depression and anxiety. This is why it is so important to understand the full range of needs and ensure that these young people have access to the same helpful evidence-based interventions as others.

69. In addition to treating co-existing conditions, the focus on the use of puberty blockers for managing gender-related distress has overshadowed the possibility that other evidence-based treatments may be more effective. The intent of psychosocial intervention is not to change the person's perception of who they are, but to work with them to explore their concerns and experiences and help alleviate their distress regardless of whether or not the young person subsequently proceeds on a medical pathway.

70. The role of therapeutic approaches needs to be understood and data and information must be collected on the applicability of approaches for gender-related distress and any co-occurring conditions. This will start to bring understanding the efficacy of treatments in line with those routinely used for other children and young people in distress

Social transition

71. There is no single definition of social transition, but it is broadly understood to refer to social changes to live as a different gender such as altering hair or clothing, name change, and/or use of different pronouns.

Recommendation 3:

Standard evidence based psychological and psychopharmacological treatment approaches should be used to support the management of the associated distress and cooccurring conditions. This should include support for parents/carers and siblings as appropriate.

72. There is a spectrum from young people who make relatively limited gender non-conforming changes in appearance to those who may have fully socially transitioned from an early age and may be living in stealth.

73. One key difference between children and adolescents is that parental attitudes and beliefs will have an impact on whether the child socially transitions. For adolescents, exploration is a normal process, and rigid binary gender stereotypes can be unhelpful.

74. There are different views on the benefits versus the harms of early social transition. Some consider that it may improve mental health for children experiencing gender-related distress, while others consider that it makes it more likely that a child's gender dysphoria, which might have resolved at puberty, has an altered trajectory potentially, culminating in life-long medical intervention.

75. In the UK and internationally, it is now the norm for many children and young people to present to gender clinics having undergone full or partial social transition.

76. The systematic review showed no clear evidence that social transition in childhood has any positive or negative mental health outcomes, and relatively weak evidence for any effect in adolescence. However, those who had socially transitioned at an earlier age and/or prior to being seen in clinic were more likely to proceed to a medical pathway.

77. Although it is not possible to know from these studies whether earlier social transition was causative in this outcome, lessons from studies of children with differences in sexual development (DSD) show that a complex interplay between prenatal androgen levels, external genitalia, sex of rearing and socio-cultural environment all play a part in eventual gender identity.

78. Therefore, sex of rearing seems to have some influence on eventual gender outcome, and it is possible that social transition in childhood may change the trajectory of gender identity development for children with early gender incongruence.

79. The clinician should help families to recognise normal developmental variation in gender role behaviour and expression. Avoiding premature decisions and considering partial rather than full transitioning can be a way of ensuring flexibility and keeping options open until the developmental trajectory becomes clearer.

Recommendation 4:

When families/carers are making decisions about social transition of pre-pubertal children, services should ensure that they can be seen as early as possible by a clinical professional with relevant experience.

Medical pathways

80. The original rationale for use of puberty blockers was that this would buy 'time to think' by delaying onset of puberty and also improve the ability to 'pass' in later life. Subsequently it was suggested that they may also improve body image and psychological wellbeing.

81. The systematic review undertaken by the University of York found multiple studies demonstrating that puberty blockers exert their intended effect in suppressing puberty, and also that bone density is compromised during puberty suppression.

82. However, no changes in gender dysphoria or body satisfaction were demonstrated. There was insufficient/inconsistent evidence about the effects of puberty suppression on psychological or psychosocial wellbeing, cognitive development, cardio-metabolic risk or fertility.

83. Moreover, given that the vast majority of young people started on puberty blockers proceed from puberty blockers to masculinising/feminising hormones, there is no evidence that puberty blockers buy time to think, and some concern that they may change the trajectory of psychosexual and gender identity development.

84. The Review's letter to NHS England (July 2023) advised that because puberty blockers only have clearly defined benefits in quite narrow circumstances, and because of the potential risks to neurocognitive development, psychosexual development and longer-term bone health, they should only be offered under a research protocol. This has been taken forward by NHS England and National Institute for Health and Care Research (NIHR).

85. The University of York also carried out a systematic review of outcomes of masculinising/feminising hormones. Overall, the authors concluded that "There is a lack of high-quality research assessing the outcomes of hormone interventions in adolescents with gender dysphoria/incongruence, and few studies that undertake long-term follow-up. No conclusions can be drawn about the effect on gender dysphoria, body satisfaction, psychosocial health, cognitive development, or fertility. Uncertainty remains about the outcomes for height/growth, cardiometabolic and bone health. There is suggestive evidence from mainly pre-post studies that hormone treatment may improve psychological health, although robust research with long-term follow-up is needed".

86. It has been suggested that hormone treatment reduces the elevated risk of death by suicide in this population, but the evidence found did not support this conclusion.

87. The percentage of people treated with hormones who subsequently detransition remains unknown due to the lack of long-term follow-up studies, although there is suggestion that numbers are increasing.

88. A problem, that has become increasingly apparent as the Review has progressed is that research on psychosocial interventions and longer-term outcomes for those who do not access endocrine pathways is as weak as research on endocrine treatment. This leaves a major gap in our knowledge about how best to support and help the growing population of young people with gender-related distress in the context of complex presentations.

Long-term outcomes

89. One of the major difficulties with planning and evaluating gender identity services for children and young people is the very limited evidence on the longer-term outcomes for people who have accessed GIDS.

90. When clinicians talk to patients about what interventions may be best for them, they usually refer to the longer-term benefits and risks of different options, based on outcome data from other people who have been through a similar care pathway. This information is not currently available for interventions in children and young people with gender incongruence or gender dysphoria, so young people and their families have to make decisions without an adequate picture of the potential impacts and outcomes.

91. A strand of research commissioned by the Review was a quantitative data linkage study. The aim of this study was to fill some of the gaps in follow-up data for the approximately 9,000 young people who have been through GIDS. This would help to develop a stronger evidence base about the types of support and interventions received and longer-term outcomes. This required cooperation of GIDS and the NHS adult gender services.

92. In January 2024, the Review received a letter from NHS England stating that, despite efforts to encourage the participation of the NHS gender clinics, the necessary cooperation had not been forthcoming.

93. This quantitative study represents a unique opportunity to provide further evidence to assist young people, their parents/carers, and the clinicians working with them to make informed decisions about the right pathway for them.

94. Although retrospective research is never as robust as prospective research, it would take a minimum of 10-15 years to extract the necessary follow-up data

95. NHS England has stated a commitment to realising the ambitions of the data linkage study beyond the life of the Review and the Review has detailed the University of York's experience in trying to move the study forward.

Recommendation 5:

NHS England, working with DHSC should direct the gender clinics to participate in the data linkage study within the lifetime of the current statutory instrument. NHS England's Research Oversight Board should take responsibility for interpreting the findings of the research.

Challenges in clinical decision making

96. One of the main areas of contention in the provision of gender services for children and young people is the use of hormone treatments for gender dysphoria. In developing its vision for the new service, the Review has considered the issue of consent, the challenges of which were starkly brought to light by the Bell vs Tavistock case.

97. The Judicial Review's responsibilities could not be extended beyond the issue of capacity and competence to consent. However, consent is more than just capacity and competence. It requires clinicians to ensure that the proposed intervention is clinically indicated as they have a duty to offer appropriate treatment. It also requires the patient to be provided with appropriate and sufficient information about the risks, benefits and expected outcomes of the treatment.

98. Assessing whether a hormone pathway is indicated is challenging. A formal diagnosis of gender dysphoria is frequently cited as a prerequisite for accessing hormone treatment. However, it is not reliably predictive of whether that young person will have longstanding gender incongruence in the future, or whether medical intervention will be the best option for them.

99. In addition, the poor evidence base makes it difficult to provide adequate information on which a young person and their family can make an informed choice.

100. A trusted source of information is needed on all aspects of medical care, but in particular it is important to defuse/manage expectations that have been built up by claims about the efficacy of puberty blockers.

101. Although young people often express a sense of urgency in their wish to access medical treatments, based on personal experience some young adults have suggested that taking time to explore options is preferable. The option to provide masculinising/feminising hormones from the age of 16 is available, but the Review would recommend an extremely cautious clinical approach and a strong clinical rationale for providing hormones before the age of 18. This would keep options open during this important developmental window, allowing time for management of any co-occurring conditions, building of resilience, and fertility preservation, if required.

102. The overarching conclusion from the evidence presented in this Review is that the puberty blocker research protocol, which is already in development, needs to be one part of a much broader research programme that seeks to build the evidence on all potential interventions and determine the most effective way of supporting these children and young people.

Recommendation 6:

The evidence base underpinning medical and non-medical interventions in this clinical area must be improved. Following our earlier recommendation to establish a puberty blocker trial, which has been taken forward by NHS England, we further recommend a full programme of research be established. This should look at the characteristics, interventions and outcomes of every young person presenting to the NHS gender services.

- The puberty blocker trial should be part of a programme of research which also evaluates outcomes of psychosocial interventions and masculinising/feminising hormones.
- Consent should routinely be sought for all children and young people for enrolment in a research study with follow-up into adulthood.

Recommendation 7:

Long-standing gender incongruence should be an essential pre-requisite for medical treatment but is only one aspect of deciding whether a medical pathway is the right option for an individual.

Recommendation 8:

NHS England should review the policy on masculinising/feminising hormones. The option to provide masculinising/feminising hormones from age 16 is available, but the Review would recommend extreme caution. There should be a clear clinical rationale for providing hormones at this stage rather than waiting until an individual reaches 18.

Recommendation 9:

Every case considered for medical treatment should be discussed at a national Multi Disciplinary Team (MDT) hosted by the National Provider Collaborative replacing the Multi Professional Review Group (MPRG).

Recommendation 10:

All children should be offered fertility counselling and preservation prior to going onto a medical pathway.

Service model

103. Since receiving the Review's interim report, NHS England has taken steps to increase capacity, establishing two new services led by specialist children's hospitals. This is the first step in commissioning a network of regional services across the country.

104. The Review had hoped to take learning from these interim services. Instead, it has gained insight from the considerable challenges faced in their establishment within a highly emotive and politicised arena. This, coupled with concerns about the weakness of the evidence base and lack of professional guidance, has impacted on the ability of the new services to recruit the appropriate multi-disciplinary workforce.

105. The Review welcomes the first steps NHS England has taken to establish a regional model of care, but maintains that a distributed model of care is needed to meet current demand and provide a more appropriate holistic, localised and timely approach to caring for children and young people needing support.

106. Services should not be located solely in tertiary centres and a much broader based service model is needed with a flexible workforce working across a regional footprint in partnership with local services. Models of care that deliver a clinical service over multiple sites have a potential to maintain geographical access to services whilst improving quality of care and optimising the use of the workforce.

107. Clinical Network and Multi-Site models provide better continuity of care, closer to home, and the ability for children and young people to move more easily between components of the service at their own pace. They also allow the workforce to be shared across the network without destabilising local services and address some of the recruitment challenges experienced by both GIDS and the new providers.

108. Establishment of a National Provider Collaborative should ensure the regional centres operate to shared standards and operating procedures, developing protocols for assessment and treatment. The Collaborative should have a role in overseeing ethics, training and professional development, data and audit, quality improvement and research requirements, as well as providing a forum for the discussion of complex cases. The aim is that no matter where in the country the child/young person is seen, they will receive the same high standards of evidence-based care.

109. In addition to the single overarching National Provider Network, each Regional Centre should work with local services within their region as a formalised Operational Delivery Network (ODN). These formalised networks and increased number of providers should allow care and risk to be actively managed at different levels according to need, reducing waiting times for specialist care.

110. This model will also support integration between different children's services and facilitate early access to local services along flexible pathways that better respond to individual needs. Overall, this model should improve the experience of care for children and young people questioning their gender identity.

111. The new regional services should establish the National Provider Collaborative without delay and quickly develop their networks, utilising existing local relationships in the first instance to accelerate service provision. This approach would act as a stepping stone to ultimately skilling up all secondary level services to provide assessment and psychological support for these children and young people, with medical intervention remaining at tertiary level.

Recommendation 11:

NHS England and service providers should work to develop the regional multi-site service networks as soon as possible. This could be based on a lead provider model, where NHS England delegates commissioning responsibility to the regional services to subcontract locally to providers in their region.

Recommendation 12:

The National Provider Collaborative should be established without delay.

Workforce

112. The Review recognises that workforce shortfalls are one of the most challenging aspects of delivering this service.

113. Within the existing model of care, the vast majority of gender-questioning children and young people who seek help from the NHS have been referred to a highly specialised workforce working solely in gender care. A smaller number are successfully supported in local Child and Adolescent Mental Health Services (CAMHS) or paediatric services. This approach has had the unintended consequence of deskilling the rest of the workforce and generating unmanageably long waiting lists.

114. Given the increasing numbers of gender diverse and gender-questioning young people, it is important that all clinical staff can support them in a range of settings across the NHS. It is equally important that professionals who are involved in their ongoing care have broad-based skills in adolescent physical and mental health so that young people are treated holistically and not solely on the basis of their gender presentation.

115. In line with international practice, the Regional Centres will need a broad multi-professional workforce. The skills of those working within the service need to reflect the broad and varied needs of this heterogenous group and the service needs to include the appropriate skill mix to support both individuals for whom medical intervention is clinically indicated and those for whom it is not.

116. This workforce should include psychiatrists, paediatricians, psychologists, psychotherapists, clinical nurse specialists, social workers, specialists in autism and other neurodiverse presentations, speech and language therapists, occupational therapists and, for the subgroup for whom medical treatment may be considered appropriate, endocrinologists and fertility specialists. Social care should also be embedded and there should be expertise in safeguarding and support for looked-after children and children who have experienced trauma.

117. When outlining the future service model, to increase the available workforce without depleting other service areas, the Review has described a flexible, multi-site staff group working under joint contracts that support flexibility.

120. Staff should maintain a broad clinical perspective by working across related non-gender services within the tertiary centre and between tertiary and secondary centres in order to

embed the care of children and young people with gender-related distress within a broader child and adolescent health context. This has the additional benefits of not destabilising existing services, supporting continuity and connection and democratising knowledge.

118. This is a highly challenging, complex and emotive area in which to work. Those working with this group should have professional supervision and support to provide a place for exploration of their own approach and the range of emotions they may feel. There should be formal processes for raising concerns that sit outside immediate supervision. This should also support consistency in approach and improve retention of the workforce.

119. The National Provider Collaborative should also explore running structured forums where all staff, clinical and non-clinical, come together regularly to discuss the emotional and social aspects of working within the service - supporting staff by giving them a safe place to raise issues.

Recommendation 13:

To increase the available workforce and maintain a broader clinical lens, joint contracts should be utilised to support staff to work across the network and across different services.

Recommendation 14:

NHS England, through its Workforce Training and Education function, must ensure requirements for this service area are built into overall workforce planning for adolescent services.

Training and education

120. There is a lack of confidence among the wider workforce to engage with gender-questioning children and adolescents. Many clinicians working with children and young people have transferable skills and expertise, but there is a need for all clinicians across the NHS to receive better training on how to work sensitively and effectively with trans, non-binary and gender-questioning young people.

121. Clinicians working with children and young people and families/carers will need to have the skills to competently engage families/carers from a broad range of backgrounds, and be aware and informed of the range of priorities that young people and their parents/carers can present to services.

122. Young people told the Review that they want clinicians to listen to them, respect how they feel and support them to work through their feelings and options. They expect clinicians to display compassion, understanding and validation, and to treat them as an individual.

123. Training programmes should follow practice in other service areas (for example, safeguarding), where the level of competency and training needs depend on the staff group and clinical area.

124. A consortium of relevant Medical Royal Colleges and professional bodies should develop a shared skills and competency framework relevant to all clinical and social care staff working in this area at different levels within the system. This should include broader skills in adolescent care, as well as the more specific aspects relevant to gender care.

125. Individual professional organisations should determine which of the transferable skills and competencies are already embedded in the training curricula of their specific staff groups and where the gaps are.

126. The consortium should then develop a curriculum to cover topics that are deemed to be missing from existing training programmes and curricula, and necessary for top-up training/ continuing professional development (CPD)/ credentialing for individuals working within this area.

Recommendation 15:

NHS England should commission a lead organisation to establish a consortium of relevant professional bodies to:

- develop a competency framework
- identify gaps in professional training programmes
- develop a suite of training materials to supplement professional competencies, appropriate to their clinical field and level. This should include a module on the holistic assessment framework and approach to formulation and care planning.

Recommendation 16:

The National Provider Collaborative should coordinate development of evidence-based information and resources for young people, parents and carers. Consideration should be given as to whether this should be a centrally hosted NHS online resource.

Service improvement

127. Central to any service improvement is the systematic and consistent collection of data on the outcomes of treatment.

128. Throughout the course of the Review, it has been evident that there has been a failure to reliably collect even the most basic data and information in a consistent and comprehensive manner; data have often not been shared or have been unavailable.

129. It will be critical that the new services form a learning environment. There should be a process of continuous service improvement and clinical reflection, with consideration of how services should evolve as the evidence base grows and care pathways are evaluated.

130. There remains the need for the collection of an agreed core dataset to inform service improvement and research, based on similar approaches already established in other specialties; for example, in paediatric critical care. This will be critical to informing current and future clinical practice and care for this population.

Recommendation 17:

A core national data set should be defined for both specialist and designated local specialist services.

Recommendation 18:

The national infrastructure should be put in place to manage data collection and audit and this should be used use this to drive continuous quality improvement and research in an active learning environment.

Clinical research capacity

131. The gaps in the evidence base regarding all aspects of gender care for children and young people have been highlighted, from epidemiology through to assessment, diagnosis and intervention.

132. It is troubling that so little is known about this cohort and their outcomes. An ongoing programme of work is required if the new case-mix of children and young people and their needs are to be fully understood, as well as the short- medium- and longer-term impacts of all clinical interventions.

133. Given the uncertainties regarding the long-term outcomes for medical and non-medical interventions, and the broader knowledge gaps in this area, research capacity is needed to:

- provide ongoing appraisal of new research and rapid translation into clinical practice;
- continue to identify areas of practice where further research is needed;
- fast-track the development of an ambitious research portfolio that will inform policy on assessment, support and clinical care of children with gender dysphoria, from presentation through to appropriate social, psychological and medical management.

134. The appropriate research questions and protocols will need to be developed with input from a panel of academics, clinicians, service users and ethicists.

135. To build on the work undertaken by the University of York and maintain an up-to-date understanding of this complex and fast-moving research area, a living systematic review (where the systematic review could be continually updated to reflect new evidence as it becomes available to inform the clinical approach of the new services, ensuring it remains up-to-date and dynamic) should be established.

136. Without an established research strategy and infrastructure, the outstanding questions relating to interventions to support this population will remain unanswered, and the evidence gaps will continue to be filled with opinion and conjecture.

137. Better quality evidence is critical if the NHS is to provide reliable, transparent information and advice to support children, young people, their parents and carers in making potentially life-changing decisions.

Recommendation 19:

NHS England and the National Institute for Health and Care Research (NIHR) should ensure that the academic and administrative infrastructure to support a programme of clinically-based research is embedded into the Regional Centres.

Recommendation 20:

A unified research strategy should be established across the Regional Centres, co-ordinated through the National Provider Collaborative and the Research Oversight Board, so that all data collected are utilised to best effect and for sufficient numbers of individuals to be meaningful.

Recommendation 21:

To ensure that services are operating to the highest standards of evidence the National Institute for Health and Care Research (NIHR) should commission a living systematic review to inform the evolving clinical approach.

Pathways

138. Clear criteria are needed for referral to services along the pathway from primary to tertiary care so that gender-questioning children and young people who seek help from the NHS have equitable access to services.

139. When the Review commenced, access to the specialist GIDS service was unusual in that the service accepted referrals directly from primary care (a GP) and from non-healthcare professionals including teachers and youth workers.

140. NHS England has since consulted on a proposal for all referrals to come via secondary care and the Review supports this approach.

141. This report sets out the different roles and responsibilities within the Review's proposed service delivery model; from primary through to tertiary care and discharge and how the network should ensure that children and young people are appropriately engaged within the health system.

Pathways within the service

142. Discussions with clinicians highlighted the importance of differentiating the subgroups within the referred population who may be at risk and/or need more urgent support, assessment or intervention; there may also be subgroups for whom early advice to parents or school staff may be a more appropriate first step.

143. Children and young people should be able to move flexibly between different elements of the service in a step-up or step-down model, allowing them and their parents/carers to make decisions at their own pace without requiring rereferral into the system.

144. The current evidence base suggests that children who present with gender incongruence at a young age are most likely to desist before puberty, although for a small number the incongruence will persist. Parents and families need support and advice about how best to support their children in a balanced and non-judgemental way. Helping parents and families to ensure that options remain open and flexible for the child, whilst ensuring that the child is able to function well in school and socially is an important aspect of care provision and there should be no lower age limit for accessing such help and support.

Recommendation 22:

Within each regional network, a separate pathway should be established for pre-pubertal children and their families. Providers should ensure that pre-pubertal children and their parents/carers are prioritised for early discussion with a professional with relevant experience.

Transfer to adult gender services

145. Currently, significant numbers of young people are being transferred from GIDS to adult services. Some will have been under the care of GIDS, however another group will still have been waiting for their first GIDS appointment at the time they turned 17, and their wait will now count in their wait for adult services. This is increasing waiting lists for adult services and disadvantaging older adults seeking NHS support.

146. This represents a significant risk of discontinuity in clinical care and loss to follow-up. It also means that data on outcomes, which are essential to improve the knowledge base, are lost.

147. A follow-through service would benefit both this younger population and the adult population. This will have the added benefit in the longer-term of increasing the capacity of adult provision across the country as more gender services are established.

148. This would be consistent with the other service areas supporting young people that are selectively moving to a '0-25 years' service to improve continuity of care.

Recommendation 23:

NHS England should establish follow-through services for 17-25-year-olds at each of the Regional Centres, either by extending the range of the regional children and young people's service or through linked services, to ensure continuity of care and support at a potentially vulnerable stage in their journey. This will also allow clinical, and research follow up data to be collected.

149. The Review requested data on the demographics of referrals into NHS adult gender clinics, which demonstrated that the majority of referrals were birth-registered females under the age of 25.

150. While provision within the adult Gender Dysphoria Clinics (GDCs) is outside the scope of this Review, a number of current and past GDC staff have contacted the Review in confidence with their concerns.

151. The Review will set out the main points of concern to NHS England separately. However, the clinicians highlighted the changing adult demographic and same complexity of presentation as seen in gender services for children and young people.

152. As the services for children and young people develop, a strategic approach will be needed to ensure that adult service provision takes account of different population needs and emerging evidence.

Recommendation 24:

Given that the changing demographic presenting to children and young people's services is reflected in a change of presentations to adult services, NHS England should consider bringing forward any planned update of the adult service specification and review the model of care and operating procedures.

Detransition

153. NHS gender services should support all those presenting with gender incongruence and dysphoria, whether that be to transition, detransition or retransition. Those who detransition should be carefully monitored in a supportive setting, particularly when coming off hormone treatments.

154. The Review has heard that people experiencing regret may be hesitant to engage with the gender services that supported them through their initial transition. Consideration should be given to whether existing service specifications need to be adapted to specifically provide detransition pathways or whether this should be a separately commissioned service. This should be in consultation with people who have been through detransition.

Recommendation 25:

NHS England should ensure there is provision for people considering detransition, recognising that they may not wish to reengage with the services whose care they were previously under.

Private provision

155. The Review has been told that a number of young people have sought private provision whilst on the waiting list for GIDS, and about families trying to balance the risks of obtaining unregulated and potentially dangerous hormone supplies over the internet with the ongoing trauma of prolonged waits for assessment. Feedback from the lived experience focus groups presents this as "a forced choice (because the NHS provision is not accessible in a timely way) rather than a preference." The ongoing cost of this treatment and the subsequent monitoring can be prohibitive for some.

156. GPs have expressed concern about being pressurised to prescribe hormones after these have been initiated by private providers and that there is a lack of clarity around their responsibilities in relation to monitoring.

157. The Review understands and shares the concerns about the use of unregulated medications and of providers that are not regulated within the UK. Any clinician who ascertains that a young person is being given drugs from an unregulated source should make the young person and their family aware of the risks of such treatment.

158. In terms of shared care and prescribing responsibility, this should mirror other areas of practice. Specifically, no clinician should prescribe outside their competence, nor should GPs be expected to enter into a shared care arrangement with a private provider, particularly if that private provider is acting outside NHS guidance. Additionally, pharmacists are responsible for ensuring medications prescribed to patients are suitable.

159. However, there should be an arrangement to carry out relevant investigations to ensure a young person is not coming to harm (for example, monitoring bone density).

160. In the case of puberty blockers, NHS England has set out that these will only be available under a research protocol. On entering the trial, the young person will have a number of tests to establish their baseline levels for monitoring purposes (for example, in relation to bone density), as well as other initial assessments. If an individual were to take puberty blockers outside the study, their eligibility may be affected.

Recommendation 26:

The Department of Health and Social Care and NHS England should consider the implications of private healthcare on any future requests to the NHS for treatment, monitoring and/or involvement in research. This needs to be clearly communicated to patients and private providers.

Recommendation 27:

The Department of Health and Social Care should work with the General Pharmaceutical Council to define the dispensing responsibilities of pharmacists of private prescriptions and consider other statutory solutions that would prevent inappropriate overseas prescribing.

NHS number

161. Currently, when a person requests to change their gender on their NHS record, NHS guidance requires that they are issued with a new NHS number. This has implications for safeguarding and clinical management of these children and young people and could affect longer-term health management (for example, the screening they are offered).

162. From a research perspective, the issuing of new NHS numbers makes it more difficult to identify the long-term outcomes for a patient population for whom the evidence base is currently weak.

Recommendation 28:

The NHS and the Department of Health and Social Care needs to review the process and circumstances of changing NHS numbers and find solutions to address the clinical and research implications.

Implementation

163. The Review recognises that delivery of the aspirations set out in this report will require significant changes. The move to the proposed service model will require a phased approach and it may be several years before the full model is operational across the country. Pragmatic strategic and operational plans are required that set out the steps that will be taken to realise the service transformation.

164. Governance needs to be put in place to oversee implementation of the required changes and provide system-wide leadership. This should be external to NHS England's Specialised Commissioning division and draw clinical leadership from professional bodies. Given the level of external interest in these services progress against the implementation plans should be reported.

165. While the Review has focused on children and young people with gender incongruence and gender-related distress, the NHS needs to be ambitious in its provision for all children and young people seeking NHS support.

166. NHS provision for children and young people across the board requires greater service and workforce development and sustained investment. Without this we are letting down future generations. NHS England should use this opportunity to integrate investment and development of gender services with the ambitions set out in the NHS Long Term Plan for broader provision, with consideration given to a complex adolescent pathway.

Recommendation 29:

NHS England should develop an implementation plan with clear milestones towards the future clinical and service model. This should have board level oversight and be developed collaboratively with those responsible for the health of children and young people more generally to support greater integration to meet the wide-ranging needs of complex adolescents.

Recommendation 30:

NHS England should establish robust and comprehensive contract management and audit processes and requirements around the collection of data for the provision of these services. These should be adhered to by the providers responsible for delivering these services for children and young people.

Wider system learning

167. Clinical staff need support and guidance from their professional bodies to apply the evidence-based approaches described in this report. The consortium brought together to develop training resources should also be a vehicle for agreeing professional guidance for their respective clinical groups. This collaborative approach should include processes for listening to the community the service is built for.

Recommendation 31:

Professional bodies must come together to provide leadership and guidance on the clinical management of this population taking account of the findings of this report.

168. Innovation is important if medicine is to move forward, but there must be a proportionate level of monitoring, oversight and regulation that does not stifle progress, but prevents creep of unproven approaches into clinical practice. Innovation must draw from and contribute to the evidence base.

Recommendation 32:

Wider guidance applicable to all NHS services should be developed to support providers and commissioners to ensure that innovation is encouraged but that there is appropriate scrutiny and clinical governance to avoid incremental creep of practice in the absence of evidence.

Approach



1. Methodology

1.1 At the outset, the Review established the core principles that would underpin the approach taken.

- The welfare of the child or young person must remain paramount in all considerations. At the centre of the Review is a group of children and young people who are seeking support, and our responsiblity is to devise a model of care that will safeguard their best interests and set each one of them on a pathway that helps them thrive as an individual.
- The Review has to be grounded in a thorough examination of the most robust existing evidence. To support this, we commissioned systematic reviews on a range of issues from epidemiology through to treatment approaches, and international models of current practice.
- The (formal) evidence would only provide part of the picture and we needed to hear from a range of people; crucially the children and young people at the centre of the Review, but also their parents and carers, as well as young adults who have been through gender care in the UK and could give a longer-term perspective.
- We also needed input from a very wide range of professionals from different agencies who have relevant experience and could contribute to our understanding of the population and the evidence.
- Finally, we wanted to ensure that key findings were shared as quickly as possible, through publication of interim findings, blogs, and any communications with NHS England over the course of the Review.

1.2 In considering the questions set out in the terms of reference (Appendix 1), this Review can only set out what is known and unknown and think about how the NHS can best respond safely, effectively and compassionately, leaving some issues for wider societal debate. However, in order to gain as broad an understanding as possible we drew on several sources of information, underpinned by basic scientific and clinical principles.

Understanding evidence

1.3 The Review's interim report in 2022 set out the importance of evidence-based service development and highlighted major gaps and weaknesses in the evidence base underpinning the clinical management of children and young people with gender incongruence and gender dysphoria, including for the appropriate approaches to assessment and treatment. In particular, it became apparent how little was known about the medium- and longer-term outcomes for children and young people receiving NHS support and/or treatment.

1.4 The quality of the evidence base for interventions for gender incongruence and gender dysphoria is a source of debate and contention. This makes it very difficult for young people and their families to know what information to trust and what to expect from the treatments offered.

1.5 A fundamental principle of clinical medicine is that treatments should be offered based on the best available evidence.

1.6 In evidence-based practice, three factors determine treatment decisions; research evidence, clinical expertise and patient values.

Figure 3: Components of evidence-based medicine



1.7 For example, if a doctor diagnoses a patient with depression and recommends a particular antidepressant medication, they should invariably explain that there is strong evidence that the drug is effective; for example, it has an 85% chance of improving the depression.

1.8 The doctor will also point out possible side effects; for example, it has a 5% chance of causing weight gain. If the patient already happens to be very distressed about being overweight, they may not feel that the potential benefits of the drug outweigh the risk that they may gain weight.

1.9 The doctor will then consider other options; for example, there may be a different drug that does not cause weight gain but increases risk of suicide. If the patient has made a recent suicide attempt that would not be an appropriate alternative to offer to this patient.

1.10 Without this evidence for benefits and harms, it is hard for the doctor to advise the patient, and for the patient to decide whether they want to try the proposed treatment.

Explanatory Box 1:

Principles of treatments studies

The following information is intended to provide some accessible explanations of the strengths and limitations of the evidence and treatment studies used to inform the Review's recommendations.

- The development of a new drug or treatment involves a number of steps to ensure that it is safe (there are minimal harms or side effects) and effective (there is a good chance the drug will produce the intended benefit). If another treatment already exists for the condition, an important step is to test whether the new treatment is better, and whether it is cost effective. This is best quantified by undertaking a randomised trial. Sometimes a drug may have severe side effects, but if the condition is life threatening, these side effects may be considered acceptable (for example, some chemotherapies for cancer).
- An important principle in treatment trials is equipoise. This means that the researchers genuinely do not know which treatment is better - the existing treatment or the new treatment. If they have very strong reasons to believe the new treatment is better, or indeed worse, they cannot ethically carry out a trial. Occasionally a trial may be stopped early if it is obvious that the new treatment is causing harm or is strongly beneficial.

Some types of treatment studies

- The 'gold standard' trial is a randomised controlled trial (RCT). In this type of trial there are at least two groups. One is given the new treatment and the other, the control group, is given a standard or alternative treatment, or perhaps no treatment. Patients are randomly allocated to the two groups, and it is important to make sure there are no important differences between the two groups.
- The term blind or blinded is used in RCTs. There are different levels of blinding: firstly, if researchers are doing the assessments, they should not know which group a patient has been allocated to. Secondly, the patient can be blinded so that they do not know if they are on the new treatment or the original treatment, or even on a placebo (dummy pills). Finally, the treating doctor (or team) should ideally be blind to the group allocation, so their treatment of the patients does not differ.
- Participants in a study must be told about blinding processes when they consent to be in the trial. It is not always possible for people to be blind to a treatment; for example, in a trial of acupuncture versus physiotherapy, patients will know which treatment they are receiving. In these situations, people interpreting the results of the study must take into account any possible placebo effect. This is when people believe that the treatment will produce a beneficial outcome and having this belief results in them feeling better.

There are hardly any RCTs in children and young people receiving endocrine treatment for gender incongruence/dysphoria, but the following are the most commonly reported types of studies:

- Two types of studies that are sometimes used to look at the effects of puberty blockers and masculinising/feminising hormones are cohort studies and cross-sectional studies, which are different ways of looking at outcomes in groups who did or did not get a particular intervention. These are all called observational studies whereas RCTs are called experimental studies. This is because in cohort or cross-sectional studies the researcher did not allocate which patients receive an intervention. There may still be a comparison group, but participants will not have been randomly allocated to the two groups.
- The most common study for patients receiving puberty suppression is a pre-post study. This is where study participants are assessed before and after they receive an intervention. Because there is no comparison group of individuals who did not receive the treatment, and because one cannot rule out changes that would have occurred over time without treatment, it is not possible to draw strong conclusions from these studies.

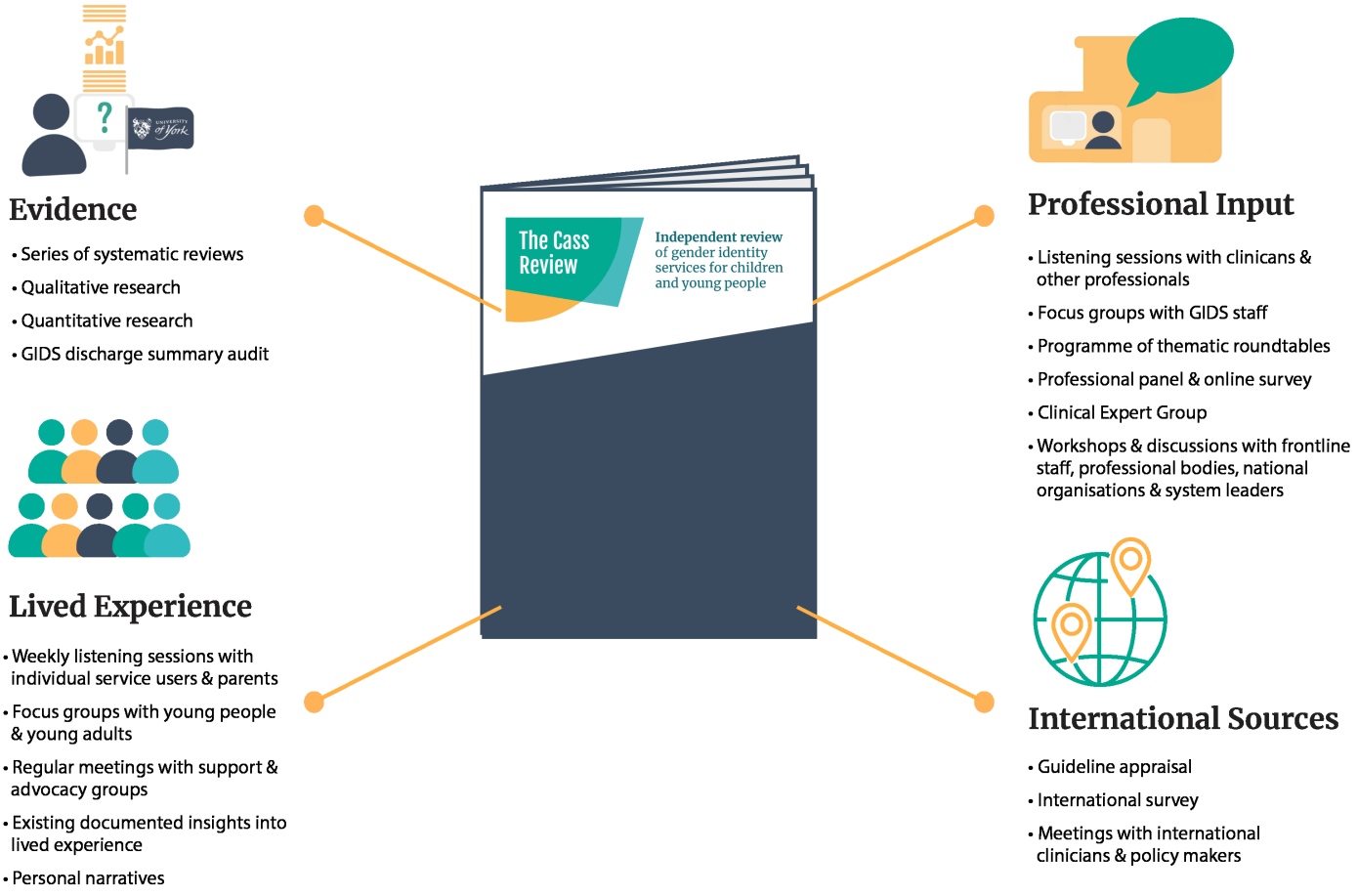
Pitfalls of treatment trials

- A major problem in making sense of trial findings is bias. There are many ways in which results can be biased. For example, if 50% of the sample drops out, this would be referred to as a high attrition rate. It is possible that the people who remained in the study are those who responded well to the treatment, whereas those who dropped out did so because the treatment was not working for them or they had bad side effects. This could result in a positive bias in the study outcomes; in other words showing an effect when there is not one. It could also fail to show the side effects that caused people to drop out.
- Another way of biasing results is if the patients in the treatment and control groups differ in some way; for example, one group has more people who are younger, or sicker. Researchers will assess the groups on several measures and compare them to see if they are similar at the start of the study (baseline assessment). Random allocation of people to the study groups and large numbers of participants help reduce the risk of differences between study groups.
- It is very important to get the inclusion and exclusion criteria of a study right (that is, which patients can and cannot be included). For example, a trial might report that a painkiller is highly effective, but if it turns out that only people with osteoarthritis in the knee were included it would mean that the results cannot be generalised to patients with headache. Although the drug may work very well for headache, it is not possible to be sure about this on the basis of the findings of this particular study.

- In any design where patients are not blinded and know they are getting a particular drug, or where they have chosen a specific treatment rather than being randomised to one, they may show improvement because of a placebo effect (that is, they believe that the treatment will produce a beneficial outcome).
- Sometimes there are confounding factors in a study, such as the patient getting another treatment at the same time as the trial treatment. Though randomisation and blinding minimise the risk of bias and confounding, this is not completely watertight.
- There must also be enough patients in a trial (the term 'sufficiently powered' is often used where there are) to be sure the results reflect the range of possible outcomes and do not give a 'positive´ result by chance, a so-called Type 1 (or alpha) error. Study outcome measures are generally reported as the average for a group, but the range is usually also given and can be very wide. For example, if the average outcome for a group is 5 points out of a possible 10, a range of 2-9 would indicate much more varied outcomes across the group than a range of 4-6. Size influences whether the reported outcomes are statistically significant. In very small studies, for example one with only four patients put on a treatment and in which three got better and one got worse, it would not be possible to understand the full range of possible outcomes. Furthermore, the benefits for three individuals could have happened by chance. For a result to be statistically significant, it must be unlikely that the result could have happened by chance. This is why substantial numbers of participants are required and a key requirement of any trial is a pre-recruitment estimate of how many will be needed for the study to produce meaningful results.
- There are many other potential problems, some of which include:
  - unconscious bias in questionnaire design where the questions are written in a way that prompts a more favourable response;
  - using the wrong kind of analysis for the available data;
  - not following up for long enough to see the full benefits or harms of a treatment;
  - seeing an improvement because patients were improving spontaneously over time;
  - publication bias where, for example, only positive results are published.

Building on evidence

Figure 4: What has informed the Review?



1.11 The Review has sought to better understand the existing evidence, as well as fill some of the gaps through qualitative and quantitative research relevant to the Review's terms of reference (Appendix 1).

1.12 Following a national open procurement process,the University of York was commissioned to deliver an independent research programme. The aim was to provide the Review with the best available collation of published evidence relevant to epidemiology, clinical management, models of care and outcomes, and to understand the experiences and perspectives of service users, their families and clinicians.

1.13 The systematic reviews were commissioned to look at:

i. How has the population of children presenting with gender dysphoria and/or gender-related distress changed over time?

ii. What are the appropriate referral, assessment and treatment pathways for children with gender dysphoria and/or gender-related distress?

iii. What are the short, medium and long-term outcomes for children with gender dysphoria and/or gender-related distress?

1.14 Additionally, an appraisal of an international guidelines and international survey were undertaken to supplement this information, looking at evidence application and clinical practice in other comparable healthcare systems.

1.15 Finally, the qualitative and quantitative studies were designed to try and fill some of the gaps in the existing literature.

1.16 The Review collated the findings from these studies and used them to determine the most appropriate clinical approach and models of care, assessment and treatment. References are made to the studies undertaken by the University of York throughout this Report. For the papers that have informed the University of York's work, please refer to the source documents (Table 1).

Table 1: Overview of academic research programme commissioned by the Review

RESEARCH TYPE	RESEARCH TITLE	REPORT IN-TEXT CITATION
SYSTEMIC REVIEWS	Characteristics of children and adolescents referred to specialist gender services: a systematic review	Taylor et al: Patient characteristics
	Impact of social transition in relation to gender for children and adolescents: a systematic review	Hall et al: Social transition
	Psychosocial support interventions for children and adolescents experiencing gender dysphoria or incongruence: a systematic review	Heathcote et al: Psychosocial support
	Interventions to suppress puberty in adolescents experiencing gender dysphoria or incongruence: a systematic review	Taylor et al: Puberty suppression
	Masculinising and feminising hormone interventions for adolescents with gender dysphoria or incongruence: a systematic review	Taylor et al: M/F hormones
	Care pathways of children and adolescents referred to specialist gender services: a systematic review	Taylor et al: Care pathways
INTERNATIONAL GUIDELINES	Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)	Taylor et al: Guidelines 1: Appraisal
	Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of recommendations (part 2)	Taylor et al: Guidelines 2: Synthesis
INTERNATIONAL SURVEY	Gender services for children and adolescents across the EU-15+ countries: an online survey	Hall et al: Clinic survey
SUMMARY REPORT	The epidemiology, care pathways, outcomes, and experiences of children and adolescents with gender dysphoria/incongruence: a series of linked systematic reviews and an international survey	Systematic review summary (Appendix 2)
QUALITATIVE STUDY	Qualitative Research Summary: Narrative accounts of gender questioning	Qualitative study summary (Appendix 3)
QUANTITATIVE STUDIES	Overview of Study Development: Assessment, Management and Outcomes for Children and Young People Referred to a National Gender Identity Development Service	Data linkage study (Appendix 4)
	Preliminary report: Epidemiology and Outcomes for Children and Young People with Gender Dysphoria: Retrospective Cohort Study Using Electronic Primary Care Records	CPRD study (Appendix 5)

Research governance

1.17 The original research studies were reviewed by the Health Research Authority's (HRA) Research Ethics Committee to ensure the interests, safety, and wellbeing of participants were protected. Where the research was to involve access to pseudonymised patient datasets, approval was also sought from the HRA's Confidentiality Advisory Group. This assessment ensures the research complies with the Data Protection Act 2018.

1.18 The systematic reviews were registered on an international database of prospective research (PROSPERO) to avoid research duplication, promote transparency, and minimise risk of bias.

1.19 The original research studies were reviewed by the Health Research Authority's (HRA) Research Ethics Committee, to ensure the interests, safety, and wellbeing of those affected were being protected. Where the research was going to involve access to pseudonymised patient data sets, approval was also sought from the HRA's Confidentiality Advisory Group. This assessment ensures compliance of the research with the Data Protection Act 2018.

1.20 Final HRA approval ensured overall integrity of the research by bringing together the assessment of governance and legal compliance.

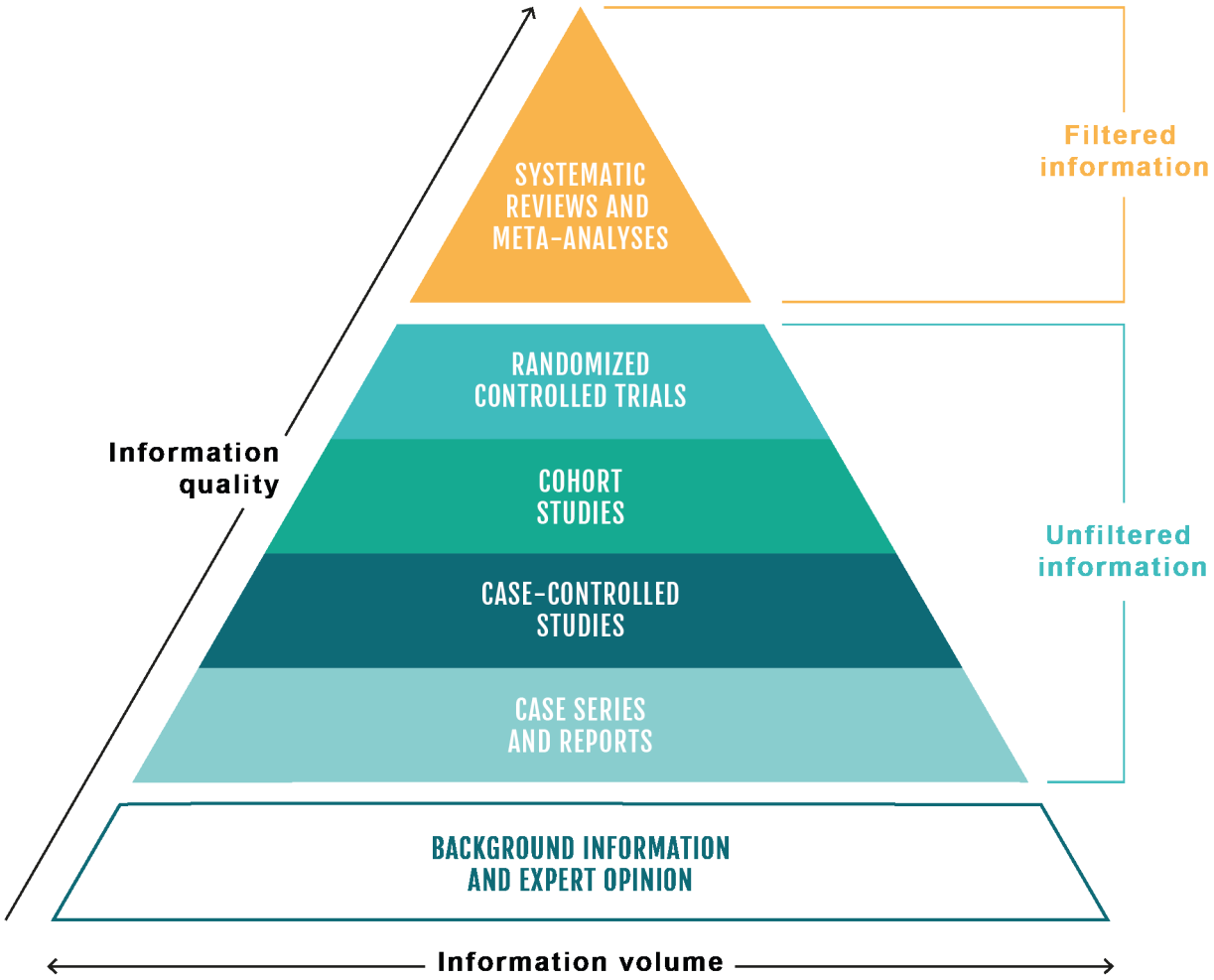
Systemic reviews

Explanatory Box 2:

Systemic reviews

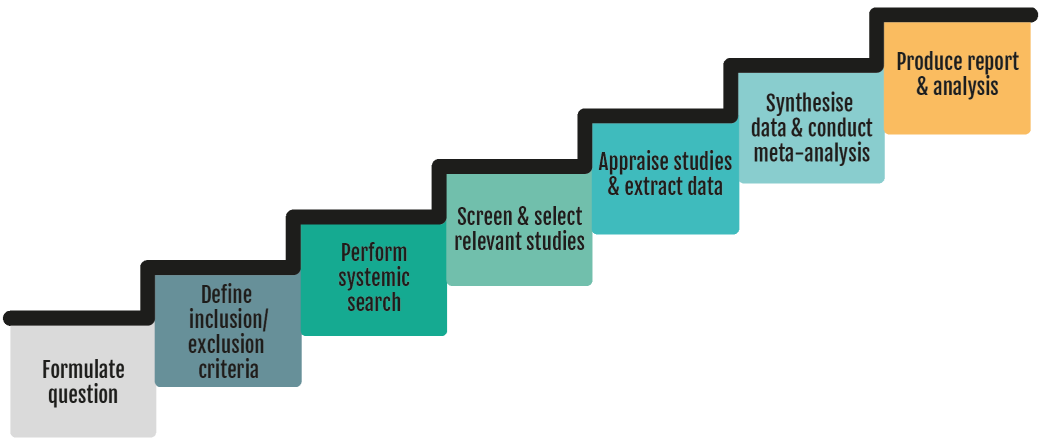
- The highest form of evidence is that generated by a systematic review (Figure 5). A systematic review is different from a general review article. It is a summary of the literature on a particular question that uses explicitly defined and reproducible methods to systematically search, critically appraise, and synthesise primary research information (Cochrane, 2016; NIHRtv, 2010). It is designed to be reproducible, reliable and to eliminate bias.
- Standardised quality assessment tools or questionnaires are available for assessing different types of studies. This ensures that, as far as is possible, different people appraising a paper will come to similar conclusions.

Figure 5: Pyramid of standards of evidence



Source: Reproduced with permission from: OpenMD. (2021, July 17). Levels of evidence. Levels of Evidence in Medical Research. https://openmd.com/guide/levels-of-evidence

Figure 6: Steps in a systematic review



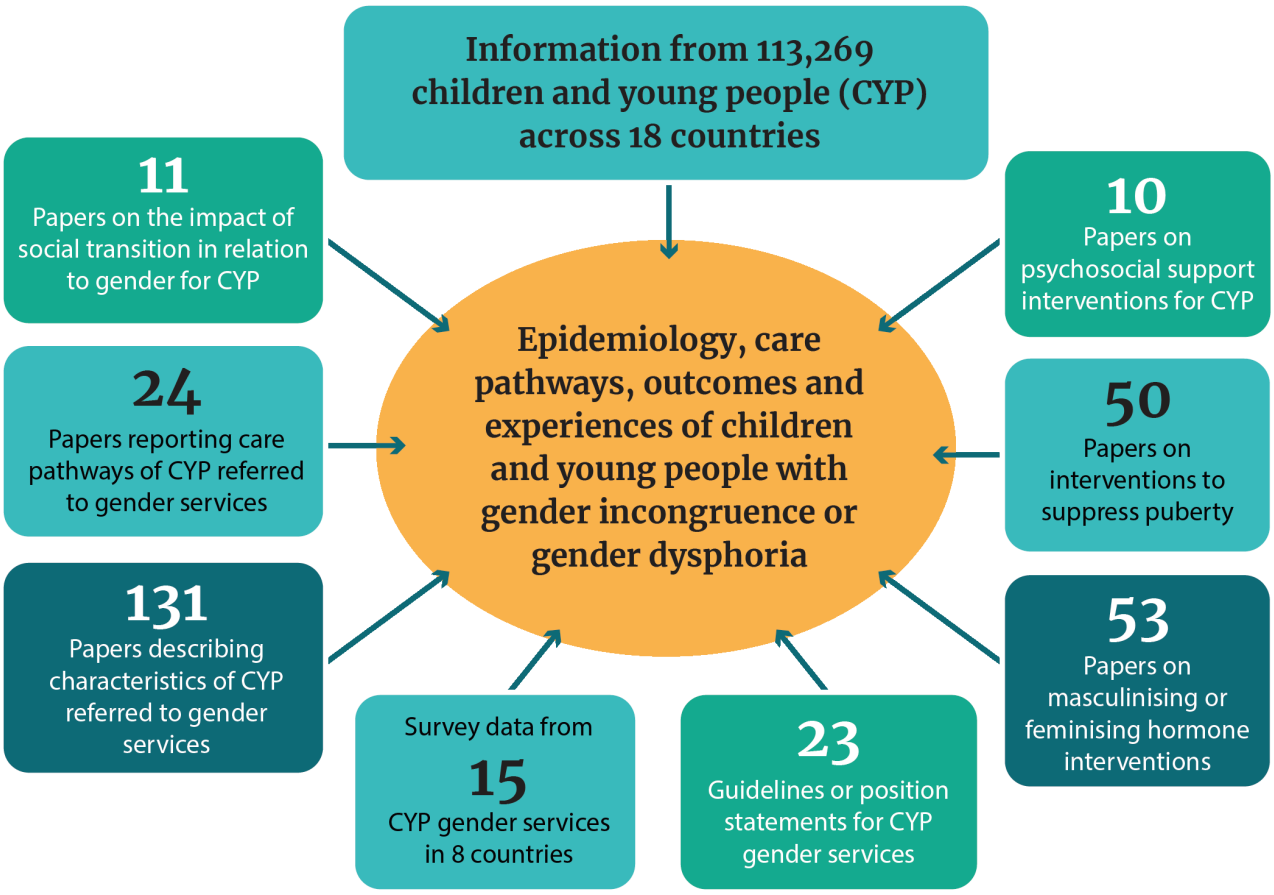
- The purpose of synthesising the data is to combine multiple different studies to get an overall impression of the strength of the evidence; for example, in favour or against a particular intervention. To do this, the reviewers need to assess the quality of the studies in terms of recruitment, bias, design, analysis and all the other factors described above. They will only include studies that meet a quality standard. Provided that those studies have used similar measures and outcomes, their outcomes can be combined (synthesised) across a much larger sample of participants.
- GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) is the system widely used by organisations such as the National Institute for Health and Care Excellence (NICE), Cochrane and the World Health Organization (WHO) to summarise the quality of evidence and make clinical recommendations (GRADE working group, n.d.). There are four levels of certainty about results:
  - **High certainty** - The authors have a lot of confidence that the true effect is similar to the estimated effect.
  - **Moderate certainty** - The authors believe that the true effect is probably close to the estimated effect.
  - **Low certainty** - The true effect might be markedly different from the estimated effect.
  - **Very low certainty** - The true effect is probably markedly different from the estimated effect.
- The certainty is not just based on what kind of trial is used, but also the various pitfalls set out above. So, for example, a RCT will be expected to produce results of high certainty, but if there is high attrition and lots of other sources of bias and confounding, the certainty will drop.
- GRADE is commonly used to describe not single studies, but the overall quality of evidence on a particular question posed in a systematic review.

1.21 The University of York is the home of the Centre for Reviews and Dissemination, one of three bodies funded by the National Institute for Health and Care Research (NIHR) to provide a systematic review service to the NHS.

1.22 The systematic reviews were commissioned because they are considered to provide the most trustworthy summary of what is known (Figure 5).

1.23 A single search strategy was developed for all the systematic reviews to identify studies examining gender dysphoria, gender-related distress or gender incongruence in children/adolescents. The search was conducted between 13 and 23 May 2021 and updated on 27 April 2022. The reference lists of eligible studies and any relevant systematic reviews including clinical guidelines that were identified were also checked.

Figure 7: Overview of studies included in the systematic reviews, international survey and guideline appraisals undertaken by the University of York



Source: The epidemiology, care pathways, outcomes, and experiences of children and adolescents experiencing gender dysphoria/incongruence: a series of linked systematic reviews and an international survey report by University of York (Appendix 2).

1.24 Overall, searches yielded 28,147 records. Figure 7 shows the number of studies that met the criteria for inclusion. In addition, the research team monitored for and appraised relevant references that were published after the primary search.

1.25 Most of the studies in the systematic reviews were cohort, cross-sectional or pre-post design, explanations for which can be found in Explanatory Box 1 and on the NICE website (NICE, 2012).

International guideline reviews and survey of gender clinics

1.26 Achieving consensus on the appropriate approach to care for gender-questioning children and young people is challenging both in the UK and internationally. An essential starting point was to obtain an appraisal and synthesis of international guidelines in order to consider whether practice was transferable to the UK.

1.27 Recognising that not all aspects of service delivery were documented in local guidelines and that some countries had changed their approach since their guidelines were written, a survey of gender clinics for children and adolescents across the UK and EU-15+ countries was carried out. This aimed to identify: the range of services provided across a group of countries with similar health services; and consistency/divergence in practice.

1.28 The results of the review of guidelines and international survey are detailed throughout this report.

Quantitative research

1.29 The Clinical Practice Research Datalink (CPRD) collects anonymised patient data from a network of GP practices across the UK to support clinical studies. For more than 30 years, research using CPRD data and services has informed clinical guidance and best practice.

1.30 Epidemiology and outcomes for children and young people with gender dysphoria: Retrospective cohort study (Appendix 5), commissioned by the Review, utilised linked primary and secondary data from the CPRD.

1.31 The overall aim was to use electronic primary care records to describe the epidemiology of gender dysphoria in people aged 18 and under in England from 2009 to 2021.

Explanatory Box 3:

Qualitative versus quantitative studies

- Quantitative research generates numerical or measurable data, whereas qualitative research generates information about subjective experiences, feelings and thoughts. Both types of research make a unique contribution to considerations about service provision, treatment options and patient-centred care.
- The methods for conducting qualitative research are as robust as the methods for quantitative research, and also involve identifying a question, and then collecting, analysing, and interpreting data, although the data will be interview-based rather than numerical.

Data linkage study

1.32 Little is known about the support and interventions received by the children and young people who accessed the Gender Identity Development Service (GIDS) and their outcomes.

1.33 The data linkage study, using data held by the NHS, was commissioned to improve the level and quality of evidence for their treatment and care by using existing data held by the NHS. Data from GIDS, hospital wards, outpatient clinics, emergency departments and adult gender dysphoria clinics (GDCs) would be used to track the journeys of all children and young people (approximately 9,000) referred to GIDS through the system and provide a population-level evidence base of the different pathways people take and the outcomes.

1.34 The objectives stated in the study protocol were:

i. To describe the clinical and demographic characteristics of this population of children and their clinical management in the GIDS service.

ii. To assess the intermediate outcomes of this population of children utilising national healthcare data.

1.35 There have been challenges in progressing this study and the findings are not available to inform this report. Further details are contained in Chapter 15 and Appendix 4.

Qualitative research

1.36 The Review commissioned a participative, qualitative research project with the aim of understanding the full range of experiences and outcomes for young people with gender dysphoria. This research used robust internationally endorsed methods appropriate for qualitative research.

1.37 It sought to capture children's, young people's and young adults' experiences of gender-related dysphoria/distress, their perspectives on their journeys, and their views on how services could and should be delivered in the future, exploring barriers or facilitators to providing this care.

1.38 The study also gathered the perspectives of parents/carers and professionals delivering services on the referral, assessment and treatment pathways currently open to them.

1.39 The objectives of the study were:

i. To explore how children, young people and young adults understand, respond and negotiate gender-related dysphoria/distress and discomfort within the context of their social networks.

ii. To examine the perspectives, understandings and responses of parents (or carers), including how they support their child.

iii. To investigate how children, young people, young adults and their families experience and negotiate current referral, assessment and possible treatment and intervention options within the national specialist service referral, assessment and (possible) treatment.

iv. To understand the role and experiences of care professionals who offer support, including identifying shared and potentially divergent views of what constitutes optimal care.

Stakeholder engagement

1.40 In addition to the formal qualitative research, the Review has been underpinned by an extensive programme of proactive engagement.

1.41 Support and advocacy groups advised that to hear from the young people at the heart of the Review, opportunities needed to be created where they felt safe, could be supported before, during and after their contribution, and would be engaged around topics on which they have a genuine ability to inform and influence decisions.

1.42 The sensitivity of the subject matter, coupled with the fierce public debate, meant that some of the usual methods one might employ when conducting a review of this kind were not appropriate. Indeed, one of the major challenges for the Review has been the difficulty in having open, honest debate as people with differing views can find it uncomfortable to sit together in the same room or on the same stage. It was abundantly clear that opportunities for people to contribute would need to be carefully navigated and well planned.

1.43 A mixed-methods approach was taken that prioritised two categories of stakeholders:

- People with relevant lived experience (direct or as a parent/carer) and organisations working with LGBTQ+ children and young people generally.
- Clinicians and other relevant professionals with responsibility for providing care and support to children and young people within specialist gender services and beyond.

1.44 Overall, the Review has met with over 1,000 individuals, some in one-to-one meetings and some in bespoke meetings on a particular topic or others focused on building awareness and improving understanding of the issues among interested parties and organisations. Below is an outline of the structured processes employed.

Figure 8: Proactive engagement methods



Lived experience engagement

Personal narratives

1.45 In the early stages of the work the team met with individuals who had conducted comparable reviews and inquiries to learn what they had done to ensure that the views of people affected were captured. Consideration was given to the merits of making an open call for evidence but, unlike for formal public inquiries, there would be no legal status for the information being provided. It was conceded that with no formal process or capacity to analyse the submissions and validate their authenticity, the Review ran the risk of raising expectations and collecting a large volume of potentially sensitive information that it would not be able to effectively process.

1.46 However, the Review did receive a number of written submissions describing individuals' personal experiences of gender services or gender identity exploration. While there was no formal process for analysing these submissions, all were read by the Review to see if the issues they raised were consistent with what had been heard from other sources or were new and relevant. If the latter, the individual was invited to attend a listening session.

Listening sessions (lived experience and professional)

1.47 The Review Chair held weekly listening sessions to hear directly from people with primary lived experience (individuals who identify as transgender, non-binary, gender fluid and/or who have been through a period of gender-questioning) or secondary lived experience relevant to the Review (a parent/carer of a gender-questioning child or young person or a clinician or other professional with direct and relevant experience working with these children and young people). These confidential sessions have provided the Review with invaluable insight into how services are currently experienced. They have contributed to the Review's understanding of the positive experiences of living as a trans or gender diverse person as well as uncertainties, complexities and challenges faced by children, young people and their families/carers.

Focus groups - (lived experience)

1.48 In autumn 2022, the Review team hosted a series of focus groups specifically to discuss the proposed data linkage study. Due to the ages of those whose data would be accessed for the research, and concern that the sessions could attract interest from those outside the scope of the study, it was deemed inappropriate to issue an open invitation to the sessions. Instead, the focus groups were promoted via the GIDS stakeholder group, related NHS-funded services, and support and advocacy groups. While this did restrict the team's ability to recruit participants, it ensured that the sessions were conducted in a safe and protected environment.

1.49 Reflecting on and responding to the previous recruitment difficulties, in spring 2023 the Review commissioned (through an Expression of Interest process) six support and advocacy organisations to facilitate 18 focus groups to better understand the thoughts and ideas of young people and adults (aged 14-30) with lived experience. This approach was taken as the commissioned organisations had access to the target audience and were able to provide a supportive environment in which participants felt comfortable and confident to speak freely.

1.50 The Review developed three sets of questions to be used in the groups. These explored:

- Past and current experiences of services including assessment, diagnosis and expectations of clinicians.
- Thoughts and ideas about future services including location, environment and support and the interventions they would want access to.
- Information needs and wider support.

View summary report.

Regular meetings with support and advocacy organisations

1.51 The Review met regularly with support and advocacy organisations for which support of gender-questioning young people is their primary function or a significant element of their work. Separate meetings were held with each organisation to encourage open and frank conversations. This two-way communication has provided the Review with a better understanding of how service users are experiencing services and policy changes, and given these organisations a greater level of understanding in the work of the Review.

Clinical and professional engagement

1.52 The Review received a high level of clinical input in a variety of forms including listening sessions, group events and workshops (for example, to test thinking on the proposed future service model). Presentations and discussion with different professional groups at conferences or training sessions helped raise awareness of the Review and the dilemmas around clinical care.

Importantly, this created opportunities for a much wider group of clinicians to pose questions, share experiences and contribute to thinking. There have also been regular meetings with the heads of relevant Royal Colleges and professional bodies.

Clinical Expert Group

1.53 A Clinical Expert Group was established to consider the strength of the evidence and findings from the Review's research programme, and assist the Review in achieving clinical consensus where evidence is not available or limited. Membership included clinical experts on children and adolescents in relation to gender, development, physical and mental health, safeguarding and endocrinology.

Thematic roundtables

1.54 Roundtable discussions were facilitated with experts in a range of associated topics to explore specific questions in greater depth. Roundtable discussions were held on:

- intersection of mental health, psychosexual development and gender-related distress
- safeguarding
- workforce
- learning from lived experience.

1.55 These discussions are reflected throughout this report.

Professional panel and gender specialists survey

1.56 In autumn 2021, in order to understand the challenges and establish a picture of competency, capacity and confidence among the workforce outside the specialist gender development service, an online professional panel was established to explore issues around

gender identity services for children and young people. The panel engaged in weekly individual or group activities over a six-week period.

View summary report.

1.57 Following the conclusion of the professional panel the Review undertook an online survey of gender specialists - clinicians and associated professionals who predominantly or exclusively work with children and young people who need support around their gender identity. The survey contained some service specific questions, but also reflected and sought to test some of what the Review had heard from specialists through our listening sessions and from primary and secondary care professionals engaged in the professional panel activities.

View summary report.

1.58 The outputs from these activities were reported in the interim report (4.29-4.39) and have continued to inform our work.

Engagement with gender specialists

1.59 Much of the clinical experience of working with these children and young people resides among staff with experience of working in GIDS.

1.60 Since the early stages of the Review, the team established fortnightly meetings with clinical and managerial leads from GIDS, providing space to hold open conversations and discuss challenges and ideas.

1.61 The Review has drawn on GIDS' insight, knowledge and experience in several ways. Senior clinical staff have participated in workshops hosted by the Review and two senior clinicians from GIDS sat on the Review's Clinical Expert Group.

1.62 In addition to the gender specialists survey, many of the GIDS clinicians (both current and former) have shared their experience and thoughts in one-to-one listening sessions and their insights have been valuable in building understanding of the challenges of and opportunities for developing a new approach.

1.63 In the latter stages, the Review hosted focus groups with GIDS staff to test and develop emerging thinking on a number of key areas:

i. workforce and training

ii. packages of care

iii. pathways and wider system working

1.64 The Review has also engaged with clinicians working in gender services in other countries.

Summary

1.65 The strengths and weaknesses of the evidence base on the care of children and young people are often misrepresented and overstated, both in scientific publications and social debate. Systematically reviewing and evaluating the evidence has been fundamental to the Review's approach.

1.66 Hearing directly from the children and young people at the heart of this Review, their parents/carers and the clinicians working in and around services trying to support them, has provided valuable insight into the ways in which services are currently delivered and experienced. This has contributed immeasurably to the Review's understanding of the positive experiences of living as a transgender or gender diverse person, as well the uncertainties, complexities and difficulties faced.

1.67 Pulling insights together from these different activities has not been easy. There are areas where there is no clear consensus and finding a middle ground is not possible where perspectives are so polarised.

1.68 Sometimes, there is a mismatch in expectations between service users, their families and advocates and what it is possible for the NHS to provide. In those instances, the Review has needed to think about what would be normal practice in the NHS and then to consider whether there is any reasonable and rational reason for services for this cohort to respond or operate differently.

1.69 This report describes what has been learnt in the course of the Review and provides advice on how the services need to operate in future. A summary of the evidence base underpinning each area of consideration is provided and links to corresponding papers are provided where available.



Context



2. History of gender services for children and young people

2.1 This Review is about services for children and young people who experience gender incongruence/dysphoria or gender-related distress. However, the evolution of care for this group, and some of the dilemmas that have emerged, need to be understood in the broader context of the struggle that transgender people have faced - and still continue to face - in accessing care, support and understanding of their clinical needs.

2.2 There are polarised debates about a range of societal issues involving transgender people in the UK, ranging from use of single-sex spaces to participation in sports. Although these issues are outside the scope of this Review, they have an impact on gender-questioning young people because of the inflexibility of the factional opinion and resulting toxicity of the debates. Services for children and young people have evolved within the context of this broader picture and every person involved in this work has been and continues to be affected by the dialogue.

Early gender services for children and young people

2.3 Services for children and young people with gender incongruence started in the mid-1970s in Canada, and in 1987 in the Netherlands. It is important to understand the early populations accessing these services to make sense of how they have changed in more recent years.

2.4 The Gender Identity Development Service (GIDS) was established in 1989 by Domenico Di Ceglie at St George's Hospital, London later moving to The Tavistock and Portman NHS Foundation Trust. Initially, the numbers seen were small (fewer than 10 per annum in the first few years), with pre-pubertal birth-registered males being the largest group.

2.5 The main focus of the early services was on therapeutic work with children and families, with only a small proportion with persisting gender incongruence being referred for hormone treatment from around age 16.

2.6 Several studies from that period (Green et al., 1987; Zucker, 1985) suggested that in a minority (approximately 15%) of pre-pubertal children presenting with gender incongruence, this persisted into adulthood. The majority of these children became same-sex attracted, cisgender adults. These early studies were criticised on the basis that not all the children had a formal diagnosis of gender incongruence or gender dysphoria, but a review of the literature (Ristori & Steensma, 2016) noted that later studies (Drummond et al., 2008; Steensma & Cohen-Kettenis, 2015; Wallien et al., 2008) also found persistence rates of 10-33% in cohorts who had met formal diagnostic criteria at initial assessment, and had longer follow-up periods. It was thought at that time that if gender dysphoria continued or intensified after puberty, it was likely that the young person would go on to have a transgender identity into adulthood (Steensma et al., 2011).

Emergence of the Dutch protocol

2.7 The approach to treatment changed with the emergence of 'the Dutch protocol', which was developed by Dr Peggy Cohen-Kettenis founder of the Utrecht clinic. One of the drivers for developing gender care services for children was the recognition of poor mental health outcomes for the adult transgender population, much of which was attributed to minority stress and difficulty "passing" in their expressed gender (Cohen-Kettenis & Van Goozen, 1998).

2.8 In 1998, a single case study (Cohen-Kettenis & Van Goozen, 1998) described a female to male transition where puberty blockers were started at age 13. The rationale for the approach was two-fold; to support the diagnostic procedure by buying time to think and to improve the longer-term ability to pass in the preferred gender.

2.9 The Dutch protocol was further elaborated in an article in 2006 (Delemarre-van de Waal & Cohen-Kettenis, 2006) by which time 54 patients were being treated, and in 2011 the Dutch team published a prospective study (de Vries et al., 2011b) of 70 patients who had received early treatment with puberty blockers between 2000 and 2008. Inclusion criteria were that the patients had to be minimum age 12, have suffered from life-long gender dysphoria that had increased around puberty, be psychologically stable without serious comorbid psychiatric disorders that might interfere with the diagnostic process, and have family support. The authors discussed the challenge in adolescents with an autistic spectrum disorder (ASD) of disentangling "whether gender dysphoria evolves from a general feeling of being just "different" or whether a true "core" cross-gender identity exists".

2.10 The 70 patients in the study (de Vries et al., 2011b) were a subset of a larger group of 111 cases consecutively referred for puberty blockers; the 70 were selected because they were the first ones ready to start the next stage of treatment - masculinising or feminising hormones. Of the 70 patients, 89% were same-sex attracted to their birth-registered sex, with most of the rest being bisexual. Only one patient was exclusively heterosexual. The outcomes for the remaining 41 cases were not reported.

2.11 During puberty suppression, there was no change in body dysphoria, but behavioural and emotional problems decreased, and general functioning improved. However, not all participants (59-73% on the various measures) completed questionnaires after treatment, a potential source of bias, making it difficult to draw conclusions from the results.

2.12 A confounding factor was that all patients in the Dutch service were seen regularly by their psychiatrist or psychologist whilst on puberty blockers, so it is difficult to separate the therapeutic effects of these sessions from the role of puberty blockers alone.

Explanatory Box 4:

Dutch protocol:

Minimum age 12, life-long gender dysphoria increased around puberty, psychologically stable without serious comorbid psychiatric disorders that might interfere with the diagnostic process and family support.



Move to an affirmative model

2.13 In 2007 Norman Spack established a clinic in Boston, USA modelled on the Dutch protocol and began prescribing puberty blockers from early puberty (Tanner stage 2).

2.14 Practice in the USA began to diverge from the models of care in Canada and the Netherlands, following instead a gender affirmative model advocated by Diane Ehrensaft (Ehrensaft, 2017).

She described the three approaches as follows (Ehrensaft, 2017):

"The first model, represented in the work of Drs Susan Bradley and Ken Zucker [Canada], assumes that young children have malleable gender brains, so to speak, and that treatment goals can include helping a young child accept the gender that matches the sex assigned to them at birth.

The second model, represented in the work of practitioners in the Netherlands, allows that a child may have knowledge of their gender identity at a young age, but should wait until the advent of adolescence before engaging in any full transition from one gender to another.

The third model, represented in the work of an international consortium of gender affirmative theoreticians and practitioners, allows that a child of any age may be cognizant of their authentic identity and will benefit from a social transition at any stage of development."

2.15 The third model - the 'affirmative model' - has subsequently become dominant in many countries. As a result, some gender services have moved away from a more exploratory approach, and this is seen by some advocacy and support groups as a move to 'gatekeeping' model.

2.16 It is important to note that staff at GIDS have told us that in their practice an affirmative model can encompass respecting the young person's experience and sense of self whilst still exploring the meaning of that experience in a non-directive therapeutic relationship.

Use of puberty blockers in the UK

2.17 The 'watchful waiting' approach continued in the UK until 2011, when puberty blockers were trialled under a research protocol; the 'early intervention study'. This was an uncontrolled study with inclusion criteria in line with the original Dutch protocol, and similar outcome measures. It is unfortunate that a controlled study was not conducted by the UK team, given that this was the only formal attempt to replicate the Dutch approach using directly comparable outcome measures. Using the same methods as the Dutch observational study meant that the same limitations apply; that is, confounding of endocrine and psychological interventions and significant attrition at follow-up.

Early intervention study

2.18 Between 2011 to 2014, 44 patients aged 12-15 were recruited to the 'early intervention study' and preliminary results were reported to The Tavistock and Portman NHS Foundation Trust Board in 2015 (Tavistock and Portman NHS Foundation Trust Board papers, 2015), at which point patients had received at least one year of treatment, and at the 2016 World Professional Association for Transgender Health (WPATH) conference when all patients had been followed up for at least two years (https://www.youtube.com/watch?v=8HQBfuV3V98).

2.19 In contrast to the Dutch group, the UK's preliminary findings did not demonstrate improvement in psychological wellbeing, and in fact some birth-registered females had a worsening of 'internalising' problems (depression, anxiety) based on parental report. In response to the Youth Self Report Scale, there was a significant increase after one

year on treatment in adolescents scoring the statement "I deliberately try to hurt or kill myself" as 'sometimes true', especially among birth-registered females (The Tavistock and Portman NHS Foundation Trust Board Papers, 2015).

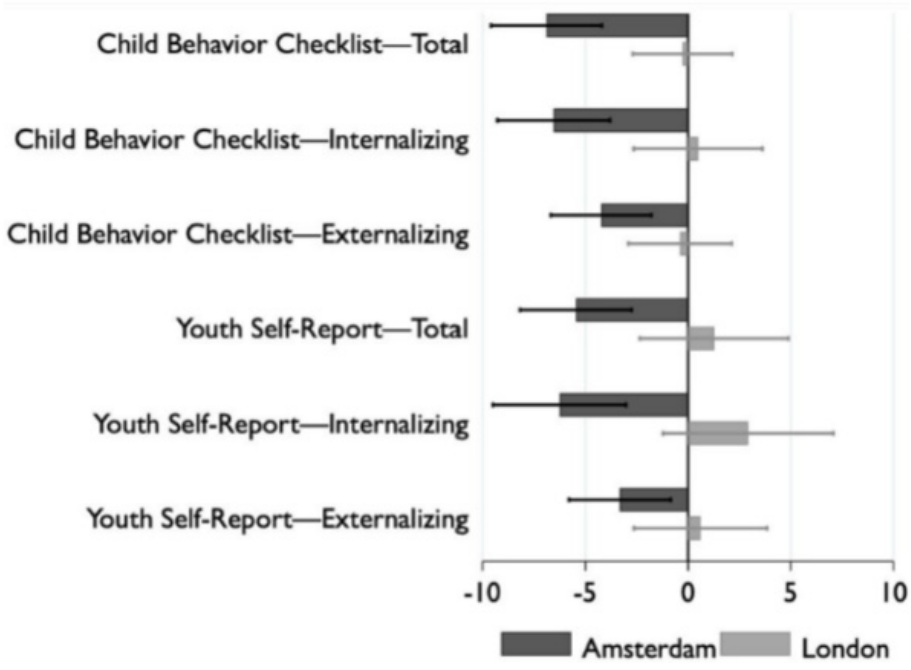
2.20 The early intervention study results were not published in preprint until December 2020 (Carmichael et al., 2021). There were no statistically significant changes reported in gender dysphoria or mental health outcome measures whilst on puberty blockers, and 98% proceeded to masculinising or feminising hormones.

2.21 A secondary analysis of the data from the Dutch and UK studies demonstrated that the two groups were the same at baseline on the key mental health outcome measures that were used to assess changes (Biggs, 2022).

Figure 9 shows the level of improvement in the Dutch cohort and the lack of improvement in the UK cohort after puberty suppression. The reasons for this are not clear but may be due to other baseline differences in the two samples, or differences in the quality of care offered by the two clinics.

2.22 A subsequent re-analysis of the early intervention study (McPherson & Freedman, 2023), using original anonymised data from the study, took account of the direction of change in mental health outcomes for individual young people rather than just reporting group means. This secondary analysis found that 37-70% experience no reliable change in distress across time points, 15-34% deteriorate and 9-29% reliably improve.

Figure 9: Change in psychological functioning after puberty suppression with GnRH [puberty blocker]



Source: Biggs, M. (2022). The Dutch protocol for juvenile transsexuals: Origins and evidence. Journal of Sex &Marital Therapy, 49(4), 348-368. https://doi.org/10.1080/0092623x.2022.2121238. Published with license (http://creativecommons.org/licenses/by-nc-nd/4.0/) by Taylor & Francis Group, LLC.

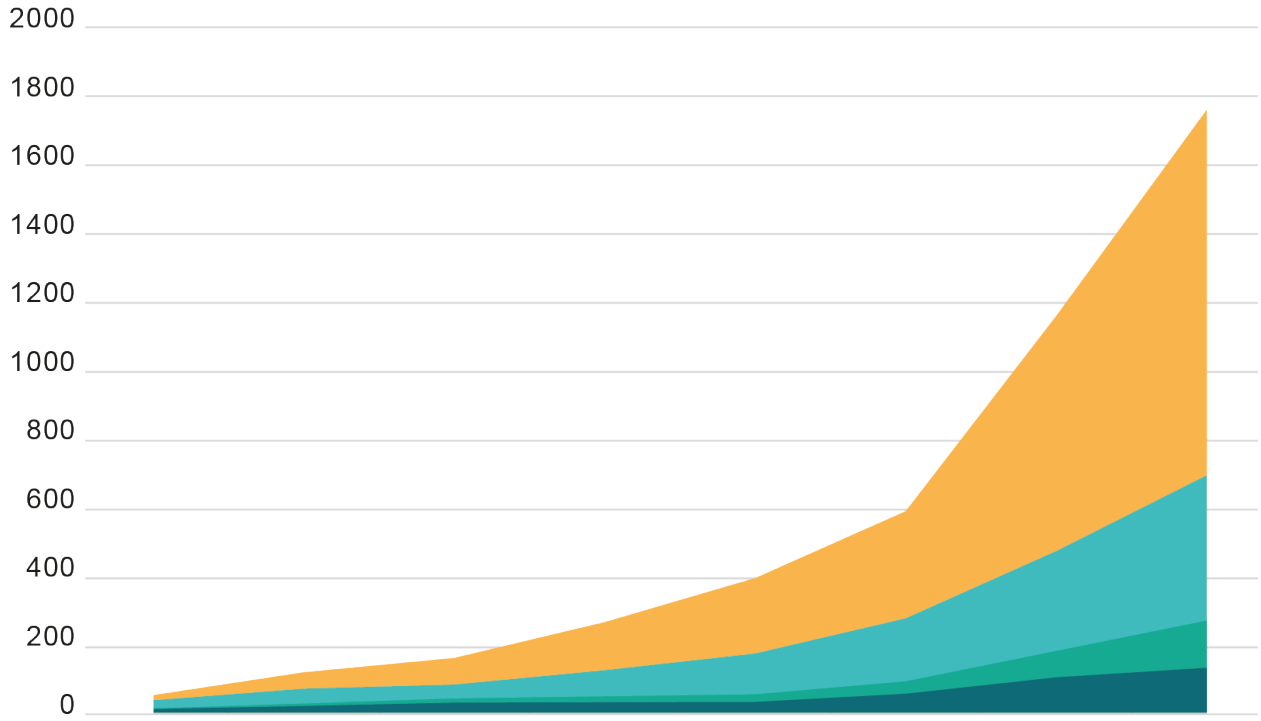
NB: The bar shows the change in T-score from baseline; negative values indicate reduced problems. The line traces the 95% confidence interval. N=54 at Amsterdam, N=41 at London. Data reported from de Vries et al. (2011, Table 2) and Carmichael et al. (2021).

Research into routine practice

2.23 As highlighted in the interim report, in 2014 the number of referrals started to grow exponentially in the UK with a higher number of birth-registered females presenting in early teenage years (Figure 10).

2.24 From 2014, puberty blockers moved from a research-only protocol to being available through routine clinical practice. In light of the above findings, the rationale for this is unclear.

Figure 10: Sex ratio in children and adolescents referred to GIDS in the UK (2009-16)



	2009	2010	2011	2012	2013	2014	2015	2016
Adolescents F	15	48*	78*	141*	221*	314*	689*	1071*
Adolescents M	24	44*	41	77*	120*	185*	293*	426*
Children F	2	7	12	17	22	36	77*	138*
Children M	10	19	29	30	31	55*	103*	131

AFAB = Assigned female at birth

AMAB = Assigned male at birth

*Indicates p< .05 which shows a significant increase of referrals compared to previous year

Source: Figure adapted from de Graaf, N. M., Giovanardi, G., Zitz, C., & Carmichael, P. (2018). Sex ratio in children and adolescents referred to the Gender Identity Development Service in the UK (2009-2016). Archives of Sexual Behavior, 47(5), 1301-1304. https://doi.org/10.1007/s10508-018-1204-9, with permission from Springer Nature.

2.25 In addition, the strict inclusion criteria of the Dutch protocol were no longer followed, and puberty blockers were given to a wider range of adolescents than would have met the inclusion criteria in either the Dutch or UK studies. These included patients with no history of gender incongruence prior to puberty, as well as those with neurodiversity and complex mental health presentations.

2.26 On its establishment, NHS England took on responsibility for commissioning services for children and young people experiencing gender dysphoria. Gender services for children and young people is considered a highly specialised service; these services for very rare and/or complex conditions are usually provided to no more than 500 patients a year. Because of the small number of patients, the services are provided in a limited number of hospitals which enables the clinicians to maintain their expertise.

2.27 In 2016, NHS England refreshed the GIDS service specification, which sets out what a healthcare provider needs to deliver (NHS England, 2019). The Tavistock and Portman NHS Foundation Trust was recontracted to deliver the service.

2.28 The service specification described a therapeutic service providing "psychological/ psychosocial support aimed at increasing the wellbeing and resilience of the client" and "therapeutic exploration of gender identity development and gender expression, including in relation to the client's familial, social and cultural situation" (NHS England, 2019).

2.29 The specification recognised that "the research evidence around the long-term impacts of some treatments is limited and still developing and that by no means all clients with [gender dysphoria] choose to have physical interventions". Recognising the uncertainty, it set out that "hormone blockers will be considered as an appropriate treatment alongside psychological intervention" (NHS England, 2019).

2.30 The specification allowed for referral of "carefully selected clients who are at least in Tanner Stage 2 of puberty and are up to the age of 15" to the Paediatric Endocrine Liaison Team's Early Intervention' Clinic. The specification stated that "The Early Intervention Clinic will continue to follow the Service's 2011 research protocol, which following evaluation, has now become established practice, with the exception that hormone blockers will now be considered for any children under the age of 12 if they are in established puberty." (NHS England, 2019).

2.31 Clinical practice subsequently appears to have deviated from the parameters set out in the service specification which required that the narrow criteria of the 2011 research protocol be followed when considering medical intervention. The adoption of a medical treatment with uncertain risks, based on an unpublished trial that did not demonstrate clear benefit, is a departure from normal clinical practice.

2.32 This, in combination with the long delay in publication of the results of the early intervention study, is likely to have had an impact on patient expectations of the benefits of the intervention and subsequent demand for treatment.

2.33 The Review has been focused on future service provision and did not have a remit to explore in detail the factors contributing to the situation that necessitated an independent review.

2.34 However, there are clearly lessons to be learned by everyone in relation to how and why the care of these children and young people came to deviate from usual NHS practice, how clinical practice became disconnected from the clinical evidence base, and why warning signs that the service delivery model was struggling to meet demand were not acted on sooner.

2.35 One of the problems that has been exposed is the governance of innovative clinical practice. Whilst care cannot improve without innovation, good clinical governance should require collection of data and evidence with appropriate scrutiny to prevent the incremental creep of new practices without adequate oversight.

3. Why this Review?

3.1 In January 2020, a Policy Working Group (PWG) was established by NHS England to undertake a review of the published evidence on the use of puberty blockers and masculinising/feminising hormones in children and young people with gender dysphoria to inform a policy position on their future use.

3.2 Given the increasingly evident polarisation among clinical professionals, Dr Cass was asked to chair the group as a senior clinician with no prior involvement or fixed views in this area.

NHS England Policy Working Group (PWG)

3.3 The PWG comprised:

- 2 senior members of the GIDS team
- 3 endocrinologists working in the linked gender services
- 3 representatives with lived experience
- representatives from the Royal College of Paediatrics and Child Health and the Royal College of Psychiatrists
- an academic child psychiatrist
- a primary care academic
- an academic ethicist

NHS England staff:

- a public health consultant
- the national head of safeguarding
- the senior pharmacy lead
- relevant members of the specialised commissioning team

3.4 NHS England uses a standardised protocol for developing clinical policies (NHS England, 2020). The first step of this involves defining the PICO (the Population being treated, the Intervention, a Comparator treatment, and the intended Outcomes). This of itself was challenging, with a particular difficulty being definition of the intended outcomes of puberty blockers, and identification of suitable comparators for both hormone interventions. However, agreement was reached on what should be included in the PICO and subsequently the National Institute for Health and Care Excellence (NICE) was commissioned to review the published evidence, again following a standardised protocol that has strict criteria about the quality of studies that can be included (NICE, 2020a; NICE, 2020b).

NICE evidence reviews

Puberty blockers (GnRH analogues)

3.5 The key questions for this evidence review were (NICE, 2020a):

- For children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?
- For children and adolescents with gender dysphoria, what is the short-term and long-term safety of GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?

3.6 The review of the evidence looked at nine studies that met the inclusion criteria. A key limitation of all the studies examined was the lack of reliable comparative studies, as well as of clear expected outcomes. All the studies were small uncontrolled observational studies, and all the results were of low certainty. Many did not report statistical significance.

3.7 The studies that reported impact on gender dysphoria, mental health, body image and psychosocial impact were of very low certainty and suggested little change from baseline to follow-up. The studies that reported bone density outcomes were similarly unreliable so no safety outcomes could be confirmed.

Masculinising/feminising hormones

3.8 The key questions for this evidence review were (NICE, 2020b):

- In children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with gender-affirming hormones compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?
- In children and adolescents with gender dysphoria, what is the short-term and long-term safety of gender-affirming hormones compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?

3.9 Ten uncontrolled observational studies met the inclusion criteria. Again, the key limitation to identifying the effectiveness and safety of gender-affirming hormones for children and adolescents with gender dysphoria was the lack of reliable comparative studies.

3.10 The included studies had relatively short follow-up, with an average duration of treatment with gender-affirming hormones between around 1 year and 5.8 years.

3.11 Results from five uncontrolled, observational studies suggested that, in children and adolescents with gender dysphoria, gender-affirming hormones are likely to improve symptoms of gender dysphoria, and may also improve depression, anxiety, quality of life, suicidality and psychosocial functioning. The impact of treatment on body image was unclear.

3.12 Most studies included in this review did not report comorbidities and no study reported concurrent treatments in detail. Because of this it is not clear whether any of the changes seen were due to gender-affirming hormones or other treatments the participants may have received.

Outcome of PWG and NICE evidence reviews

3.13 The evidence produced by the NICE reviews was inconclusive to the extent that NHS England could not form a policy position on the use of these medications.

3.14 It was clear that although the PWG and NICE evidence reviews were an important step, they did not give NHS England all the answers needed.

3.15 At the same time, concerns about the increasing numbers of gender-questioning children and young people presenting to the NHS were growing. There had also been questions raised about the capacity of GIDS to manage the caseload, as well as the clinical practice.

Commissioning of the Independent Review

3.16 The need for an independent review was clear and driven by the changing situation over the last 10-15 years:

- The exponential increase in the numbers of children and young people presenting to the NHS for help, outstripping the capacity of services to support them. This had led to a waiting list for specialist services in excess of 2 years.
- The marked change in the case-mix, from predominantly pre-pubertal birth-registered males to predominantly peri or post-pubertal birth-registered females, with no clear explanation for this changed demographic.
- The introduction of earlier medical intervention and the weakness of the evidence underpinning the use of puberty blockers (the 'Dutch approach') prior to masculinising or feminising hormones at age 16.
- The lack of long-term follow-up, and a weak evidence base to support decision making and development of a policy position on appropriate care.

3.17 This independent Review was commissioned to make recommendations on models of care, appropriate treatment approaches, audit, long-term follow-up and research, as well as workforce requirements. It was also asked to explore the reasons for the increase in referrals and the change in the demographics of the referred population.



4. Wider context

4.1 Since the Review was commissioned, there have been a number of public policy initiatives that, while outside the scope of the Review, have nudged up against its work and may have an effect on the support offered to young people in the future.

4.2 These have led to increased public attention on these issues, creating increasingly hostile and polarised debate. Within this, the Review and the children and young people at its heart have at times been weaponised or misrepresented to justify different positions.

4.3 On occasion the Review has been asked to speak to teams developing these policy areas. In such instances, the Review has provided evidence-based information but has tried not to step beyond the clinical focus of its remit.

Bell v Tavistock

4.4 In October 2019, a legal complaint was lodged against GIDS. It raised concerns about the adequacy of the consent procedures for hormone treatment and described hormone therapy as "experimental" (*Bell v Tavistock*) ([2020] EWHC 3274 (Admin)).

4.5 The case was based on whether the processes whereby the complainant was assessed and referred for hormone treatment were adequate and lawful. The case was heard as a Judicial Review, which focuses on the lawfulness of a particular practice. The High Court found that the processes were lawful.

4.6 The High Court considered that the information that the child would need to understand to have the requisite competence in relation to puberty blockers, would be as follows ([2020] EWHC 3274 (Admin)):

- the immediate consequences of the treatment in physical and psychological terms;
- the fact that the vast majority of patients taking puberty blockers go on to cross-sex hormones and therefore that s/he is on a pathway to much greater medical interventions;
- the relationship between taking cross-sex hormones and subsequent surgery, with the implications of such surgery;
- the fact that cross-sex hormones may well lead to a loss of fertility;
- the impact of cross-sex hormones on sexual function;
- the impact that taking this step on this treatment pathway may have on future and life-long relationships;
- the unknown physical consequences of taking puberty blockers; and
- the fact that the evidence base for this treatment is as yet highly uncertain.

4.7 Controversially they went on to conclude that it would be "doubtful" that 14/15-year-olds have such competence, and "highly unlikely" that children aged 13 or under have competence.

4.8 This High Court decision was overruled on appeal ([2021] EWCA 1363 (Civ)). The Court of Appeal was critical of the High Court's reliance on contested evidence and of the age-based guidelines for competence, given that the very basis of Gillick is that the stage at which a child can demonstrate competence in relation to a decision about a particular medical intervention is individual.

4.9 The *Bell v Tavistock* case points to the contested nature of the evidence around the factors listed above and the understanding needed in order for a child or young person to be able to consent to enter onto a hormone pathway.

4.10 The ability of the child or young person to lawfully consent to this proposed treatment is only one issue. There are two other issues to be addressed; the judgement that the clinician makes as to whether a treatment is indicated for a patient, and the information they provide to them about the potential benefits, risks and alternatives.

Care Quality Commission (CQC) report

4.11 In October and November 2020, the Care Quality Commission (CQC) inspectors carried out an announced, focused inspection of GIDS due to concerns reported to them by healthcare professionals and the Children's Commissioner for England. Concerns related to clinical practice, safeguarding procedures, and assessments of patients' ability to consent to treatment.

4.12 The CQC report, published in January 2021 (CQC, 2021), gave the service an overall rating of inadequate. The report noted the high level of commitment and caring approach of the staff but identified a series of issues that needed improvement. In addition to the growing waiting list pressures, the CQC identified problems in several other areas including: the assessment and management of risk; the variations in clinical approach; the lack of clarity and consistency of care plans; the lack of any clear written rationale for decision making in individual cases; and shortfalls in the multidisciplinary mix required for some patient groups. Recording of capacity, competency and consent had improved since new procedures were put in place in January 2020; however, there remained a culture in which staff reported feeling unable to raise concerns.

4.13 The CQC reported that when it inspected GIDS, there did not appear to be a formalised assessment process, or standard questions to explore at each session, and it was not possible to tell from the notes why an individual child might have been referred to endocrinology whilst another had not. Current GIDS data demonstrate that a majority of children and young people seen by the service do not get referred for endocrine treatment, but there is no clear information about what other diagnoses they receive, and what help or support they might need.

4.14 In response to both the original Bell v Tavistock judgment and the CQC findings, NHS England established a Multi-Professional Review Group (MPRG). Its remit is to review cases referred to the endocrinology clinic for puberty blockers to determine whether the agreed processes for assessment and informed consent have been properly followed.

The outcome of the Bell Court of Appeal decision did not change this requirement, given the concerns raised by CQC regarding consent, documentation and clarity about decision making within the service.

Interim report and subsequent developments

4.15 The Review has taken an iterative approach and has provided advice at various stages where there was sufficient clarity and clinical agreement about the way forward. In March 2022, the Review published an Interim Report and has subsequently written to NHS England in July 2022 (Appendix 6) and January 2023 (Appendix 7) setting out initial findings and early advice.



4.16 In response, NHS England has begun to implement changes to the clinical service offer in parallel to the Review conducting its business. This includes its decision to decommission GIDS as part of a managed transition of the service, initially to two new nationally networked services (Phase 1 providers) based in specialist children's hospitals.

4.17 While it is positive that improvements have already been made, it has added a layer of complexity to the work of the Review as the clinical landscape has shifted. This will be described in more detail in Part 5 of this report.

4.18 This has inevitably meant that, alongside establishing the longer-term vision for NHS gender identity services for children and young people, some of the Review's focus was redirected to ensure that the development of these interim services focused on the comprehensive, patient and family centred service the Review has outlined.

4.19 It is against this ever-moving, often turbulent backdrop and significant public, political and media attention, that the Review has been conducting its own programmes of work.



Understanding the patient cohort



AR-000129

This part of the report sets out what is currently understood about the characteristics of children and young people who are seeking NHS support for gender incongruence and/or dysphoria and considers what may be driving the rise in prevalence and the change in the case-mix.

Within its terms of reference (Appendix 1), the Review was asked to explore "the reasons for the increase in referrals and why the increase has disproportionately been [birth-registered] females, and the implications of these matters".

This goes to the heart of some of the core controversies in this area, specifically the nature and causes of gender incongruence and dysphoria, which then has bearing on the appropriate clinical response.

A failure to consider the cause, potential influences and contributory factors can lead to people taking polarised positions. Nuanced discussion is needed about how best to understand and respond to the children and young people at the centre of the debate.

Explanatory Box 5:

Gender incongruence

A marked and persistent incongruence between an individual's experienced gender and the assigned sex (ICD-11).

Gender dysphoria

Clinically significant distress or impairment of function (DSM-5).

5. Changes in the patient profile

5.1 Throughout the lifetime of the Review, the long waiting lists to access clinical services have been a significant concern for the NHS, and all those supporting this group of children and young people. Child and Adolescent Mental Health Services (CAMHS) and paediatric services are stretched across the UK, but as highlighted in the Review's interim report, gender-questioning children and young people appear to be disproportionately disadvantaged because they are frequently bypassed by local services once on a waiting list for gender services.

5.2 Understanding the numbers being referred is not enough of a basis for the NHS to plan gender services for children and young people. Underlying the numbers is a group of young people who often have a range of needs and/or associated conditions. Any service design has to take account of their holistic needs, not just their gender identity.

Sources of information

5.3 Several sources of information were used to understand the patient profile. These included:

- a systematic review (Taylor et al: Patient characteristics)
- data from the Clinical Practice Research Datalink (CPRD), a database of anonymised patient data from general practices across the UK
- an audit of referral data to the Gender Identity Development Service (GIDS), carried out by NHS Arden & GEM Commissioning Support Unit
- information from international colleagues
- discussions with a range of clinical staff through roundtable events and one-to-one meetings. The points represented are those where there was consistency in clinical perspective.

5.4 The systematic review (Taylor et al: Patient characteristics) examined the numbers of children and adolescents up to the age of 18 referred to specialist NHS gender or endocrinology services. It aimed to determine whether the change in characteristics of the population reported by various national clinics was reflected in published evidence, and how the population had changed over time.

5.5 In total, 131 papers met the inclusion criteria for the systematic review. These covered a wide international base but were primarily from North America, Europe and Australia.

5.6 Information on demographics, gender-related data, mental health, neuro-developmental conditions and adverse childhood experiences were collated from the study papers.

5.7 Where comparable numeric data were available between studies, these data were combined to improve understanding. Where numeric data were not available, the authors described the findings of the research studies in a narrative form.

5.8 At the time of writing, the CPRD study has reported preliminary findings on prevalence of gender dysphoria, co-occurrence of autism spectrum disorder (ASD), anxiety and

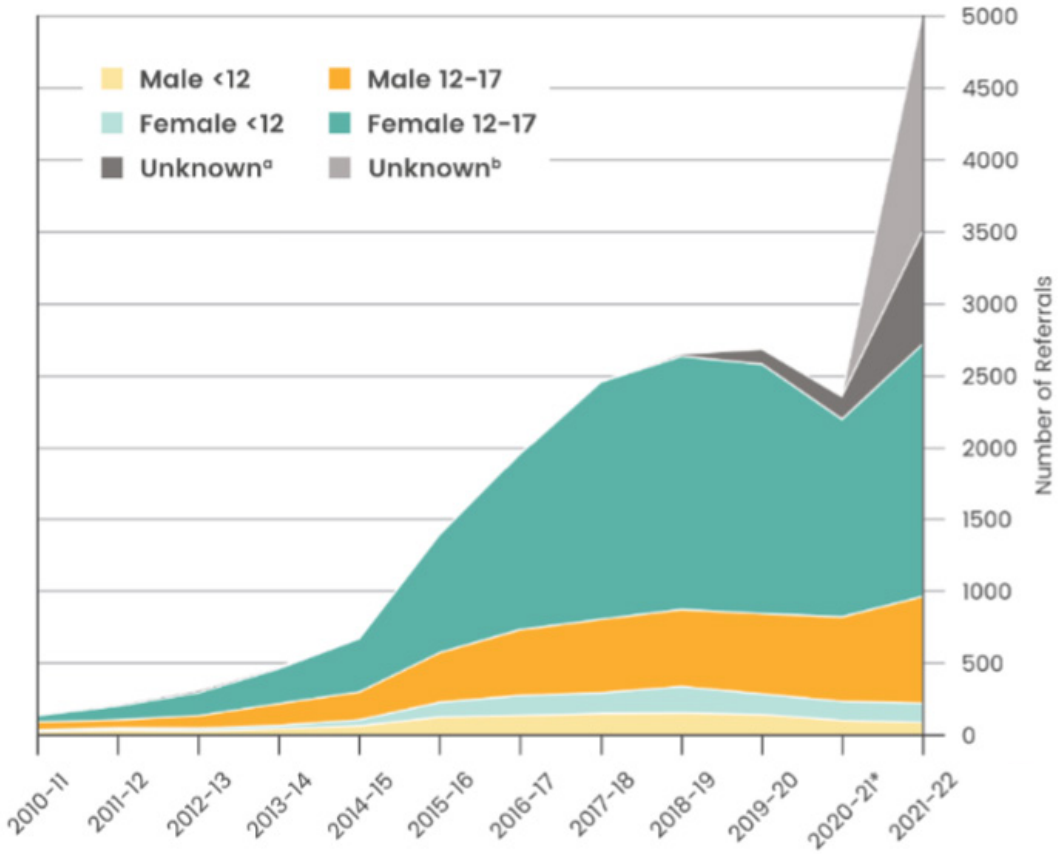
depression. Data for 3,782 people with gender dysphoria under the age of 18 were identified by primary care and hospital care codes for the study period 2009 to 2021. The full methodology for the CPRD study can be found in Appendix 5, as well as the strengths and limitations of the data. Only the incidence and prevalence data are included in this report, pending release of the fuller findings by the University of York on completion of the study.

Demographics

UK data

5.9 From 2014 referral rates to GIDS began to increase at an exponential rate, with the majority of referrals being birth-registered females presenting in early teenage years (Figure 11).

Figure 11: Child and Adolescent Referrals for Gender Dysphoria (UK, GIDS), 2010/11 to 2021/22



**Referral activity to GIDS/Tavistock was sharply limited in 2020-2021 due to COVID-19.*

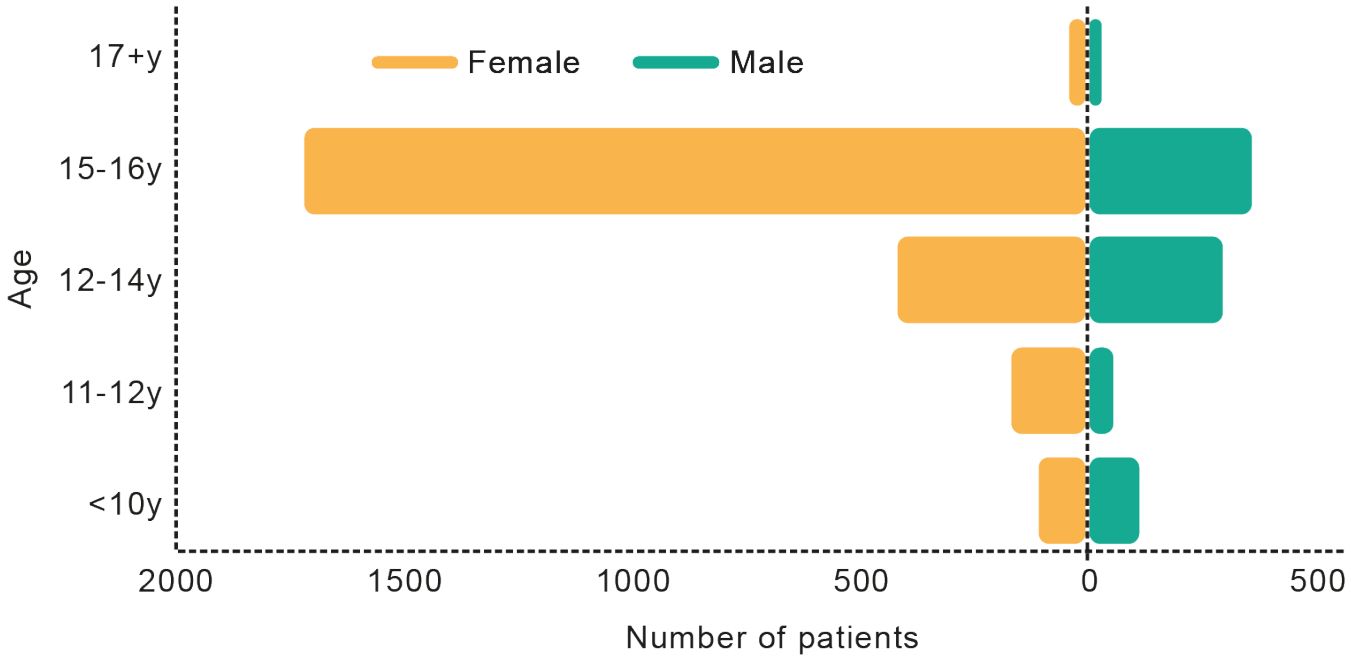
a Beginning in 2018-19, increasing numbers of referrals are not reported by birth registered sex.

b Limitations of the data: From the end of July 2021, AGEM CSU received referrals for GIDS from non-NHS sources (GP, schools, local authority, voluntary sector). All NHS referrals into GIDS went directly to the Tavistock and Portman GIDS. Data from the Tavistock and Portman GIDS website indicated that during 2021/22 they received in excess of 3000 referrals and further referrals received by AGEM CSU (approximately 1500 referrals) were not counted. Combined this indicated that the GIDS received a total of approximately 5000 referrals in 2021/22 alone. When reviewing the data that the GIDS provided against the number of referrals transferred into AGEM CSU as part of the waiting list transfer, the CSU only received 3115 referrals that were "new". This is significantly less than the number expected considering that they reported that in 2021/22 there were over 5000 referrals received. It is difficult to know if the quoted, over 5000 referrals in 2021/22, is correct. There is a strong possibility that there was double counting during 2021/22 as the referral numbers received by AGEM CSU were being reported to the GIDS who were then also sharing this information with the Care Quality Commission.

AGEM CSU: Arden & GEM Commissioning Support Unit.

5.10 Figure 12 below shows referral data from an audit of discharge notes of GIDS patients discharged from the service between 1 April 2018 and 31 December 2022 (Appendix 8). The youngest age of patients referred to GIDS was 3 years, the oldest age was 18 years and the mean and median 14 years. Of these referrals, 73% were birth-registered females and 27% birth-registered males.

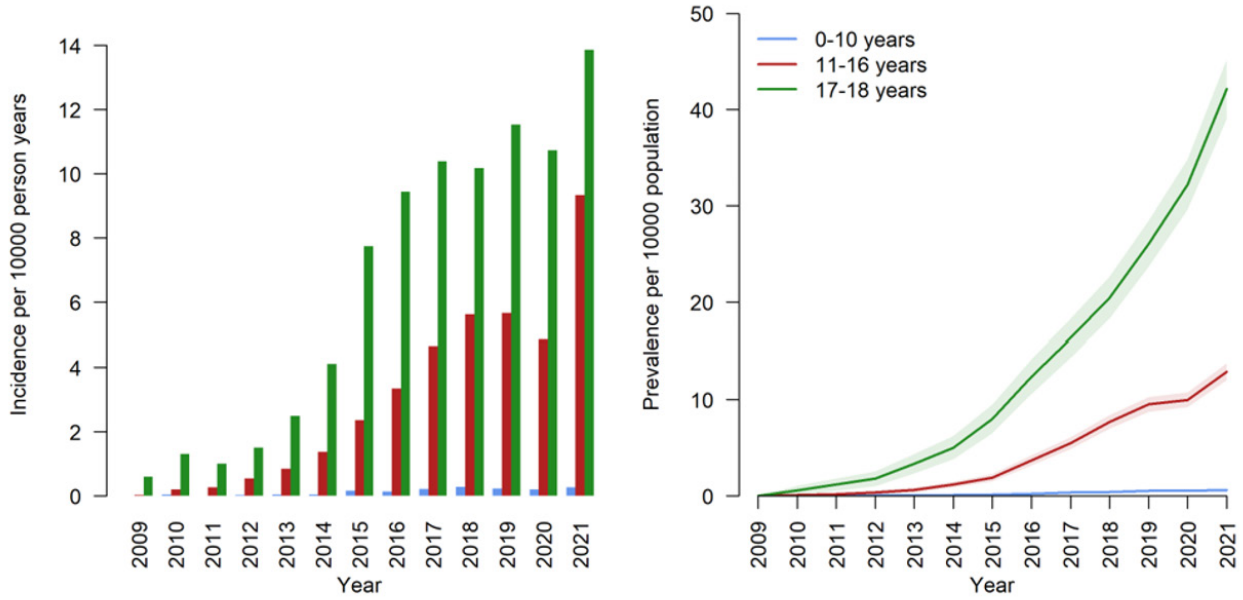
Figure 12: Distribution of patient's age on referral and birth-registered gender on referral to GIDS, 1 April 2018 to 31 December 2022



Source: The Gender Identity Development Service Audit Report, Arden & GEM.

5.11 In the sample drawn from CPRD data (Figures 13 & 14) (Appendix 5), recorded prevalence of gender dysphoria in people aged 18 and under increased over 100-fold between 2009 and 2021. This increase occurred in two phases; a gradual increase between 2009 and 2014, followed by an acceleration from 2015 onwards. Increases in this second phase were more rapid for people registered as female, although clinical records do not indicate whether their recorded gender had been changed.

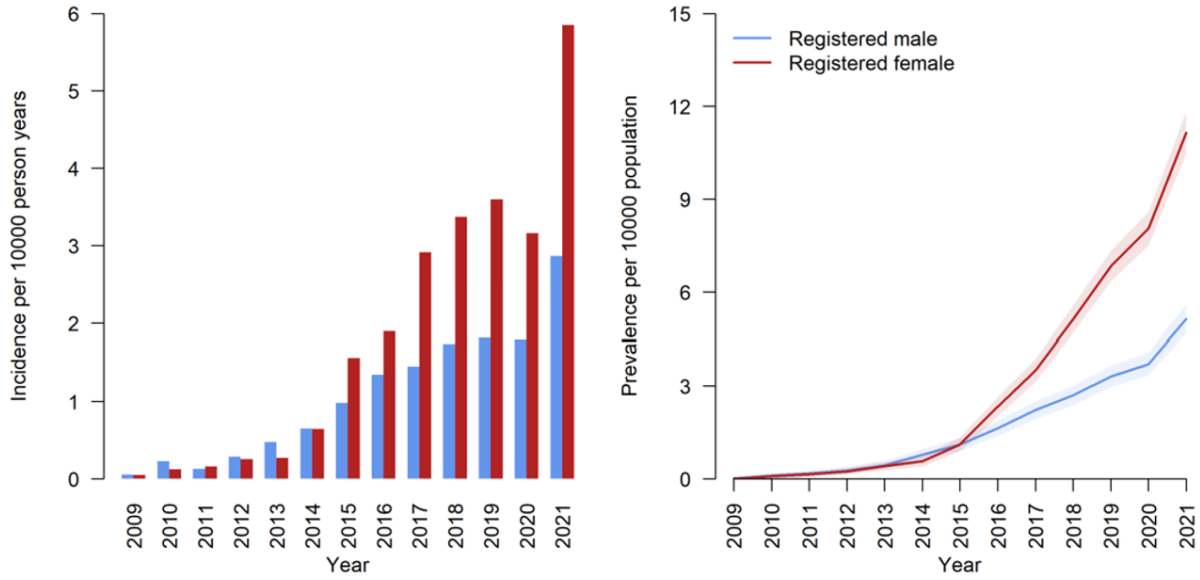
Figure 13: Incidence and recorded prevalence of gender dysphoria by age group



Source: Epidemiology and Outcomes for Children and Young People with Gender Dysphoria: Retrospective Cohort Study Using Electronic Primary Care Records. (Appendix 5).

NB: Shaded areas on prevalence graph denote 95% confidence intervals.

Figure 14: Incidence and recorded prevalence of gender dysphoria by registered gender



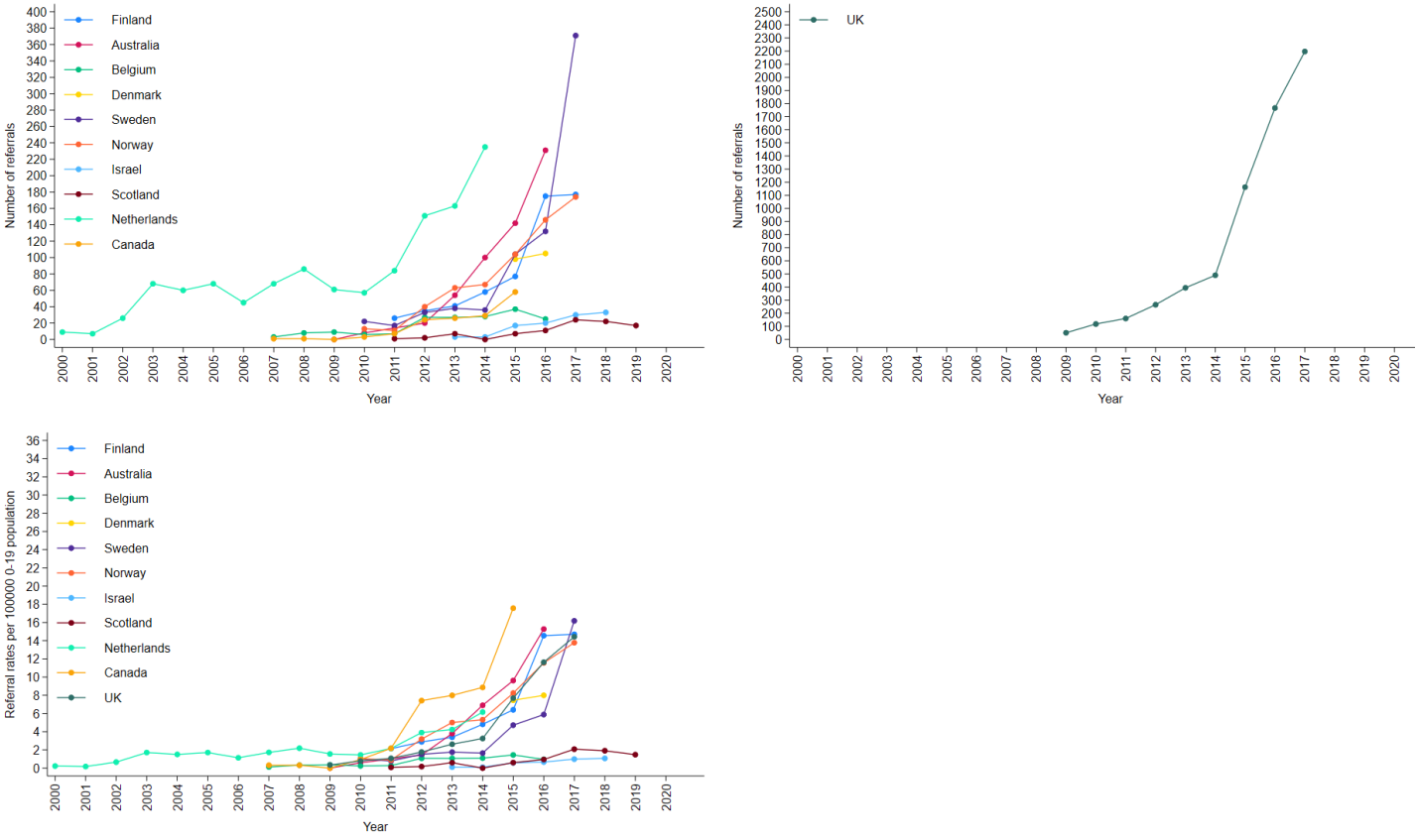
Source: Epidemiology and Outcomes for Children and Young People with Gender Dysphoria: Retrospective Cohort Study Using Electronic Primary Care Records (Appendix 5).

NB: Shaded areas on prevalence graph denote 95% confidence intervals. Patients can request to have their recorded gender changed on their clinical records without undergoing gender reassignment treatment, and CPRD reports the latest recorded gender only.

Comparison of UK and international data

5.12 The systematic review (Taylor et al: Patient characteristics) documented the increase in referrals across 11 countries. Around 5-6 years into each graph there is a sharp increase in referrals. The inflection point for the increase in referrals in the UK was in 2014, with similar timing in several other countries. In the Netherlands, the increase started from 2001, with an inflection point in 2011.

Figure 15: Number of referrals over time by country



Source: Taylor et al: patient characteristics

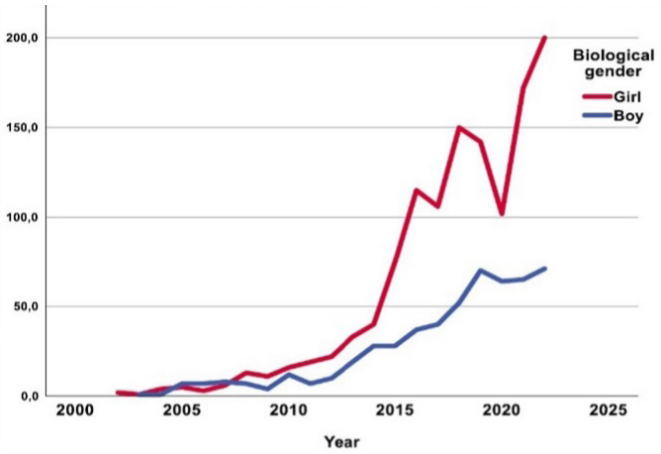
5.13 The first two graphs (Figure 15) show absolute numbers of referrals, and the UK appears to be an outlier with much larger numbers of referrals. However, the third graph is adjusted for the size of the 0-19 year old population in each country (that is, numbers per 100,000) and this brings the UK in line with other countries.

5.14 Whereas in the early days of providing gender services for children and young people, the majority of referrals were pre-pubertal children, between 2006 and 2013 both the Canadian and Dutch gender clinics reported that adolescent referrals had overtaken child referrals (Aitken et al., 2015).

5.15 Multiple countries reported a gradual switch in sex ratio towards a birth-registered female prevalence. Further data from Canada and the Netherlands showed that child referrals of birth-registered males still outnumbered those of birth-registered females, with the ratio switching in adolescence.

5.16 Figure 16 from the Norwegian national gender clinic demonstrates the divergence of the birth-registered male/female curves, and a transient fall off during the Covid-19 pandemic (Anne Waehre, personal communication, 2023).

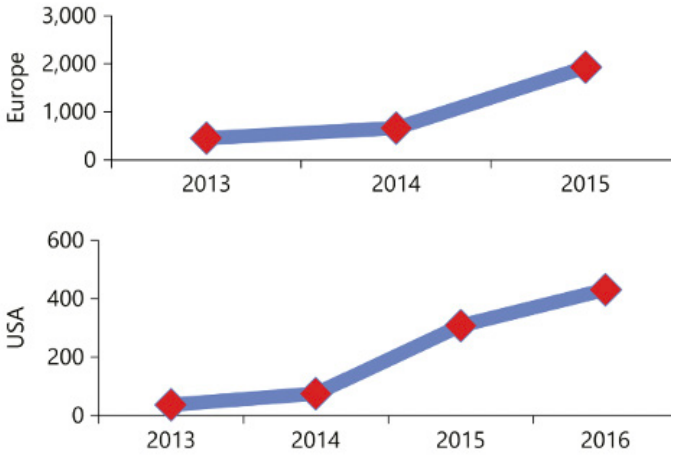
Figure 16: Referrals to the National Gender Clinic for children and young people in Norway



Source: Anne Wæhre, personal communication, 2023

5.17 The number of children and young people referred to endocrine clinics has increased in parallel to the numbers referred to gender clinics (Figure 17). An international survey conducted by the European Society of Paediatric Endocrinology and Paediatric Endocrinology Society in 2017 collated data over the preceding three years from 25 centres across Europe, the USA and South America (Skordis et al., 2019). This represents the largest single international pooled sample of referrals. Again, this shows an increase in referrals beginning in 2014. Of this group, 63% were transitioning from female to male.

Figure 17: Numbers of referrals to participating endocrine European and U.S. centres, 2013-2016



Source: Skordis, N., Butler, G., de Vries, M. C., Main, K., & Hannema, S. E. (2019). ESPE and PES International Survey of Centers and Clinicians Delivering Specialist Care for Children and Adolescents with Gender Dysphoria. Hormone Research in Paediatrics, 90(5), 326-331. https://doi.org/10.1159/000496115
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Gender characteristics

5.18 The systematic review (Taylor et al: Patient characteristics) looked at four key features of gender presentation: gender identity; formal diagnosis; age at onset; and social transition. Reporting of these characteristics was inconsistently documented and highly variable. Data on the percentage of children and young people who had socially transitioned prior to referral is discussed in Part 4.

5.19 Formal diagnosis of gender dysphoria was reported in 65 studies, with proportions ranging from 29% to 100%. The variable rates may be because of the different criteria for referral to the specialist gender clinics.

5.20 In most studies gender identity was not specifically reported. Where it was, estimates of non-binary identity ranged from 0-19%. The UK census, capturing data on the UK population over the age of 16, first enquired about gender identity in 2021 (Office for National Statistics, 2023a). Methodological issues regarding terminology have raised concerns about the validity of some of the data (Office for National Statistics, 2023c). However, the data is of interest in relation to young people and adults identifying as non-binary. The 16-to-24-year age-group had the highest proportions of people who identified as a transgender woman (0.15% or 9,000), as a transgender man (0.22% or 14,000), and as non-binary (0.26% or 17,000). The proportions who identified with these categories then decreased in each increasing age group.

5.21 The higher number of people who identified as non-binary compared to those who identified as a transgender woman or transgender man is important in raising awareness of the need to recognise and deliver appropriate support for this group when they present to the NHS. The census data are also consistent with clinicians reporting seeing an increasing number of non-binary young people.

Co-occurring conditions

5.22 In addition to the change in referral numbers, sex ratio and gender identities, clinical staff working in GIDS and other gender services internationally have reported a change in the case-mix. Adolescents in particular seem to have more complex presentations, with greater mental health and psychosocial needs, as well as additional diagnoses of ASD and/or attention deficit hyperactivity disorder (ADHD).

5.23 The Review has spoken to clinicians working in child and adolescent mental health and in paediatric services. They report seeing an increase in children and young people presenting with issues around gender identity alongside mental health difficulties, suggesting young people are seeking and accessing care across a broader range of NHS services.

5.24 An important aim of this Review is to find ways to ensure that these children and young people are able to get their needs met as efficiently as possible, regardless of their point of first contact so that they are not having to navigate and negotiate multiple referrals.

5.25 A serious shortcoming of the literature was that it was challenging to track changes over time due to overlapping datasets, and a lack of consistency in the reporting of key characteristics of the population. This is a major problem in trying to understand how the pattern of co-occurring conditions has evolved, which is key to understanding what approaches have been put in place to help young people address them and whether these delivered benefit to the young person.

Mental health needs

General mental health problems

5.26 Of the studies identified in the systematic review (Taylor et al: Patient characteristics) almost 50% reported data on depression and/or anxiety, and close to 20% reported other mental health issues. In short, rates of depression, anxiety and eating disorders were higher in the gender clinic referred population than in the general population.

5.27 Table 2 gives synthesised summary data on mental health where these are available.

5.28 A study comparing Dutch and Canadian gender clinic populations (de Vries et al., 2015) found that mental health problems were more common among them than in the general population, but levels were similar to those children and young people referred to mental health services for other non gender-related problems.

5.29 The Dutch clinic cohort, where a puberty blocker protocol was first introduced (the Dutch protocol), was found to have a lower incidence of associated problems compared to the Canadian clinic cohort. Other studies also demonstrated lower rates of mental health problems in the population referred in the Netherlands (de Vries, et al., 2011a) (only approximately 33%) compared to the Finland and the UK gender clinics.

5.30 In Finland (Kaltiala-Heino et al., 2015; Karvonen et al., 2023) more than three-quarters of the referred adolescent population needed specialist child and adolescent psychiatric support due to problems other than gender dysphoria, many of which were severe, predated and were not considered to be secondary to the gender dysphoria.

5.31 A more recent paper from Finland (Kaltiala et al., 2023) looked at whether the mental health needs of children and young people referred to gender services had changed in combination with the increase referral rate. This found that the gender dysphoria group had much greater mental health needs than age matched peers, and that those presenting more recently (2016-2019) had greater needs than those presenting in earlier cohorts (1996-2000). This appears to be the only paper which has systematically reported on changes over time in mental health needs.

Table 2: Synthesised data on mental health diagnoses in the gender clinic referred population

DIAGNOSIS	COUNTRIES INCLUDED	DATE RANGE	% REFERRED CYP	95% CI	RANGE (%)
Eating disorders	8	1998-2019	5	2-8	0-23
Depression	13	1980-2021	38	31-45	3-78
Anxiety	13	1980-2021	38	31-46	8-100

Source: Taylor et al: Patient characteristics.

NB: A patient population (country) may have had multiple study reports over time. In which case, data, from the study over the longest time period or that was most representative of the population was selected.

CYP: Children and young people; CI: confidence interval.

Specialist mental health conditions

5.32 The Review held a series of discussions with clinicians seeing children and young people with conditions usually referred to specialist services, for example, clinicians working in: specialist clinics for children with body dysmorphic disorder; specialist eating disorder services; and services for children with tics. A common factor with many of these specialist conditions is that they can occur when a person's mental stress or distress shows itself through physical symptoms, such as pain, tics, neurological symptoms or other problems which affect their ability to function.

5.33 The consultants and psychologists working in these services described young people presenting with these conditions in combination with gender-questioning or gender-related distress.

5.34 One example is functional movement disorders, particularly functional tic-like behaviours (FTLB). Classic neurodevelopmental tics usually start in childhood and if they last longer than a year a child could be diagnosed with Tourette's syndrome; of those diagnosed, around 70-80% are boys. In contrast, "FTLB are typically found to occur in young females, with complex, disabling and tic-lookalike patterns, usually triggered by exposure to videos portraying tic-like behaviours on social media". FTLB are associated with high levels of depression and anxiety (Nilles et al., 2022).

5.35 The association between FTLB and gender diversity described by clinical staff is reported in the literature, with one study (Martino et al., 2023) reporting that 41% of patients with functional tics had a gender minority identity, and the gender minority group also had significantly higher rates of anxiety, depression, social phobia and social interaction anxiety.

5.36 Body dysmorphic disorder (BDD) is another condition for which there has been an increase in presentations of young people. It is one of the obsessive-compulsive disorders (OCD), where there is a preoccupation with body image and with compulsive revisiting or avoidance of thoughts to manage distress. A recent study using population data (Krebs et al., 2024) found that BDD is more common in females than males (prevalence of 1.8% versus 0.3%), and that adolescent girls are at highest risk with an estimated prevalence of 3.4%. The condition is relatively rare before puberty. Many patients were found to be on the autistic spectrum and 80% of patients with BDD included in the study had suicidal ideation.

5.37 BDD is often underdiagnosed or misdiagnosed - young people do not access mental health services because they feel that their concerns about their appearance may be dismissed. However, there are improved treatment outcomes for young people who have profound distress from BDD, with exposure-based cognitive behavioural therapy (CBT), sometimes combined with medication (Rautio et al., 2022).

5.38 Clinicians have described to the Review how in patients with BDD, the intense focus on appearance is most commonly on facial features, but that some experience distress about genitalia or breasts. In this situation it can be difficult to determine whether the distress is due to BDD or gender dysphoria. However, at the end of a treatment package for BDD some young people say they no longer feel ill at ease with their birth-registered gender, while some may have less distress about their genitalia or breasts but still have marked gender incongruence and proceed to a social or medical gender transition.

5.39 The distressing symptoms that occur in these 'body and mind' conditions are real, and like pain or discomfort that arises from other causes can be addressed and helped with psychological interventions. It is very important that gender-questioning young people are able to access these evidence-based treatments alongside any other clinically appropriate interventions to support their gender care.

Neurodiversity

5.40 Table 3 shows synthesised summary data on prevalence of ASD and ADHD where this was available in the papers included in the systematic review.

5.41 Some research studies have suggested that transgender and gender diverse individuals are three to six times more likely to be autistic than cisgender individuals, after controlling for age and educational attainment (Warrier et al., 2020).

5.42 These findings are echoed by clinicians who report seeing teenage girls who have good cognitive ability and are articulate, but are struggling with gender identity, suicidal ideation and self-harm. In some of these young people the common denominator is undiagnosed autism, which is often missed in adolescent girls. Others may go on to receive a diagnosis of emotionally unstable personality disorder (EUPD) when they enter adult services.

5.43 Despite often being highly articulate, intelligent and skilled in many areas, autistic young people have difficulties with social communication and peer relationships, which may make it difficult for them to feel accepted and 'fit in'.

5.44 Difficulties with interoception (making sense of what is going on in their bodies) and alexithymia (recognising and expressing their emotions) can sometimes make it hard for these young people to express how they are feeling about their internal sensations, their gender identity and their sexual identity.

Table 3: Synthesised data on neurodiversity in the gender clinic referred population

DIAGNOSIS	COUNTRIES INCLUDED	DATE RANGE	% REFERRED CYP	95% CI	RANGE (%)
ASD	9	1998-2019	9	6-11	0-26
ADHD	9	1998-2021	10	7-13	2.5-27

Source: Taylor et al: Patient characteristics

NB: A patient population (country) may have had multiple study reports over time. In which case, data, from the study over the longest time period or that was most representative of the population was selected.

CYP: Children and young people; CI: confidence interval; ASD: Autistic Spectrum Disorder; ADHD: Attention Deficit Hyperactivity Disorder

5.45 In addition, mental health disorders including anxiety, depression, eating disorders, functional neurological disorder, OCD and BDD are more common in autistic children and young people (González-Herrero et al., 2022; Lai et al., 2019).

5.46 Mind and body understanding and integration are dependent on an individual child/young person's chronological age, developmental level and the presence or absence of neurodevelopmental differences. These factors may mean that these individuals identify and communicate experiences of stress/distress differently from other neurotypical individuals.

5.47 Working this out may take longer than it does for neurotypical individuals, making neurodiverse young people potentially vulnerable into their early 20s or longer because of their tendency to want black and white answers, and their difficulty in tolerating uncertainty.

Adverse childhood experiences

5.48 The systematic review (Taylor et al: Patient characteristics) highlighted the fact that relatively few studies reported on adverse childhood experiences (ACEs), but those that did demonstrated high rates amongst children and young people referred to gender services (ranges given below):

- combined neglect or abuse (11-67%)
- physical abuse (15-20%)
- sexual abuse (5-19%)
- emotional abuse (14%)
- maternal mental illness or substance abuse (53% and 49%)
- paternal mental illness or substance abuse (38%)
- exposure to domestic violence (23-25%)
- death or permanent hospitalisation of parent (8-19%)
- loss of parent through abandonment resulting in adoption (1-8%), foster care (1-12%) or children's home placement (0.5 - 5%).

5.49 While the high numbers of ACEs reported in the systematic review are notable, as relatively few studies have documented ACEs, it is not possible to determine how the number has varied over time.

5.50 However, a review of the first 124 cases seen by GIDS (Di Ceglie et al., 2002) found that just over a quarter of all referrals had spent some time in care and nearly half of all referrals had experienced living with only one parent. It showed that 42% of the children covered by the audit experienced the loss of one or both parents, mainly through separation; 38% had family physical health problems; and 38% had family mental health problems. Physical abuse was documented in 15% of cases.

5.51 This suggests that regardless of the change in demographics, ACEs and broader adversity within the family unit are important issues to be aware of when assessing young people's needs and planning a support package for them.

Suicidality and death by suicide

5.52 There is considerable concern about the risk of death by suicide among gender diverse youth and debate about whether gender-affirming treatments reduce this risk. This section discusses what is known about suicidality and the risk of suicide in this population and Chapter 15 discusses what is known about whether gender-affirming treatments reduce that risk.

5.53 Suicide is the act of taking one's own life voluntarily and intentionally, whilst suicidality encompasses suicidal thoughts (sometimes called suicidal ideation), suicide plans and suicide attempts.

5.54 Understanding the factors that can put young gender-questioning people at risk is of crucial importance to the young people themselves, their families and the clinical staff looking after them. Balanced information, which is realistic and practical, and does not over-exaggerate or underestimate the risks, is essential to support everyone involved and identify young people in most urgent need of help.

5.55 Table 4 gives synthesised summary data on suicide attempts, self-harm and suicidal ideation where this was available. The majority of studies that separated self-harm or suicidality by birth-registered sex found higher rates in birth-registered females versus males.

5.56 A large study (de Graff et al., 2020) examined rates of suicidality across Canadian, UK and Dutch gender clinic cohorts, generating 2,771 youth in the sample. Suicidality was assessed using two questions from standardised scales. Carers and young people were asked to rate 'now or within past 6 months' in response to: carers - "Deliberately harms self or attempts suicide", "Talks about killing self"; and young people - "I deliberately try to hurt or kill myself", "I think about killing myself". The study compared rates of suicidality in the gender clinic referred population with standardised data from the general adolescent population and non-trans identified youth referred to child and adolescent mental health services.

5.57 There was variation between clinics, but across the three clinics, rates of suicidality ranged from 27% to 55%. These rates of suicidality were significantly higher than for the general adolescent population, but similar to non-trans identified youth referred to child and adolescent mental health services. Higher rates of suicidality were observed in birth-registered females, as is the case in the general adolescent population.

5.58 The same paper (de Graaf et al., 2020) reviewed 17 previous studies that had reported rates of suicidal ideation ranging from 17% to 87%, and of suicide attempts ranging from 12% to 54%. The wide range reflects different methodologies and gender clinic populations.

Deaths by suicide

5.59 Deaths by suicide in children and young people are relatively rare events, compared to adult suicide. However, each one is a tragic event. In the UK, the death of every child and young person under 18 is reviewed and information about causation is collected by the National Child Mortality Database (NCMD).

Table 4: Synthesised data on suicide attempts, self-harm and suicidal ideation in the gender clinic referred population

DIAGNOSIS	COUNTRIES INCLUDED	DATE RANGE	% REFERRED CYP	95% CI	RANGE (%)
Suicide attempts	11	1976-2021	14	11-17	9-30
Self-harm	11	1976-2021	29	23-25	8-56
Suicidal ideation	10	2002-2021	39	30-48	10-87

Source: Taylor et al: Patient characteristics

NB. A patient population (country) may have had multiple study reports over time. In which case, data, from the study over the longest time period or that was most representative of the population was selected.

CYP: Children and young people CI: Confidence interval.

5.60 The latest NCMD report on suicide in children and young people (NCMD, 2021) looked at deaths between 1 April 2019 and 31 March 2020. There were 108 deaths that were assessed as highly or moderately likely to be due to suicide (about 2 deaths per week of under 17-year olds). The overall suicide rate in England was 1.8 per 100,000 9-17-year olds.

5.61 The Child Death Overview Panel reviewed 91 of the cases (NCMD, 2021). They examined a range of background factors which included household functioning (for example, family members with a medical or mental health problem, domestic abuse, divorce or parental separation), mental health needs, neurodevelopmental conditions, sexual orientation, sexual identity and gender identity, abuse and neglect, bullying, problems in school, social media use, and drug or alcohol use.

5.62 Household functioning was found to be the most common factor - 63 (69%) of deaths, with mental health needs in 50 (55%), bullying in 21 (23%), neurodevelopmental conditions in 15 (16%) and sexual orientation, sexual identity and gender identity in 8 (9%).

5.63 Of the children or young people, 81 (89%) had more than one recorded factor and 51 (56%) had factors in five or more categories. Over one-third (33, 36%) had never been in contact with mental health services.

5.64 Another source of data in the UK is the National Confidential Inquiry into Suicide and Safety in Mental Health (2023). This looked at all-age suicide in people already under the care of mental health services. Between 2016-2020, there were 223 deaths by suicide of patients who identified as lesbian, gay or bisexual and 37 patients that the report described as "within a trans group" in the UK. They qualified this by explaining that "we are using "trans" as an umbrella term to include transgender, transsexual, or non-binary but we acknowledge that the terms people use to describe their own identity can be dynamic and we will be monitoring this in future reports". The report stated that 13 of the 37 were under 25. A high proportion of these individuals had experienced childhood abuse. Self-harm and personality disorder diagnosis were common in this group.

5.65 The Review met with The Tavistock and Portman NHS Foundation Trust to discuss deaths of patients (where known) who had been referred to or were currently or previously under the care of GIDS. The patients who died by suicide between 2018 and 2023 were described as presenting with multiple comorbidities and/or complex backgrounds. In addition, the trust observed that risk of suicidality was heightened at transition points in patient care; for example, between child and adult services. The young people were more likely to be registered female at birth, identifying as male in adolescence.

5.66 Looking to international data, a recent study in Finland (Ruuska et al., 2024) reviewed all gender clinic referred adolescents between 1996 and 2019 (2,083) and compared them to age-matched controls (16,643). There were 55 deaths in the study population, of which 20 were deaths by suicide. Although the suicide rate in the gender-referred youth was higher than in the general population, this difference levelled out when specialist-level mental health treatment was taken into account. Overall, it is difficult to draw firm conclusions because the absolute risk of suicide in the population of gender dysphoric youth and in the control population was very low, so numbers were thankfully small.

5.67 Although the data suggest that the numbers of deaths by suicide in this group of young people is very low, every death of a children or young people is a tragedy and a devastating loss. In each case, there is a strong need to understand what happened and why, so that anything that can be done to prevent future deaths is identified and acted upon.

Changes in the patient profile

5.68 The systematic review (Taylor et al: Patient characteristics) documented the rapid increase in referrals across many countries and concluded "These children show higher than expected levels of ASD, ADHD, anxiety, depression, eating disorders, suicidality, self-harm, and ACEs. Agreement on the core characteristics data to be collected at referral/assessment would help to ensure studies measure key outcomes and enable services to develop to meet the needs of these children. Services need to assess and respond to any co-occurring needs and complexities".

5.69 Today's population is different from that for which clinical practice was developed with a higher proportion of birth-registered females presenting in adolescence. They are a heterogenous group with wide-ranging co-occurring conditions, often including complex needs. This needs to be reflected in the services offered by the NHS.

6. Developmental considerations for children and adolescents

6.1 Two particularly critical periods of development are early childhood and adolescence. It is very important to understand several aspects of typical development - from what happens before birth through early childhood to adolescence, as well as the range of normal variations.

6.2 This has bearing on what might happen when clinical interventions are used and on the different issues involved in considering gender care for children and young people compared to that for older adults.

6.3 The issues covered in this section have relevance for:

- understanding what is known about the biology of gender incongruence.
- understanding about mental health vulnerability.
- considerations for social transition (see Chapter 12).
- potential impacts of puberty blockers (see Chapter 14).
- potential impacts of masculinising/ feminising hormones (see Chapter 15).
- obtaining consent (See Chapter 16).

Gender development through childhood and adolescence

6.4 Biological sex is determined by sex chromosomes. Males have an X and Y chromosome (XY) and females have two X chromosomes (XX). In early pregnancy, all foetuses have the potential to become male or female. A gene on the Y chromosome drives production of testosterone, which is necessary to produce internal and external male genitalia. In the absence of testosterone, the foetus will develop female anatomy.

6.5 There are many biological differences between males and females; for example, height, muscular strength, life expectancy, as well as susceptibility to certain illnesses such as lung cancer or heart disease. There are also very large overlaps between characteristics.

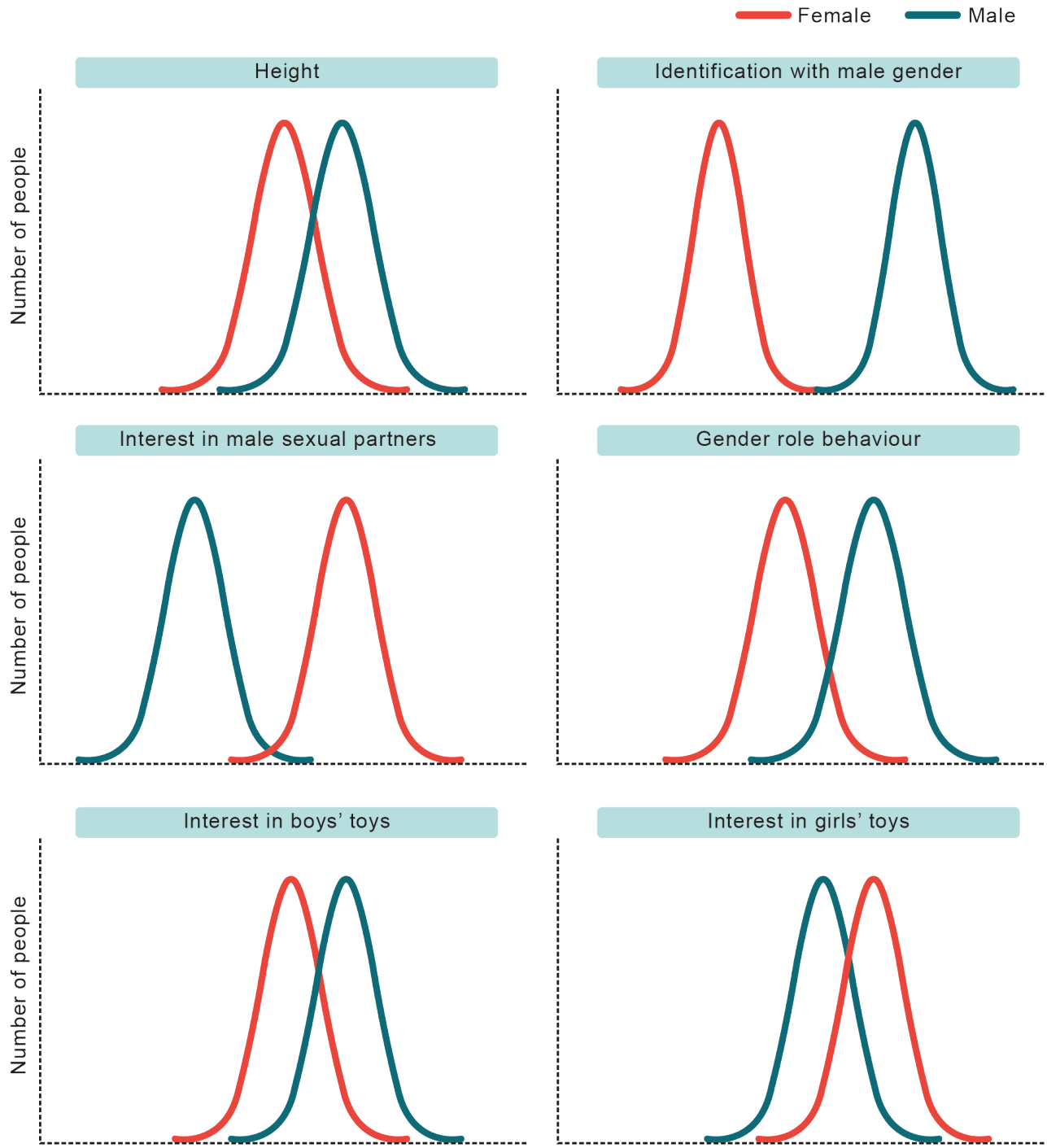
6.6 Academics have identified three important ways in which sex differences are expressed (Babu & Shah, 2021):

- gender role behaviours (these are behaviours such as toy preferences, play, physicality)
- gender identity (an innate sense of belonging and self-identification of one's gender as male, female or an alternative gender)
- and later, sexual orientation (the sex of the individuals to whom one is sexually attracted).

6.7 It is thought that all three of these can be influenced by biological and social factors, and this is an evolving area of research.

6.8 Figure 18 summarises these characteristic sex differences in humans. The use of the terms 'boys' toys' and 'girls' toys' by the author may feel uncomfortable but it is a classification that is used in academic study. The figure also illustrates the size of the sex difference in adult human height. Height is included to provide a familiar comparator for contextualising the sizes of the behavioural/psychological sex differences (Hines, 2020a).

Figure 18: Illustration of the overlap in distributions of scores for males and females for psychological/behavioural characteristics that show large and reliable sex differences



Source: Adapted from Hines, M. (2020). Human gender development. Neuroscience & Biobehavioral Reviews, 118, 89-96. https://doi.org/10.1016/j.neubiorev.2020.07.018, with permission from Elsevier.

NB: Higher scores for gender role behaviour represent more male-typical behaviour. The overlap for height is included as a familiar comparison.

6.9 In the UK, the average male is 5'9" tall and the average female 5'4". Some females are taller than some males, and this is part of normal variation. It would be very difficult to guess whether a 5'7" person was male or female from their height alone, because this falls right in the middle of the overlap.

6.10 Societal expectations and stereotypes have driven the idea that gender role behaviours, gender identity and sexuality should all align with birth-registered sex. This is not always the case. Gender role behaviours, gender identity and sexuality can vary independently of each other.

6.11 Females are most commonly attracted to male partners, and vice versa, but there is an overlap between males and females, with some individuals being same-sex attracted, attracted to both sexes, neither sex, or more fluid in their sexual preferences.

6.12 Children's sense of gender identity most commonly aligns with their birth-registered sex, but there is considerable variability in the rate at which they develop gender constancy, and the expression of their gender identity.

6.13 Some children will have gender role behaviours that do not align strongly with their birth-registered sex, but a gender identity that does align. They may grow up to be heterosexual or same-sex attracted.

Development of gender role behaviours

6.14 Like other areas of development, gender identity and gender role behaviours have typical milestones (de Vries et al., 2013; deMayo et al., 2022).

6.15 Differences in gender role behaviours are apparent in pre-school, when children start to show gender stereotyped behaviour in their play. Around this time, they seek to play with same-sex peers.

6.16 Toy choice has been extensively studied. Researchers classify toys into those that are typically preferred by boys (for example, cars and trucks) and those that are typically preferred by girls (for example, dolls). A systematic review (Davis & Hines, 2020) demonstrated that these differences in toy choice are very large.

6.17 Like biological characteristics such as height, there is a large overlap in gender role behaviours. This variability in gender role expression exists from an early age (some girls exhibit behaviours that are traditionally perceived as more masculine, and some boys exhibit behaviours that are perceived as more feminine).

6.18 A common assumption is that toy choice and other gender role behaviours are solely a result of social influences; for example, that boys will only be given trucks and girls will only be given dolls to play with. Although this is partially true, there is evidence for prenatal and postnatal hormonal influence on these behaviours, which will be discussed later.

Development of gender identity

6.19 In 1966, Kohlberg set out a theory of gender identity development (Kohlberg, 1966). Kohlberg's theory describes the typical progression of children acquiring gender identity (realising they are boys or girls) at 2-3 years old, acquiring gender stability (realising that gender does not change) at 3-4 years, and acquiring gender constancy (realising that superficial indicators such as clothes do not change gender) at 5-6 years.

6.20 Modern childhood experiences are different from when Kohlberg was writing, and contemporary research is needed to better understand and examine these fundamental principles, as well as the influence of early childhood experiences on gender identity development.

Interaction of nature and nurture

6.21 Sex differences in the brain emerge in the second half of pregnancy. There is strong evidence from animal studies that these changes are driven by the presence or absence of testosterone and have a long-term effect on sex-typed development (Bakker, 2014).

6.22 All three of the human characteristics that show particularly large sex differences (childhood sex-typed play, sexual orientation and gender identity) have been found to relate to early testosterone exposure.

6.23 Sex-typed play has been studied more extensively than any other human behaviour in this context, and at least 10 independent research groups have reported a link to prenatal testosterone exposure (Hines, 2015).

6.24 Much of this work is based on children who are born with atypical sex hormone levels. These conditions are called differences in sex development (DSD), previously termed intersex.

6.25 The most commonly studied DSD is congenital adrenal hyperplasia (CAH). In this condition, genetic females (XX) usually have high levels of testosterone caused by changes in their genes. These high testosterone levels start antenatally, and result in partially masculinised genitalia (Babu & Shah, 2021).

6.26 Genetic females (XX) with CAH are usually reared as females as they have female internal organs with reproductive capacity, yet they are more likely than other females to have male role behaviours (for example, male-type play and toy choice), and reduced female-typical play. In adulthood, 50-75% will be exclusively heterosexual, whilst the remainder will be bisexual or same-sex attracted. Only 2-5% will have gender dysphoria that leads to gender reassignment; however, some will have a weaker female identity (Berenbaum & Beltz, 2011). Therefore, it appears that in CAH, while prenatal testosterone exposure has a strong impact on gender role behaviour, gender identity predominantly aligns with sex of rearing.

6.27 Similarly, genetic males (XY) with complete androgen insensitivity syndrome (CAIS) have functioning testes but their cells are unable to respond to testosterone, and they show female-typical play patterns (Hines, 2020a).

6.28 A more unpredictable situation is when genetic males (XY) are born with a range of conditions where they have normal testosterone levels but have a very deformed or absent penis. If these children are raised as girls, the majority will continue to identify as female, despite their normal male hormone levels (Meyer-Bahlburg, 2005).

6.29 There are numerous other forms of DSD. Practice has changed from the earlier era management approach of early surgical modification to match an individual's assigned sex. Now the emphasis is on assessing the

infant's biology and using that to predict the most likely developmental outcomes with which to guide sex of rearing. This approach makes it less likely that irreversible surgery or medical intervention will be given before the individual is able to understand their body (and its capabilities), and their psychosexual development is advanced.

6.30 An important finding is that some DSD conditions have more predictable gender identity outcomes. In other DSD conditions, long-term predictions are less reliable, and in those cases sex of rearing seems to be a stronger predictor of gender identity in childhood and beyond.

6.31 In summary, studies of children with DSD suggest that a complex interplay between testosterone levels, external genitalia, sex of rearing and socio-cultural environment all play a part in eventual gender identity. This is important to consider when trying to understand the range of pathways that might lead to gender incongruence.

Changes from adolescence into adulthood

6.32 There are two important periods of brain development - the first up to age three, and the second from adolescence into adulthood.

6.33 Adolescence is a period of rapid social, emotional, physical and cognitive development that can be difficult for some young people to navigate. Pubertal changes in hormones result in changes to the physical body and the brain, alongside major changes in social expectations and demands.

6.34 An understanding of brain development and the stages of adolescence is essential in understanding how gender identity relates to the other aspects of adolescence. It is also important to consider in relation to the management of gender incongruence and gender-related distress during this period.

Changes in the brain during adolescence

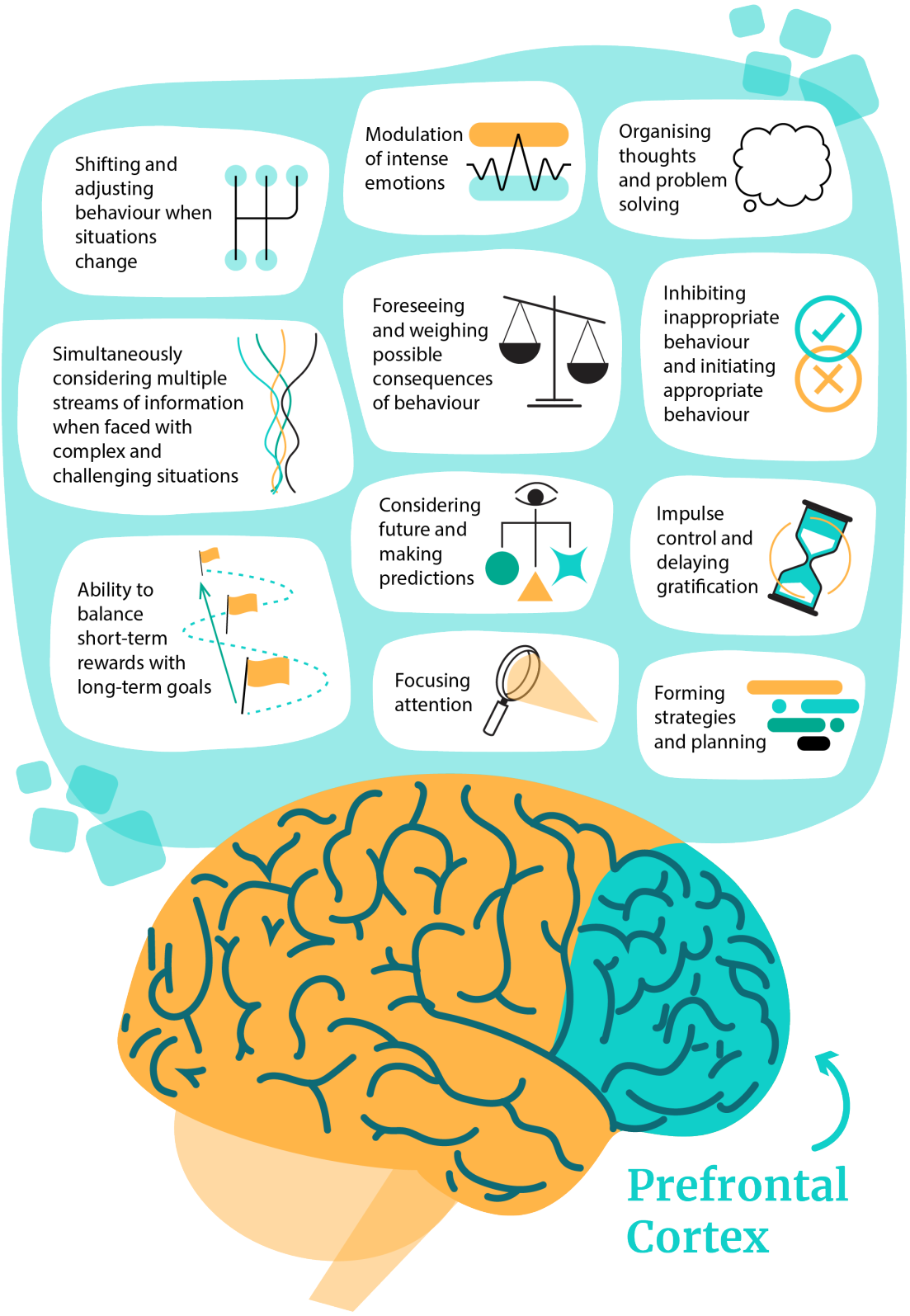
6.35 Starting in early puberty unused neural connections are pruned, and other important connections are made stronger and faster.

6.36 It used to be thought that brain maturation finished in adolescence, but it is now understood that this remodelling continues into the mid-20s as different parts become more interconnected and specialised (Giedd, 2016).

6.37 This brain remodelling does not proceed evenly. Changes in the limbic area, which is 'present-orientated' and concerned with risk taking and sensation seeking, begin with puberty; this part of the brain becomes super sensitised, drives emotional volatility, pleasure and novelty seeking, and also makes adolescents more sensitive to social rejection, as well as vulnerable to addiction and a range of mental health problems.

6.38 The 'future orientated' prefrontal cortex matures later, with development continuing into an individual's 20s, and as illustrated in Figure 19, is concerned with executive functions such as complex decision making, rational judgement, inhibition of impulsivity, planning and prioritisation.

Figure 19: Maturation of the adolescent brain



Neuropsychiatric Disease & Treatment 2013:9 449-461 - Originally published by, adapted and used with permission from Dove Medical Press Ltd.

6.39 By the age of 15 an adolescent will make similar decisions in relation to hypothetical situations as an adult. However, although adolescents can balance the possible harm or benefit of different courses of action in theory, in the real world they may still engage in dangerous behaviours, despite understanding the risks involved. Hence, both the role of emotions and the connection between feeling and thinking are relevant to how adolescents make decisions (Arain et al., 2013).

The 'social brain'

6.40 The 'social brain' is the network of brain regions that are involved in understanding other people's intentions, desires and beliefs. The slowly maturing prefrontal cortex is a key part of this network, so there are considerable changes in these abilities through teens to adulthood.

6.41 Through adolescence, peers have an increasing influence and parents a lessening influence. Adolescents' evaluation of their social and personal worth is strongly influenced by what their peers think about them. Studies have shown adolescents to be hypersensitive to social isolation, so much so that going along with peers in order to avoid social risk, even if it means taking health and legal risks, might be seen as the rational choice because it reduces the possibility of social exclusion (Blakemore, 2018).

Role of sex hormones in brain maturation

6.42 There is increasing evidence that the changes in brain maturation described above are driven by a combination of chronological age and sex hormones released through puberty (Goddings et al., 2019; Ravindranath et al., 2022; Sisk & Zehr, 2005). Sex hormones are also responsible for increasing divergence in the structure of the male and female brain (Beck et al., 2003).

6.43 Some researchers have suggested there may be a 'critical period' in adolescence for the development of more complex thinking and analytical processes (Baxendale, 2024; Larsen & Luna, 2018), and more work is needed to clarify this.

6.44 In summary, childhood, adolescence and young adulthood are dynamic developmental periods for gender expression, cognitive development and overall brain maturation, and at the same time, young people are having to navigate an increasingly complex world. This important developmental backdrop needs to be taken into account when thinking about how gender incongruence may develop in any one individual and how best to address it.



7. Growing up in the 2000s

7.1 A generation is a group of people who share similar birth years, life experiences and cultural influences. Every generation encounters new experiences, advances, technologies, challenges and stressors that have a profound effect on their behaviours, attitudes and beliefs.

7.2 It may appear somewhat simplistic to divide people by birth year, but this is a helpful way of understanding how perspectives, as well as health and illness, can be shaped by major world events (most recently the Covid-19 pandemic), as well as social and economic conditions.

7.3 Generation Z is the generation in which the numbers seeking support from the NHS around their gender identity have increased, so it is important to have some understanding of their experiences and influences.

7.4 They are defined as those who were born between 1995 and 2009 and are characterised by their digital nativism (proficiency in using technology and social media) and unique characteristics such as being entrepreneurial, socially conscious, pragmatic and diverse (Jayatissa, 2023).

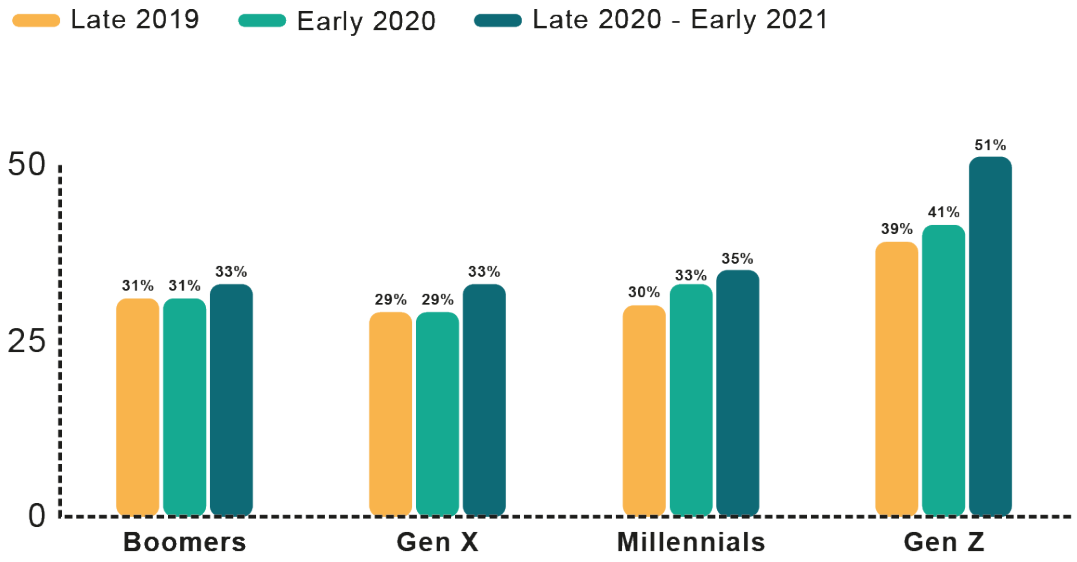
7.5 In terms of broader context, Generation Z and Generation Alpha (those born since 2010) have grown up through a global recession, concerns about climate change, and most recently the Covid-19 pandemic. Global connectivity has meant that as well the advantages of international peer networks, they are much more exposed to worries about global threats.

Generational beliefs and gender identity

7.6 Generation Z and some younger Millennials (Generation Y) generally have different beliefs about the fluidity and mutability of gender than older generations. Attitudes have changed at speed, such that within a 6-month period between early 2020 and late 2020/early 2021 Generation Z adults surveyed in the USA became the first generation in which the majority responded negatively to the statement "there are only two genders, male and female" (Twenge, 2023).

7.7 There are also generational differences in the numbers of young adults reporting that their experienced gender does not align with their birth-registered sex. Based on US Census data, in 2021-2022, 5.6% of Generation Z adults identified as transgender or non-binary, compared to 2.4% of Millennials and 1.5% of Generation X.

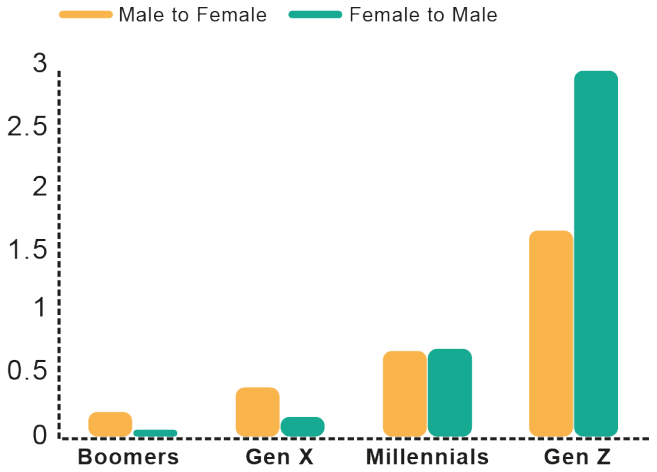
Figure 20: Percentage of U.S. adults who believe there are more than two genders, by generation 2019-2021



Source: Adapted from Twenge, J. M. (2023). Generations: The real differences between gen Z, millennials, gen X, boomers, and silents - and what they mean for America's future. Atria Books.

NB: Shows percent who disagree with the statement "There are only two genders, male and female." Late 2019 data were collected July 18 to December 26; early 2020 data were collected January 2 to June 25; late 2020-early 2021 data were collected July 2, 2020 to January 12, 2021.

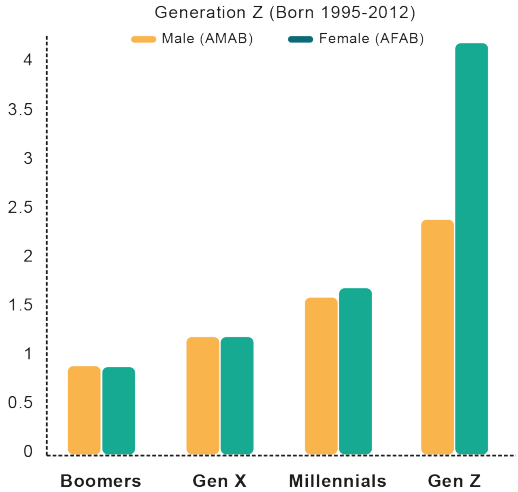
Figure 21: Percent of U.S. adults identifying as transgender, by sex assigned at birth and generation, 2021-2022



Source: Adapted from Twenge, J. M. (2023). Generations: The real differences between gen Z, millennials, gen X, boomers, and silents - and what they mean for America's future. Atria Books.

NB: Data collected between July 21, 2021, and October 17, 2022. Terms are from the BRFSS survey, although they are increasingly considered outdated and are replaced with transgender women and transgender men, respectively.

Figure 22: Percent of U.S. adults identifying as nonbinary, by sex assigned at birth and generation, 2021-2022



Source: Adapted from Twenge, J. M. (2023). Generations: The real differences between gen Z, millennials, gen X, boomers, and silents - and what they mean for America's future. Atria Books.

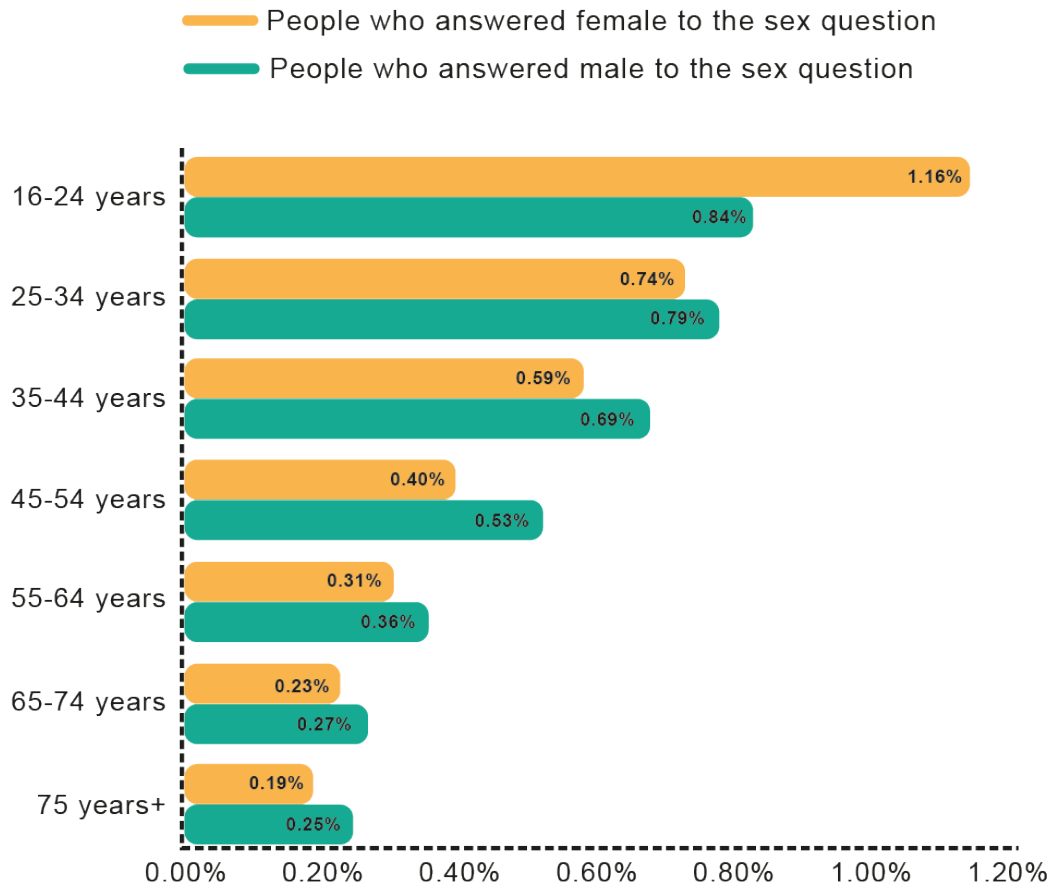
NB: Data collected between July 21, 2021 and October 17, 2022. AMAB = assigned male at birth; AFAB = assigned female at birth.

7.8 In common with other trends documented internationally, the 2022 UK census (Office for National Statistics, 2023a) reported that the group with the highest percentage (1.16%) identifying as transgender (defined as gender different from that registered at birth) was birth-registered females aged 16-24. This was the only age group in which the number of birth-registered females identifying as trans exceeded the number of birth-registered males identifying as trans.

7.9 Changes in beliefs about gender identity in Generation Z have led to much more flexible thinking about how gender is expressed, and a move away from gender stereotypes. Young people within Generation Z, as well as younger Millennials, are much more open to experiment with gender expression than previous generations.

7.10 Many of these young people will not require any input from the NHS. They may see themselves as being anywhere on a spectrum from gender non-conforming through to binary trans. Many will remain fluid in their gender identity for an extended period. Some will partially or fully socially transition, but not seek medical intervention.

Figure 23: Percentage of usual residents aged 16 years and over who identified as trans by sex and age, England and Wales, 2021



Source: Office for National Statistics. (2023b, January 25). Gender identity: age and sex, England and Wales: Census 2021. Contains public sector information licensed under the Open Government Licence v3.0.

Online stressors and harm

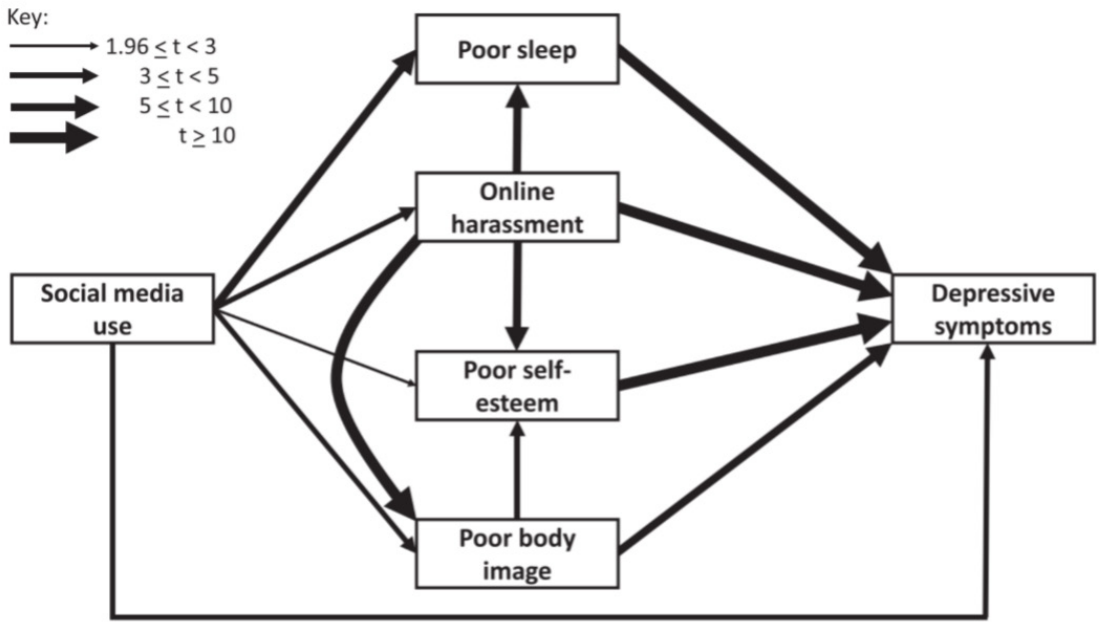
7.11 Generation Z and Generation Alpha (the generation born since 2010) have grown up with unprecedented online access. This has huge advantages, but also brings new risks and challenges. Access to the online world has given children and young people learning resources, global information and methods of communication unavailable to previous generations, but it has also made them vulnerable to new dangers.

7.12 The Millennium Cohort Study (MCS) is a UK nationally representative prospective cohort study of children born into 19,244 families between September 2000 and January 2002. A study (Kelly et al., 2018) used this data to examine the relationship between social media use and mental health for 14-year-olds within the cohort (10,904 individuals):

- girls reported more hours of social media use than boys; 43% of girls used social media for three or more hours per day compared with 22% of boys.
- girls were more likely to be involved in online harassment as a victim or perpetrator (38.7% versus 25.1% respectively).
- girls were more likely to have low self-esteem (12.8% versus 8.9% of boys), to have body weight dissatisfaction (78.2% versus 68.3% of boys) and to be unhappy with their appearance (15.4% versus 11.8% of boys).
- girls were more likely to report fewer hours of sleep than boys and to report experiencing disrupted sleep often (27.6% versus 20.2%) or most of the time.

7.13 On average, girls had higher depressive symptom scores compared with boys. Online harassment, poor sleep quality and quantity, poor self-esteem and body image were all strongly associated with depressive symptom scores. Figure 24 illustrates the relationship between these different factors. The thickness of the arrows shows the strength of the relationships.

Figure 24: Social media use and depressive symptoms - summary of path analysis



Source: Kelly, Y., Zilanawala, A., Booker, C., & Sacker, A. (2018). Social Media Use and Adolescent Mental Health: Findings from the UK millennium cohort study. EClinicalMedicine, 6, 59-68. https://doi.org/10.1016/j.eclinm.2018.12.005
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NB: The thickness of the arrow shows the strength of the relationships.

7.14 As social media use increased from 0 to 5 or more hours a day, there was a stepwise increase in depressive symptom scores and the proportion of young people with clinically relevant symptoms (Kelly et al., 2018).

7.15 A systematic review of 20 studies found that use of social media was associated with body image concerns and disordered eating (Holland & Tiggermann, 2016). Numerous other studies implicate smartphone and social media use in mental distress and suicidality among young people, particularly girls, with a clear dose-response relationship (Abi-Jaoude et al., 2020); that is, the more hours spent online the greater the effect. The mediating effects of social media on poor sleep, poor body image and cyberbullying are common themes across much of the literature.

Access to sexually explicit content

7.16 The Children's Commissioner's report in 2023 (Children's Commissioner, 2023) found that pornography is so widespread and normalised that children cannot 'opt out'. The average age when children first see pornography is 13, but 10% have seen it by age 9, and 27% by 11. The pornography that they are exposed to is frequently violent, depicting coercive, degrading or pain-inducing acts. Younger exposure had a negative impact on self-esteem.

7.17 Young people may passively stumble on pornography online, receive explicit images from people they know and, by the age of 16-21, 58% of boys and 42% of girls were actively seeking out pornographic material.

7.18 Young people aged 16-21 were more likely than not to assume that girls expect or enjoy sex involving physical aggression. Among all respondents, 47% stated that girls 'expect' sex to involve physical aggression such as airway restriction or slapping, a further 42% stated that most girls 'enjoy' acts of sexual aggression. A greater proportion of young people stated that girls 'expect' or 'enjoy' aggressive sex than boys do.

7.19 Several longitudinal studies have found that adolescent pornography consumption is associated with subsequent increased sexual, relational and body dissatisfaction (Hanson, 2020).

7.20 Research commentators recommend more investigation into consumption of online pornography and gender dysphoria is needed. Some researchers (Nadrowski, 2023) suggest that exploration with gender-questioning youth should include consideration of their engagement with pornographic content.

Mental health in children and adolescents

7.21 The striking increase in young people presenting with gender incongruence/dysphoria needs to be considered within the context of poor mental health and emotional distress amongst the broader adolescent population, particularly given their high rates of co-existing mental health problems and neurodiversity.

7.22 Internationally, there have been increasing concerns about the mental health of Generation Z. The reasons for this are highly speculative, although there is ongoing debate about the contribution of excessive smartphone use and social media as discussed above.

7.23 The Review spoke to a wide range of mental health professionals about their observations of rising mental health presentations across the child and adolescent population, and reviewed some of the available UK data.

7.24 UK national surveys between 1999 and 2017 show that there has been a substantial increase in rates of mental health problems in child and adolescent populations, with increased anxiety and depression being most evident in teenage girls. In 2014, there was a marked increase in young women aged 16-24 presenting with anxiety, depression and self-harm (NHS Digital, 2018).

7.25 The prevalence of 'probable mental health disorder' in children aged 8-16 years rose from 12.5% in 2017 to 20.3% in 2023. In young people aged 17-19 years, rates increased from 10.1% in 2017 to 23.3% in 2023 (NHS Digital, 2023).

7.26 Some conditions (for example, eating disorders) have increased more than others, particularly in girls and young women (Table 5).

7.27 Studies of rates of self-harm have shown similar increases. For example, between 2011 and 2014 there was an almost 70% increase in young girls between 13 and 16 years old presenting with self-harm, which was not paralleled in boys or in other age groups. Rates of self-harm in 13 and 19 year old girls were elevated throughout compared to boys (Morgan et al., 2017).

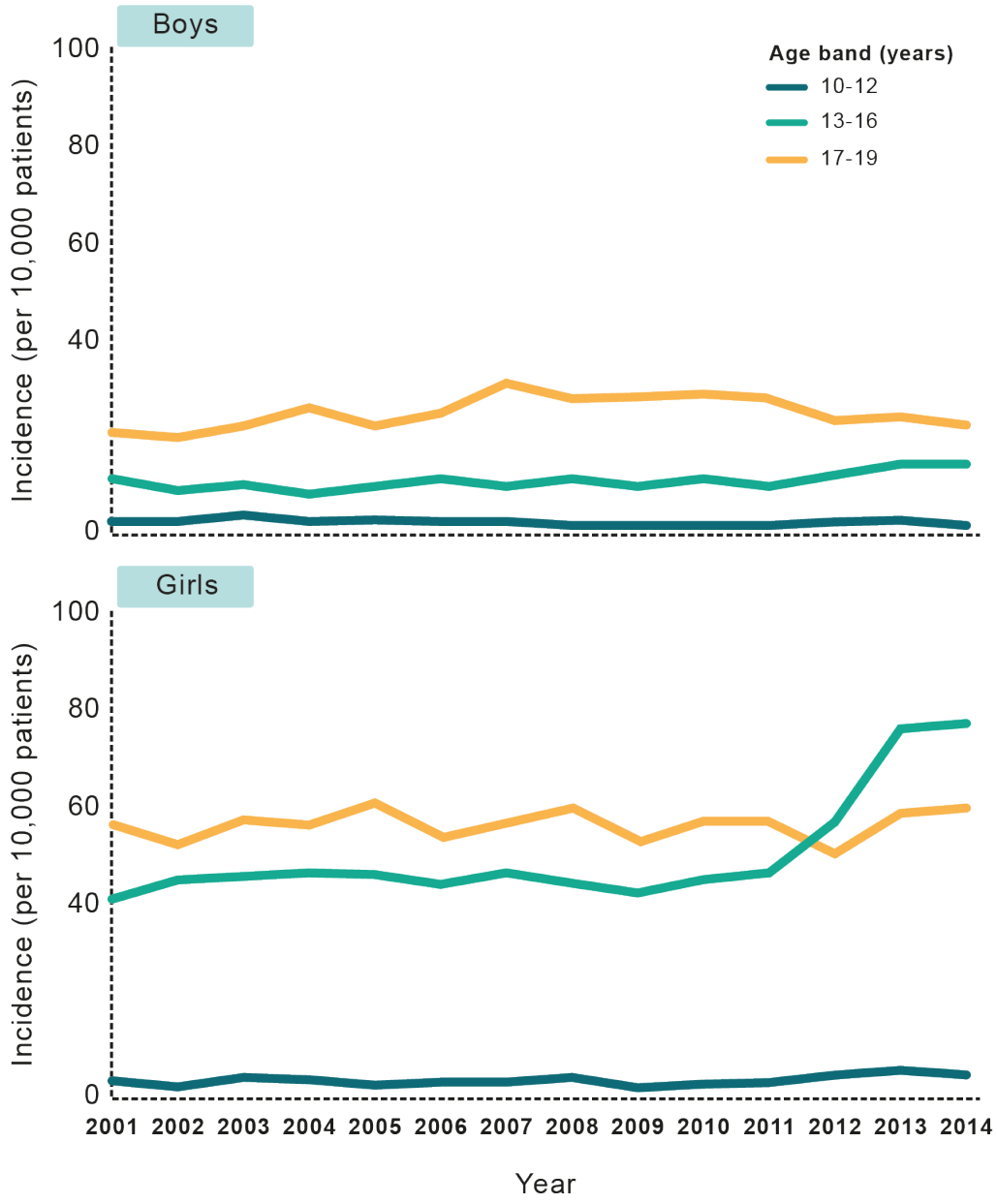
7.28 The increase in presentations to gender clinics has to some degree paralleled this deterioration in child and adolescent mental health. Mental health problems have risen in both boys and girls, but have been most striking in girls and young women. In addition to increasing prevalence of depression and anxiety, presentations of eating disorders and self-harm have increased since the Covid-19 pandemic (Trafford et al., 2023).

Table 5: Percentage of children and young people with an eating disorder, by age and sex, 2017 and 2023

	11 - 16-YEAR OLDS			17 - 19-YEAR OLDS		
	BOYS %	GIRLS %	ALL %	YOUNG MEN %	YOUNG WOMEN %	ALL %
2017	0.2	0.9	0.5	0	1.6	0.8
2023	1.0	4.3	2.6	5.1	20.8	12.5

Source: NHS Digital (2023, November 21). Mental Health of Children and Young People in England, 2023 - wave 4 follow up to the 2017 survey.

Figure 25: Temporal trends in annual age specific self-harm incidence stratified by sex, 2001-2014



Source: Reproduced from Morgan, C., Webb, R. T., Carr, M. J., Kontopantelis, E., Green, J., Chew-Graham, C. A., Kapur, N., & Ashcroft, D. M. (2017). Incidence, clinical management, and mortality risk following self harm among children and adolescents: Cohort study in primary care. BMJ. https://doi.org/10.1136/bmj.j4351 with permission from BMJ Publishing Group Ltd.

NB: Standardised by index of multiple deprivation fifth and region of residence.

7.29 As well as the issues highlighted above, clinicians working in the NHS have seen increased rates of some more specialist mental health conditions such as functional tic-like behaviours, BDD and functional neurological conditions. These changes have been observed internationally, and preceded Covid-19, although some got worse during the pandemic.

7.30 Many young people with gender dysphoria are presenting with combinations of the above conditions. Sometimes the associated conditions pre-date the gender dysphoria and sometimes they follow it. The complex interplay between these issues is not well understood.



8. Possible factors influencing the change in patient profile

8.1 More than two decades ago, Cohen-Kettenis and Gooren (1999) wrote: "Adult gender identity and gender role behaviour develop gradually over a long period of time and are influenced by multiple, interacting factors, active at different developmental periods… our understanding of this process has increased considerably, but a large part of it still remains enigmatic". This quote still resonates in 2024.

8.2 This report has described the very altered profile of the children and young people who are now being seen in NHS gender services. To inform how to best care for them, it is essential to understand more about the factors that are influencing the change in patient profile.

8.3 The change in the profile (with the majority now being adolescent, birth-registered females) needs to be considered in the context of changes in the wider population discussed in Chapter 7.

8.4 This chapter explores the evidence for biological factors in the development of a transgender identity and discusses the more dynamic contemporary psychosocial factors.

Biological factors

8.5 For many centuries transgender people have been predominantly trans females, commonly presenting in adulthood. Some transgender adults describe being aware of their gender incongruence and/or being gender dysphoric from childhood.

8.6 The search for a biological cause for gender incongruence is important to some transgender people and for some clinicians it is seen to strengthen the justification that medical treatment is warranted.

8.7 There are three main areas of research relating to biological factors: prenatal and/or pubertal hormone exposure; genetics (twin studies); and brain structure (imaging studies).

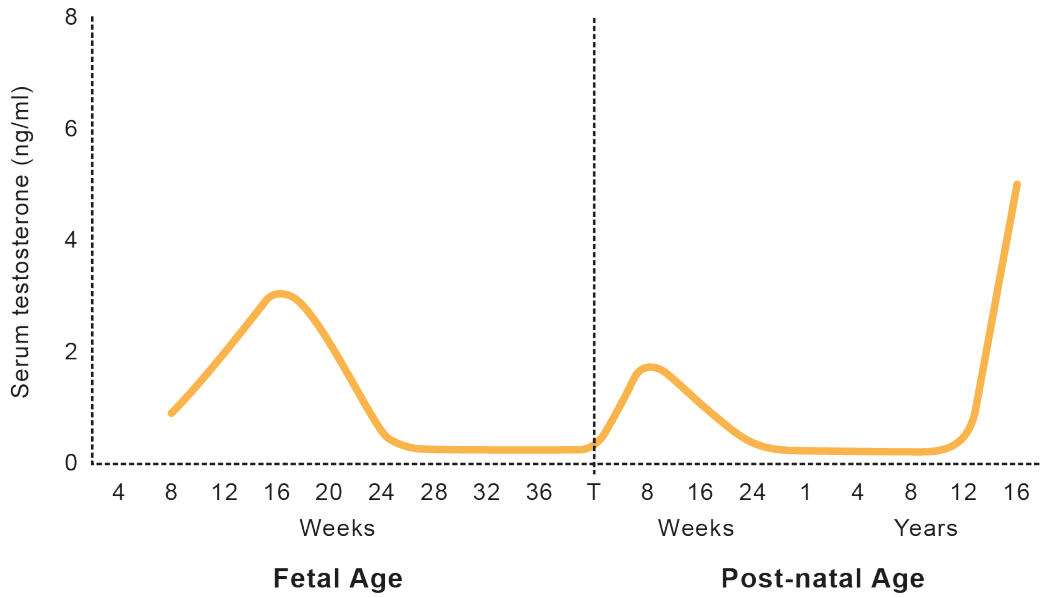
Prenatal and/or pubertal hormone exposure

8.8 Some authors have hypothesised that because sexual differentiation of the genitals takes place in the first two months of pregnancy but sexual differentiation of the brain only starts in the second half of pregnancy, these two processes can be influenced independently, which may result in gender incongruence (Swaab & Garcia-Falgueras, 2009).

8.9 As discussed previously, most of the evidence about the influence of prenatal hormones comes from the study of people with DSD. That evidence suggests that prenatal hormones have a large effect on gender role behaviours, a moderate effect on sexual orientation and a small effect on gender identity.

8.10 The second potential period when hormones may influence gender expression is puberty. There is evidence that masculinising/feminising hormone treatments alter brain structure (Ristori et al., 2020). The neuropsychological impact of arresting pubertal development with puberty blockers remains poorly understood (Baxendale, 2024).

Figure 26: Concentrations of serum testosterone in males from conception to puberty.



Source: Adapted from Hines, M. (2020b). Neuroscience and sex/gender: Looking back and forward. The Journal of Neuroscience, 40(1), 37-43. https://doi.org/10.1523/jneurosci.0750-19.2019 under: https://creativecommons.org/licenses/by/4.0/

8.11 However, there is still no clear evidence that altered hormonal levels prenatally or during puberty are responsible for the development of gender incongruence, apart from in those with DSD, and this is a difficult area in which to test hypotheses.

Genetics (twin studies)

8.12 As identical twins have identical genes, when a single gene is responsible for a characteristic (for example, blood group), the twins will always have the same outcome (they will both have the same blood group). Non-identical twins are like any other siblings; they only share approximately 50% of their genes, so they may have different blood groups. Twin studies compare how often identical twins are concordant for a condition (that is, both have the same condition), compared to non-identical twins. If a condition is strongly genetically determined, identical twins will have a high level of concordance compared to non-identical twins.

8.13 Twin studies in gender identity are complicated; until recently, most of the large studies just looked at masculinity or femininity and did not include diagnosis of gender incongruence or dysphoria. The few studies that have included diagnosis primarily relied on parental report, did not follow through into adulthood and/or had small sample size. The older studies suggested that identical twins were more likely to manifest the same gender identity than non-identical twins, suggesting some genetic influence (Klink & Den Heijer, 2014).

8.14 In contrast, a more recent paper (Karamanis et al., 2022) looked at a large register-based population in Sweden over the period 2001 to 2016 and found no evidence for genetic influence in individuals who had been formally diagnosed with gender dysphoria and/or had gender-affirming treatment. The most important finding was that non-identical twins of different sex were much more likely than ordinary siblings to be concordant for gender

dysphoria (37% compared to 0.16%). One explanation is that environmental influences during pregnancy are a more likely explanation for the development of gender dysphoria than genetics. This finding therefore gives more credence to the theories about sex hormone exposure in the womb mentioned above, than to genetic factors.

Brain structure

8.15 Researchers have also investigated whether there are differences in brain structure in people with gender incongruence. Studies that look at brain structure, either from post-mortem evidence or neuroimaging, are complex. To date, some evidence has suggested that the brains of transgender females have some commonalities with the brains of birth-registered females in terms of the size of certain structures. However, as there are large overlaps in the characteristics of male and female brains it is not possible to tell if a brain is male or a female (Steensma et al., 2013a).

8.16 Notwithstanding the problems in determining how 'male' or 'female' a brain is outside of extremely large group averages, some studies do suggest that the brains of male-attracted transgender females have changes in a female direction, whilst those who are female-attracted do not. So, if there are differences, they may be related to sexuality rather than gender identity (Steensma et al, 2013a).

8.17 A further issue is that brains are not static. They change and adapt over time in response to various activities like learning a new skill, meditation, exercise or stress. This is known as brain plasticity. Thus, even if it were possible to reliably observe any differences in the brain, these could be a result of rather than a cause of a transgender identity.

8.18 Interpretation of studies on the brain are also problematic for a number of other reasons. For example, most studies:

- have examined brains of transgender females and not of transgender males
- are based on small numbers and have not been reliably replicated
- have examined brain structures after treatment with feminising hormones (rather than before and after treatment), so changes could be caused by treatment rather than any inherent differences.

8.19 More recently there has been a shift from studies that examine whether brains of transgender individuals are more 'male' or 'female' to trying to determine whether there is a unique 'transgender brain' (Mueller, 2021). To examine this, researchers combined the results of previous imaging studies in one 'mega' analysis. The researchers reported that "rather than being merely shifted towards either end of the male-female spectrum, transgender persons seem to present with their own unique brain phenotype". However, this type of analysis commonly generates false-positive findings. Given that this is such a heterogeneous population, this would be equivalent to suggesting that all neurodiverse people had the same unique brain, which does not seem to be a plausible hypothesis.

8.20 As imaging technology continues to advance, brain studies will remain a rich source of further information. However, to date, research in this area has not reliably identified brain changes directly linked to gender incongruence. Even if they could, this might not provide information on causality.

Summary of biological evidence

8.21 While there is no clear evidence for a straightforward biological cause for gender incongruence, it is possible that some individuals have a biological predisposition, which may make them more likely to develop gender incongruence.

8.22 Expressions of being human vary greatly in how much biological versus psychological versus social (environment) causes contribute. As an unrelated but illustrative example to help explain this, people who carry the BRCA gene have a high genetic risk of breast cancer, whereas for those without the BRCA gene and with no family history, factors like smoking, obesity and lack of exercise play a much greater part. In other words, the end result is the same, but the causes are different.

8.23 For children and young people with gender incongruence, 'innate' or biological factors may play a part in some individuals, in ways that are not yet understood, and in others psychosocial factors, including life experiences, societal and cultural influences, may be more important. Since biological factors have not changed in the last 10 years it is necessary to look at other possible reasons for the increase in referrals and the disproportionate representation of birth-registered females.

Psychosocial factors

8.24 Various explanations have been advanced for the increase in predominantly birth-registered females presenting to gender services in early adolescence often with complex presentations, and/or additional mental health problems and/or neurodiversity:

- **Societal acceptance:** The proposition is that greater acceptance of transgender identities has allowed young people to come out more easily and the increased numbers now reflects the true prevalence of gender incongruence within society.
- **Changes in concepts of gender and sexuality**: These might include a change in expressions of sexuality versus gender and a wider spectrum of expression (for example, non-binary and other gender identities that are more common presentations in birth-registered females).
- **Manifestation of broader mental health challenges:** For example, in the same way that distress can manifest through eating disorders or depression, it could also show itself through gender-related distress.
- **Peer and socio-cultural influence:** For example, the influence of media and changing generational perceptions. This is potentially the most contested explanation, with the term 'social contagion' causing particular distress to some in the trans community.
- **Availability of puberty blockers:** The change in the trajectory of the referral curve across many countries coincided with the implementation of the Dutch approach, starting first in the Netherlands and then similarly adopted in other countries.

8.25 Simplistic explanations of either kind ("all trans people are born that way" or "it's all social contagion") do not consider the wide range of factors that can lead young people to present with gender-related distress and undervalues their experiences.

Societal acceptance

8.26 Although it is certainly the case that there is much greater acceptance of trans identities, particularly amongst Generation Z, and this may account for some of the increase in numbers, this is not an adequate explanation for the overall phenomenon. Arguments that counter this explanation include:

- the exponential increase in numbers within a 5-year timeframe is very much faster than would be expected for the normal evolution of acceptance of a minority group;
- the rapid increase in numbers presenting to gender services across Western populations;
- the change in prevalence from birth-registered males to birth-registered females. The current profile of transgender presentations is unlike that in any prior historical period;
- the sharp differences in the numbers identifying as transgender and non-binary and presenting to gender services in Generation Z and younger Millennials compared to those over the age of 25-30. It would be expected that older adults would also show some signal of distress regarding their gender, even if they felt unable to 'come out';
- the failure to explain the increase in complex presentations.

Changes in concepts of gender and sexuality

8.27 The relationship between sexuality and gender identity is complex and contested. A transgender identity does not determine an individual's sexuality. However, in the context of the Review, it is important to consider the relationship between sexual identity and gender identity given that sexuality contributes to a person's sense of identity, and both may be fluid during adolescence.

8.28 In the original Dutch study (de Vries et al., 2011b), 89% of the 70 patients were same-sex attracted to their birth-registered sex, with most of the others being bisexual. Only one patient was heterosexual.

8.29 In contrast, in a detailed study of young people with ASD and gender dysphoria (de Vries et al., 2010), it was noted that ''while almost all adolescents with GID [gender identity dysphoria] are sexually attracted to individuals of their birth sex, the majority of the gender dysphoric adolescents with ASD were sexually attracted to partners of the other sex".

8.30 A paper from the GIDS service in 2016 (Holt et al., 2016) reported sexual orientation in 57% (97) of a clinic sample of patients over 12 years of age for whom this information was available. Of the birth-registered females, 68% were attracted to females, 21% were bisexual, 9% were attracted to males and 2% were asexual. Of the birth-registered males, 42% were attracted to males, 39% were bisexual and 19% were attracted to females.

8.31 The Review has not been able to obtain recent data relating to the sexual orientation of the GIDS patient cohort. When asked, mixed responses were given by GIDS clinicians about the extent to which they explore sexuality with patients seen in the service, and this may reflect differences in practice.

8.32 In terms of narratives and case histories, the Review received several reports from parents of birth-registered females that their child had been through a period of trans identification before recognising that they were cisgender same-sex attracted. Similar narratives were heard from cisgender adults (some same sex-attracted and some heterosexual) regarding early experiences of gender-questioning.

8.33 Clinicians and parents reported that gay students are still being stigmatised and bullied in school and there is sometimes a perception that there is less validation for them than for trans pupils. However, the Review also heard multiple testimonies attesting that having a diverse gender identity is a difficult path with young people subjected to bullying and abuse.

8.34 It is widely accepted that exposure to sexuality is happening at a younger age. The impact of this on young people's understanding of their sexuality and/or gender identity is unclear.

8.35 In some strictly religious cultures, being transgender is seen as preferable to being same-sex attracted as it is then perceived as a physical rather than a psychological issue.

8.36 It is common in adolescence to experience same-sex attraction and not to conform to gender stereotypes. In making sense of these feelings young people are now having to navigate an increasingly complex interplay between sex and gender.

8.37 In reality, for any individual young person, there will be different socio-cultural influences that impact on their understanding of both their gender and sexual identity, and this is an area that warrants better exploration and understanding.

Manifestation of broader mental health challenges

8.38 As described previously, rates of mental ill health in the general population of children and young people, particularly in girls and young women, have increased over the past decade. This parallels the increase in numbers of children and young people seeking support from NHS gender clinics.

8.39 The gender clinic referred population has high rates of mental health diagnoses, neurodiversity and adverse childhood experiences (ACEs). At the same time, young people now seem more likely to mention gender identity when they attend mental health services.

8.40 Early audits and research suggest that ACEs are a predisposing factor. This was demonstrated from the earliest audit of the GIDS service (Di Ceglie et al., 2002) and in the systematic review (Taylor et al: Patient characteristics)

8.41 Some people rebut the notion that trans identity may be secondary to mental health problems, and instead suggest that the mental health problems that are observed are a response to minority stress.

8.42 The association is likely to be complex and bidirectional - that is, in some individuals, preceding mental ill health (such as anxiety, depression, OCD, eating disorders), may result in uncertainty around gender identity and therefore contribute to a presentation of gender-related distress. In such circumstances, treating the mental health disorder and strengthening an individual's sense of self may help to address some issues relating to gender identity. For other individuals, gender-related distress may

be the primary concern and living with this distress may be the cause of subsequent mental ill health. Alternatively, both sets of conditions may be associated with and influenced by other factors, including experiences of neurodiversity and trauma.

8.43 There are well established effective treatments for many common mental health disorders. Individuals presenting with gender dysphoria should be able to access these if required, including those with neurodevelopmental differences who are frequently disadvantaged in being able to access mental health services.

8.44 Diagnosis and treatment of mental ill health in a young person with gender incongruence/dysphoria should not be a barrier to their gender issues being considered and evaluated in parallel.

Peer and socio-cultural influences

8.45 Sources of information for young people are predominantly online and peer-to-peer, and this applies to multiple aspects of their lives.

8.46 The generational changes in understanding and beliefs about the mutability of gender form the basis for many young people's understanding of their own experiences and the experiences of those around them.

8.47 It is the norm that all experiences of health and illness are understood through the norms and beliefs of an individual's trusted social group. Thus, it is more likely that bodily discomfort, mental distress or perceived differences from peers may be interpreted through this cultural lens.

8.48 More specifically, gender-questioning young people and their parents have spoken to the Review about online information that describes normal adolescent discomfort as a possible sign of being trans and that particular influencers have had a substantial impact on their child's beliefs and understanding of their gender.

8.49 The Review's focus groups with gender diverse young people found that "Young people struggle to find trusted sources of information, favouring lived experience social media accounts over mainstream news outlets".

> "I've always found that talking to people who have life experience is the best, either on like forums or like places like Reddit or on social media and other places"
>
> "A lot of trans people make YouTube videos which I think is a [major] informational source for a lot of people, and that's mainly where I get my information from, not so much professional services."
>
> "I have to spend time picking apart information and assessing it. I feel like I always have to be sceptical of the information I read, and really think about why they are writing it."
>
> **Young people**
> **Lived experience focus groups**

Availability of puberty blockers

8.50 The dramatic increase in presentations to NHS gender clinics from 2014, as well as in several other countries, coincided with puberty blockers being made available off protocol and to a wider group of young people. The only country with an earlier acceleration in referrals is the Netherlands, where the Dutch protocol was developed.

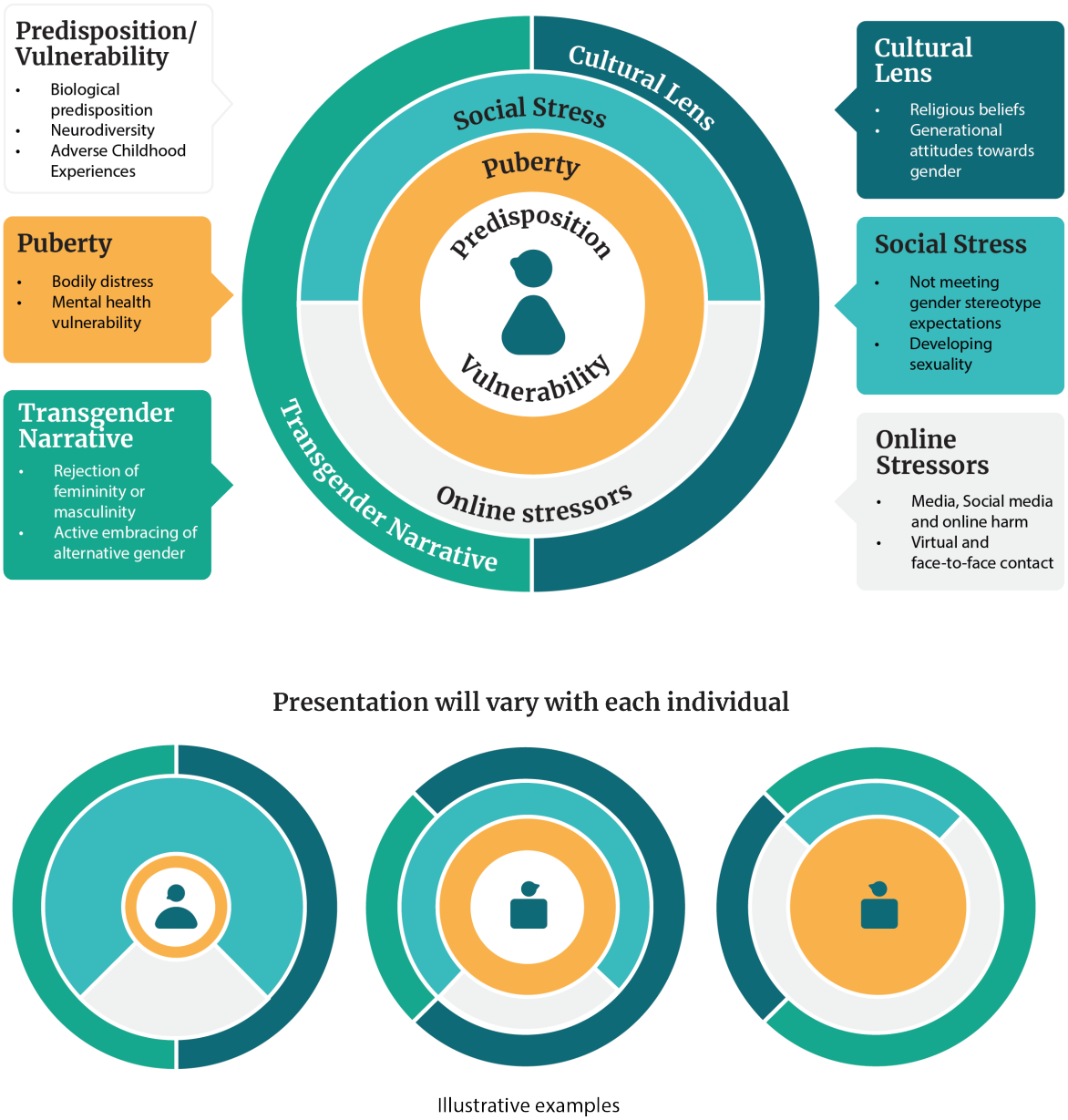
8.51 It is not possible to attribute causality in either direction to this association, but it remains a possibility that a lower threshold for medicalisation has had an influence on the number of young people seeking this intervention.

Conclusion

8.52 There is broad agreement that gender incongruence is a result of a complex interplay between biological, psychological and social factors. This 'biopsychosocial' model for causation is thought to account for many aspects of human expression and experience including intelligence, athletic ability, life expectancy, depression and heart disease.

8.53 Figure 27 demonstrates how in any one individual, gender incongruence and/or dysphoria may be a result of one or two factors, or it may result from a series of factors that underpin a young person's experience and sense of self.

Figure 27: Complex interplay between biological, psychological and social factors



8.54 Although we do not have definitive evidence about biological causes of gender incongruence it may be that some people have a biological predisposition. However, other psychological, personal and social factors will have a bearing on how gender identity evolves and is expressed.

8.55 In later childhood and into early puberty, online experience may have an effect on sense of self and expectations of puberty and of gender. As discussed in relation to adolescent development, this is a time where the drive to fit in with peers is particularly strong. Young people who are already feeling 'different' may have that sense exacerbated if they do not fit in with the demonstrations of masculinity and femininity they are exposed to socially and/or online.

8.56 Peer influence during this stage of life is very powerful. As well as the influence of social media, the Review has heard accounts of female students forming intense friendships with other gender-questioning or transgender students at school, and then identifying as trans themselves.

8.57 It is the norm for people to view their experiences of life events, health and illness through their own cultural lens and personal beliefs. Cultural norms in younger people might impact how they interpret their personal, sexual and gender identity.

8.58 Puberty is an intense period of rapid change and can be a difficult process, where young people are vulnerable to mental health problems, particularly girls. Unwelcome bodily changes and experiences can be uncomfortable for all young people, but this can be particularly distressing for young neurodiverse people who may struggle with the sensory changes.

8.59 The data on young people's mental health, social media use and increased risks associated with online harm give an appreciation and understanding that going through the teenage years is increasingly difficult, with stressors that previous generations did not face. This can be a time when mental distress can present through physical manifestations such as eating disorders or body dysmorphic disorders. It is likely that for some young people this presents as gender-related distress.

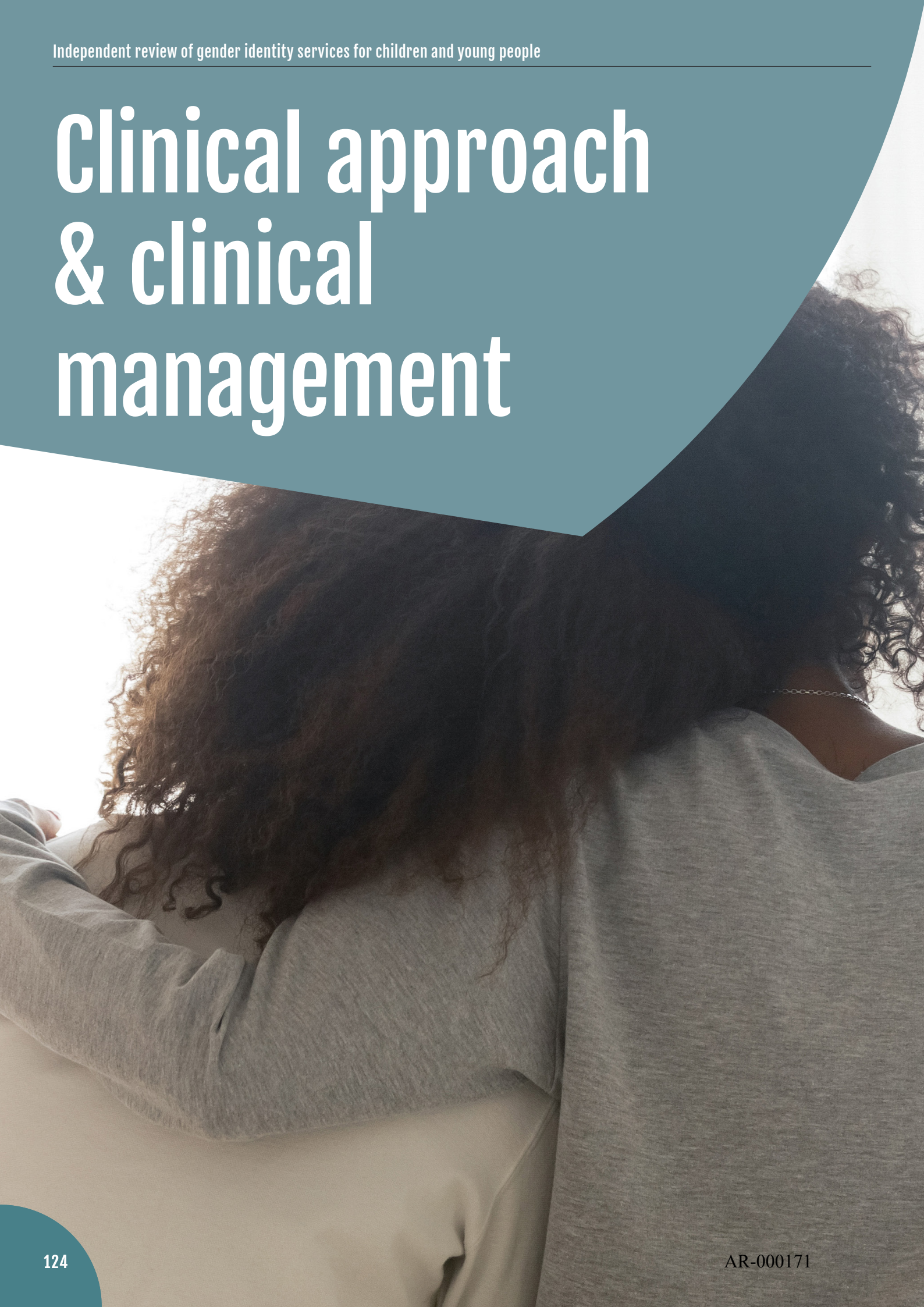
8.60 A study followed 2,772 adolescents from age 11 to 26. Gender non-contentedness (as defined by the question "I wish to be of the opposite sex") was high in early adolescence, reduced into early 20s, and was associated with a poorer self-concept and mental health throughout development. It was also more often associated with same-sex attraction when compared to those who did not have gender non-contentedness (Rawee et al., 2024).

8.61 There is no single explanation for the increase in prevalence of gender incongruence or the change in case-mix of those being referred to gender services. Pragmatically all the above explanations for the observed changes in this heterogeneous population are likely to be true to a greater or lesser extent, but for any individual a different mix of factors will apply.

8.62 Working through this complex multi-layered personal development with the young person is likely to take some time, and the role of the clinical team is to help them address some of these complex issues so that they can better understand their gender identity and evaluate the options available to them.



Clinical approach & clinical management



This section looks at clinical approaches and clinical management. It seeks to address the following areas on which the Review has been asked to provide recommendations:

- clinical management approaches at each point of the specialised pathway of care from assessment to discharge, including a description of objectives, expected benefits and expected outcomes for each clinical intervention in the pathway;
- best clinical approach for individuals with other complex presentations;
- the use of gonadotropin-releasing hormone analogues and gender affirming drugs.

Any treatment recommendations will include a description of treatment objectives, expected benefits and expected outcomes, and potential risks, harms and effects to the individual.

Where relevant, each chapter summarises the Review's commissioned research, other published work and insights from engagement with service users, parents/carers, clinicians and others.

9. International practice and guidelines

9.1 There is understandable public focus on young people who access medical interventions. However, from the outset, the Review has tried to understand what happens for all gender-questioning children and young people seeking NHS support, including those who do not go on to a medical pathway.

9.2 The question is: what is the best way to address, support and manage the whole population of children and young people presenting to services with gender incongruence and/or dysphoria?

9.3 When considering the best clinical approach, the Review first wanted to understand how care is arranged and delivered in other health systems. If good guidance and practice already exists internationally it was important to learn from this and adopt it where appropriate.

9.4 The Review commissioned the University of York to undertake:

- an appraisal and synthesis of available international guidelines (Taylor et al: Guidelines 1: Appraisal; Taylor et al: Guidelines 2: Synthesis)
- an international survey of gender services (Hall et al: Clinic survey)
- a review of published papers on other service models.

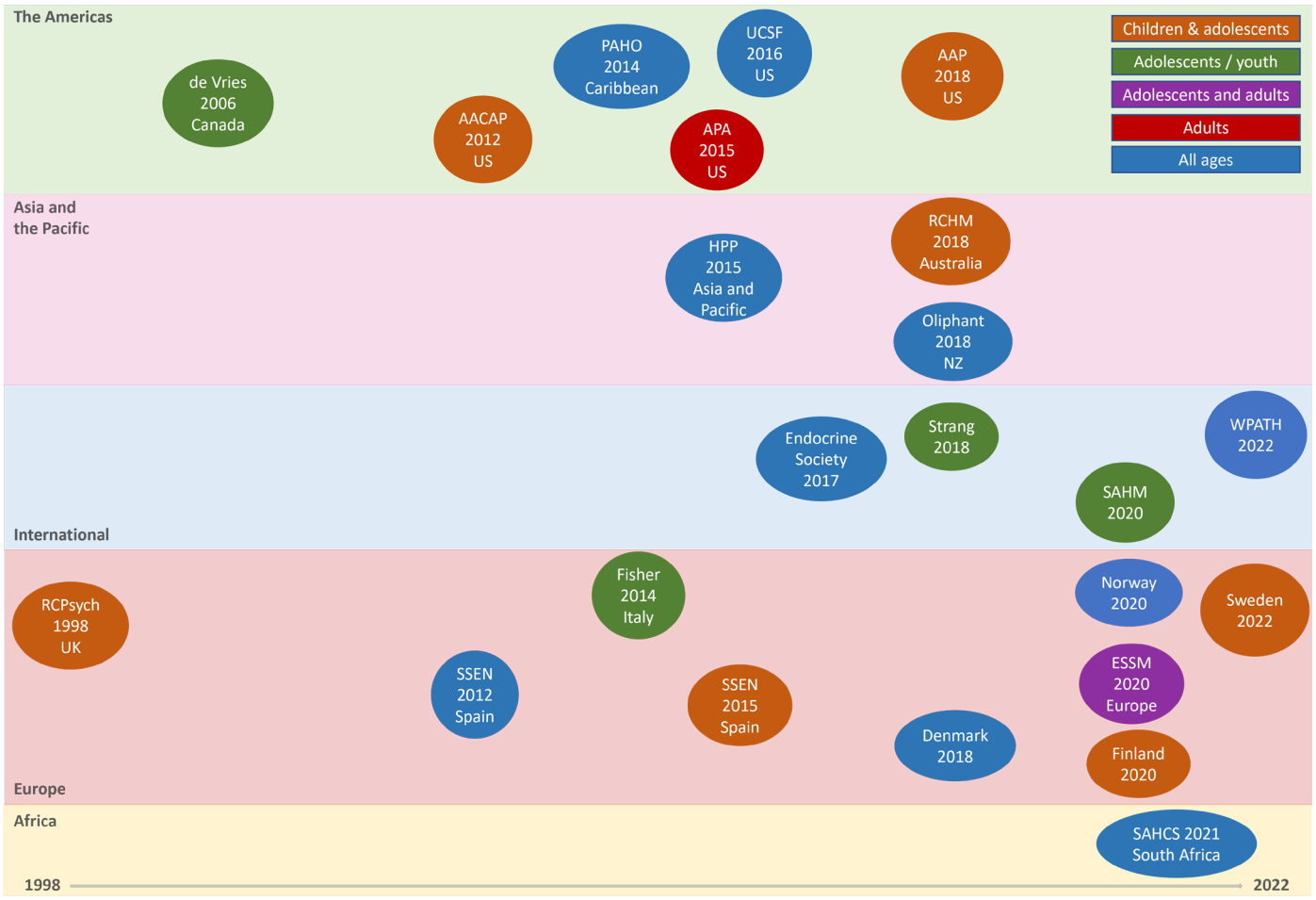
9.5 During the lifetime of the Review, it has become apparent that practice is changing rapidly on the international stage with Nordic countries, and France, as well as some clinics in Australia, taking a more cautious approach to gender-related care for children and young people. The Review's interim report (2022) also advised a more cautious approach for the NHS in England, pending the more comprehensive findings presented in this final report.

Guideline appraisal

9.6 Clinical guidelines are recommendations on how healthcare and other professionals should care for people with specific conditions; for example NICE guidelines in England and SIGN guidelines in Scotland. Recommendations are based on the best available evidence and expert consensus. There are standard methods for analysing the research evidence, with systematic reviews being the highest level of analysis and most trusted way to determine what the available research tells us (see Figure 28).

9.7 A number of guidelines on the care of children and young people with gender incongruence and/or gender dysphoria have been published, some specific to individual countries and some intended for international audiences.

Figure 28: A timeline for the included guidelines by geographical region, country and target population.



Source: Taylor et al: Guidelines 1: Appraisal

NB: AACAP, American Academy of Child and Adolescent Psychiatry; AAP, American Academy of Pediatrics; APA, American Psychological Association; ESSM, European Society for Sexual Medicine; HPP, Health Policy Project; PAHO, Pan American Health Organisation; RCHM, Royal Children's Hospital Melbourne; RCPsych, UK Royal College of Psychiatrists; SAHCS, South African HIV Clinicians Society; SAHM, Society for Adolescent Health and Medicine; SSEN, Spanish Society of Endocrinology and Nutrition; UCSF, University California, San Francisco; WPATH, World Professional Association for Transgender Health.

9.8 The starting point for the Review was to seek an appraisal of these guidelines and determine if some components might be directly transferable to the NHS in England.

9.9 The University of York identified 23 guidelines published between 1998 and 2022 that contained recommendations about children and young people with gender dysphoria (four international, three regional and 16 national).

9.10 The guidelines covered the following key areas of practice:

- care models, principles and practices
- multi-disciplinary team (MDT) composition, roles, competencies, and training
- assessment
- psychosocial care (child and family)
- information, education and advocacy
- social transition
- puberty suppressant hormones
- cross-sex hormones
- surgical interventions
- fertility care
- other interventions (for example, voice therapy, hair removal)
- sexual health and functioning
- physical health and lifestyle.

9.11 The quality of clinical guidelines was assessed using AGREE II (AGREE Next Steps Consortium, 2017), which is the most commonly applied and comprehensively validated appraisal tool. The AGREE II approach considers six domains:

- scope and purpose
- stakeholder involvement
- rigour of development
- clarity of presentation
- applicability
- editorial independence.

9.12 This was followed by an overall assessment of quality and whether a guideline should be recommended for use in practice.

9.13 Rigour of development is an important bedrock of guideline development. It includes systematically searching the evidence, being clear about the link between recommendations and supporting evidence, and ensuring that health benefits, side effects and risks have been considered in formulating the recommendations.

9.14 A 2018 study (Hoffmann-Eßer et al., 2018) looked at which of the AGREE II domains were most influential in the overall assessment scores. The authors found that experienced reviewers were most strongly influenced by rigour of development and editorial independence. This is not a surprising finding. A guideline may be clear in scope, purpose and presentation, and have good stakeholder engagement, but would be hard to recommend for use in practice if there were weaknesses in the development process.

9.15 Of the 23 guidelines identified, four did not provide any information about the development process, so could not be appraised. The remaining guidelines were appraised independently by three reviewers.

Table 6: Critical appraisal domain scores

Guideline ID	Scope and Purpose	Stakeholder involvement	Rigour of development	Clarity of presentation	Applicability	Editorial Independence
AACAP 2012	65	39	44	63	7	31
American Academy of Paediatrics 2018	70	26	12	30	6	69
American Psychological Association 2015	74	74	24	50	18	14
Council for Choices in Healthcare Finland 2020	91	69	51	72	56	0
de Vries 2006	63	31	10	74	17	6
Endocrine Society 2009	65	33	44	70	22	31
Endocrine Society 2017	63	33	42	72	21	92
European Society for Sexual Medicine 2020	63	52	39	70	7	58
Fisher 2014	65	20	12	35	17	44
Health Policy Project 2015	63	63	16	24	33	6
Norwegian Directorate of Health 2020	76	81	30	57	47	17
Oliphant 2018	44	39	12	33	21	0
Pan American Health Organisation 2014	52	44	13	31	21	0
Royal Children's Hospital Melbourne 2018	81	59	19	41	19	14
Society for Adolescent Health and Medicine 2020	41	24	17	41	7	0
South African HIV Clinicians Society 2021	59	59	21	43	24	69
Strang 2018	87	31	18	37	15	19
Swedish National Board of Health & Welfare 2022	91	87	71	83	25	36
UCSF 2016	70	41	23	37	26	0
WPATH 2012	85	61	26	56	17	17
WPATH 2022	83	63	35	56	24	39

≥70%, 31%-69%, ≤30%.
AACAP, American Academy of Child &Adolescent Psychiatry; UCSF, University of California, San Francisco; WPATH, World Professional Association for Transgender Health

Source: Taylor et al: Guidelines 1: Appraisal

9.16 Most guidelines scored well on the scope and purpose domain, but poorly on the rigour of development, applicability and editorial independence domains. Only the Finnish guideline (Council for Choices in Healthcare in Finland, 2020) and Swedish guideline (Swedish National Board of Health and Welfare, 2022) scored above 50% for rigour of development.

9.17 Most of the guidelines were developed by a core group of experts in broader consultation with other professional stakeholders, although there was lack of clarity about how this input was incorporated. Just over half engaged with service users, and again it was unclear how this influenced recommendations.

9.18 Only five guidelines described using a systematic approach to searching for and/or selecting evidence (AACAP 2012, Endocrine Society 2017, Finland 2020, Sweden 2022 and WPATH 2022).

9.19 For many of the guidelines it was difficult to detect what evidence had been reviewed and how this informed development of the recommendations. For example, most of the guidelines described insufficient evidence about the risks and benefits of medical treatment in adolescents, particularly in relation to long-term outcomes. Despite this, many then went on to cite this same evidence to recommend medical treatments.

9.20 Alternatively, they referred to other guidelines that recommend medical treatments as their basis for making the same recommendations. Early versions of two international guidelines, the Endocrine Society 2009 and World Professional Association for Transgender Healthcare (WPATH) 7 guidelines influenced nearly all the other guidelines.

9.21 These two guidelines are also closely interlinked, with WPATH adopting Endocrine Society recommendations, and acting as a co-sponsor and providing input to drafts of the Endocrine Society guideline. WPATH 8 cited many of the other national and regional guidelines to support some of its recommendations, despite these guidelines having been considerably influenced by WPATH 7. The links between the various guidelines are demonstrated in the graphics in the guideline appraisal paper (Taylor et al: Guidelines 1: Appraisal).

9.22 The circularity of this approach may explain why there has been an apparent consensus on key areas of practice despite the evidence being poor.

9.23 Only the Swedish and Finnish guidelines differed by linking the lack of robust evidence about medical treatments to a recommendation that treatments should be provided under a research framework or within a research clinic. They are also the only guidelines that have been informed by an ethical review conducted as part of the guideline development. However, these guidelines like others lack clear recommendations regarding certain aspects of practice and would benefit from more detailed guidance regarding implementation of recommendations.

9.24 The guideline appraisal raises serious questions about the reliability of current guidelines. Most guidelines have not followed the international standards for guideline development (AGREE Next Steps Consortium, 2017). Therefore, only the Finnish (2020) and the Swedish (2022) guidelines could be recommended for use in practice.

9.25 Because of the very widespread influence and adoption of the WPATH guidance and the very different approach in the Swedish and Finnish guidelines, some further detail on the link between evidence and recommendations in these guidelines is discussed below.

World Professional Association for Transgender Healthcare (WPATH) 8 guideline (2022)

9.26 The WPATH 8 commentary on adolescence gives a clear account of how dynamic this period of life is in terms of cognitive, emotional, gender and personal development, and how individualised that can be. The guideline also sets out some of the knowns and unknowns about the possible biological contributions to gender incongruence, as well as recent changes in how gender diverse young people present to healthcare services, and the uncertainty regarding how stable or fluid their gender identity may be.

9.27 WPATH commissioned a systematic review to underpin version 8, an approach it had not undertaken for WPATH 7. This systematic review (Baker et al., 2021) found that "hormone therapy was associated with increased quality of life, decreased depression, and decreased anxiety". However, "certainty in this conclusion is limited by high risk of bias in study designs, small sample sizes, and confounding with other interventions". The recommendation was that "future studies should investigate the psychological benefits of hormone therapy among larger and more diverse groups of transgender people using study designs that more effectively isolate the effects of hormone treatment".

9.28 The WPATH 8 narrative on gender-affirming medical treatment for adolescents does not reference its own systematic review, but instead states: "Despite the slowly growing body of evidence supporting the effectiveness of early medical intervention, the number of studies is still low, and there are few outcome studies that follow youth into adulthood. Therefore, a systematic review regarding outcomes of treatment in adolescents is not possible. A short narrative review is provided instead".

9.29 Within the narrative account the guideline authors cite some of the studies that were already deemed as low quality, with short follow-up periods and variable outcomes, as well as a selected account of detransition rates.

9.30 WPATH 8 concludes in its statement on the use of gender-affirming medical treatment that: "The evolving evidence has shown a clinical benefit for transgender youth who receive their gender-affirming treatments in multidisciplinary gender clinics (de Vries et al., 2014; Kuper et al., 2020; Tollit et al., 2019)".

- De Vries et al. (2014) is the original study of the Dutch protocol sample, which has marked differences to the population being treated currently, and as discussed had much stricter criteria for treatment.
- Kuper et al. (2020) is a study with a one year follow-up that showed very modest change. It fell into the group rated by the University of York research team as too low quality to be included in their synthesis of evidence on masculinising/feminising hormones (Taylor et al: M/F hormones).
- Tollit et al. (2019) is a study protocol and does not include any results.

9.31 The systematic review commissioned by WPATH is referenced in the chapter on WPATH 8 standards as one of several references in support of the statements that "There is strong evidence demonstrating the benefits in quality of life and well-being of gender-affirming treatments, including endocrine and surgical procedures, properly indicated and performed as outlined by the Standards of Care (Version 8), in transgender people in need of these treatments" and "Gender-affirming interventions are based on decades of clinical experience and research; therefore, they are not considered experimental, cosmetic, or for the mere convenience of a patient. They are safe and effective at reducing gender incongruence and gender dysphoria".

9.32 Clinical consensus is a valid approach to guideline recommendations where the research evidence is inadequate. However, instead of stating that some of its recommendations are based on clinical consensus, WPATH 8 overstates the strength of the evidence in making these recommendations.

Swedish (2022) and Finnish (2020) guidelines

9.33 The Swedish guideline took a different stance to WPATH 8 based on three considerations:

- The change in epidemiology and lack of understanding of the cause of the more recent presentations to gender services.
- The lack of clear data on how frequently detransition or regret occurs in young adults.
- A re-evaluation of the evidence base through its own systematic review, which demonstrated uncertainty about the strength of evidence in favour of gender-affirming care. It was also noted that previous guidelines relied much more heavily on expert opinion rather than on systematic reviews of the evidence.

9.34 Based on the above considerations, the Swedish guideline recommended that medical treatment should follow the original Dutch criteria and should only be given under a research protocol, or in exceptional circumstances.

9.35 The Finnish guideline had reached similar conclusions on the uncertainty of the evidence and proposed extreme caution in relation to the use of puberty blockers in young people under the age of 18, also reverting largely to the original Dutch entry criteria. The guideline recommended that puberty blockers should be administered under the supervision of the national specialist clinic.

Key points of learning for the NHS

9.36 The University of York has produced a narrative synthesis of the guidelines (Taylor et al: Guidelines 2: Synthesis). Relevant information from this synthesis can be found in later chapters in this report.

9.37 It was clear from the guideline quality appraisal process that no single guideline could be applied in its entirety to the NHS in England, although some had useful and transferrable recommendations that have been incorporated where consistent with the rest of the Review's findings.

9.38 The Review has based its recommendation on its commissioned systematic reviews, advice from clinical experts across a range of relevant areas in the care of children and young people with gender dysphoria and in other relevant and important areas of child and adolescent health, as well as on the mixed methods approach to stakeholder engagement described earlier.

9.39 When the new clinical services are well-established and there is further available evidence, it may be possible to employ more formal guideline development approaches to those aspects of gender-related care that still remain contested.



10. Assessment and diagnosis

10.1 As set out in Part 3 of this report, the individual presentations of many of the children and young people seeking support are diverse and complex.

10.2 The heterogeneity of the patient cohort makes assessment and diagnosis challenging, and many clinicians, both nationally and internationally, have told us that there is no reliable way to accurately predict which young people might benefit from a medical transition and which might benefit from alternative pathway(s) or interventions(s).

International practice

10.3 The York synthesis of international guidelines (Taylor et al: Guidelines 2: Synthesis) found that all guidelines recommend multi-disciplinary assessment of the child/young person, usually over multiple sessions.

10.4 There is limited clarity about the purpose of assessment. Some guidelines were focused on diagnosis, some on diagnosis and eligibility for hormones, some on psychosocial assessment, and some on readiness for medical interventions.

10.5 Only the Swedish and WPATH 8 guidelines contain detail on the assessment process. Both recommend that the duration, structure and content of the assessment be varied according to age, complexity and gender development.

10.6 Within the international guidelines there is also marked variability in whether both children and adolescents should be assessed and if so, how these assessments might differ.

10.7 All guidelines recommend that discussion of gender development and identity forms part of assessment, but few provide detail. Several recommend assessing duration, severity and persistence of gender dysphoria, and exploring different aspects including incongruence, distress, identity, expression, plans and future desires.

10.8 Very few guidelines recommend formal measures/clinical tools to assess gender dysphoria, and a separate analysis demonstrated that the formal measures that exist are poorly validated.

10.9 Five guidelines recommend assessing for neurodevelopmental conditions.

10.10 The range of recommendations in the guidelines regarding domains that should be assessed are shown in Table 7.

Table 7: Recommended assessment domains

Guideline ID	Gender	Body image	Mental health difficulties	Neuro-diversity or ASC	Sexuality or sexual orientation	Sexual functioning or health	Psychosocial functioning	Cognitive functioning / intelligence	Family functioning or support	Physical health or conditions
American Academy of Child & Adolescent Psychiatry	Yes	No	Yes	No	Yes	Yes	Yes	No	Yes	No
American Psychological Association	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Danish Health Authority	Yes	No	Yes	No	Yes	No	Yes	No	Yes	Yes
de Vries *et al*	Yes	Yes	Yes	No	Yes*	Yes*	Yes	No	Yes	No
Endocrine Society	Yes	No	Yes	No	Yes†	No	Yes	No	Yes	No
European Society for Sexual Medicine	Yes	No	Yes	No	No	No	Yes	No	Yes	No
Health Policy Project	Yes	No	Yes	No	Yes*	Yes*	Yes	No	Yes	Yes
Norwegian Directorate of Health	Yes	No	Yes	No	Yes	No	Yes	No	Yes	Yes
Oliphant *et al*	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	No
Pan American Health Organisation	Yes	No	Yes	No	No	No	No	No	No	Yes
Royal Children's Hospital Melbourne	Yes	No	Yes	No	No	No	Yes	Yes	Yes	No
Royal College of Psychiatrists	Yes	No	Yes	No	No	No	Yes	No	Yes	No
SIAMS-SIE-SIEDP-ONIG	Yes	No	Yes	No	Yes	No	Yes	Yes	Yes	No
South African HIV Clinicians Society	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No
Swedish National Board of Health and Welfare	Yes	No‡	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
World Professional Association for Transgender Health	Yes	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes

*HEEADSSS suggested as tool which includes sexuality. †Assessment of psychosexual development. ‡Body image scale identified as useful tool.
ASC, autism spectrum condition; HEEADSSS, psychosocial assessment tool covering Home & Environment, Education & Education, Eating & Exercise, Activities, Drugs/Substances, Sexuality, Suicide/depression, Safety .

Source: Taylor et al: Guidelines 2: Synthesis

10.11 The University of York's international survey (Hall et al: Clinic survey) provides insight into how clinical practice compares to guideline recommendations and found marked variability:

- Duration and number of assessment appointments that a young person would receive varied within and between clinics and were often said to be tailored to individual need. Only Spain had a single assessment appointment with psychology involvement optional.
- Most clinics assess mental health and gender development, and usually psychosocial functioning. Only five clinics reported routine discussion of fertility preferences, and only two discussed sexuality. Finland was the only country to report routinely assessing for history of trauma.
- Fourteen tools were used across 10 clinics to measure gender incongruence. Only five were used in more than one clinic. There were 36 measures used to assess co-occurring conditions, with only 10 used by more than one clinic.

NHS practice

10.12 In a survey of the Gender Identity Development Service (GIDS) clinicians conducted by the Review in its early stages, the range of opinion on the purpose of assessment was apparent. The survey found that "There is not a clear view amongst the specialists who responded to the survey as to the purpose of the assessment. Some respondents felt that assessment should be focused on whether medical interventions are an appropriate course of action for the individual. Other respondents believe that assessment should seek to make a differential diagnosis, ruling out other potential causes of the child or young person's distress." **(PowerPoint Presentation: cass.independent-review.uk)**

10.13 The majority (79%) of respondents to the gender specialists survey agreed or strongly agreed that psychological formulation can be helpful in assessing children and young people needing support around their gender identity. Those respondents who agreed reasoned that it can provide a structured process for understanding the child/young person's distress and provide a more holistic picture of them which can be helpful in developing an appropriate care plan.

10.14 The University of York also invited GIDS to participate in the international survey (Hall et al: Clinic Survey) to record practice in England, but GIDS did not respond.

10.15 In the absence of a formal clinical audit from GIDS or a response to the international survey, the Multi-Professional Review Group's (MPRG's) updated report (Appendix 9) represents the most comprehensive review of clinical notes and approach available, albeit only for those children and young people referred for puberty blockers.

10.16 The MPRG's reflections should be considered with General Medical Council guidance in mind: "Medical notes should provide an accurate record of the exchange of information leading to a decision in order to inform [the patient's] future care and to help explain and justify the clinician's decisions and actions" (General Medical Council, 2020).

In summary, the MPRG's findings are as follows:

- The structure of the assessment process was rarely provided.
- It was not clearly evidenced how thoroughly 'gender identity and consideration of different options for gender expression' and 'different treatment options/choices' [as per the Standard Operating Procedure] were explored.
- There was inconsistent evidence as to whether the individual impact of social transition had been explored.
- The clinical notes rarely provided a structured history or physical assessment even though the children and young people presenting had a wide range of familial and congenital conditions.
- Sexuality was not consistently discussed.
- The history of the child/young person's gender journey was rarely examined closely for signs of difficulty, regret or wishes to alter any aspect of their gender trajectory.
- Autism spectrum disorder (ASD) or attention deficit hyperactivity disorder (ADHD) traits or diagnoses were mentioned in the majority of cases, but it is not clear how fully or appropriately these had been explored.
- No family trees were made available, making it difficult to understand family structure and relationships.
- There was a lack of evidence of professional curiosity as to how the child/young person's specific social circumstances may impact on their gender dysphoria journey and decisions.
- Although external reports (for example, from the child/young person's school) were useful, they were frequently not up-to-date.

Perspectives from service users and families

10.17 There was also a general lack of understanding among service users participating in the lived experience focus groups about what the assessment was for and confusion about what was assessment and what was diagnosis. Thoughts on the purpose of assessment included:

- To support young people to explore their options and access the care that's right for them.
- To get validation of their trans identity and access to the medication pathway.
- To make the person comfortable and focus on what they're looking for from the service.
- To ensure patients have an understanding of the healthcare options available.

10.18 Young people describe a mismatch between what they want and expect from the process and their experience or perception of what actually happens. While the public narrative has often asserted that decisions about interventions were taken with insufficient exploration, the experiences or perceptions of some of the young people who were seen by GIDS, and some of their parents was that the process of assessment was too onerous and invasive.

10.19 Qualitative research, undertaken by the University of York (Appendix 3), found that service user experiences and perceptions of the assessment process vary. "Some young people looked forward to talking with someone who understood them. Some, however, felt uncomfortable and initially found it difficult to talk about how they felt. Others expressed frustration, disappointment and at times, anger. They believed talking slowed down or prevented access to medical pathways."

"What is needed is a space whereby people's understandings of themselves are valued, whilst also providing an open space for exploration of what this means to the individual, and what support they need in order to live a happy and fulfilled life."

GIDS clinician
Specialist questionnaire

"Everyone's needs are different and I think having an open space where it's patient focused and patient-led is essential."

Young person
Focus group

10.20 There was consensus among service users, parents/carers and clinicians around the need for a holistic approach to care, where children and young people and their families feel listened to and able to explore what they may need to feel happy, confident and able to thrive.

Holistic assessment framework

10.21 Based on the uncertainties, differing recommendations and lack of clear detail found in international guidelines and practice, the Review's Clinical Expert Group (CEG) concluded that there was no approach to assessment that could be directly adopted for use in the NHS.

Development process

10.22 It was agreed that the CEG should work with the Review to develop a consistent, reproducible, developmentally informed, holistic assessment framework to:

- support identification of individual needs
- allow outcomes to be measured more consistently and
- ensure children and young people have a similar experience of the service.

10.23 Clinical experts in a range of related areas of child and adolescent development, health, and wellbeing contributed to the development of the framework and the views of stakeholders have been considered and incorporated where appropriate.

10.24 The CEG agreed the following statement of the key aims and principles for assessment:

"The purpose of assessment is to derive a multi-level formulation for a child or young person who presents to the NHS seeking help around their gender or experience of gender-related distress.

Assessment should seek to understand the holistic needs of the child or young person and their family. This process should determine whether there are any cooccurring and/ or contributory elements of the individual's presentation that are affecting their psychosocial wellbeing or functioning and require support as the basis of an individual care plan.

Presentations, pathways and outcomes for this cohort are very individual, and there needs to be a focus on helping each person to find the best pathway for them. Assessments should be respectful of their experience and be developmentally informed.

Not all children and young people will need an in-depth assessment and will get what they need from other forms of local support, informed by consultation and advice from specialist practitioners.

Clinicians along the pathway should remain open and explore the patient's experience and the range of support and treatment options that may best address their identified needs. Taking a collaborative needs-based approach supports the development of the child or young person's broader wellbeing and functioning with the aim of reducing distress, improving their psychological functioning, sense of wellbeing and quality of life."

The framework provides a starting point for services to assess immediate risk and determine the complex care needs of the children and young people referred to the service.

Structure and content

10.25 The holistic assessment framework has been split into eight non-sequential domains centred around the individual child/young person and their parents/carers. Weight given to each component is dependent on individual needs. These domains are consistent with assessment models used in the care of children, young people and families in other child, adolescent clinical care, and consider the individual as a whole.

10.26 Domains that connect more specifically to understanding gender development, gender incongruence and gender-related distress and dysphoria have also been incorporated drawing upon relevant literature.

10.27 When undertaking an assessment, clinicians should remain open-minded, have no preconceived outcome and should have an appreciation that the child/young person's priorities may change over time. They should also be aware of parent/carer expectations and the impact these may have on the young person's priorities, or alternatively the potential for significant disagreement/fragmentation within families about the nature of the child/young person's distress.

Figure 29: Holistic needs assessment - essential components



Family context

10.28 Understanding children in the context of their families and home environments, including family makeup, key relationships, strengths, resources and social circumstances, as well as parental/carer health and well-being, is a core principle of good practice across health and social care settings.

10.29 It is particularly important in this group of young people given that there is evidence of an increased frequency of family parental physical and/or mental ill health and other family stressors in this group (Di Ceglie et al., 2002; Taylor et al: Patient characteristics).

Development

10.30 A detailed developmental history seeks to gather information from parents/carers about the young person's development, including physical, language, cognitive and social development.

10.31 Environmental, social and psychological factors unique to every child and family can affect development. During the transition from childhood to adolescence young people can experience substantial social, emotional and physical changes. This domain requires additional areas of focus where a neurodevelopmental condition is either confirmed or suspected.

10.32 Given the high prevalence of neurodiversity identified within this population, all those attending children and young people's NHS gender services should receive screening for neurodevelopmental conditions (Strang et al., 2018). Where appropriate, consideration should be given to cognitive and language assessments.

Physical health needs

10.33 An understanding of the child or young person's physical health history and the impact of any health issues on development and wellbeing is important.

10.34 Long-term health conditions can influence various aspects of children's development and may include elevated anxiety around health and wellbeing for both children and their parents.

10.35 The child/young person may have needed to make complex adjustments both socially and emotionally. They could also have experienced trauma in relation to medical experiences or hospitalisations.

Mental health

10.36 Children and young people referred to specialist gender services have higher rates of mental health difficulties than the general population. Because gender incongruence is not considered to be a mental health condition clinicians are often reluctant to explore or address co-occurring mental health issues in children and young people presenting with gender distress. Regardless of any other causes for mental health conditions, living with gender issues and the process of transitioning (if this is felt to be the appropriate path for an individual) comes with challenges.

10.37 The mental health assessment within a gender clinic should follow the structure of a standard evidence-based core CAMHS assessment. There are many published examples of suggested structures for this assessment, which may involve the use of validated questionnaires for children and young people and their carers to inform further assessment.

10.38 In a standard mental health assessment, all of the other seven domains described as part of this holistic assessment framework are usually considered in depth in relation to mental health. Systematic questioning should include enquiry about mood, anxiety, emotional regulation, beliefs around weight, potential somatic symptoms, concentration, sleep and appetite, self-harm, and suicidal thoughts and behaviours. A mental state examination should be included as appropriate.

10.39 A mental health diagnostic formulation incorporates diagnosis, level of impairment, risk assessment, and consideration of predisposing, precipitating and perpetuating/maintaining factors and how they impact on current functioning.

10.40 Identifying and treating mental health difficulties should be an integrated part of the care for children and young people presenting with gender dysphoria. Evidence-based treatments to support mental health and resilience, should be available to children and young people presenting with gender issues as they would be to any other young people presenting to NHS services.

Education, peer relationships and social context

10.41 Consideration of the child/young person's functioning in relation to education, their broader well-being and the nature of their peer relationships is important in assessing their overall functioning and supports a holistic understanding of their strengths and vulnerabilities.

10.42 It is important to obtain information about school attendance and any difficulties in educational achievement, as well as a recent Education, Health and Care plan for any young person with special educational needs.

Safeguarding

10.43 As with all health care provision, when working with children and young people safeguarding must be a consideration. There are complex ways in which safeguarding issues may be present. Clinicians working with children and young people experiencing gender dysphoria have highlighted that safeguarding issues can be overshadowed or confused when there is focus on gender or in situations where there are high levels of gender-related distress.

10.44 Sources of risk in this group include:

- transphobic bullying in school and in other settings
- breakdown in relationships with families
- online grooming or harm
- cultural or religious pressure.

10.45 The Review has heard about a small number of cases where the child's gender identity was consciously or unconsciously influenced by the parent. It is very important that the child/young person's voice is heard and that perceptions of gender identity represent the child/young person's sense of self.

10.46 The Review has also heard a series of accounts of children and young people at safeguarding risk being lost to follow-up and/or of young people presenting to the emergency department with a safeguarding history that staff were unaware of because of changes of name and NHS number.

10.47 Staff should remain alert to these complexities and know when to act, raising them during supervision and with the wider Multi-Disciplinary Team (MDT), and adhering to recognised principles of safeguarding and risk management as applied to children/young people and their parents/carers.

10.48 Clinicians should assess and consider safeguarding across each domain of the assessment framework, documenting issues fully within this dedicated domain.

Gender development and experiences

10.49 Clinicians should undertake an in-depth assessment of the child/young person's gender development over time, how this manifested and how it has been managed within the family.

10.50 Clinicians should seek to understand whether any steps have been taken towards social transition and any impacts on well-being, or whether the child/young person wants to make changes.

10.51 An assessment of the presence and impact of any distress should be undertaken, including the impact and experience of puberty and pubertal changes. The clinician should examine the impact of any distress on, for example, daily functioning, social or relationship issues, any sensory issues that may be contributing to the distress and steps that may have been taken to manage this.

10.52 The child/young person's expectations and hopes about support pathways, their understanding of the range of pathways and outcomes, and the pros and cons of interventions at different points in time should also be considered, including potential fertility and broader health impacts.

10.53 Depending on the age and stage of development of each individual child/young person, this may need to be discussed with the child/young person and parent/carer, both together and apart to generate a thorough record of what has been observed, by whom and when, to gain a sense of their individual gender feelings and history. It is also important to understand whether there are any differences in perception between the child/young person and their parents/carers and whether this has been the cause of conflict or family breakdown.

Sexual development, knowledge and sexual orientation

10.54 Clinicians should seek to understand the child/young person's emerging sexuality and sexual orientation, consistent with assessments in other adolescent settings, where deemed appropriate to age and context.

10.55 If this has been an area of concern for younger children, the clinician could capture this elsewhere, for example when looking at safeguarding, developmental history and exposure to adversity and trauma.

Formulation, diagnosis and care plan

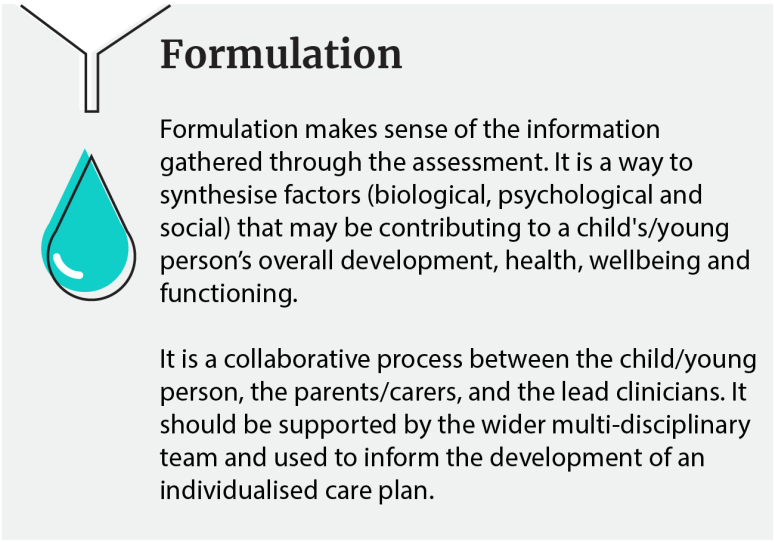
10.56 The assessment is a first step in forming a relationship with a child/young person and their family/carers and developing an understanding of the child/young person as an individual in the context of their aspirations and needs. The assessment should lead to three further steps:

- A formulation of all the factors that are important to the child/young person's presentation
- A list of any relevant diagnoses
- An individualised care plan.

Formulation

10.57 The clinician working with the child/young person should use the information gathered to develop an evidenced formulation. This should be created and agreed with the child/young person and their parents/carers.

Figure 30: Formulation



10.58 Formulation is used to make sense of and pull together information gathered through an assessment to create a shared understanding of the child/young person's strengths and assets, as well as difficulties and needs, to inform the development of an individualised holistic care plan. It is a widely practised approach by a range of professionals and across health services and is endorsed by professional and other organisations (Havighurst & Downey, 2009; Skills for Health, 2016).

10.59 The formulation approach offers a structure for synthesising the information gathered during the assessment and for negotiating differences of opinion. It can be carried out at various levels of detail and complexity and can be helpful in identifying other factors that may be influencing gender-related distress and where there is agreement about areas to work on, even if differences of opinion remain. Importantly, it allows all parties to hold an open and mutually respectful position about a child/young person's gender identity whilst defining a personalised intervention package.

Diagnosis and differential diagnosis

10.60 The clinician's role in a consultation is to integrate information from a patient's history, assessment and any investigations or tests, in order to determine the most likely cause of their symptoms, and how best to address them.

10.61 In addition to the process of formulation described above, this often involves arriving at a formal diagnosis. The diagnostic process is a complex, collaborative activity that involves clinical reasoning and information gathering to understand the patient's problem (Balogh et al., 2015).

10.62 Differential diagnosis is the process of ruling out other possible diagnoses that present in a similar way.

10.63 Differential diagnosis is seen by some as an attempt to find 'any other reason' for the person's distress rather than them being transgender and they feel strongly that clinicians should not be actively looking for reasons to "excuse away" how the young person feels.

10.64 There are several reasons why listing all relevant formal diagnoses is important for this group of children and young people:

- In order to provide the best evidence-based care, it is important that the clinician considers all possible diagnoses which may be hindering the young person's wellbeing and ability to function and thrive.
- The clinician carries responsibility for the assessment, subsequent treatment recommendations, and for any harm that might be caused to a patient under their care. They need to define, as clearly and reproducibly as they possibly can, exactly what condition they are treating, in order to be accountable for their decisions on the options offered to the patient. In the case of offering potentially irreversible medical treatments to patients, it is important to specify whether they meet formal diagnostic criteria for gender dysphoria or any other conditions.
- The University of York's systematic review (Taylor et al: Patient characteristics) demonstrated that other diagnoses were not consistently documented, and in order to better understand and support these children and young people it is essential that all diagnoses are systematically recorded for clinical and research purposes.

10.65 There are two widely used frameworks which provide diagnostic criteria. The International Classification of Diseases (ICD), which is the World Health Organization (WHO) mandated health data standard, and the Diagnostic and Statistical Manual of Mental Disorders (DSM), which is the classification system for mental health disorders produced by the American Psychiatric Association. The current versions - ICD-11 and DSM-5-TR - came into effect in January 2022 and March 2022 respectively.

10.66 ICD-11 (WHO, 2022) has attempted to de-pathologise gender diversity, removing the term 'gender identity disorders' from its mental health section and creating a new section for gender incongruence and transgender identities in a chapter on sexual health. ICD-11 defines gender incongruence as being "characterised by a marked incongruence between an individual's experienced/expressed gender and the assigned sex." It refers to a mismatch between birth registered and experienced gender but does not include dysphoria (distress) as part of its diagnostic requirements. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis. The full criteria for gender incongruence of childhood and gender incongruence of adolescence or adulthood are listed in Appendix 10.

10.67 DSM-5 (American Psychiatric Association, 2013), revised in 2022 (DSM-5-TR) (American Psychiatric Association, 2022) is the most widely used framework for diagnosing gender dysphoria (Appendix 10). In addition to describing the incongruence between experienced/expressed gender and assigned gender, DSM-5-TR specifies that "In order to meet criteria for the diagnosis, the condition must also be associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning."

10.68 The University of York (Taylor: Guidelines 2: Synthesis) found no clear consensus across international guidelines reviewed as to whether DSM-5 diagnosis of gender dysphoria or ICD 11 diagnosis of gender incongruence is preferred. However, the international survey (Hall et al: Clinic Survey) demonstrated that in clinical practice the DSM-5 diagnosis of gender dysphoria is more widely used, this also applies to research publications.

10.69 The Review has heard mixed views about how young people perceive the value of a diagnosis of gender dysphoria. Many young people do not see themselves as having a medical condition and some may feel it undermines their autonomy and right to self-determination. Others see diagnosis as validating, and important when looking to access hormone treatment.

> "It is a good thing because then solutions can be made. However, the way that it is diagnosed is important so that dysphoria is not increased. It is important to be able to make sure people are safe and mentally well."
>
> "I don't care personally, but it is important to me that medical professionals understand that I require gender-related medical care, and that diagnosis can function for that. I would prefer that diagnosis is not a prerequisite for care."
>
> "Having a diagnosis doesn't make you "any more trans" than someone who doesn't."
>
> **Young people**
> **Lived experience focus groups**

10.70 The qualitative research conducted by the University of York (Appendix 3) found that:

"For many young people - and young adults - dysphoria is a useful medical label, helping to legitimise and explain experience. It also helped justify asking for support […] Overtime, however, some expressed ambivalence. They continued to understand the value of dysphoria, but thought it could also represent an unhelpful diagnosis, in which their social experience could only be regarded as legitimate if a medical label were attached."

10.71 The qualitative study goes on to say "Clinicians understand the importance of diagnosis, particularly when justifying decision making, but remained sensitive to over-medicalisation, especially when a person's dysphoria was socially located."

10.72 Previously, a diagnosis of gender dysphoria has been the basis for initiating medical treatment, however, this is not predictive that the individual will go on to have longstanding trans identity.

10.73 Understanding how the gender-related distress has evolved in that particular individual, what other factors may be contributing, and the individual's needs and preferences for treatment are equally important. It is also important to ensure that there is a focus on functioning, general well-being and resilience, to ensure the child/young person is able to make considered decisions about their future pathway.

Individualised care plan

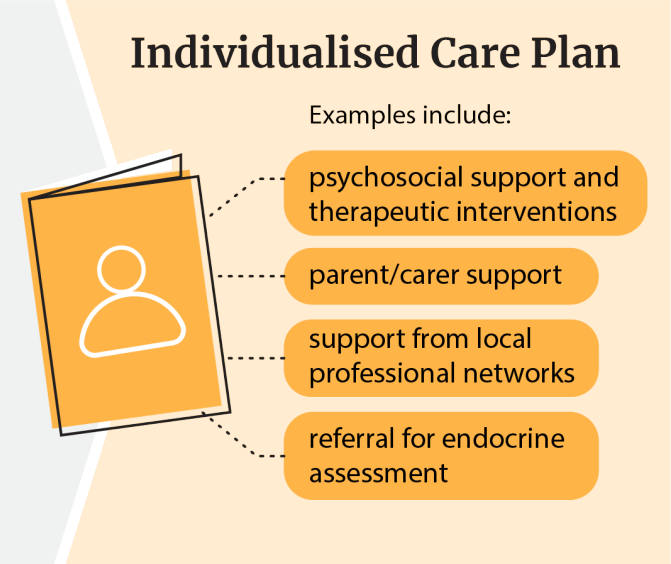
10.74 The holistic needs assessment and subsequent formulation should lead to the development of an individualised care plan with input from the multidisciplinary team.

10.75 This should be a collaborative process that involves a young person and their healthcare professional working together to reach a joint decision about care. Shared decision making involves choosing treatments based both on evidence, and on the person's individual preferences, beliefs and values (NICE, 2021).

10.76 An individualised care plan should include potential pathways of psychosocial support, recommendations on therapeutic interventions, referral for endocrine assessment where clinically indicated, parent/carer and

sibling support options as well as wider recommendations for further support that might be accessed from local professional networks.

Figure 31: Individualised Care Plan



10.77 The Review has kept at its heart the concern that the NHS is dealing with a group of young people who frequently, albeit not always, will be in a state of considerable distress by the time they reach the NHS, and will often have multiple unmet needs.

10.78 There should be a tiered approach to any intervention package outlined in an individualised care plan which:

- addresses urgent risk
- reduces distress and any associated mental health issues and psychosocial stressors, so the child/young person is able to function and make complex decisions
- co-develops a plan for addressing the gender dysphoria, which may involve a combination of psychological and physical treatment options.

10.79 The controversy surrounding the use of medical treatments has taken focus away from what the individualised care and treatment plan is intended to achieve, both for the individual seeking support from NHS gender services and for the overall population.

10.80 Young adults, interviewed for the University of York's qualitative research study, "expressed an incredibly diverse range of experiences and pathways. Many benefitted from access to medical pathways, which they said, enabled them to lead the lives they wanted. Others explored equally empowering options, such as social transitioning and more fluid and non-binary expressions of gender." (Appendix 3).

10.81 Several young people and young adults participating in the lived experience focus groups similarly reflected that it is important to inform people that medical transition is not the only option and that choosing not to go down that route does not invalidate their identity.

> "I think it's helpful for people to know that there's not only one route or one set way to transition or be trans. They might want just hormones, or just surgery, people are different with different experiences, presentations and bodies. It's fine for that to be the case, it's okay to have different plans for your medical transition."
>
> **Young person**
> **Lived experience focus group**

10.82 The qualitative study found that "For some, initial gender questioning created a sense of urgency, much of which focused on accessing medical pathways. These young adults acknowledged that their original response was to "fix" the problem. This became less important to them as they grew older. Some explained that discovering different ways to express gender identity was one of the most important things they had learned. They wished this had been explained to them when younger but remain uncertain about the extent they would have listened to such advice." (Appendix 3).

10.83 The central aim of the assessment process and individualised care plan is to help young people to thrive and achieve their life goals. For the majority of young people, a medical pathway may not be the best way to achieve this. For those young people for whom a medical pathway is clinically indicated, it is not enough to provide this in the absence of addressing any wider mental health and/or psychosocially challenging problems such as family breakdown, barriers to participation in school life or social activities, bullying and minority stress.

Recommendation 1:

Given the complexity of this population, these services must operate to the same standards as other services seeing children and young people with complex presentations and/or additional risk factors. There should be a nominated medical practitioner (paediatrician/child psychiatrist) who takes overall clinical responsibility for patient safety within the service.

Recommendation 2:

Clinicians should apply the assessment framework developed by the Review's Clinical Expert Group, to ensure children/young people referred to NHS gender services receive a holistic assessment of their needs to inform an individualised care plan. This should include screening for neurodevelopmental conditions, including autism spectrum disorder, and a mental health assessment. The framework should be kept under review and evolve to reflect emerging evidence.



11. Psychological and psychosocial interventions

11.1 There are many different ways of helping gender-questioning young people improve their health and wellbeing, regardless of their longer-term decisions about medical or social transition.

11.2 Part 3 described the wide range of associated conditions that may be part of a picture of gender related distress. A holistic package of care to address these issues may involve a broad range of options such as:

- supporting a young person to get back into school
- diagnosing autism or ADHD
- supportive group sessions
- psychological interventions to help anxiety, depression or trauma
- building resilience
- working with the whole family to address breakdowns in relationships
- providing more information about gender expressions and the range of possible interventions.

11.3 The terms psychological therapies, psychotherapy, psychosocial interventions and talking therapies are often used interchangeably in everyday settings. Strictly speaking, psychological interventions refer to treatments based on a theory of psychological functioning, while the term psychosocial interventions is less specific and is used to describe a wide range of supportive approaches to improving mental health, wellbeing and functioning.

11.4 The role of psychological therapies in supporting children and young people with gender incongruence or distress has been overshadowed by an unhelpfully polarised debate around conversion practices. Terms such as 'affirmative' and 'exploratory' approaches have been weaponised to the extent that it is difficult to find any neutral terminology. This has given the impression that a young person can have either therapeutic interventions or a medical pathway.

11.5 Whilst the Review's terms of reference do not include consideration of the proposed legislation to ban conversion practices, it believes that no LGBTQ+ group should be subjected to conversion practice. It also maintains the position that children and young people with gender dysphoria may have a range of complex psychosocial challenges and/or mental health problems impacting on their gender-related distress. Exploration of these issues is essential to provide diagnosis, clinical support and appropriate intervention.

11.6 The intent of psychological intervention is not to change the person's perception of who they are but to work with them to explore their concerns and experiences and help alleviate their distress, regardless of whether they pursue a medical pathway or not. It is harmful to equate this approach to conversion therapy as it may prevent young people from getting the emotional support they deserve.

11.7 No formal science-based training in psychotherapy, psychology or psychiatry teaches or advocates conversion therapy. If an individual were to carry out such practices they would be acting outside of professional guidance, and this would be a matter for the relevant regulator.

Perspectives from service users and families

11.8 The Review's work with service users, parents/carers and clinicians revealed a perceived gap in provision for those who are exploring/questioning their gender identity but are unsure of what it means for them. The length of the wait before being seen means many young people are forced to undertake this exploration on their own.

> "Good mental health services would have really been a big benefit for me as I was exploring my identity, dealing with things like dysphoria…."
>
> **Young person**
> **Lived experience focus group**

> "I would hope that going forwards, there would be more treatment options available for young people experiencing gender-based distress as well as physical interventions, such as third wave CBT, family therapy or psychotherapy at GIDS"
>
> **GIDS clinician**
> **Specialist questionnaire**

> "My GP was fine with gender stuff but he was only willing to give me one diagnosis in my life… I can have more than one thing 'wrong' with me, many people do, there's also a link between ADHD, Autism and Gender stuff – but it all feels ignored, like they just see my diagnosis for dysphoria and they refuse to see the rest. It doesn't feel like my other experiences are valid."
>
> **Young person**
> **Lived experience focus group**

11.9 Young people want a non-judgemental space to talk about how they are feeling and options for care. They also want help to reduce the dysphoria (distress) that they are feeling.

11.10 Parental and personal narratives described children and young people having more than one issue presenting, but services (e.g. GIDS, CAMHS, GP), dealing with each issue in isolation, without considering the impact of issues on each other. This may include neurodivergence or significant mental health issues, including past history of eating disorders, experiences of loss and/or trauma and bullying.

> "I knew walking in that I wasn't going to get any help from them, I just had to tell them what they wanted to hear. I knew that they were the doorway to getting me what I wanted. I wouldn't speak openly about any concerns I had because I knew that could prevent me from accessing the care I needed."
>
> **Young person**
> **Lived experience focus group**

11.11 Some young people have spoken about the perception that disclosing neurodiversity, mental health issues or trauma would be used to discredit their sense of identity. It is concerning that young people may not feel they can be honest with their health professionals. They describe the sense that they need to play a role and manage services to get what they need. This has led to some people actively not seeking help with their mental health or hiding mental health issues.

International guidelines and practice

11.12 Historically the model of care for children and young people presenting with gender incongruence or distress was entirely based on a psychosocial model, with early medical intervention with puberty blockers being introduced more recently. Most clinical teams would still see this as the starting point in a care pathway.

11.13 This is in part reflected in the University of York's synthesis of international guidelines (Taylor et al: Guidelines 2: Synthesis) which found that all but two guidelines describe psychosocial support as a key component of care.

11.14 Earlier guidelines described psychosocial care as the mainstay of treatment, and the recent Finnish and Swedish guidelines describe it as the first line treatment. However, there is now an emerging international divergence, with five guidelines saying that not all children or adolescents will need psychosocial care, and all but one of these five promoting a gender-affirmative approach to care.

11.15 Another problem across the international guidelines is the lack of detail on the aims, approach or end point of psychological/psychosocial interventions. There is variability, and a lack of definition and consensus about gender exploration, in particular about whether it should form part of the assessment, and whether it is important for children and adolescents or just children.

11.16 These discrepancies in approach echo the tensions that have entered the debate in the UK about affirmative or exploratory approaches.

11.17 Most guidelines discuss psychosocial support for parents and highlight the importance of parental care and support for children and young people in their gender care. Most also suggest providing education about gender development and identity to young people and their families.

11.18 The additional challenges in supporting looked after children are flagged in six guidelines.

11.19 Despite recommendations regarding the need for psychosocial interventions, the international survey (Hall et al: Clinic Survey) reported that in practice psychosocial interventions were quite limited across the responding gender services. Five clinics had no in-house provision, and others offered a small range of options and/or psychoeducation. This highlights a gap between aspiration and delivery.

Understanding the evidence

11.20 The University of York conducted a systematic review to identify and summarise evidence on the outcomes of psychosocial interventions for children and adolescents experiencing gender incongruence (Heathcote et al: Psychosocial support).

11.21 Only ten studies met the inclusion criteria. Study quality was assessed as low in nine of the studies and moderate in one study. Selection criteria for participants were not clearly defined, and the studies lacked appropriate comparators.

11.22 The studies used various interventions:

- Some using standardised approaches such as cognitive behaviour therapy, mindfulness and self-compassion, or attachment-based family therapy,
- Some using more focused approaches developed or adapted specifically for gender or sexual minority youth.

11.23 All studies included in the final analysis used validated instruments to assess outcomes, but there was little congruence between studies on the measures used.

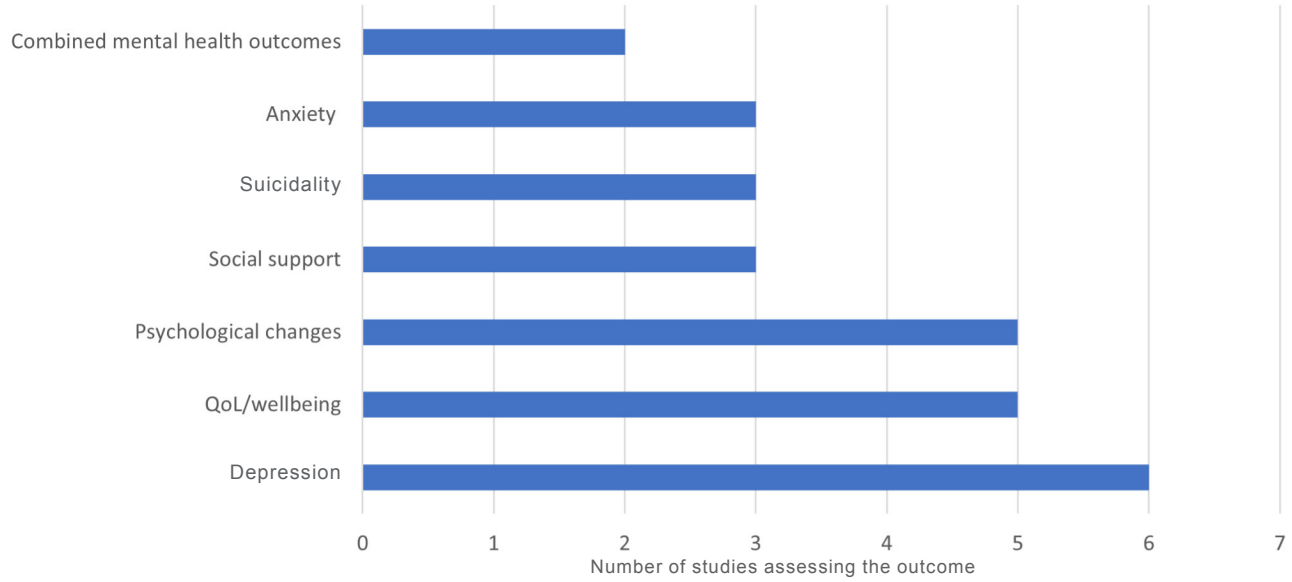
11.24 The most commonly reported outcomes related to mental health (depression, anxiety and suicidality).

- Four out of eight studies which reported on depression (either alone or within a combined mental health outcome) reported significant improvements.
- Three out of five studies which reported on anxiety (either alone or within a combined mental health outcome) also reported significant improvement.
- Three out of four studies that looked at suicidality found significant improvements in suicidality scores, and one found no change.

11.25 The studies focusing on psychological changes and/or psychosocial changes found improvements in a range of aspects such as resilience, self-compassion and self-acceptance, as well as quality of life, global functioning, participation and well-being.

11.26 Where there was adequate follow-up, studies found that many of these outcomes fell off over time. There was no indication across the studies of adverse or negative effects.

Figure 32: Psychosocial support interventions: outcomes measured



Source: Data from Heathcote et al: Psychosocial support

QoL: Quality of Life

11.27 Because of the low quality, poor reporting of the intervention details and heterogeneity of the interventions and their aims and outcome measures, it was not possible to directly compare the different types of interventions. It was also not possible to determine which specific approach might work best for whom.

11.28 The University of York concluded that there is limited research evaluating outcomes of psychosocial interventions for children and adolescents experiencing gender incongruence, and low quality and inadequate reporting of the studies identified. Therefore, firm conclusions about their effects cannot be made. Identification of the core approach and outcomes for these interventions would ensure they are addressing key clinical goals, attending to the needs of children and families as well as supporting future aggregation of evidence.

Current NHS practice

11.29 GIDS reports that only a minority of children and young people go on to an endocrine pathway, so the Review was keen to hear about what support and treatment packages were offered to those who did not go on to a medical pathway. However, despite a number of discussions and a focus group with GIDS staff on this topic, it has not been possible to obtain any clear information about the range of options offered.

11.30 Within the GIDS service, patients may have had anything from a one or two appointments to in excess of 100. This indicates that some practitioners must have been providing therapeutic input to patients, despite the fact that there was not a formal structured programme in place.

11.31 Because the assessment process at GIDS appears to have been organic, without a clear end point, it seems that an assessment has formed the starting point for a therapeutic relationship which could continue over many sessions.

11.32 It appears that, for those young people for whom an endocrine option was not the best option, staff at GIDS were doing their best to provide ongoing support, perhaps because local services were not able to offer this. In addition, staff were clearly in a difficult position balancing the needs of ongoing patients with the pressure of the waiting list.

> "It's bit controversial and I don't wanna upset or anger anyone, but like buffer periods and I know it is just like a touchy subject but I personally when I was 14, like found [social media influencer] YouTube and was like, oh my gosh, I'm a trans man. This is me, like I need to go on testosterone, I need to get top surgery, I need to like do all these things. And I was so sure I wanted to testosterone for like 2, 3 years.
>
> I am really glad that I didn't go on testosterone, because I realized during like my 17 sessions at GIDS that that wasn't for me. And it was really through those sessions and also a lot of self-exploration, and I was so, so, sure that I wanted it.
>
> So I think, buffer periods of like 7 years - no, that's not the vibe, but having spaces where you can have proper informed consent. Like is really important and exploring all of your options and being aware of all of the consequences. Consequences is a very negative, heavy loaded term, but like, yeah, consequences because, sometimes people do things and it's not right for them at the time, or maybe it is right for them at the time, but isn't later on. So yeah. Sorry, if that offends anyone."
>
> **Young person**
> **Lived experience focus group**

> "If someone is like dead set on wanting something be that like hormone treatment or surgery. Making sure those referrals happen and they don't have to wait years on years just to get on the list. I think that's quite important. You know, if someone is well informed they know exactly what they want, I don't see why there should be any, like obviously giving informed consent, but I don't see why there should be like a buffer period if someone's very much like, no I know what I want."
>
> **Young person**
> **Lived experience focus group**

11.33 Clinicians have also reported that the length of the waiting list can be a barrier to having exploratory discussions with children and young people that could provide them with a broader range of options for addressing their distress. This is because by the time young people are seen they have often made their minds up that an endocrine pathway is their chosen option and do not want to consider other approaches.

11.34 The Review also heard that some staff had looked at how standard evidence-based treatments (in this case third-wave CBT) could be used to help young people to manage their gender-related distress, stressing that this can be achieved without pathologising or changing a young person's gender identity (Canvin 2022). However, this was not developed into a full research study.

Summary – psychological and psychosocial interventions

11.35 Psychological and psychosocial interventions serve multiple different purposes for this group of children and young people, dependent on any underlying mental health problems and the particular features of their gender presentation. However, there has been a failure to systematically consider how psychosocial interventions should be used and to research their efficacy.

11.36 Some therapies, which are well proven for associated mental health problems, already have a strong evidence base. Where it is clear that children/young people have such problems, they should receive the appropriate therapies in the same way as any other young person seeking support from the NHS. Outcome measures should include evaluating the impact on the associated medical health condition, and any additional impact on the gender-related concerns and distress.

11.37 Beyond this first line approach, it is important to understand how specific therapeutic modalities may help the core gender dysphoria and bodily distress.

11.38 One of the given rationales for puberty blockers is that they may improve gender dysphoria or overall mental health. The evidence to date does not provide strong support for this (see Chapter 14). Furthermore, even after masculinising/feminising hormones, dysphoria may still persist. Therefore, it is important to explore other approaches for addressing the gender-related distress, which in itself is debilitating. These may be of value regardless of whether or not an endocrine pathway is chosen.

11.39 Navigating life as a transgender person can be challenging. Individuals may encounter hostility for being who they are and are likely to suffer from minority stress. If the ultimate goal of any intervention is to help the child or young person to function and thrive, they need to be provided with tools and strategies to give them the best opportunity to do so.

> "I also feel there should be support with mental health. Whether it be towards gender identity or towards the stress. And having a way to cope with the stress that comes with going through the process and that comes with being trans in general."
>
> **Young person**
> **Lived experience focus group**

> "I know lots of trans kids who are really struggling with their mental health, not because of their gender not because they struggle with where they fit in but because of how society and institutions treat them."
>
> **Parent**
> **Listening session**

11.40 Children and young people thrive best when in a supportive family environment and facilitating the health and well-being of all family members will be important in achieving this end. Some participants in the Review's lived experience focus groups highlighted the positive role of families, carers and others in supporting them to navigate transition and related care.

11.41 Other participants spoke of the personal damage that a lack of parental support had had on their adult relationships with their family. They suggested that in-person and online support groups for parents and carers to meet other parents and carers and professionals who can answer their questions and provide mental health support/counselling if needed was incredibly important.

> "I think that access to informational texts are really important. I did a lot of my research on the internet and got told so much false information because there were so many sources, so some trustworthy informational sources about being transgender, social and medical transitions, etc, would have benefited me a lot."
>
> **Young person**
> **Lived experience focus group**

> "I feel like there is a lack of support for parents who are uneducated and want to learn how they can support their child, and also for ones who have to essentially go through a loss in their life. It may be hard for them to come to terms with the fact that they've lost something and gained another, so a service that could provide support and guidance for parents would be extremely useful."
>
> **Parent**
> **Listening session**

11.42 The role of family therapists in addressing some of the above problems and challenges should also be considered.

11.43 In summary, there is a lack of evidence about alternative approaches for managing gender-related distress, and it is difficult to obtain information about routine clinical practice or pathways of care for children and young people who do not receive medical interventions. An explicit clinical pathway must be developed for non-medical interventions, as well as a research strategy for evaluating their effectiveness.

Recommendation 3:

Standard evidence based psychological and psychopharmacological treatment approaches should be used to support the management of the associated distress and cooccurring conditions. This should include support for parents/carers and siblings as appropriate.

12. Social transition

12.1 Through discussions with stakeholders, it is clear that social transition is a cause of concern for many people, and our remarks about social transition were some of the most quoted parts of the Review's interim report.

12.2 The approach taken to social transition is very individual but it is broadly understood to refer to social changes to live as a different gender such as altering hair or clothing, name change and/or use of different pronouns. There is a spectrum from relatively limited gender non-conforming changes in appearance in adolescence to young people who may have fully socially transitioned from an early age and be 'living in stealth' (that is, school friends/staff may be unaware of their birth-registered sex).

12.3 There are different views on the benefits versus the harms of early social transition. Some consider that it may improve mental health and social and educational participation for children experiencing gender-related distress. Others consider that a child who might have desisted at puberty is more likely to have an altered trajectory, culminating in medical intervention which will have life-long implications.

12.4 One key difference between children and adolescents is that parental/carer attitude and beliefs will have an impact on a child's ability to socially transition, whereas adolescents have more personal agency.

12.5 Social transition may not be thought of as an intervention or treatment, because it is not something that happens in a healthcare setting and it is within the agency of an adolescent to do for themselves. However, in an NHS setting it is important to view it as an active intervention because it may have significant effects on the child or young person in terms of their psychological functioning and longer-term outcomes.

12.6 Although the focus of the Review is on support from point of entry to the NHS, no individual journey begins at the front door of the NHS, rather in the child's home, family and school environment. The importance of what happens in school cannot be under-estimated; this applies to all aspects of children's health and wellbeing. Schools have been grappling with how they should respond when a pupil says that they want to socially transition in the school setting. For this reason, it is important that school guidance is able to utilise some of the principles and evidence from the Review.

International practice

12.7 The University of York's review of international guidelines (Taylor et al: Guidelines 2: Synthesis) found that most guidelines recommend providing information about the benefits and risks of social transition but vary in whether the recommendations apply to both children and adolescents or just to children.

12.8 WPATH 8 guidance has moved from a 'watchful waiting' approach for children to a position of advocating for social transition as a way to improve children's mental health.

12.9 Several guidelines recommend that social transition should be framed in a way that ensures children can reconsider or reconceptualise their gender feelings as they grow older.

12.10 Several guidelines discuss education about the risks and benefits of binders and packers, and safe use as appropriate.

Reflections from the Multi-Professional Review Group

12.11 The Multi Professional Review Group (MPRG) report (Appendix 9) notes that many children and young people attending GIDS have changed their names by deed-poll, attend school in their chosen gender and some have changed NHS numbers by the time they are seen. Based on the MPRG review of the notes, this history/journey was rarely examined closely by GIDS for signs of difficulty, regret or wishes to alter any aspect of the child/young person's gender journey trajectory.

12.12 The MPRG is concerned that some children living in stealth have a common, genuine fear of "being found out", suffering rejection either due to not having taken friends into their confidence (withholding personal information regarding biological sex or specific sex-based experiences), or due to trans-prejudice or transphobia. They observed that this fear of "being found out" is driving a sense of urgency to access puberty blockers, which may not allow consideration of other pros and cons of the treatment.

12.13 The MPRG also observed that living in stealth appears to increase a child's level of stress and anxiety with resultant behaviour and mental health problems. These included social withdrawal, with children becoming increasingly isolated, including resorting to home-schooling or tutoring and even rarely leaving their house.

Perspectives from service users and families

12.14 Young people and young adults have spoken positively about how social transition helped to reduce their gender dysphoria and feel more comfortable in themselves. However, it is the reaction of those around them that can make it difficult. Young people identified that space to talk about socially transitioning and how to handle conversations with parents would be helpful. They feel that parents and carers need more information about social transition and the best way to support their child through that process.

> "It would be helpful to show that there is no judgement in experimenting with their appearance such as clothing and makeup. Also to be shown how they don't need to have a specific label to use and should try to feel as comfortable as they can."
>
> **Young person**
> **Lived experience focus group**

> "To me social transition is an act undertaken by the child, so I wouldn't call it an active intervention. [The] question is whether to support it or not and to factor in if the child is considering it or has already announced it. [The] act by community is supporting or not supporting."
>
> **Young trans adult**
> **Listening session**

12.15 The qualitative research conducted by the University of York (Appendix 3) found that, while waiting for clinical input many young people "took steps to help manage how they felt and most socially transitioned while waiting. The process, although dynamic and flexible, was positively regarded by young people. Many parents, although initially hesitant, come to understand the value of social transitioning. A few, however, remained anxious about its impact. Families would have welcomed advice on how to negotiate social transitioning but many experienced difficulties in accessing support".

12.16 However, the Review heard concerns from many parents about their child being socially transitioned and affirmed in their expressed gender without parental involvement. This was predominantly where an adolescent had "come out" at school but expressed concern about how their parents might react. This set up an adversarial position between parent and child where some parents felt "forced" to affirm their child's assumed identity or risk being painted as transphobic and/or unsupportive.

12.17 Some parents who spoke to the Review felt that social transition was of more benefit to their child in terms of its social impact than it helping to manage their gender incongruence. They describe how their children were previously isolated and bullied but their status amongst peers had improved as a result of "coming out".

> "Pre-social transition, [child] had social difficulties due to ASD and was bullied. After social transition [child] was given enormous kudos at school. They were geeky and awkward, but became a celebrity."
>
> **Parent**
> **Listening session**

> "Her whole friends group has some sort of trans or nonbinary identity. Older friends don't seem to be in that camp – they are open and supportive but not identifying. It seems to have been socially beneficial to her to present as trans – as a high functioning autistic person – it has helped her with her social life. Her friends seem to be celebrating in trans identities."
>
> **Parent**
> **Listening session**

12.18 Clinicians have said that most children have already socially transitioned before reaching the specialist gender service. Some clinicians have suggested that support to think through social transition could happen within local services and does not need to sit within NHS specialist services.

> "Ideally local services should be available to young people where they can discuss and explore their gender, be supported to try out social transition etc. If this was the case a specialist service would only be needed if they wanted assessment for physical interventions or there were multiple factors at play that local services felt unable to support with."
>
> **Clinician**
> **Specialist survey**

Understanding the evidence

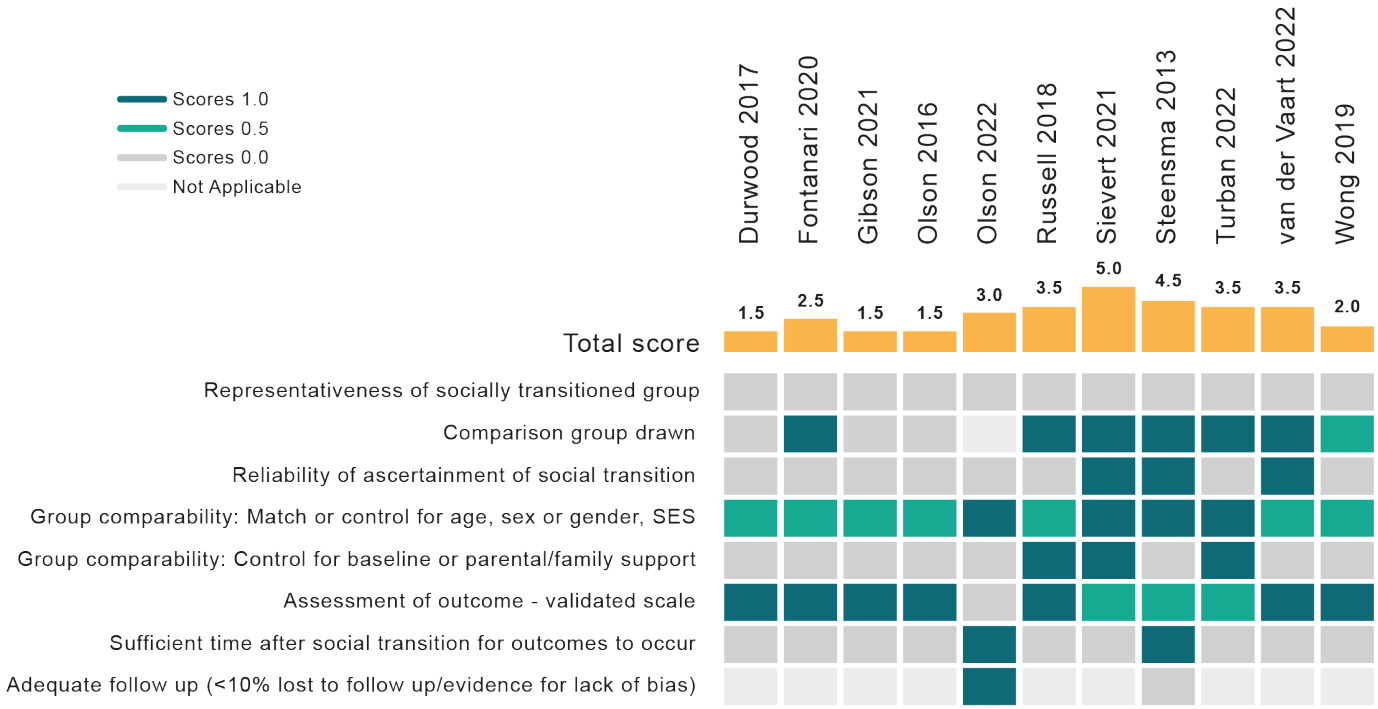
12.19 The University of York's systematic review on social transition aimed to identify and summarise evidence on the outcomes of social transition for children and adolescents with gender dysphoria. (Hall et al: Social transition).

12.20 This systematic review is a useful example demonstrating how systematic reviewers rate the quality of studies. The scale (called a modified version of the Newcastle-Ottawa Scale) was used to assess the items shown in Figure 33 and then give a summary score for each of the studies. The maximum score is 8, a score of 0-3.5 is low quality, 4-5.5 moderate quality and 6-8 high quality.

12.21 Of the 11 studies that met the search criteria, nine were low quality (scoring between 1.5 and 3.5) and two were moderate quality (scoring between 4.5 and 5.0). The most problematic aspects were sample selection, and samples were not reliably representative of the broader population. Most studies were US based.

12.22 The quality of the studies was not good enough to draw any firm conclusions, so all results should be interpreted with caution.

Figure 33: Quality scores for included studies assessed using a modified Newcastle-Ottawa Scale



Source: Hall et al: Social transition

NB: The gird indicates individual scores for each study on each of the criteria. Bars at the top (and numbers at top of bars) indicate overall score. SES: socioeconomic status.

Mental health outcomes

12.23 Different studies looked at different outcomes of social transition. The only consistent benefit from social transition was for use of chosen name in adolescence:

- one study found this was associated with some improvements in mental health and reduced suicidality for 15-21 year-olds
- another study found that parental use of chosen name and being able to express one's gender was associated with some improvements in mental health/distress for 16-24 year-olds.

12.24 One study looking at transgender adults found that lifetime suicide attempts and suicidal ideation in the 'past year' was higher among those who had socially transitioned as adolescents compared to those who had socially transitioned in adulthood.

Gender identity outcomes

12.25 One study (Olson et al, 2022) used a self-selected community sample of children (the Trans Youth Project). Children had to be between three and 12 years of age at enrolment and had to have made a "complete" binary social transition, including changing their pronouns to the binary gender pronouns that were not those used at their births. The study found that 93% of those who socially transitioned between three and 12 years old continued to identify as transgender at the end of the study (about 5.4 years later). Of the remainder, 2.5% were living as cisgender, 3.5% as non-binary and 1.3% had retransitioned twice. This study also demonstrated that the majority of children who had socially transitioned went on to progress to medical interventions.

12.26 Another study (Steensma et al., 2013b) found that childhood social transition was a predictor of persistence of gender dysphoria for those birth-registered male, but not those birth-registered female. In this study 96% of those birth-registered male and 54% of those birth-registered female who later desisted had not socially transitioned at point of referral and none had fully socially transitioned (see Table 8). The study noted that the possible impact of the social transition on cognitive representation of gender identity (that is, how the child came to see themself) or on persistence had not been studied.

12.27 However, there was also an association between childhood social transition and more intense gender dysphoria, so it may be that the intensity of the dysphoria was the factor that led to persistence and the more pressing drive for the children to socially transition.

Table 8: Childhood social transition and likelihood of persistence

	PERSISTERS % (n=47)		DESISTERS % (n=80)	
	BR-M (n=23)	BR-F (n=24)	BR-M (n=56)	BR-F (n=24)
No social transition	57	42	96	54
Partial social transition	30	54	4	45
Full social transition	13	4	0	0
Total	100	100	100	100

Source: Data from Steensma et al., 2013b.

BR-M: birth-registered male | BR-F: birth-registered female

Relevance to existing guidelines

12.28 There has been a shift in recommendations between WPATH 7 (2012), which was more cautious about social transition, and WPATH 8 (2022) which argues in favour of social transition in childhood.

12.29 WPATH 8 justifies this change in stance on the basis that there is more evidence on improved mental health outcomes with social transition, that fluidity of identity is an insufficient justification not to socially transition, and that not allowing a child to socially transition may be harmful.

12.30 However, none of the WPATH 8 statements in favour of social transition in childhood are supported by the findings of the University of York's systematic review (Hall et al: Social Transition).

Summary – social transition

12.31 Given the weakness of the research in this area there remain many unknowns about the impact of social transition. In particular, it is unclear whether it alters the trajectory of gender development, and what short- and longer-term impact this may have on mental health.

12.32 Early research cited in Chapter 2 found low rates of persistence of childhood gender incongruence into adulthood, around 15% (for example, Zucker, 1985). Papers from this period were criticised because the children were not formally diagnosed using ICD or DSM. At that time, it was rare for children to have socially transitioned before being seen in clinic.

12.33 Later studies, which showed higher rates of persistence at 37% (for example Steensma et al., 2013b) did use formal diagnostic criteria, but by that time a greater proportion of the referrals had socially transitioned prior to being seen.

12.34 It is not possible to attribute causality in either direction from the findings in these studies. This means it is not known whether the children who persisted were those with the most intense incongruence and hence more likely to socially transition, or whether social transition solidified the gender incongruence.

12.35 Earlier in this report it was explained that much has been learnt about the role of sex of rearing on the development of gender identity from follow-up studies of individuals with health conditions known as differences of sex development (DSD). It is helpful to recap on some of this learning when considering the role of social transition. In summary:

- Individuals who are genetically female (XX) but have high androgen levels (i.e. those with Congenital Adrenal Hyperplasia) are usually reared as females; they tend to have some male role behaviours but are most commonly heterosexual and usually have a female gender identity.
- In those with DSD in whom gender identity outcome is less well established, the sex of rearing is a better predictor of gender identity outcome than prenatal androgen exposure.
- The conclusion is that a complex interplay between prenatal androgen levels, external genitalia, sex of rearing and socio-cultural environment all play a part in eventual gender identity, and we have yet to understand the relative influence of these various elements.

12.36 The information above demonstrates that there is no clear evidence that social transition in childhood has positive or negative mental health outcomes. There is relatively weak evidence for any effect in adolescence. However, sex of rearing seems to have some influence on eventual gender outcome, and it is possible that social transition in childhood may change the trajectory of gender identity development for children with early gender incongruence. For this reason, a more cautious approach needs to be taken for children than for adolescents:

Children:

- Parents should be encouraged to seek clinical help and advice in deciding how to support a child with gender incongruence and should be prioritised on the waiting list for early consultation on this issue.
- Clinical involvement in the decision-making process should include advising on the risks and benefits of social transition as a planned intervention, referencing best available evidence. This is not a role that can be taken by staff without appropriate clinical training.
- It is important to ensure that the voice of the child is heard in any decision making and that parents are not unconsciously influencing the child's gender expression.
- For those going down a social transition pathway, maintaining flexibility and keeping options open by helping the child to understand their body as well as their feelings is likely to be advantageous. Partial rather than full transition may be a way of ensuring flexibility, particularly given the MPRG report which highlighted that being in stealth from early childhood may add to the stress of impending puberty and the sense of urgency to enter a medical

Adolescents:

- For adolescents, exploration is a normal process, and rigid binary gender stereotypes can be unhelpful. Many adolescents will go through a period of gender non-conformity in terms of hairstyle, make-up, clothing and behaviours. They also have greater agency in how they present themselves and their decision-making.
- For those considering full social transition, the current long waiting lists make it unlikely that a formal clinical assessment will be available in a timely manner. However, it is important to try and ensure that those already actively involved in their welfare (parents/carers, any involved clinical staff such as their GP, school staff or counsellors) provide support in decision making and plans to ensure that the young person is protected from bullying and has a trusted source of support.

For both children and adolescents:

- Outcomes for children and adolescents are best if they are in a supportive relationship with their family. For this reason parents should be actively involved in decision making unless there are strong grounds to believe that this may put the child or young person at risk.
- Help may be needed if a child/young person wishes to reverse their decision on transitioning, which can be a difficult step to take.

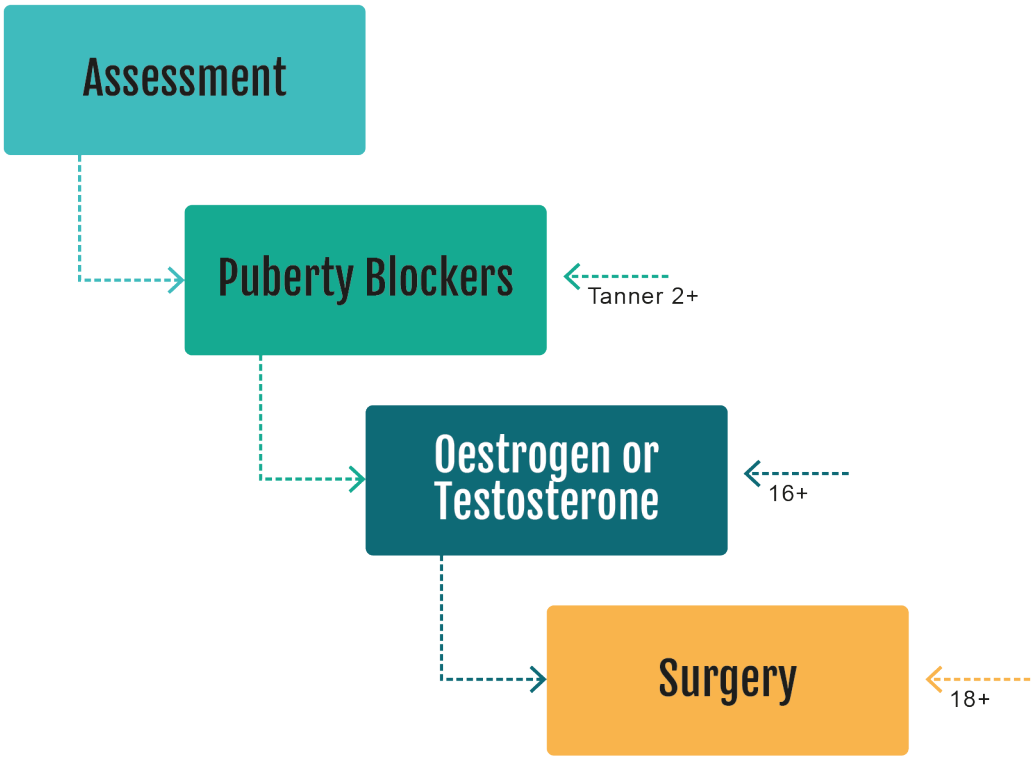
- **12.37** The clinician should help families to recognise normal developmental variation in gender role behaviour and expression. Avoiding premature decisions and considering partial rather than full transitioning can be a way of ensuring flexibility and keeping options open until the developmental trajectory becomes clearer.

Recommendation 4:

When families/carers are making decisions about social transition of pre-pubertal children, services should ensure that they can be seen as early as possible by a clinical professional with relevant experience.

13. Medical pathways

Figure 34: Outline of medical pathway at start of Review



13.1 When the Review began, the medical interventions for gender incongruence/dysphoria available on the NHS were puberty blockers followed by masculinising or feminising hormones. The history of their use was outlined in Part 2.

Perspectives from service users and families

13.2 Young people participating in the lived experience focus groups explained that while they do want access to counselling and spaces to openly explore their gender, this should be alongside not instead of the option to medically transition. They also felt there needed to be recognition that mental health may still be a concern after starting on a medical pathway, while waiting for changes to take effect.

> "I just wanted to get my bloody hormones, that was what I was there for, that's what I wanted, that would've been my therapy, all my distress was related to needing to get on hormones and I was expressing this, I had a trans history, I was clearly aware of what I wanted and what care was on offer."
>
> **Young person**
> **Lived experience focus group**

13.3 For those who are considering a medical transition, there is a strong sense among service users that this should be facilitated by the NHS, but a recognition that there is a need for better information on which to base decisions/consent.

13.4 Young people and young adults participating in the Review's focus groups highlighted a lack of reliable and accurate information about medical transition. In particular, the need to be informed of any known and unknown risks and potential side effects of hormone interventions when making informed decisions about care and treatment. Some participants felt there needed to be more information for people wanting to come off the medical pathway.

> "What are the benefits, what have people who've gone through each process thought about it, what are the side-effects, what are the possible drawbacks, what is the time-scale, how reversible is it, what the process actually involves (e.g. not being able to do stuff for several months after certain surgeries), what medical professionals think about it, what everyday people who've done it think about it, what are the things nobody tells you (e.g. post-surgery dysphoria), what is the satisfaction rate (preferably with some stories of people who've done it and loved it, and some who've done it and didn't love it as much)."
>
> **Young person**
> **Lived experience focus group**

Existing endocrine practice in the UK

13.5 One of the most problematic data gaps for the Review has been trying to obtain robust data on the numbers of young people who go on to a hormone pathway at GIDS, and what care pathways or interventions are available for those who do not. This seems unacceptable in the digital age.

13.6 Our working assumption, based on original data provided to the Review, was that approximately 20% of those referred to GIDS go on to a medical pathway.

13.7 Performance data received by NHS England and shared with the Review indicated that this was probably an accurate proportion of all cases seen by the service. However, the data suggested that around 50% of these patients received only one appointment before being discharged from GIDS, usually because they had 'aged out' of the service before the assessment could be completed.

13.8 If those patients are discounted, it appeared that a significantly higher percentage of active cases (those undergoing full assessment) were being referred to endocrinology. In order to get a clear picture, the Review wrote to NHS England requesting that an audit of discharge records be undertaken.

13.9 NHS England approached NHS Arden and Greater East Midlands Commissioning Support Unit to undertake this audit on behalf of the Review and NHS England. The audit (Appendix 8) looked at discharge records of patients who had been discharged from GIDS between 1 April 2018 and 31 December 2022. This covered the period pre and post the Bell v Tavistock judgments.

13.10 The following patients were included in the data collection:

- patients who have attended at least two appointments at GIDS
- patients who have been discharged from GIDS between 01 April 2018 and 31 Dec 2022.

13.11 Of the 3,499 patients audited, 3,306 were included within the analysis. 73% were birth-registered female and 27% birth-registered male. The audit did not include patients who had received fewer than two appointments at GIDS or those who lived outside England and Wales. Headline findings from the audit were:

- Overall, 27% of patients were referred to endocrinology (34.6% of [birth-registered] males compared to 24.2% of [birth-registered] females). This equates to 584 birth-registered females and 308 birth-registered males.
- Patients received an average of 6.7 appointments prior to referral to endocrinology.
- 81.5% of patients referred into endocrinology received puberty blockers, of whom 52.5% were between 15-16 years old.

At the point of discharge from GIDS:

- 54.8% of all patients referred to endocrinology were on both puberty blockers and masculinising/feminising hormones (57.9% of [birth-registered] females compared to 47.7% of [birth-registered] males).
- For patients who initially received puberty blockers upon referral to endocrinology, 64% had gone on to receive both puberty blockers and masculinising/feminising hormones at point of discharge from GIDS.
- < 10 patients detransitioned back to their [birth-registered] gender, all of whom were female, and all but one were confirmed as having received puberty blockers as their first intervention. These patients had received an average of 6.5 appointments prior to referral to endocrinology (range 3-10 appointments).
- 89% of patients who were referred to endocrinology were discharged to an adult Gender Dysphoria Clinic (GDC).

13.12 Table 9 on the next page shows the end point intervention recorded on patients' discharge summaries: 54.8% ended up on both puberty blockers and masculinising/feminising hormones.

Table 9: Final intervention received by GIDS patients referred to endocrinology

FIRST INTERVENTION TYPE	% OF PATIENTS
Puberty blockers AND cross-sex hormones	54.8
Puberty blockers ONLY	19.9
Patient declined treatment	11.4
Accessed treatment outside of the NHS	3.9
Did not access physical treatment	3.3
Puberty assessment ONLY	2.0
Treatment withdrawn	1.5
Detransitioned/detransitioning	X
Unknown/unclear	X
Puberty blocker not started due to JR	X
Treatment recommended but supply issues (GP prescribing or pharmacy)	X
Treatment withdrawn - professional advice/side effects	X
Cross-sex hormones ONLY	X
Puberty blockers AND cross-sex hormones (privately)	X

Source: The Gender Identity Development Service Audit Report, Arden & GEM

NB: X indicates <10 patients

13.13 The GIDS audit report (Appendix 8) also sets out that 73% (2,415) of the audited patients were not referred to endocrinology by GIDS. Of these:

- 93.0% did not access any physical treatment whilst under GIDS
- 5.0% accessed treatment outside NHS protocols
- 1.5% declined treatment
- 0.5% of patients detransitioned or were detransitioning back to their [birth-registered] gender.
- 69% were discharged to an adult GDC (possibly due to ageing out of the GIDS service). It is not known how many of these went on to hormone treatment through the adult services.

13.14 The Review received reports from support and advocacy groups that some young adults who had been discharged from GIDS remained on puberty blockers into their early to mid 20s, but did not progress to masculinising/feminising hormones. A review of the audit data suggested 177 patients were discharged whilst still on puberty blockers only (that is, not with masculinising/feminising hormones), but it is not possible to tell from this data how many subsequently came off puberty blockers and/or progressed to masculinising/feminising hormones through adult or private services.

13.15 Puberty blockers are intended to be a short-term intervention and the impact of use over an extended period of time is unknown, although the detrimental impact to bone density alone makes this concerning. The Review raised this with NHS England and GIDS.

International practice

13.16 The University of York carried out a systematic review and narrative synthesis of the international care pathways of children and young people referred to specialist gender or endocrinology clinics (Taylor et al: Care pathways). This places GIDS data in a wider context.

13.17 The systematic review aimed to synthesise information on numbers referred, assessed, diagnosed and considered eligible for medical intervention, numbers who later desist or detransition, reasons for leaving the service/ pathway and provision of psychological care.

13.18 The systematic review included 23 studies across nine countries; 14 specialist gender and nine endocrinology services. A major problem in interpreting these results is that models of care differ and there is a lack of clarity in the source papers as to how individual clinics function. Some endocrinology services may receive patients who have already been assessed by a gender service, as is the case in the UK, whilst in other countries, referrals may go directly to endocrinologists. This will affect the percentage diagnosed with gender dysphoria and/or offered endocrine treatments.

Patients accessing medical pathways

13.19 The numbers of young people receiving puberty blockers was reported in 21 of the papers, with the pooled estimates from across these services being 36% of those referred (95% confidence interval 23-51%). The ages at which they received puberty suppression ranged from 9 to 18, with an average age of 15.

13.20 Across all clinics, 68% received either puberty blockers and/or masculinising/ feminising hormones, although there was very wide variability between clinics.

There was neither any information about what happened to the approximately one-third of patients who did not access an endocrine pathway, nor any information about psychological care for those under the care of the specialist gender service.

13.21 Four studies published since the systematic review search are of interest, two from the Netherlands (van der Loos et al., 2023; van der Loos et al., 2022) and two from the UK (Butler et al., 2022; Masic et al., 2022).

13.22 In the UK clinic, more birth-registered female (65%) than birth-registered male (35%) adolescents were referred to endocrinology (Masic et al., 2022). Of those adolescents referred to the endocrinology clinic, 100% consented to a medical pathway, 98% of whom were on a puberty blocker pathway and 2% directly on masculinising/feminising hormones. The mean age of consenting to puberty blockers was 15.8. Not all of those who consented went on to access endocrine treatment.

The second UK paper (Butler et al., 2022) reported on discharge outcomes; 91.7% of those discharged continued to identify as transgender or gender variant, and 86.8% were discharged to adult GDCs.

13.23 In one Dutch study (van der Loos et al., 2023), 882 adolescents received puberty blockers, again with higher rates in birth-registered females than males (73% compared to 47%). Of 707 adolescents who received puberty blockers and were eligible for masculinising/feminising hormones during follow up 93% progressed to treatment. The other Dutch study (van der Loos et al., 2022) reported a 98% progression from puberty blockers to hormones.

Patients discontinuing medical pathways

13.24 The care pathways systematic review (Taylor et al: Care pathways) reported that 0-8% of patients discontinued puberty suppression (discussed in Chapter 14) and 0-2 patients discontinued masculinising/feminising hormones.

13.25 In the two UK studies published since the University of York's systematic review search, there were no discontinuations of masculinising/feminising hormones in the first UK study (Masic et al., 2022), but in the second UK study (Butler et al., 2022) 90 (8.3% of those referred for medical treatment) stopped identifying as gender incongruent, and 58 (5.3%) stopped treatment with either puberty blockers or masculinising/feminising hormones. However, the lack of information about length of time to discharge makes interpretation difficult.

Summary – medical pathways

13.26 A common theme in examining both the GIDS and international data is how difficult it is to understand the different pathways that young people follow, what alternative options are available for those who do not follow a medical pathway, and the reasons for treatment decisions at all stages along the pathway.

13.27 The GIDS audit found that 27% of patients were referred to endocrinology, and that 89% of patients referred to endocrinology were discharged to an adult GDC.

13.28 Of the 73% of patients not referred to endocrinology, 69% of these were referred to an adult GDC.

13.29 Since it is common for people attending an adult GDC to receive masculinising/feminising hormones, it is all the more critical to get follow-up data to better understand the outcomes for those who are referred to adult GDCs and those who are not.

14. Puberty blockers

14.1 When the Review began, the medical interventions for gender incongruence/dysphoria available on the NHS were puberty blockers, followed by masculinising/feminising hormones. The history of their use was outlined in Part 2.

Normal pubertal development

14.2. Puberty begins between 8 and 13 in girls (average age 11) and between 9 and 14 in boys (average age 12). The process starts in an area of the brain called the hypothalamus.

14.3. Puberty is triggered when the hypothalamus starts a hormone cascade which results in the ovaries and testes producing oestrogen and testosterone respectively. Both males and females proceed through the 5 stages of puberty known as Tanner stages.

Table 10: Tanner stages

TANNER	MALES	FEMALES
Stage 1	• No major physical changes yet • Brain is starting to signal the body to start making changes	
Stage 2	• Testes begin to grow • Public hair around base of penis	• Breast buds, darker nipple • Small amount of pubic hair
Stage 3	• Penis gets longer • Thicker pubic hair • Wet dreams • Voice starts to change • Muscles get larger • Start of growth in height	• Breast buds increase in size • More pubic hair • Hair under armpits • Acne • Most rapid growth in height • Start to increase fat on hips and thighs
Stage 4	• Testes, penis and scrotum continue to grow, scrotum gets darker • Hair in armpits • Deeper voice • Acne • Most rapid growth in height	• Further breast growth • First period • Growth in height slows • Pubic hair gets thicker
Stage 5	• Testicles, penis, scrotum adult size • Pubic hair spread to inner thighs • Facial hair • Growth in height slows down	• Adult breast size • Periods more regular • Adult height • Hips, thighs, buttocks fill out

Rationale for the use of puberty blockers for gender dysphoria

14.4 As set out in Chapter 2, the practice of pausing puberty at Tanner Stage 2 was initiated in the Netherlands, and subsequently adopted in the UK and internationally. The idea was based on a theory from Dr Peggy Cohen-Kettenis whose initial clinical experience was in adult care. Her rationale was that pausing puberty early would help young people to 'pass' better in adulthood and 'extend the diagnostic period' by buying time to think. The use of puberty blockers for this purpose was initially reported in a single case study (Cohen-Kettenis & van Goozen, 1998) and then in the original Dutch cohort (de Vries et al., 2011b).

14.5 It may appear surprising that the novel use of a drug for this purpose did not require a more rigorous drug trial. This is because of the way drugs are licensed and can be used off-label (see Explanatory Box 5).

14.6 GnRH hormones (referred to as puberty blockers in the treatment of young people) are licensed for patients with precocious puberty (that is, young children who enter puberty too early), as well as for the treatment of some cancers in adults and some gynaecological issues in adults. They have undergone extensive testing for use in precocious puberty (a very different indication from use in gender dysphoria) and have met strict safety requirements to be approved for this condition.

Explanatory Box 5:

Licensing, indications and contraindications

Licences are granted for a drug if strict safety and quality standards are met for its use. In the UK, licences are granted by the Medicines and Healthcare products Regulation Agency (MHRA).

An indication for a drug is a medical condition that the drug can be used to treat. Drugs are licensed for specific indications or purposes; for example, semaglutide was originally licensed for the treatment of diabetes. Recently some brands of semaglutide (Wegovy) have received additional licensing for weight loss.

If a drug is used for a purpose for which it is not licensed, this means it is being used off-label. This may be because it is considered to be effective for this indication, but the manufacturer has not gone through the processes to apply for a licence for that particular condition. For example, tetracyline, a kind of antibiotic, is licensed for a range of conditions including acne and rosacea. It is also used to treat Helicobacter pylori, a bacteria that infects the stomach lining and can cause stomach ulcers, but it is not licensed for that purpose.

Many drugs are not licensed for use in children, but can still be given to them safely. This is because the trials to test safety were only done in adults, so the licence specifies adult use only. In these circumstances the drug is usually given to children for exactly the same reason as for adults (for example, treatment of a severe infection).

14.7 The situation for the use of puberty blockers in gender dysphoria is different. Although some endocrinologists have suggested that it is possible to extrapolate or generalise safety information from the use of puberty blockers in young children with precocious puberty to use in gender dysphoria, there are problems in this argument. In the former case, puberty blockers are blocking hormones that are abnormally high for, say, a 7-year-old, whereas in the latter they are blocking the normal rise in hormones that should be occurring into teenage years, and which is essential for psychosexual and other developmental processes.

14.8 This approach to the use of puberty blockers in gender dysphoria has been an ongoing source of controversy both nationally and internationally.

14.9 The lack of consensus across the clinical community was highlighted by a 2015 study (Vrouenraets et al., 2015), which approached 17 multi-professional treatment teams worldwide to determine their views on use of puberty blockers. They identified seven themes on which there were widely disparate views:

- the (non-) availability of an explanatory model for gender dysphoria
- the nature of gender dysphoria (normal variation, social construct or [mental] illness)
- the role of physiological puberty in developing gender identity
- the role of comorbidity
- possible physical or psychological effects of refraining from) early medical interventions
- child competence and decision-making authority
- the role of social context in how gender dysphoria is perceived.

14.10 The professionals who participated in the study were often conflicted because they recognised the distress of young people and felt the urge to treat them, but at the same time, most had doubts because of the lack of information on long-term physical and psychological outcomes. For several participants, a reason to use puberty suppression was the fear of increased suicidality in untreated adolescents with gender dysphoria.

14.11 The authors of the study concluded that as long as debate remains on these seven themes and only limited long-term data are available, there will be no consensus on treatment. Eight years later, the position is unchanged and many of the same considerations apply to the use of masculinising/feminising hormones in young people.

International practice

14.12 The synthesis of international guidelines by the University of York (Taylor et al: Guidelines 2: Synthesis) found that there is no clarity about the treatment aims of puberty suppression, with options including reducing gender dysphoria, improving quality of life, allowing time to make decisions, supporting gender exploration, extending the diagnostic phase and 'passing' better in adult life.

14.13 Most guidelines emphasise full reversibility as a justification for their use, whilst highlighting potential adverse effects on bone health and uncertainty regarding cognitive development.

14.14 Where eligibility is discussed, the earlier requirement to wait for the patient to reach age 12 before they can access puberty blockers has been removed from some guidelines (for example, WPATH 8). The majority of guidelines recommend waiting until a child has reached Tanner Stage 2 of puberty. The Swedish guideline recommends Tanner Stage 3.

14.15 There is also considerable variation about the criteria for starting puberty blockers, with the commonest being the presence of gender dysphoria that has emerged or worsened at puberty. Only two guidelines specified the need for gender incongruence rather than dysphoria. Several specified that mental health difficulties should be managed and/or were unlikely to impact treatment. Another specification in several guidelines was that the young person has decision-making capacity, parental consent is obtained and/or that there is family social support.

14.16 The Swedish and Finnish guidelines differ from others in recommending that puberty suppression should be provided under a research protocol or the supervision of a research clinic.

14.17 The international survey (Hall et al: Clinic survey) looked at what is happening in practice. All clinics offered puberty blockers and masculinising/feminising hormones apart from one regional service. Menstrual suppression with progestogens (the contraceptive pill) was routine in four clinics.

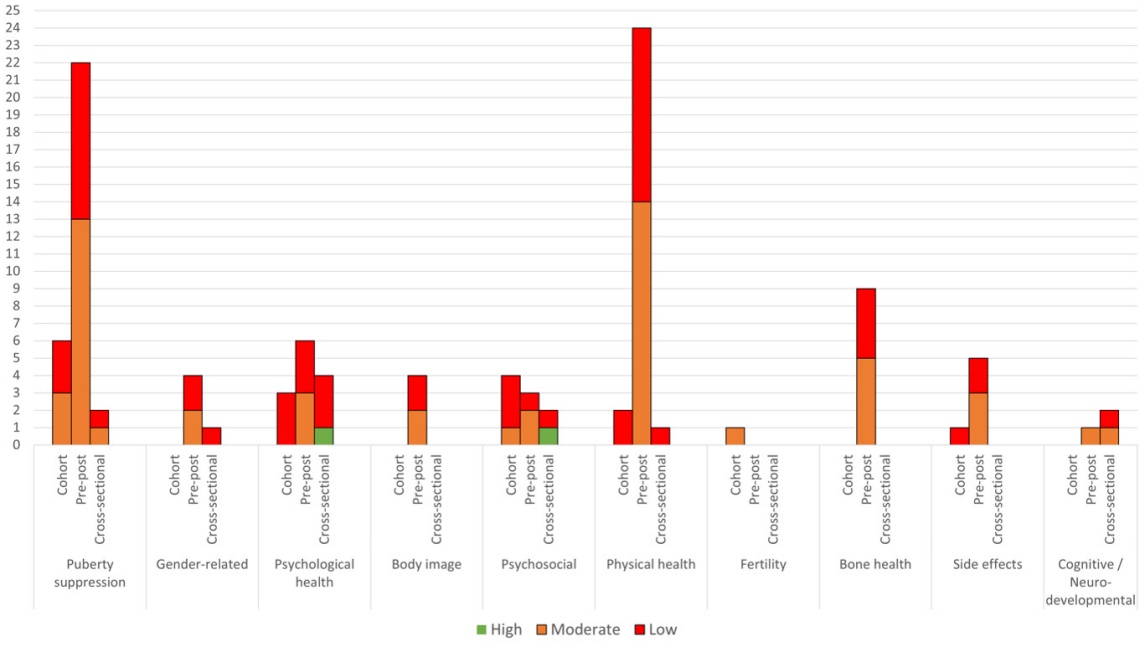
14.18 Most clinics required a diagnosis of gender dysphoria or incongruence, reaching Tanner stage 2 and stable mental health for puberty blockers. Belgium, Finland, Denmark and Norway required gender dysphoria/ incongruence to have been long-lasting/since childhood and Finland specified that distress had to intensify in puberty. Five clinics excluded those in late puberty from having blockers.

Understanding intended benefits and risks of puberty blockers

14.19 The systematic review on interventions to suppress puberty (Taylor et al: Puberty suppression) provides an update to the NICE review (2020a). It identified 50 studies looking at different aspects of gender-related, psychosocial, physiological and cognitive outcomes of puberty suppression. Quality was assessed on a standardised scale. There was one high quality study, 25 moderate quality studies and 24 low quality studies. The low quality studies were excluded from the synthesis of results.

14.20 A large proportion of the studies only looked at how well puberty was suppressed (expected effects) and at side effects, with fewer looking at the other intended outcomes. There was evidence from multiple studies that puberty suppression exerts its expected physiological effect, and this has never been at issue.

Figure 35: Outcome categories by study quality and design (puberty blockers)



Source: Taylor et al: Puberty Suppression

Intended benefits

14.21 As set out in Explanatory Box 5, an indication for a drug is the purpose for which it is prescribed. As the Review has progressed it has become more difficult to be clear about the indications for puberty blockers in this population of young people.

14.22 As explained above, when the Dutch gender clinic first started using puberty blockers to pause development in the early stages of puberty, it was hoped that this would lead to a better cosmetic outcome for those who went on to medical transition and would also aid diagnosis by buying more time for exploration. Since then, other proposed benefits have been suggested, including improving dysphoria and body image, and improving broader aspects of mental health and wellbeing.

Buying time to think/explore

14.23 The University of York's systematic review of care pathways (Taylor et al: Care pathways) reported that 0-8% of young people discontinued puberty suppression. Compared to those who continued with treatment, young people who discontinued had initiated treatment at an older age and included a higher proportion of those with mental health and autism spectrum conditions. In the gender clinic with a discontinuation rate of 8% (6 of 73), median age at start of treatment was 15.2 years (range 15.0-15.6 years) and all were post-pubertal at presentation.

14.24 In the UK early intervention study (Carmichael et al., 2021), 98% (43 of 44) of those who started on puberty suppression progressed to masculinising/feminising hormones. A more recent discharge study (Butler et al., 2022) looked at 1,089 patients referred from GIDS to the paediatric endocrine clinic. It showed that 7.4% (16 of 217) of those under 16 at referral discontinued puberty blockers.

14.25 These data suggest that puberty blockers are not buying time to think, given that the vast majority of those who start puberty suppression continue to masculinising/feminising hormones, particularly if they start earlier in puberty. It was on the basis of this finding that the High Court in Bell v Tavistock suggested that children/young people would need to understand the consequences of a full transition pathway in order to consent to treatment with puberty blockers ([2020] EWHC 3274 (Admin)).

Reducing gender dysphoria/improving body satisfaction

14.26 Only two moderate quality studies looked at gender dysphoria and body satisfaction; the original Dutch protocol (de Vries et al., 2011b) and the UK early intervention study (Carmichael et al., 2021). Neither reported any change before or after receiving puberty suppression.

Psychological and mental health improvements

14.27 As outlined in Chapter 2, the original Dutch protocol (de Vries et al., 2011b) found improvements in mental health in a pre-post study without a comparison group, but the GIDS early intervention study (Carmichael et al., 2021) did not replicate this finding. The systematic review on interventions to suppress puberty (Taylor et al: Puberty suppression) identified one other good quality study (van der Miesen et al., 2020), which produced an intermediate result with improvements in some mental health measures but not others.

14.28 The University of York concluded that there is insufficient and/or inconsistent evidence about the effects of puberty suppression on psychological or psychosocial health. This is in line with the finding of the NICE review (2020) and other systematic reviews, apart from the systematic review commissioned by WPATH (Baker et al., 2021), which reported some benefit. However, in the latter systematic review,

eight of the 12 studies reporting psychological outcomes were rated as low quality, which may explain the difference.

14.29 It is often the case that when an intervention is given outside a randomised control trial (RCT), a large treatment effect is seen, which sometimes disappears when an RCT is conducted. This is especially the case when there is a strong belief that the treatment is effective. The fact that only very modest and inconsistent results were seen in relation to improvements in mental health, even in the studies that reported some psychological benefits of treatment with puberty blockers, makes it all the more important to assess whether other treatments may have a greater effect on the distress that young people with gender dysphoria are suffering during puberty.

Cosmetic outcomes/'passing' in adult life

14.30 The Multi-Professional Review Group (MPRG) request a letter from young people being put forward for puberty blockers so they can ensure that they hear the young person's voice and understand their aspirations. The MPRG have now reviewed approximately 200 such letters. As explained in Chapter 12, many young people are living 'in stealth' and consequently often in a state of considerable anxiety about developing pubertal changes that may 'out' them to their friends. However, since most young people are not starting puberty blockers until the age of 15 and above, it is unclear how helpful they might be in maintaining stealth, particularly for birth-registered girls who will often be in the later stages of puberty by that time.

14.31 In the longer-term, being able to 'pass' is of great importance to some transgender adults, and not to others. Although there is a lack of long-term outcome data for children and young people in adult life, the Review team has been able to talk to both young people and older adults about their experience of early access to puberty blockers. This has been particularly important for the transgender women, who were able to access puberty blockers before developing facial hair and dropping their voice.

14.32 In terms of helping young people to 'pass' in adult life, an important question is what impact puberty blockers might have on adult height for those who subsequently go on to masculinising/feminising hormones. Evidence to date suggests that puberty blockers neither lead to substantially reduced adult height in transgender females (Boogers et al., 2022), nor increased eventual height in transgender males (Loi-Koe et al., 2018). This is an important issue for further research.

Risks

14.33 When the use of puberty blockers was introduced by the Dutch clinic, the target population was patients who had been gender incongruent since childhood. Prior to the introduction of puberty blockers, the clinical experience of that group suggested that although in the vast majority the gender incongruence resolved by puberty, for those for whom persisted into puberty, a long-term transgender identity was more likely.

14.34 For the more recently presenting population of predominantly birth-registered females who develop gender dysphoria in early to mid-puberty, there is even less understanding of what in medical terms is called the 'natural history' of their gender dysphoria (that is, what would happen without medical intervention). Because an intervention intended for one group of young people (predominantly pre-pubertal birth-registered males) has been given to

a different group, it is hard to know what percentage of these young people might have resolved their gender-related distress in a variety of other ways.

14.35 Earlier, this Report set out the very complex events that take place in the adolescent brain during puberty. Neuroscientists believe that these changes are driven by a combination of chronological age and sex hormones. Blocking the release of these sex hormones could have a range of unintended and as yet unidentified consequences.

Altering the trajectory of development of sexuality and gender identity

14.36 Adolescence is a time of overall identity development, sexual development, sexual fluidity and experimentation.

14.37 Blocking this experience means that young people have to understand their identity and sexuality based only on their discomfort about puberty and a sense of their gender identity developed at an early stage of the pubertal process. Therefore, there is no way of knowing whether the normal trajectory of the sexual and gender identity may be permanently altered.

Impact on neurocognitive development

14.38 A further concern, already shared with NHS England (July 2022) (Appendix 6), is that adolescent sex hormone surges may trigger the opening of a critical period for experience-dependent rewiring of neural circuits underlying executive function (i.e. maturation of the part of the brain concerned with planning, decision making and judgement). If this is the case, brain maturation may be temporarily or permanently disrupted by the use of puberty blockers, which could have a significant impact on the young person's ability to make complex risk-laden decisions, as well as having possible longer-term neuropsychological consequences.

14.39 The University of York's systematic review identified one cross-sectional study that measured executive functioning. This found no difference between adolescents who were treated with puberty blockers for less than one year compared to those not treated, but found worse executive functioning in those treated for more than one year compared to those not treated (Taylor et al: Puberty suppression).

14.40 A recent review of the literature on this topic found very limited research on the short-, medium- or longer-term impact of puberty blockers on neurocognitive development (Baxendale, 2024).

Impact on subsequent genital surgery

14.41 If puberty suppression is started too early in birth-registered males it can make subsequent vaginoplasty (creation of a vagina and vulva) more difficult due to inadequate penile growth. In some transgender females this has necessitated the use of gut in place of penile tissue, which has a higher risk of surgical complications.

14.42 A recent paper suggests that for transgender females it is recommended to wait until Tanner Stage 4 to allow adequate penile growth for vaginoplasty (Lee et al., 2023).

Other physical health impacts

14.43 Multiple studies included in the systematic review of puberty suppression (Taylor et al: Puberty supression) found that bone density is compromised during puberty suppression, and height gain may lag behind that seen in other adolescents. However, much longer-term follow-up is needed to determine whether there is full bone health recovery in adulthood, both in those who go on to masculinising/feminising hormones and those who do not.

14.44 The same is true of other short-term physical effects of puberty suppression, with little knowledge about whether it leads to any long-term effects, such as on metabolic health and weight.

Prolonged exposure to puberty suppression

14.45 Puberty suppression was never intended to continue for extended periods, so the complex circumstances in which young people may remain on puberty blockers into adulthood is of concern. In some instances, it appears that young adults are reluctant to stop taking puberty blockers, either because they wish to continue as non-binary, or because of ongoing indecision about proceeding to masculinising or feminising hormones. For others, there may have been a delay in adult services taking over their care.

Summary – puberty blockers

14.46 There are many reports that puberty blockers are beneficial in reducing mental distress and improving the wellbeing of children and young people with gender dysphoria, but as demonstrated by the systematic review the quality of these studies is poor.

14.47 The Review has heard that the widespread claims that puberty blockers reduce the risk of death by suicide in this population may place pressure on families to obtain private treatment.

14.48 The Review has also heard from GPs who have been put under pressure to continue prescribing such treatments on the basis that failing to do so will put young people at risk of suicide.

14.49 The University of York systematic review found no evidence that puberty blockers improve body image or dysphoria, and very limited evidence for positive mental health outcomes, which without a control group could be due to placebo effect or concomitant psychological support.

14.50 It is important not to lose sight of the fact that hormonal surges are a normal part of puberty and are known to lead to mood fluctuations and depression, the latter particularly in girls.

14.51 It is not unexpected that blocking these surges may dampen distress and improve psychological functioning in the short-term in some young people, but this may not be an appropriate response to pubertal discomfort.

14.52 Conversely, a known side effect of puberty blockers on mood is that it may reduce psychological functioning. This variability in individual response to predicted physiological effects is reflected in the secondary analysis of the GIDS early intervention study (McPherson & Freedman, 2023).

14.53 The very strongly held beliefs amongst some young people and parents/carers that puberty blockers are highly efficacious may be attributed to a number of factors:

- the support for this position in published papers and from some clinicians working in the field
- signposted information and advice provided to children, young people and their families on the perceived benefits, including on social media
- the fact that puberty blockers have come to be seen as the entry point into and start of a transgender treatment pathway
- a lack of information about the limitations of the evidence base
- the lack of other options offered to address symptoms of distress and bodily discomfort.

14.54 The focus on puberty blockers and beliefs about their efficacy has arguably meant that other treatments (and medications) have not been studied/developed to support this group, doing the children and young people a further disservice.

14.55 Studies should evaluate whether simple measures such as stopping periods with the contraceptive pill have the potential to manage immediate distress, as well as other more conventional evidence-based techniques for managing depression, anxiety and dysphoria. None of these alternative approaches preclude continuing on a transition pathway, but they may be more effective measures for short-term management of distress.

14.56 Transgender males masculinise well on testosterone, so there is no obvious benefit of puberty blockers in helping them to 'pass' in later life, particularly if the use of puberty blockers does not lead to an increase in adult height.

14.57 For transgender females, there is benefit in stopping irreversible changes such as lower voice and facial hair. This has to be balanced against adequacy of penile growth for vaginoplasty, leaving a small window of time to achieve both these aims.

14.58 In summary, there seems to be a very narrow indication for the use of puberty blockers in birth-registered males as the start of a medical transition pathway in order to stop irreversible pubertal changes. Other indications remain unproven at this time.



15. Masculinising/feminising hormones

15.1 The use of masculinising/feminising hormones in transgender adults was pioneered by Magnus Hirshfield in the first half of the 20th century. It is a well-established practice that has transformed the lives of many transgender people.

15.2 Treatment with masculinising/feminising hormones is not without long-term problems and side effects, but for those who have undergone a successful transition, the physical costs are dramatically outweighed by the long-term benefits.

15.3 The use of masculinising/feminising hormone in those under age 18 is a more recent development that started in the late twentieth century (Carswell et al., 2022), so is less well understood. As set out in Part 3, it is not the practice of masculinising/feminising hormones that has changed more recently, but the heterogeneous population of people seeking this treatment.

15.4 Studies looking at outcomes of those taking masculinising/feminising hormones are not straightforward. As is the case with puberty blockers, the desired effects - in this case masculinisation/feminisation - are predictable and well understood. Understanding side effects and longer-term complications are important for the health of the transgender community, but in terms of patient choice are unlikely to have a major impact on treatment decisions.

15.5 The key questions are therefore, what are the short- and long-term outcomes in terms of mental health, psychosocial functioning, quality of life and satisfaction with gender transition including sexual functioning?

International practice

15.6 The University of York's synthesis of commissioned guidelines (Taylor et al: Guidelines 2: Synthesis) found that almost all international guidelines discuss the use of masculinising/feminising hormones.

15.7 Most require that gender dysphoria or incongruence has persisted over time and that an individual has the capacity to consent to taking these hormones as part of their treatment. Most also reference age 16 as a typical starting point, but a smaller number specify this as a minimum age.

15.8 In some guidelines, other requirements are that mental health difficulties are managed/unlikely to impact treatment. Some guidelines require parental consent and/or family/social support.

15.9 Only the Swedish and Finnish guidelines recommend that hormone treatment is given under a research framework or in exceptional circumstances.

15.10 The majority of guidelines recommend providing information on the impact of hormones and surgery on fertility, and fertility preservation measures.

15.11 The Swedish and WPATH guidelines mention the need to support those who discontinue treatment or detransition, but no detail is provided on how this should be managed.

15.12 Most guidelines recommend that gender is viewed as a spectrum, but only three discuss treatment for those who identify as non-binary. The Swedish and Norwegian guidelines do not recommend hormone treatments in this group due to lack of evidence, whilst WPATH recommends providing tailored hormones treatments in a separate chapter on non-binary people, rather than in the adolescent chapter, so it is unclear if this applies to adults only or includes adolescents.

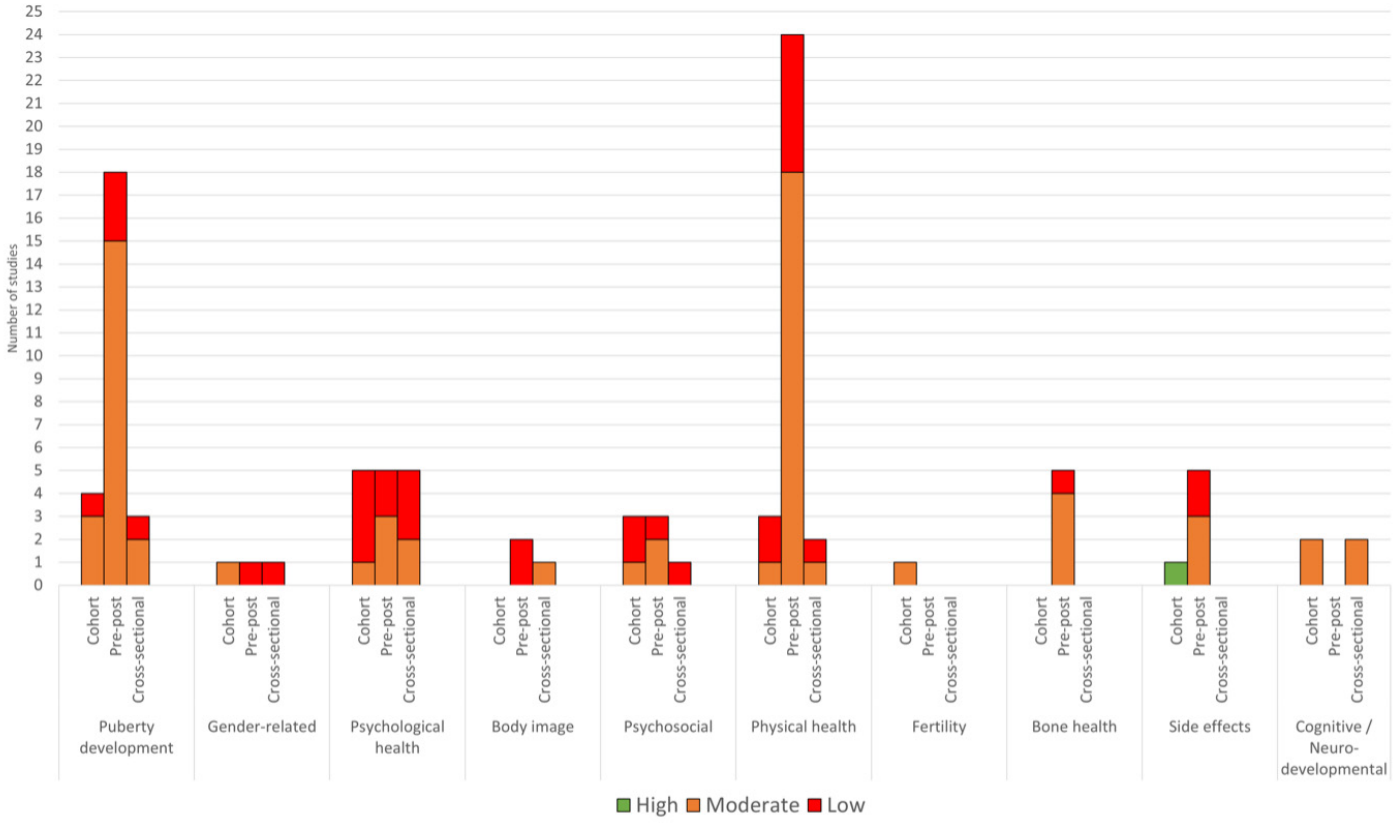
15.13 The international survey (Hall et al: Clinic survey) found that in practice most gender clinics require stable mental health in those prescribed masculinising/feminising hormones. Some clinics have no minimum ages, and the range for those that do is 14-16. There is also variation in the required duration of gender dysphoria, ranging from since childhood to long-lasting/permanent and stable, or stable over two years.

15.14 Most gender clinics provide access to fertility preservation services.

Understanding the evidence

15.15 In addition to the systematic review on care pathways (Taylor et al: Care pathways) discussed in Chapter 13, the University of York conducted a systematic review of the use of masculinising/feminising hormones in adolescents with gender dysphoria (Taylor et al: M/F hormones). This systematic review aimed to synthesise the evidence for gender-related, psychosocial, physiological or cognitive outcomes for the use of masculinising/feminising hormones in adolescents with gender dysphoria/incongruence.

Figure 36: Outcome categories by study quality and design (masculinising/feminising hormones)



Source: Taylor et al: M/F hormones

15.16 A total of 53 studies met the inclusion criteria. The most frequently reported outcomes were adverse physical health outcomes and the intended development of puberty in the identified gender. A smaller number of studies looked at side effects in relation to bone health and fertility.

15.17 Psychological/mental health was measured in 15 studies, psychosocial in seven, and cognitive outcomes in four. Gender dysphoria and body satisfaction were each measured in three studies.

15.18 The only high-quality study identified by the systematic review was one that looked at side effects. All the rest were moderate or low quality.

15.19 The studies had many methodological problems including the selective inclusion of patients, lack of representativeness of the population, and in many of the studies there were no comparison groups. Where there was a comparison group, most studies did not control for key differences between groups.

15.20 As expected, hormone treatment induced puberty in the desired gender. Inconsistent results were found for height/growth, bone health and cardiometabolic health. Evidence relating to gender dysphoria, body satisfaction, psychosocial and cognitive outcomes was insufficient to draw clear conclusions. No study assessed fertility in birth-registered females.

15.21 There was moderate quality evidence from mainly pre-post studies that hormone treatment may improve psychological health in the short-term.

15.22 There were inconsistencies regarding suicidality and/or self-harm, with three of four studies reporting an improvement and one no change.

15.23 A significant weakness of the studies evaluating psychological or psychosocial function was the short follow-up interval, with many following-up for less than 1 year, and a smaller number for up to 3 years.

15.24 The University of York also looked at studies published since the original search for the systematic review. Two further studies were reported, which added to the moderate quality evidence that hormones may improve psychological health.

15.25 Overall, the systematic review authors concluded that: “There is a lack of high-quality research assessing the outcomes of hormone interventions in adolescents with gender dysphoria/incongruence, and few studies that undertake long-term follow up. No conclusions can be drawn about the effect on gender dysphoria, body satisfaction, psychosocial health, cognitive development, or fertility. Uncertainty remains about the outcomes for height/growth, cardiometabolic and bone health. There is suggestive evidence from mainly pre-post studies that hormone treatment may improve psychological health although robust research with long-term follow-up is needed”. This is in line with other systematic reviews published previously (Ludvigsson et al., 2023).

Key considerations

Mental health and psychosocial outcomes

15.26 It is not just the methodological issues highlighted that make it hard to draw firm conclusions about the role of masculinising/feminising hormones in mental health and psychosocial outcomes. There are important clinical considerations that complicate the picture.

15.27 When a young person has been on puberty blockers, a short-term boost in mental wellbeing is to be expected when sex hormones are introduced. Testosterone is faster to produce physical changes than oestrogen, and birth-registered girls can expect to start seeing body changes in line with their identified gender within a few months. The start of long anticipated physical changes would be expected to improve mood, at least in the short term, and it is perhaps surprising that there is not a greater effect size. However, much longer-term follow-up is needed to understand the full psychological impact of medical transition.

15.28 Discussions in Chapter 11 touched on whether mental health problems may be caused by gender dysphoria and minority stress or whether in some instances a range of adverse childhood experiences and stressors could lead to gender-related distress. Regardless of causality, the focus should be on treating all the young person's needs, rather than expecting that hormone treatment alone will address longstanding mental ill health.

15.29 This point is illustrated in a recent Australian paper (Elkadi et al., 2023), which reviewed outcomes of a clinic cohort of young people 4-9 years post presentation. At initial assessment 70 of 79 (88.6%) received comorbid mental health diagnoses or displayed other indicators of psychological distress. A diagnosis of gender dysphoria was received by 68 young people who were deemed eligible for a gender-affirming pathway. Of these, six stopped medical treatment, three while on puberty blockers alone and three after starting on masculinising/feminising hormones. Where follow-up data were available, ongoing mental health concerns were reported by 44 of 50 participants (88.0%), and educational/occupational outcomes varied widely.

15.30 Recent national register-based studies from Finland and Denmark have been published that examine mental health needs of people presenting to specialist gender services before and after treatment. Using data from a national health register is a much more robust way of capturing total population data. Both studies compared those presenting to the gender services with age-matched controls.

15.31 The Danish national register-based study of 3,812 transgender people examined a range of outcomes in routine health records compared to age-matched controls (Glintborg et al., 2023). This was a mixed group of adults and children/young people. Follow-up was a maximum of 10 years after diagnosis.

15.32 At baseline, transgender persons were five times more likely than controls to have mental health disorders. The proportion of transgender persons with a prescription for psychopharmacological agents (medications to treat mental health) increased from less than 20% at baseline to more than 30% during follow-up. After the first year of treatment, there was a decreasing trend for the risk of mental and behavioural disorders in transgender persons, but they still remained at higher risk than controls throughout follow-up, especially transgender persons registered male at birth.

15.33 This demonstrates how difficult it is to separate out and understand the impact of the various elements of care; for example, the extent to which psychopharmacological treatments improve mental health, and how much of the improvements is a result of gender-affirming treatment.

15.34 The Finnish paper (Russka et al., 2024) identified 3,665 individuals between 1996 and 2019. Again, this was a mixed group of children, young people and adults. The gender dysphoria group had received many times more specialist-level psychiatric treatments, both before and after contacting gender services, than their matched controls. There was also a marked increase over time in psychiatric needs in 2016-2019 compared to 1996-2000. The need for psychiatric support persisted, regardless of gender-affirming treatment.

15.35 In summary, both young people and adults presenting with gender dysphoria often have complex additional mental health needs. It is hard to know the extent to which hormone treatment mitigates these issues, and the role played by treatment and support in the additional ongoing mental health issues.

Suicidality

15.36 As discussed in Part 3, it is well established that children and young people with gender dysphoria are at increased risk of suicide, but suicide risk appears to be comparable to other young people with a similar range of mental health and psychosocial challenges. Some clinicians feel under pressure to support a medical pathway based on widespread reporting that gender-affirming treatment reduces suicide risk. This conclusion was not supported by the University of York's systematic review (Taylor et al: M/F hormones).

15.37 Commonly suggested reasons for the suicidality in the gender diverse population are:

- the inherent distress from the gender dysphoria
- minority stress due to discrimination and bullying
- distress caused by delayed access to medical treatment
- underlying co-occurring mental health problems that are common in the population.

15.38 A systematic review of suicide-related outcomes following gender-affirming treatment (Jackson, 2023) reported that in a majority of studies there was a reduction in suicidality following gender-affirming treatment. However, there were major methodological problems in most of the studies, with the biggest problem being a failure to adequately control for the presence of psychiatric comorbidity and treatment, such that no firm conclusions could be drawn.

15.39 A UK paper (Lavender et al., 2023) reporting a retrospective analysis of 38 children who had received puberty blockers followed by masculinising/feminising hormones noted that suicidality and self-harm showed a general decrease. However, there had been 109 eligible participants, and of the 38 included in the study only 11 had completed the suicidality/self-harm questions, rendering this observation flawed.

15.40 The authors of a paper reporting on psychosocial outcomes of 315 young people treated with masculinising/feminising hormones (Chen et al., 2023) stated that the most common adverse event was suicidal ideation (11 participants [3.5%]) and two participants [0.6%] died by suicide. Suicidality at baseline was one of the exclusion criteria for this study.

15.41 A paper from the Belgium gender clinic reported five deaths by suicide among 177 adolescents clients aged 12-18 years who were seen between 2007 and 2016 (Van Cauwenberg et al., 2021) All five had commenced on masculinising/feminising hormones.

15.42 Another recent paper (Ruuska, 2024), compared deaths by suicide in young people who had been seen in the Finnish national gender service with age-matched controls. The study also did not find a statistically

significant link between hormone treatment and reduced risk of suicide. However, there was a statistically significant relationship between a high rate of co-occurring mental health difficulties and increased suicide. Because suicides were fortunately very rare events, regardless of transition status, it is hard to draw firm conclusions from this study.

15.43 In summary, the evidence does not adequately support the claim that gender-affirming treatment reduces suicide risk. However, the distress is real for these children and young people, some of whom hold strong beliefs about the efficacy of both puberty blockers and masculinising/feminising hormones. This will be exacerbated by long waits to be seen in specialist gender services with only internet and peer group sources of support and information, and without access to clinical advice on the range of available options to manage their distress. Thus, fear that delayed access to medical treatment may lead to suicidal thoughts and behaviours remains high in parents and clinicians, and this is regardless of how effective the treatments may be once accessed.

Detransition

15.44 The term detransition is generally used to describe people who have previously medically/surgically transitioned and then reverted to their birth-registered gender. It is not necessarily applied to those who have a period of trans identification, potentially with a social transition, and later revert to live as their birth-registered gender. This tends to be referred to as 'desistance'.

15.45 During the lifetime of the Review, the term trans has moved from being a quite narrow definition to being applied as an umbrella term to a broader spectrum of gender diversity. This clearly has implications for conceptualisations of detransition.

15.46 Narratives around detransition and regret have become increasingly fraught and weaponised in the time since the Review started. Initially, the Review heard from those who strongly support gender-affirming care and contested that cases are vanishingly rare and are mostly a response to lack of acceptance and minority stress.

15.47 Over time there has been an increasing acceptance that people choose to detransition for many reasons. The term has been rebadged by some as 'retransition'. Some young adults who have detransitioned have told the Review that they would not want their experience to be used to invalidate that of other people.

> "I felt like it wasn't, you know, acceptable to go back. It wasn't a thing to go back, you know. It wasn't something that was talked about. It didn't feel like an option that they wanted to discuss or even mention […] I want detransition to be something that can be openly talked about, and regret to be openly talked about."
>
> **Young person**
> **University of York Qualitative Summary**

15.48 Young people may also choose to stop hormone treatment but carry on identifying as transgender or non-binary.

15.49 A retrospective case note review from an NHS adult GDC (Hall et al., 2021) reported on the outcomes of 175 consecutively discharged service users; 12 cases (6.9%) met the criteria for detransitioning, and a further six had some ongoing uncertainties about their gender identities or treatment goals.

15.50 Estimates of the percentage of individuals who embark on a medical pathway and subsequently have regrets or detransition are hard to determine from GDC clinic data alone. There are several reasons for this:

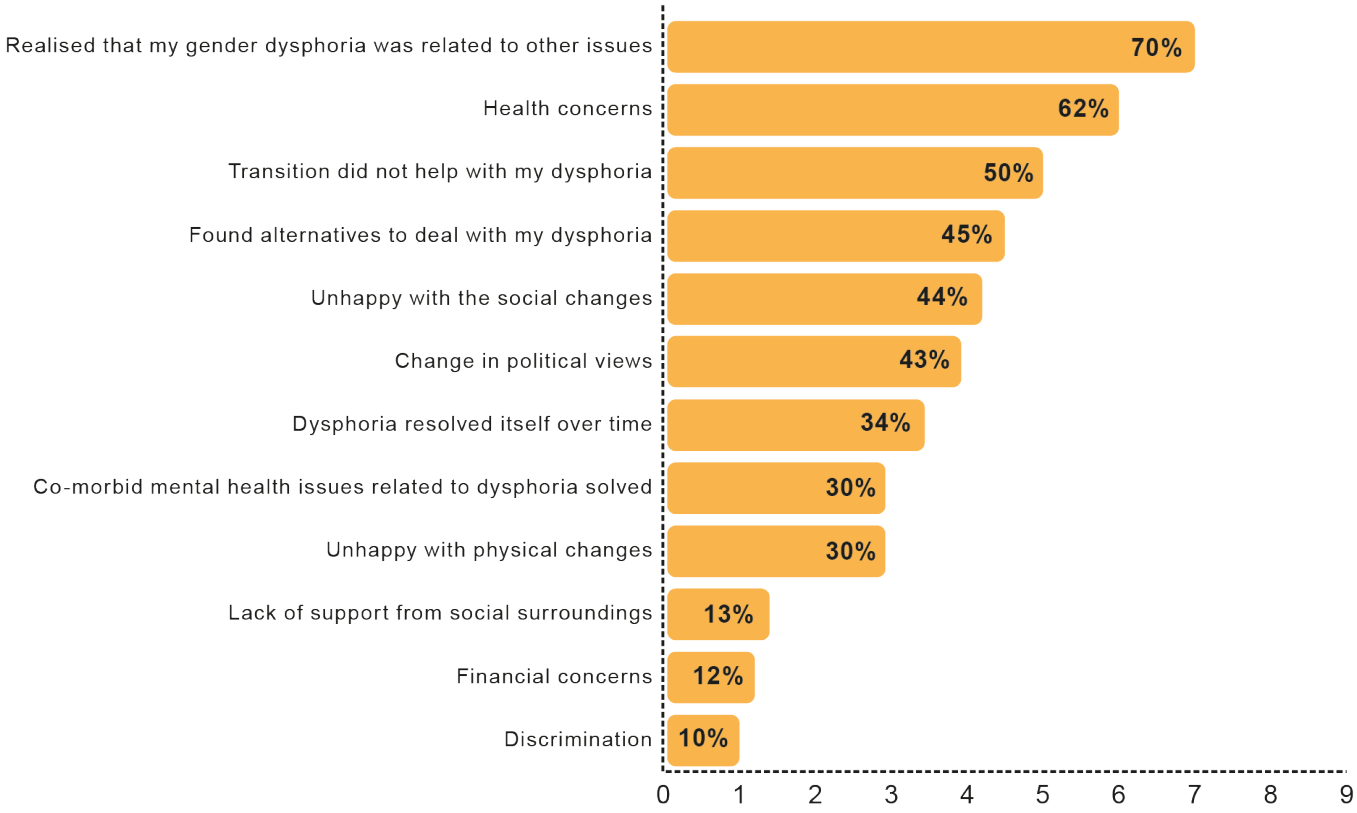
- those who do detransition may not choose to return to the gender clinic and are hence lost to follow-up
- the Review has heard from a number of clinicians working in adult gender services that the time to detransition ranges from 5-10 years, so follow-up intervals on studies on medical treatment are too short to capture this
- the inflection point for the increase in presentations to gender services for children and young people was 2014, so even studies with longer follow-up intervals will not capture the outcomes of this more recent cohort.

15.51 One primary care audit from a multi-site general practice sited near a university (Boyd et al., 2022) reported on a cohort of 68 patients at various stages along the gender pathway with a mean age 27.8 years. Of 41 patients who were started on hormones, eight (20%) chose to stop after a mean period of 5 years (range 17 months to 10 years). These comprised six trans men and two trans women.

15.52 Regardless of the numbers who detransition, reasons for detransition are complex, and there is a lack of adequate service provision for this group of individuals who have a range of physical and psychological needs.

15.53 A self-identified sample of 100 detransitioners (Littman, 2021) completed an anonymous online questionnaire. Of these, 69% were birth-registered females and 31% were birth-registered males. A range of issues were reported prior to onset of gender dysphoria, including diagnosis of mental illness, neurodiversity, a history of trauma or self-injury. Reasons for detransition were diverse and included individuals becoming more comfortable in their natal sex, being concerned about medical complications of transitioning, that mental health did not improve during transitioning, being dissatisfied with physical results, and discovering gender dysphoria was caused by something specific such as trauma or abuse. Homophobia or difficulty accepting themselves as lesbian, gay or bisexual was expressed by 23.0% as a reason for transition and subsequent detransition.

Figure 37: Self-reported reasons for detransitioning



Source: Vandenbussche, E. (2021). Detransition-related needs and support: A cross-sectional online survey. Journal of Homosexuality, 69(9), 1602-1620. https://doi.org/10.1080/00918369.2021.1919479. Published with http://creativecommons.org/licenses/by-nc/4.0/ license by Taylor & Francis Group, LLC.

15.54 Figure 37 shows some of the reasons given for detransitioning in response to a cross-sectional online survey of 237 self-identified participants (Vandenbussche, 2022).

15.55 An audit was undertaken at The Tavistock and Portman GDC on the characteristics of individuals who had detransitioned. Most papers on detransition are based on community samples, and questionnaire reports, but this was a case series of 40 patients who had all been examined by a psychiatrist.

15.56 Findings from the audit were discussed with the Review. The time for people to choose to detransition was 5-10 years (average 7 years). Common presenting features and risk factors such as high levels of adverse childhood experiences, alexithymia (inability to recognise and express their emotions) and problems with interoception (making sense of what is going on in their bodies) were identified in the audit, and this audit would be informative for clinicians assessing young people with a view to starting masculinising/feminising hormones. The Review asked to have access to this audit in order to understand some of the qualitative findings, but the trust did not agree to this.

Long-term outcomes

15.57 One of the major difficulties with planning interventions for children and young people is the very limited evidence on the longer-term outcomes for people who have accessed GIDS.

15.58 When clinicians talk to patients about which interventions may be best for them, they usually talk about the longer-term benefits and risks of different options, based on outcome data from other people who have been through a similar care pathway. This information is not currently available for interventions in children and young people with gender incongruence or gender dysphoria, so young people and their families have to make decisions without an adequate picture of the potential impacts and outcomes.

15.59 A strand of the research the Review commissioned from the University of York was a data linkage study. The study aimed to use existing data held by the NHS, including data from GIDS, hospital wards, outpatient clinics, emergency departments and NHS adult GDCs, to track the journeys of all young people (approximately 9,000) referred to the GIDS service through the system to provide a population-level evidence base of the different pathways people take and the outcomes.

15.60 This type of research is usual practice in the NHS when looking to improve health services and care received. However, this has not been the case for gender-questioning children and young people and the hope was that this data linkage would go some way to redress this imbalance.

15.61 The study received ethics approval from the Health Research Authority (HRA), a process that took over a year. While the methodology proposed for the research is not particularly unusual, the robust scrutiny and consideration its Research Ethics Committee (REC) and Confidentiality Advisory Committee (CAG) applied to the study was entirely appropriate given the sensitivity of the subject matter.

15.62 The University of York undertook stakeholder engagement and developed the patient notifications and communications resources to explain the research and provide information about how to opt-out of the study should an individual choose to do so. It was at the point of trying to launch the 3-month opt-out period that the NHS gender clinics indicated their unwillingness to participate.

15.63 In January 2024, the Review received a letter (Appendix 11) from NHS England stating that, despite efforts to encourage the participation of the NHS gender clinics, the necessary co-operation had not been forthcoming.

15.64 This research represents a unique opportunity to provide further evidence to assist young people, their parents/carers and the clinicians working with them to make informed decisions about the right pathway for them.

15.65 Although retrospective research is never as robust as prospective research, a prospective study would take a minimum of 10-15 years to extract the necessary follow-up data.

15.66 NHS England in its letter has committed to realising the ambitions of this study beyond the life of the Review. As a single integrated health service, which for the period in question had one provider of specialist gender care for children and young people, the NHS offers a world leading opportunity to look at outcomes for around 9,000 patients and add to the evidence base.

15.67 NHS England will take over responsibility for this work and the NHS National Research Oversight Board for Children and Young People's Gender Services will support the task.

15.68 NHS England asked the Review for details on the circumstances that led the University of York to reach the conclusion that it was not yet possible to move ahead with the next stages of the data linkage study and specific recommendations for moving forward. The Review wrote to NHS England in March 2024 (Appendix 12).

Recommendation 5:

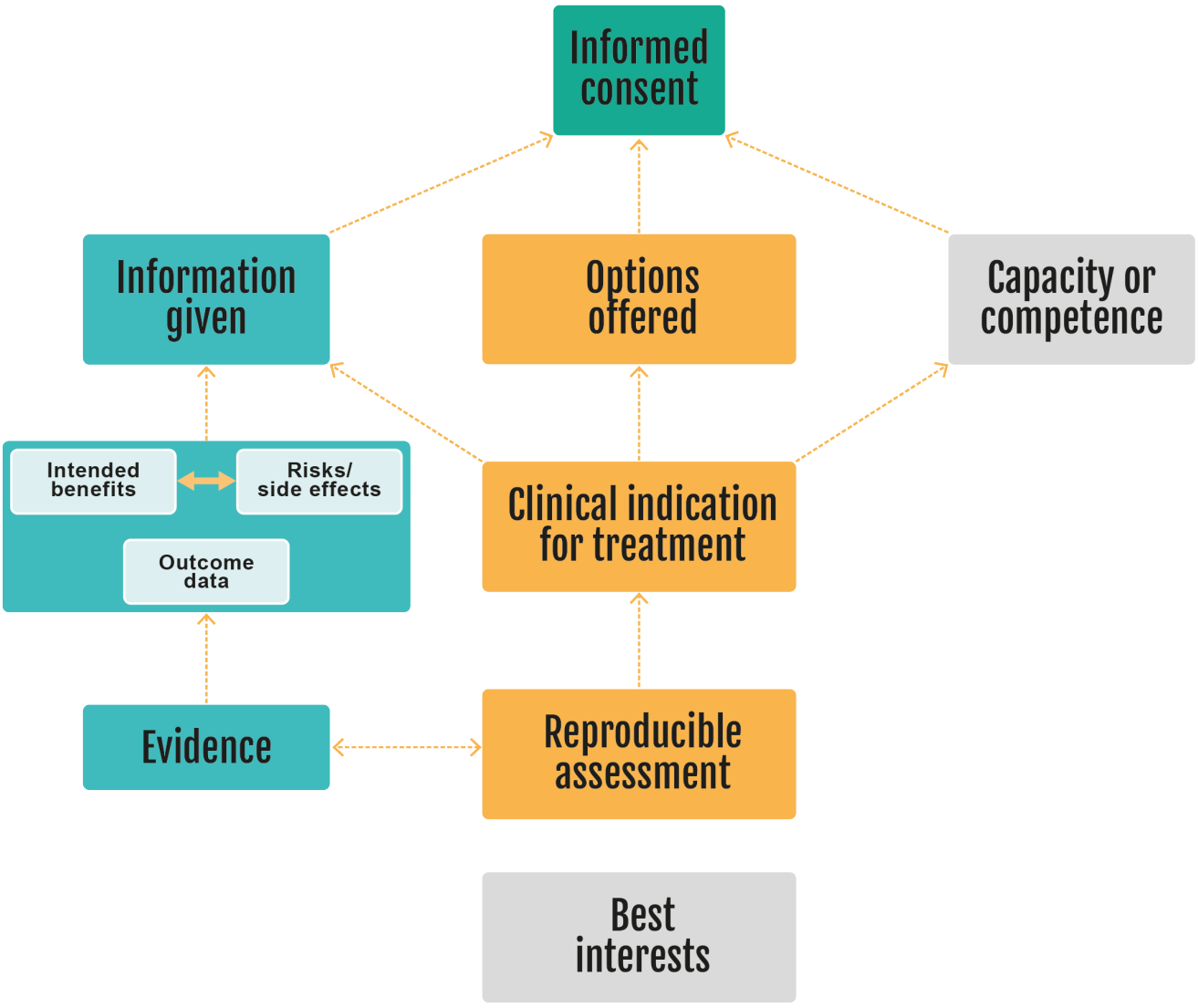
NHS England, working with DHSC should direct the gender clinics to participate in the data linkage study within the lifetime of the current statutory instrument. NHS England's Research Oversight Board should take responsibility for interpreting the findings of the research.

16. Challenges in clinical decision making

16.1 There was considerable public interest in the Bell v Tavistock case referenced in Chapter 2, which focused on competence/capacity of the child or young person to consent to medical treatments. However, this is only part of the process of decision making about treatment options.

16.2 The clinician must first decide what treatments options are appropriate/clinically indicated, and then provide the information that the patient needs in order to make an informed decision about the options offered.

Figure 38: Informed consent



16.3 GMC guidance (GMC, 2021) makes it clear that doctors are responsible for any prescriptions they provide and accountable for their decisions and actions when supplying or administering medicines. 'Prescribing' is used to describe many related activities, not just prescription medicines. For example, it can also include activities such as exercise, and it may also be used to describe any written information or advice that is given to patients; thus, in the context of gender services, this could reasonably be deemed to apply to any advice ranging from social transition to hormone treatments.

16.4 General Medical Council (GMC) guidance (GMC, 2024) states that a doctor must "propose, provide or prescribe drugs or treatment (including repeat prescriptions) only when [they] have adequate knowledge of the patient's health and are satisfied that the drugs or treatment will meet their needs".

16.5 There are multiple problems in making these judgements in this complex area of healthcare.

Assessing whether a treatment is clinically indicated

16.6 As discussed in Chapters 9 and 10, international guidelines on assessment of children and young people with gender incongruence or dysphoria lack clarity about purpose, content or duration. Formal assessment tools have not been adequately validated.

16.7 Although the most cited reasons for carrying out an assessment are to inform a care plan or assess eligibility for endocrine treatment, few guidelines provide detail about operational criteria for eligibility for puberty blockers or masculinising/feminising hormonal prescriptions. The Review was unable to obtain clear criteria from the GIDS team on their criteria for referral for endocrine intervention.

16.8 A formal diagnosis of gender dysphoria is frequently cited as a prerequisite for accessing hormone treatment. However, it is not reliably predictive of whether that young person will have longstanding gender incongruence in the future, or whether medical intervention will be the best option for them. Depending on what has caused their distress or dysphoria, it may be resolved by medical treatment, but it may also be resolved in other ways.

16.9 As discussed in Chapter 8, the nature and causes of gender dysphoria/incongruence are complex and poorly understood, and there is very limited understanding of the currently presenting population of predominantly birth-registered adolescent females. Each individual will have a different mix of biopsychosocial factors, but if potentially dynamic psychosocial or sociocultural factors predominate in a significant proportion of people, one of the most challenging ethical questions is whether and/or when medical intervention is the correct response.

16.10 As set out in the section on brain development, maturation continues into a person's mid-20s, and through this period gender and sexual identity may continue to evolve, along with sexual experience. Priorities and experiences through this period are likely to change, and this was reflected in the differences in feedback from young adults compared to teenagers. Furthermore, the Review heard accounts from young adults and parents about young people who felt certain about a binary gender identity in teenage years and then became more fluid in young adulthood or reverted to their birth-registered gender.

16.11 For these reasons, many clinicians who the Review has spoken to nationally and internationally have stated that they are unable to reliably predict which children/young people will transition successfully and which might regret or detransition at a later date.

16.12 Some commentators suggest that since there is no evidence that gender assessments by clinicians can reliably predict or prevent detransition/regret any better than self-reported gender identity and embodiment goals, services should adopt an 'informed consent' model of care (Ashley et al., 2023). This model may be used to support proceeding with gender affirming interventions based primarily or solely on the person's own assessment of the risks and benefits of a treatment, rather than a decision by the doctor about the different treatment options that may meet the patient's needs. This would also be in line with the views of some service users who see the assessment process as intrusive and 'gatekeeping'.

16.13 In the opinion of the Review, this is inconsistent with the approach to joint decision making with patients set out in the GMC's professional standards. These standards highlight the importance of doctors recommending, prescribing, or providing treatments only when they have adequate knowledge of the patient's health and are satisfied that the drugs or treatment will meet their needs (GMC, Prescribing 2021, Good medical practice 2024). Doctors must make sure the patient has the information they need to make a well-informed decision about the options for treatment (GMC, Decision making and consent 2020).

Best evidence and information

16.14 The University of York's systematic reviews demonstrated poor study design, inadequate follow-up periods and a lack of objectivity in reporting of results. As a result, the evidence for the indicated uses of puberty blockers and masculinising/feminising hormones in adolescents are unproven and benefits/harms are unknown.

16.15 In addition to this making it difficult for clinicians to know whether these are appropriate treatments to offer, it is also challenging to provide children, young people and families with sufficient information on which to make an informed choice.

16.16 Montgomery makes it clear that clinicians must not merely disclose information but also take reasonable care to ensure that patients are aware of material risks ([2015] UKSC 11). This is an active responsibility that involves assessing what the patient has understood.

16.17 This duty applies not just to the recommended treatments but also to any reasonable alternatives or treatments. This means that it would not be enough to discuss endocrine options, but also other non-endocrine options, as well as the pros and cons of delaying endocrine intervention.

16.18 The duty of information disclosure is complicated by many 'unknown unknowns' about the long-term impacts of puberty blockers and/or masculinising/feminising hormones during a dynamic developmental period when gender identity may not be settled.

16.19 For example, when young people commence on the hormones of their identified gender after a period of puberty suppression, they start to experience a sense of libido and a change in their physical appearance. Many report a period of 'gender euphoria'. This makes it surprising that the observed improvements

in psychological functioning in the first year of masculinising/feminising hormones are relatively modest. Their experience of puberty will then be based on their identified gender, which may have permanent neuropsychological effects.

16.20 For birth-registered females, the impact of testosterone will give a higher sex drive than they might have experienced during their biological puberty, and after one year will result in robust increases in muscle mass and strength (while birth-registered males will maintain their muscle strength) (Wiik et al., 2020). In the absence of any experience as an adult cis-woman, they may have no frame of reference to cause them to regret or detransition, but at the same time they may have had a different outcome without medical intervention and would not have needed to take life-long hormones.

16.21 There is no information on the natural history (that is, untreated trajectories) of the current cohort of predominantly birth-registered females presenting in early adolescence because endocrine interventions have been initiated.

16.22 Tragically deaths by suicide in trans people of all ages continue to be above the national average, but there is no evidence that gender-affirmative treatments reduce this. Such evidence as is available suggests that these deaths are related to a range of other complex psychosocial factors and to mental illness.

16.23 This raises the question of whether, for those who are in late adolescence and not on puberty blockers, managing any mental health problems, ensuring participation in education or work, supporting social transition and organising fertility preservation if required are more pressing issues than commencing masculinising/feminising hormones.

16.24 All of these difficult questions make provision of sound information and properly informed consent very challenging.

Competency and capacity to consent

16.25 Over the age of 16, the Mental Capacity Act 2005 presumes that a patient is able to make their own decision about their medical treatment - that is, choosing among the options made available to them - unless it is shown that they are unable to do so because they cannot understand or retain or use/weigh the information relevant to that decision because of an impairment or disturbance in the functioning of their mind or brain. The Family Law Reform Act 1969 s8 set out that the consent of a person aged 16 is as effective as the consent of a patient aged 18.

16.26 Under the age of 16, the ability to make the decision means having sufficient maturity and understanding to make the relevant decision ('Gillick competence').

16.27 Although as described in Chapter 4, in the Bell v Tavistock judgment, the Court of Appeal rejected the High Court's guidance on whether particular age groups would be likely to be able to make such decisions, these decisions would be uniquely difficult for children to be able to make for themselves, for all the reasons set out above.

16.28 The age for starting puberty blockers varies between clinics. Many guidelines have removed a lower age limit as puberty is now starting earlier than it was previously. This means that children as young as 9 can be started on treatment. However, such early treatment has not been the practice in the UK ([2021] EWCA Civ 1363).

16.29 Even at Tanner stages 2-3, young people have had minimal experience of their own biological puberty, and such experience as they have had may have been distressing for a wide range of reasons.

16.30 Once on puberty blockers, they will enter a period when peers are developing physically and sexually whilst they will not be, and they may be experiencing the side effects of the blocker. There are no good studies on the psychological, psychosexual and developmental impact of this period of divergence from peers.

16.31 However, if a young person is already on puberty blockers they will need to make the decision to consent to masculinising/feminising hormones at a point when their psychosexual development has been paused, and possibly with little experience of their biological puberty.

Best interests of the child/young person

16.32 For children and young people there may also need to be an assessment of best interests when it comes to making a choice among the treatment options which are made available, if they cannot make that decision for themselves. This must take account of the views, culture and beliefs of the child or young person, the parents and/or other close carers, as well as the views of other healthcare professionals involved in their care, or professionals involved in their welfare. Account should also be taken of "which choice, if there is more than one, will least restrict the child's or young person's future options" (GMC, 2018).

16.33 Best interests decisions are especially difficult where the proposed treatment is very significant, not readily reversible and the outcome of treatment is less predictable.

Conclusion

16.34 In considering endocrine interventions, the large number of unknowns regarding the risk/benefits in any one individual and the lack of robust information to help them make decisions present a major problem in obtaining informed consent.

16.35 The more fundamental issue though is determining the circumstances under which such treatments should be offered to children and young people in the first place.

16.36 A trusted source of information is needed on all aspects of medical care, but in particular it is important to defuse/manage expectations that have been built up by claims about the efficacy of puberty blockers.

16.37 Although younger people experience a sense of urgency to access medical treatments, some young adults have suggested that taking time to explore options is preferable.

16.38 The Review has already advised that because puberty blockers only have clearly defined benefits in quite narrow circumstances, and because of the potential risks to neurocognitive development, psychosexual development and longer-term bone health, they should only be offered under a research protocol. This has been taken forward by NHS England and the National Institute for Health and Care Research (NIHR).

16.39 The option to provide masculinising/feminising hormones from age 16 is available, but the Review would recommend an extremely cautious clinical approach. There should be a clear clinical rationale for providing hormones at this stage rather than waiting until an individual reaches 18. This would keep options open during this important developmental window, allowing time for management of any co-occurring conditions, building of resilience and fertility preservation, if required.

16.40 A more fundamental problem that has become more apparent as the Review has progressed is that research on psychosocial interventions and longer-term outcomes of those who do not access endocrine pathways is as weak as research on endocrine treatment. This leaves a major gap in our knowledge about how best to support and help this growing population of young people with gender-related distress in the context of complex presentations.

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16.41 The overarching conclusion from the evidence presented in this Review is that the puberty blocker trial, which is already in development, needs to be one part of a much broader research programme that seeks to build the evidence on all potential interventions, and to determine the most effective way of supporting these children and young people.

Recommendation 6:

The evidence base underpinning medical and non-medical interventions in this clinical area must be improved. Following our earlier recommendation to establish a puberty blocker trial, which has been taken forward by NHS England, we further recommend a full programme of research be established. This should look at the characteristics, interventions and outcomes of every young person presenting to the NHS gender services.

- The puberty blocker trial should be part of a programme of research which also evaluates outcomes of psychosocial interventions and masculinising/ feminising hormones.
- Consent should routinely be sought for all children and young people for enrolment in a research study with follow-up into adulthood.

Recommendation 7:

Long-standing gender incongruence should be an essential pre-requisite for medical treatment but is only one aspect of deciding whether a medical pathway is the right option for an individual.

Recommendation 8:

NHS England should review the policy on masculinising/feminising hormones. The option to provide masculinising/feminising hormones from age 16 is available, but the Review would recommend extreme caution. There should be a clear clinical rationale for providing hormones at this stage rather than waiting until an individual reaches 18.

Recommendation 9:

Every case considered for medical treatment should be discussed at a national Multi Disciplinary Team (MDT) hosted by the National Provider Collaborative replacing the Multi Professional Review Group (MPRG).

Recommendation 10:

All children should be offered fertility counselling and preservation prior to going onto a medical pathway.

Service model



This part looks at the service model for children and young people's gender services, clinical pathways, workforce and training, service improvement and research. It seeks to address the following aspects on which the Review has been asked to provide recommendations:

- pathways of care into local services, including clinical management approaches for individuals with less complex expressions of gender incongruence who do not need specialist gender identity services
- pathways of care into specialist gender identity services, including referral criteria into a specialist gender identity service and referral criteria into other appropriate specialist services
- current and future workforce requirements
- ongoing clinical audit, long-term follow-up, data reporting and future research priorities.

17. Existing service models

17.1 The interim report highlighted a number of issues in relation to the existing service model:

17.2 It is unusual for there to be direct referral into specialist services, as was the case for The Tavistock and Portman NHS Foundation Trust Gender Identity Development Service (GIDS). Early in the Review it became clear that referring a rapidly increasing number of children and young people into a single national service with insufficient links to local services was not working. The service did not have the ability to respond to the increasing demand and was not a safe or viable long-term option.

17.3 This has led to an increasingly long waiting list, which clinicians, young people and their parents/carers cite as the single biggest challenge in providing high quality care to gender dysphoric children and young people.

17.4 The long wait can further add to distress, result in deterioration of co-occurring mental health problems, and make it difficult for children and young people to explore the full range of options for addressing their gender-related distress.

17.5 Young people participating in the focus groups and the qualitative research study described how the lack of communication and support while waiting for specialist services meant they had to do their own research. They had often decided what they needed by the time they were seen by GIDS and had already taken steps to help manage how they felt, including social transition.

17.6 Parental and personal narratives described children and young people having more than one presenting issue, but services (for example, GIDS, CAMHS, general practice) dealing with each issue in isolation, without considering the impact of different issues on each other. This may include the impact of neurodivergence or significant mental health issues, including past history of eating disorders, experiences of loss and/or trauma and bullying.

17.7 Parents described how an absence of support following referral left them worried and frustrated, not knowing where to get help. The University of York qualitative study (Appendix 3) found that: “Parents express continuing uncertainties and doubts about what was best for their child. They worry about getting it “wrong”. They also worry about the extent to which services can understand their child and respond appropriately”.

17.8 In addition, young people and their families have highlighted that referral into a service with a single focus on gender raises the issue of ‘diagnostic overshadowing’. They described children having more than one presenting issue, but different services (for example, GIDS, CAMHS, general practice), dealing with each issue in isolation, without considering how they might impact on each other.

17.9 Lack of clarity over clinical responsibility for a child/young person following referral, and the fact that there has often been little or no preliminary assessment of risk and safeguarding, is also a cause for concern.

17.10 Addressing these issues requires a system-wide response. The Review’s interim report concluded that a fundamentally different service model is required, and the Review subsequently undertook stakeholder testing of different service models that would:

- increase capacity both at tertiary and secondary care level

- allow initial assessment at an early point in the patient pathway
- approach clinical management through a broader paediatric and mental health lens
- have a multi-disciplinary workforce able to take a holistic view of children and young people
- skill-up a wider range of clinicians to work with gender-questioning children and young people, thus democratising knowledge and expanding capacity through the system.

17.11 The Review also considered the practicalities:

- care needs to be provided as close to home as possible
- roles need to be attractive for recruitment and tap into as broad a range of skills as possible
- recruitment to tertiary centres should not destabilise local services.

17.12 In July 2022, the Review wrote to NHS England expanding its advice in the interim report (Appendix 6). The letter set out the key components of a regional networked model of care to ensure this population of children and young people receive the holistic service described in Part 4 at appropriate levels within the NHS.

17.13 The aim of the proposed new regionalised NHS gender service for children and young people is to provide a comprehensive patient and family-centred service and package of care, supporting children and young people who are questioning their gender identity or experiencing gender dysphoria to get on the right pathway for them as an individual.

NHS England's interim service – establishing Phase 1 providers

17.14 Since receiving the Review's interim report, NHS England has taken steps to increase capacity and manage the closure of GIDS, establishing two new nationally networked services to be led by specialist children's hospitals. This is the first step in commissioning a network of regional services across the country over the coming years.

17.15 These Phase 1 service providers will take over clinical responsibility for seeing children and young people on the national waiting list, as well as providing continuity of care for the GIDS open caseload at the point of transfer as part of a managed transition of the service.

17.16 There have been delays due to the complexity of the programme and the phenomenal challenge of building the new service. This has meant designing and commissioning a new clinical and service model rather than simply transferring the existing model across to the Phase 1 providers. There has also been the need to recruit and train a clinical workforce to meet the requirements of the new service.

17.17 The Review had hoped to take learning from the clinicians seeing the patients in the interim services, about the characteristics of the patient cohort and optimum pathways of care. Instead, it has gained insight and learning from the considerable challenges faced in establishing the interim service. These have included: how best to manage the existing caseload and the recruitment to and training of staff for the new services.

Existing caseload

17.18 One of the key challenges in establishing the interim service has been the transfer of the open caseload. This has proven difficult in light of a lack of information on the patient cohort and the expectations of young people and their families/carers who have started care under a different clinical model.

17.19 Although representatives of GIDS have been involved in these discussions, the transfer of information to the new providers about the open caseload has proven challenging as the characteristics of the population have been difficult to ascertain. The situation is similar for those on the waiting list.

Recruitment and training

17.20 The reluctance of clinicians to engage in the clinical care of gender-questioning children and young people was recognised earlier in this report. Clinicians cite this stems from the weak evidence base, lack of consistent professional guidance and support, and the long-term implications of making the wrong judgement about treatment options. In addition, concerns were expressed about potential accusations of conversion practice when following an approach that would be considered normal clinical practice when working with other groups of children and young people.

17.21 Throughout the Review, clinicians working with this population have expressed concerns about the interpretation of potential legislation on conversion practices and its impact on the practical challenges in providing professional support to gender-questioning young people. This has left some clinical staff fearful of accepting referrals of these children and young people.

17.22 Clinical staff must not feel that discharging their clinical and professional responsibility may expose them to the risk of legal challenge, and strong safeguards must be built into any potential legislation on conversion practices to guard against this eventuality. This will be of paramount importance in building (as opposed to diminishing) the confidence of clinicians working in this area. Any ambiguity could serve to further disadvantage these children and young people rather than support them.

17.23 Clinicians are being asked to work within a highly emotive and politicised arena. This, coupled with concerns about the weakness of the evidence base and a lack of professional guidance, has impacted on the ability of the new services to recruit the appropriate multi-disciplinary workforce.

17.24 For these reasons, whilst the Review welcomes the first step NHS England has taken to begin to establish a regional model of care, it maintains that a much more distributed model of care is needed to meet current demand and provide a more appropriate holistic, localised and timely approach to care for children and young people needing support around their gender identity.

17.25 This means services should not be located solely in tertiary centres. A much broader based service model is needed with a flexible workforce working across a regional footprint in partnership with designated local specialist services.

International practice

17.26 The University of York looked at how services are organised in other health systems.

17.27 Each of these models considers the gender service in isolation. However, models of care that deliver a clinical service over multiple sites have the potential to maintain geographical access to services whilst improving quality of care and optimising the use of the workforce.

Figure 39: Variations in service models for specialist gender care



Fully integrated multi-disciplinary team

eg. Netherlands



Psychologically focused gender clinic with separate but linked endocrine service

eg. UK, Finland



Endocrinology focused gender clinic with referral to external mental health professionals if appropriate

eg. USA, Canada

NB: These are just exemplars of models that have been described within different countries, but there is also considerable within-country variation.

Different service models in the NHS

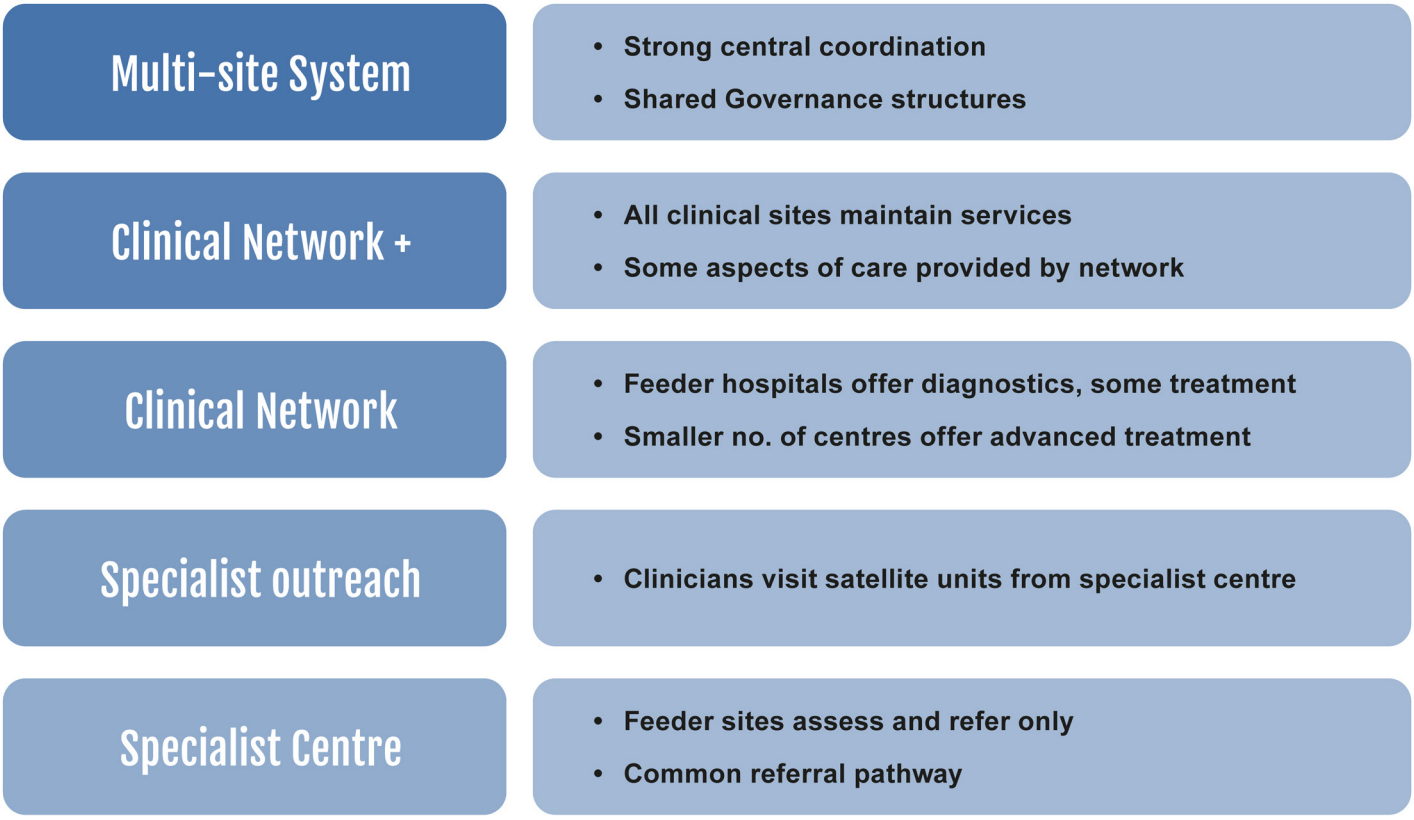
17.28 A systematic review of 'multiple site single service' models of care was published by Public Health England (2019) and described a number of such models.

17.29 The interim service, with two initial hubs, is a 'specialist centre' model of care that involves a specialist ('tertiary') centre accepting referrals from feeder hospitals in a defined geographical area. This is intended as a step towards a clinical network approach.

17.30 'Specialist outreach' involves clinicians from a specialist centre travelling out from the centre to smaller sites to offer some elements of peer support, clinical advice and/or patient care. Many specialties in both paediatric and adult care deliver outreach clinics. GIDS operated this model, running outreach clinics in various locations around the UK.

17.31 'Clinical network' describes a network in which a specialist centre provides specialist treatment to patients who reside in a defined area, but whose feeder hospitals complete some form of initial assessment, diagnostics and medical management before transferring the patient. This is the model NHS England consulted on for its interim services: secondary care provides initial assessment before referring a patient to the specialist centres.

Figure 40: Descriptive framework describing different types of multiple site, single service models of care



Source: Public Health England (October 2019)

17.32 'Clinical network plus' describes a network in which all sites provide the same treatment to patients, but some aspects of care are restricted to a smaller number of sites at certain times. Within these models, some secondary-level services take an intermediate role between secondary and tertiary care and with additional staffing and training provide an additional level of care that is not routine in all secondary-level services (for example, different levels of neonatal care).

17.33 'Multi-site system' describes a model of care in which all clinical sites provide the same level of care to patients, based on shared treatment pathways and clinical policies and with shared governance across the system.

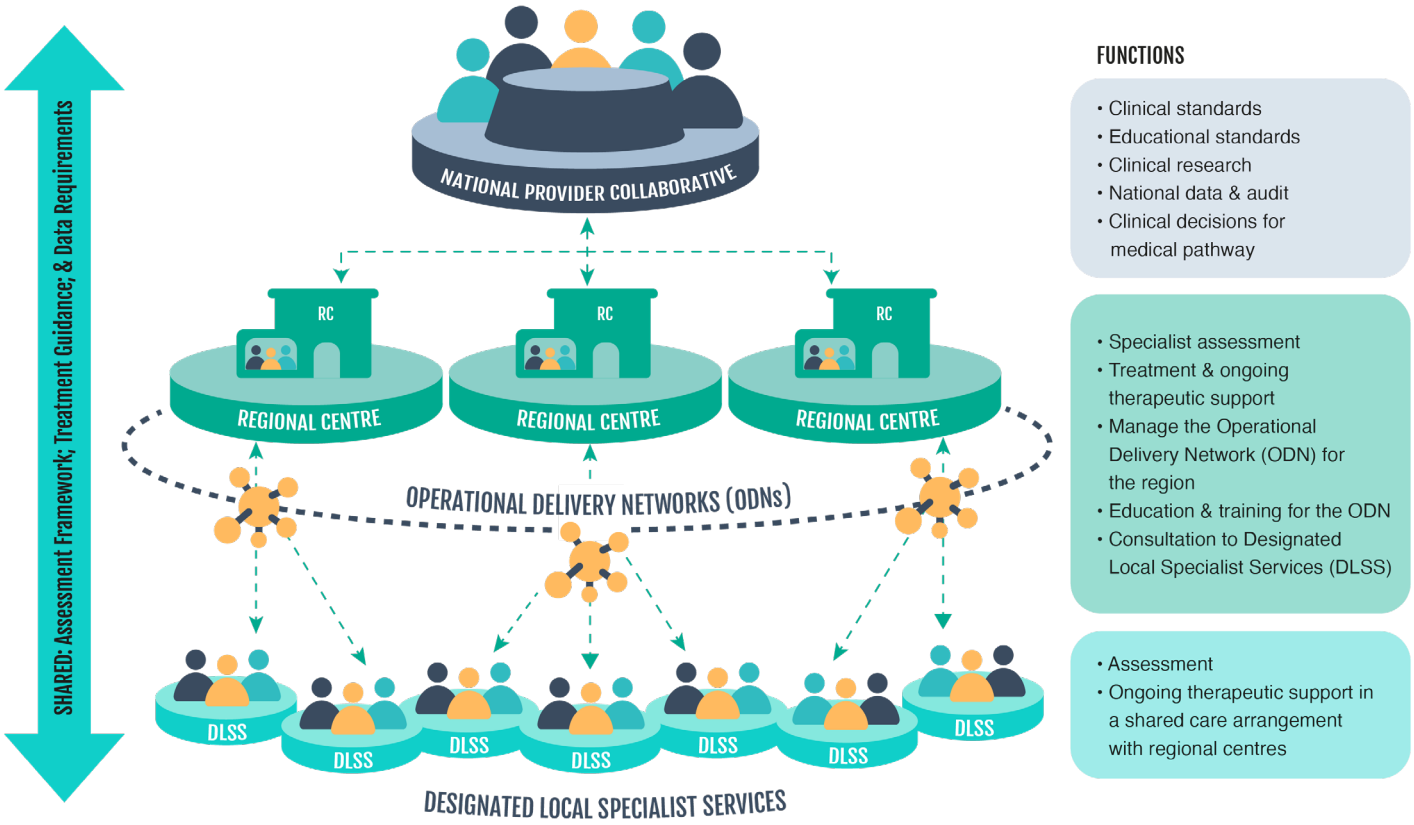
17.34 The clinical network plus and the multi-site system models are most closely aligned with the Review's proposed model because:

- they provide better continuity of care, closer to home, and the ability for children and young people to move between components of the service at their own pace
- there is a finite workforce available to serve the needs of this population and the wider population of young people with complex needs. Therefore, partnerships with local services must be developed so that workforce can be shared across the network without destabilising local services.

17.35 Without this approach the challenges in recruitment experienced by both GIDS and the Phase 1 providers will continue.

18. A new model for gender services for children and young people

Figure 41: Proposed service model



Regional Centres

18.1 Despite the growth in the numbers of children and young people requiring support from the NHS for gender-related issues, the number remains relatively small and there will still be a need for specialist tertiary care for some of the cohort.

18.2 The regional centres will play a pivotal role in delivering the new services. They will be responsible for managing the caseload of individuals requiring support around their gender identity and hold responsibility for the assessment and treatment of those with more complex presentations and requiring more specialist care. They will oversee and work through an operational delivery network (ODN) within their region and will also provide consultation support and training to local providers.

18.3 The Review has advised that these centres be situated within experienced providers of paediatric tertiary care that have the ability to provide essential related services to support the broad range of presentations this group of children and young people may have (or be able to access such services through provider collaborations). These essential services should include, but not be limited to: mental health services, services for children and young people with autism and other neurodiverse presentations, and access to endocrinology services and fertility services, where appropriate for those seeking medical intervention.

18.4 It will also be essential that the regional centres have established academic and education functions to ensure that ongoing research and training is embedded within the service delivery model.

Designated Local Specialist Services

18.5 Although the Review recognises that much of the assessment described in Part 4 could be undertaken more locally by secondary care services, it recognised that not all local services will have the capacity, capability and/or aspiration to support this cohort, particularly given that Child and Adolescent Mental Health Services (CAMHS) services are already stretched, with a high threshold for referrals.

18.6 It is recommended that a smaller number of secondary services within CAMHS and paediatrics should be identified initially to act as Designated Local Specialist Services (DLSS) within each area. This would increase the available workforce through a flexible, multi-site staff group working between the DLSS and the regional centre, with the opportunity to provide targeted training and upskilling.

18.7 This mix of paediatric and mental health services is a fundamental change to the existing service model. In order to meet the wider needs of this population these services will need to demonstrate experience in working in child and adolescent health and with young people with complex needs, in addition to having access to mental health support. Among the workforce GPs with a special interest in adolescent health could be included.

18.8 Initially the Review advises the Regional Centres work within existing relationships to allow this provision to be established as quickly as possible with appropriate funding. Joint contracts between the Regional Centres and the DLSS should be used to support flexibility of the workforce.

18.9 Several children's hospitals operate community paediatric and/or mental health services. For example, Alder Hey Children's NHS Foundation Trust provides both acute, community and mental health paediatric services for its local population of children and young people. The range of mental health services includes Child and Adolescent Community Mental Health Services, Community Eating Disorder Service, 24/7 Crisis Care Service including Home Based Treatment Service, Mental Health in Schools Service, Enhanced Support Team and Tier 4 Children's Inpatient Regional Unit (Sunflower House). The services are located with Community and Neurodevelopmental Paediatric Services including autism spectrum disorder (ASD) and attention deficit hyperactivity disorder (ADHD) assessment and diagnostic services, which ensures an integrated, holistic and supportive approach to the physical and emotional health needs of children and young people.

18.10 The Review has met with clinicians working in services established to support a wide range of adolescent health and wellbeing needs; for example, the Well Centre, a GP-led service in Lambeth, London, and the Onward Clinic in the Brandon Centre, a community-based service with secondary care staffing based in Kentish Town, London.

18.11 These centres provide a wide range of services, helping young people to overcome the psychological and social needs and challenges they might face, and providing support with mental health and physical and emotional wellbeing through GPs, mental health and wellbeing practitioners. There are also youth workers to support young people along their care pathway.

18.12 There is an opportunity for Regional Centres to partner with these types of services to provide the holistic needs assessment and some of the treatment pathways that might be identified through formulation and the individualised care plan. Such services may also provide parenting and broader family support.

18.13 The expansion of such models could support not only this population of young people, but also the wider population of children and young people presenting to the NHS, with gender being one component of the needs addressed. In the future, consideration could also be given to the inclusion of long-term physical care; for example, screening and supporting the public health needs of this population within a community setting.

18.14 There is considerable scope for local innovation and voluntary sector partnerships in developing these services in a range of settings. Yellow Door - Gender Identity Therapy Service, for example, is a voluntary sector Southampton-based service commissioned by the NHS that aims to provide a safe and supported thinking space for children and young people who are negatively affected by confusion, distress or interpersonal difficulties related to gender.

18.15 NHS provision for young people across the board requires service and workforce development and additional sustained investment. There is an opportunity to integrate investment and development of gender services with the ambitions set out in the NHS Long Term Plan (2019) for broader adolescent provision. In doing so, consideration should be given to integration across health, social care and other sectors, especially for young people with complex and/or multiple needs.

Operational Delivery Networks

18.16 Each Regional Centre should have an ODN. ODNs are network groups comprising representatives from the regional centre, DLSS and relevant agencies; for example, social care and education. The ODN should hold shared care agreements with DLSS to ensure this population has access to supportive care and appropriate treatment as close to home as possible.

18.17 An ODN board should be established with formal governance responsibility for children and young people in the region. An ODN is an established NHS England structure (NHS Commissioning Board, 2012). Its purpose is to:

- ensure effective clinical flows through the provider system with clinical collaboration for networked provision of services
- take a whole-system, collaborative provision approach, ensuring the delivery of safe and effective services across the patient pathway
- improve cross-organisational, multi-professional clinical engagement to improve pathways of care
- enable the development of consistent provider guidance and improved service standards, ensuring a consistent patient and family experience
- focus on quality and effectiveness through the facilitation of comparative benchmarking and auditing of services, with implementation of required improvements
- fulfil a key role in assuring providers and commissioners of all aspects of quality as well as co-ordinating provider resources to secure the best outcomes for patients across wide geographical areas.

18.18 In relation to this specific population the ODN Board will:

- support capacity planning and activity monitoring with collaborative forecasting of demand and matching of demand and supply
- ensure the DLSS meet data collection requirements and standards as established by the National Provider Collaborative
- establish sub-groups to manage the administrative functions around data, referrals and oversight of ongoing local training and CPD.

18.19 This approach should ensure clinical risk is held at the local level and help to facilitate access to and integration of local support services. The shared care arrangements will require organisations to use the same record system to allow joined-up working.

National Provider Collaborative

18.20 The Regional Centres will need to come together to form a National Provider Collaborative to ensure standards of care and equitable access is maintained. This governance role will be key to the success of the model and should include the following functions:

- the development of shared standards, operating procedures and clinical protocols, for example, for assessment and treatment
- updating the assessment framework in line with emerging evidence, audit and quality improvement
- the development of clear referral criteria and intake procedures to ensure equitable access to services

- a forum for discussion of complex cases and all decisions about medical care (a national multi-disciplinary team), ultimately subsuming the role of the Multi-Professional Review Group (MPRG)
- an ethics forum for cases where there is uncertainty or disagreement about best interests or appropriate care
- a process of peer review between Regional Centres
- development of a programme of ongoing continuing professional development (CPD) for staff at all levels, as well as educational standards for practitioners within the various tiers of service provision
- collation of the national dataset and conduct of national audit
- development of a quality improvement programme to ensure evolving best practice
- consideration of research requirements
- ongoing research in areas of weak evidence.

18.21 The National Provider Collaborative should consist of clinical and academic representatives from across the Regional Centres, as well as any external experts considered to be necessary for its work. This will require resourcing for a secretariat and time allocated in job roles to deliver the responsibilities.

Summary – service model

18.22 The aim is that no matter where in the country the child/young person is seen, they will receive the same high standards of evidence-based care and better information upon which to base their decisions, avoiding a so-called 'postcode lottery'.

18.23 The proposed new service model with its formalised network structures at national and regional levels, and increased number of providers, should allow care and risk to be actively managed at different levels according to need, reducing waiting times for specialist care.

18.24 It is envisaged that this model will also support integration between different children's services and facilitate early access to local services along flexible pathways that better respond to children and young people's individual needs. Overall, this model should improve the experience of care for children and young people questioning their gender identity.

18.25 The new providers of these services should quickly develop their ODN and DLSS networks, utilising existing relationships in the first instance with those services that have the capacity, capability and interest in supporting this cohort to establish this vital level of service provision more quickly.

18.26 This approach would act as a stepping stone to ultimately skilling up all secondary-level services to provide assessment and psychological support for these children and young people, with medical intervention remaining at tertiary level.

Recommendation 11:

NHS England and service providers should work to develop the regional multisite service networks as soon as possible. This could be based on a lead provider model, where NHS England delegates commissioning responsibility to the regional services to subcontract locally to providers in their region.

Recommendation 12:

The National Provider Collaborative should be established without delay.

Workforce

18.27 The Review recognises that workforce shortfalls are one of the most challenging aspects of delivering this service.

18.28 Within the existing model of care, the vast majority of gender-questioning children and young people who seek help from the NHS have been referred to a highly specialised workforce working solely in gender care. A smaller number are successfully supported in local CAMHS or paediatric services. This approach has had the unintended consequence of de-skilling the rest of the workforce and generating unmanageably long waiting lists.

18.29 Given the increasing numbers of gender diverse and gender-questioning young people, it is important that all clinical staff are able to support them in a range of settings across the NHS. It is equally important that professionals who are involved in their ongoing care have broad-based skills in adolescent physical and mental health so that young people are treated holistically and not solely on the basis of their gender presentation.

18.30 Most international guidelines recommend that there should be a multi-professional team involved in assessment and care. The exact composition of the recommended team varies, but access to mental health professionals within the specialist team and/or within local teams is a common theme.

18.31 In line with international practice, the Regional Centres will need to have a broad multi-professional workforce. The skills of those working within the service need to reflect the needs of this heterogenous group and the service needs to include the appropriate skill mix to support both individuals who require medical intervention and those who do not.

18.32 This workforce should include paediatricians, psychiatrists psychologists, psychotherapists, clinical nurse specialists, social workers, family therapists, specialists in autism and other neurodiverse presentations, speech and language therapists, occupational therapists and, for the subgroup for whom medical treatment may be considered appropriate, endocrinologists and fertility specialists. Social care should also be embedded and there should be expertise in safeguarding and support for looked-after children and children who have experienced trauma.

18.33 The role of paediatric and mental health professionals in this area is well recognised, but the role of allied health professionals has been under recognised. Speech and language therapists are particularly important given that a large subset of this population are neurodiverse or have other communication needs. Screening for these issues and/or advising on accessibility of written and verbal information for consent is essential. Some young people may need specialist voice intervention.

18.34 This group of young people may equally need access to occupational therapy support, again because of issues of neurodiversity and sensory distress, but also because they may experience a wide range of barriers to participation in school or other peer settings that may require assessment and advice.

18.35 Staff should maintain a broad clinical perspective by working across related non-gender services within the tertiary centre and as a multi-site staff group between tertiary and secondary centres in order to embed the care of children and young people with gender-related distress within a broader child and adolescent health context. This has the additional benefits of not destabilising existing services, supporting continuity and connection and sharing expertise and knowledge.

18.36 This is a highly challenging, complex and emotive area in which to work. Those working with this group should be given professional supervision and support to provide a place for exploration of their own approach and the range of emotions they may feel. There should be formal processes for raising concerns that sit outside immediate supervision. This should support consistency in approach and improve retention of the workforce.

18.37 The National Provider Collaborative should also explore running structured forums where all staff, clinical and non-clinical, come together regularly to discuss the emotional and social aspects of working within the service - supporting staff by giving them a safe place to raise issues and ask questions.

Recommendation 13:

To increase the available workforce and maintain a broader clinical lens, joint contracts should be utilised to support staff to work across the network and across different services.

Recommendation 14:

NHS England, through its Workforce Training and Education function, must ensure requirements for this service area are built into overall workforce planning for adolescent services.

Training and education

18.38 During the course of the Review, it has become clear that there is a general lack of confidence among the wider workforce to engage with gender-questioning children and adolescents. Many clinicians working with children and young people more generally have transferable skills and expertise, but there is a need for all clinicians across the NHS to receive better training about how to work sensitively and effectively with trans, non-binary and gender-questioning young people.

18.39 Clinicians working with children and young people and families/carers will need to have the skills to competently engage families/carers from a broad range of backgrounds, and be aware and informed of the range of priorities that young people and their parents/carers can present to services.

18.40 Young people have told the Review that they want clinicians to listen to them, respect how they feel and support them to work through their feelings and options. They expect clinicians to display compassion, understanding, and to treat them as an individual.

18.41 Training programmes should follow practice in other service areas (for example, safeguarding), where levels of competency and training needs depend on the staff group and clinical area.

18.42 In addition, providers should work with commissioners to realise the NHS Long Term Workforce Plan commitment that: "Additional specialist training in gender dysphoria will be provided to meet the workforce shortage in this specialist service; we will raise awareness of this patient group across the workforce and support healthcare professionals to signpost and support patients" (NHS England, 2023).

18.43 An effective approach would be to establish a consortium to include relevant Medical Royal Colleges, special interest groups and other professional bodies, including but not limited to:

- Association of Clinical Psychologists
- Association of Psychotherapists
- Royal College of Speech and Language Therapists
- Royal College of Occupational Therapists
- British Association of Social Workers.

18.44 The consortium should develop a shared skills and competency framework relevant to all clinical and social care staff working in this area at different levels within the system. This should include broader skills in adolescent care, as well as the more specific aspects relevant to gender care.

18.45 Individual professional organisations should determine which of the transferable skills and competencies are already embedded in the training curricula of their specific staff groups and where the gaps are.

18.46 The consortium should then develop a curriculum to cover topics that are deemed to be missing from existing training programmes and curricula, and necessary for top-up training/CPD/credentialing for individuals working within this area.

18.47 Training materials developed by MindEd and the induction materials developed for the Phase 1 providers will be helpful starting points for this work (MindEd, 2023).

18.48 The National Provider Collaborative will have responsibility to engage with the education consortium and ensure that new evidence and practice is integrated into teaching materials.

18.49 In addition to the development of national training resources, the National Provider Collaborative and individual Regional Centres/ODNs will have responsibility for ensuring a CPD programme comprising case presentations, research updates and other methods of shared learning as in all other specialty areas.

18.50 Service users and families have told the Review that there is not a single trusted source of information available from the NHS. The Provider Collaborative should work to develop regularly updated information for service users, families and other agencies such as schools and social care services.

Recommendation 15:

NHS England should commission a lead organisation to establish a consortium of relevant professional bodies to:

- develop a competency framework
- identify gaps in professional training programmes
- develop a suite of training materials to supplement professional competencies, appropriate to their clinical field and level. This should include a module on the holistic assessment framework and approach to formulation and care planning.

Recommendation 16:

The National Provider Collaborative should coordinate development of evidence-based information and resources for young people, parents and carers. Consideration should be given as to whether this should be a centrally hosted NHS online resource.

Service improvement

18.51 As set out in the interim report, central to any service improvement is the systematic and consistent collection of data on the outcomes of treatment.

18.52 Throughout the course of the Review, it has been evident that there has been a failure to reliably collect even the most basic data and information in a consistent and comprehensive manner; data have often not been shared, or have been unavailable. This has led to challenges in understanding the patient cohort, referral data and outcomes, all of which have hindered the work of the Review. More importantly, this has been to the detriment of young people and their families being able to make informed decisions.

18.53 There needs to be a cultural shift, with active leadership supporting all providers to adopt a proactive learning culture across the new services.

18.54 There should be a process of continuous service improvement and clinical reflection, with consideration to how services should evolve as the evidence base grows and care pathways are evaluated.

18.55 The Review has previously advised that the National Provider Collaborative should oversee this process, ensuring national treatment protocols and guidelines are in place to enable standardisation and consistency in practice, including for case management, assessment, consent and safeguarding.

18.56 Regional Centres should ensure these standards are disseminated and implemented through their networks and that the relevant workforce is recruited and trained, contingent on the type of support, therapy or treatment this population needs.

18.57 The National Provider Collaborative should have independent oversight of quality improvement (for example, through a Healthcare Quality Improvement Partnership commissioned approach) to ensure the highest possible standards of data management and utilisation. Regional Centres should also have oversight and reporting structures to monitor quality and improvement across their networks.

18.58 There remains the need for the collection of an agreed core dataset to inform service improvement and research, based on similar approaches already established in other specialties; for example, PICANet - Paediatric Intensive Care Audit Network for the UK and Ireland in paediatric critical care. This will be critical to informing current and future clinical practice and care for this population.

Recommendation 17:

A core national dataset should be defined for both specialist and designated local specialist services.

Recommendation 18:

The national infrastructure should be put in place to manage data collection and audit and this should be used to drive continuous quality improvement and research in an active learning environment.

Research capacity

18.59 The gaps in the evidence base regarding all aspects of gender care for children and young people have been highlighted, from epidemiology through to assessment, diagnosis, therapeutic support and treatment.

18.60 It is troubling that so little is known about this cohort and their outcomes. An ongoing programme of work is required if the new case-mix of children and young people and their needs are to be fully understood, as well as the short-, medium- and longer-term impacts of all clinical interventions.

18.61 Given the particular uncertainties regarding the long-term outcomes of medical and non-medical interventions, and the broader knowledge gaps in this area, the Review has previously advised on the need to build research capacity into the national network.

18.62 This research capacity is needed to:

- provide ongoing appraisal of new literature and rapid translation into clinical practice
- continue to identify areas of practice where further research is needed
- develop a research portfolio that will inform policy on assessment, support and clinical care of children with gender dysphoria, from presentation through to appropriate social, psychological and medical management.

18.63 The appropriate research questions and protocols will need to be developed with input from a panel of academics, clinicians, service users and ethicists.

18.64 In order to build on the work undertaken by the University of York and maintain an up-to-date understanding of this complex and fast-moving research area, a living systematic review approach should be considered. Through this approach the systematic reviews could be continually updated, incorporating relevant new evidence as it becomes available to inform the clinical approach of the new services, ensuring it remains up-to-date and dynamic.

18.65 As detailed in this report, priorities for research should include analysis of the characteristics of the population and formal research protocols underpinning both medical and non-medical interventions with follow-up into adulthood.

18.66 Without an established research strategy and infrastructure, the outstanding questions will remain unanswered, and the evidence gaps will continue to be filled with opinion and conjecture.

18.67 This is critical if the NHS is to provide reliable, transparent information and advice to support children, young people, their parents and carers in making potentially life-changing decisions.

Recommendation 19:

NHS England and the National Institute for Health and Care Research should ensure that the academic and administrative infrastructure to support a programme of clinically-based research is embedded into the Regional Centres.

Recommendation 20:

A unified research strategy should be established across the Regional Centres, co-ordinated through the National Provider Collaborative and the Research Oversight Board, so that all data collected are utilised to best effect and for sufficient numbers of individuals to be meaningful.

Recommendation 21:

To ensure that services are operating to the highest standards of evidence the National Institute for Health and Care Research should commission a living systematic review to inform the evolving clinical approach.

19. Pathways

19.1 The interim report set out that: "Clear criteria will be needed for referral to services along the pathway from primary to tertiary care so that gender-questioning children and young people who seek help from the NHS have equitable access to services".

International practice

19.2 The University of York's review of international guidelines (Taylor et al: Guidelines 2: Synthesis) and international survey (Hall et al: Clinic survey) found that:

- There is variability in whether services required that referrals come from child and adolescent mental health services or not. Several clinics specify that a referral must come from a clinician. Finland is unique in also having referral criteria related to co-occurring conditions, which need to be addressed prior to a referral being accepted.
- The care pathway for most guidelines is similar, starting with psychosocial care for pre-pubertal children, followed by puberty blockers then hormones for eligible adolescents.
- There is usually a separate pathway for pre-pubertal children, involving a one-off assessment followed by local management until eligible for puberty blockers.
- Denmark and Finland reported a different pathway for young people with psychosocial concerns or a short history of distress.
- Co-occurring mental health conditions or neurodiversity are usually managed by other providers, and sometimes have a longer assessment process.
- The approach among those countries that reported on their approach to non-binary individuals is generally cautious, usually delaying treatment until adulthood.
- Only one guideline mentioned transition [transfer] to adult services.

Current referral pathway

19.3 Usual practice in the NHS is that for patients to access tertiary (specialist) care, they need to be seen by a secondary care practitioner (for example, CAMHS, paediatrics) in the first instance. If, following an initial assessment, that practitioner felt that their case was sufficiently complex or the individual met the criteria for tertiary (specialist) care, they would make a referral.

19.4 When the Review commenced, access to the specialist GIDS service was unusual in that the service accepted referrals directly from primary care (a GP) and from non-healthcare professionals including teachers and youth workers.

19.5 The audit of GIDS discharge notes, undertaken by Arden & Gem CSU in spring 2023 (Appendix 6), found that 48.6% of patients referred to GIDS were referred by CAMHS and 40.68% were referred by their GP. Of the remaining, referrals were made by other healthcare providers (2.6%), local authorities (3.3%), the voluntary sector (3.1%) and schools (1.8%).

19.6 This created a number of problems:

- The information recorded on the referral was highly variable and often lacked even the basic information that the specialist team would need to screen and triage the patient.
- Patients who would not usually meet the threshold for a specialist service were being referred, meaning waiting times increased for everyone without a way to discern those who genuinely required specialist input from those who could be managed in secondary care or even primary or community care.
- Once referred, it was unclear who held clinical responsibility for the care of the young person.
- Usual assessments that would be undertaken by a secondary care practitioner (for example, safeguarding assessment, mental health assessment) were not being completed for these young people, particularly those referred through a non-healthcare route. This means that there is an unknown level of risk inherent in the legacy waiting list, that is, it is not known which young people may be at risk of self-harm or suicide, and which may be at risk due to family breakdown or other safeguarding issues.

19.7 Following the Review's interim report, NHS England consulted on a proposal for all referrals to the Regional Centres to come via secondary care. The Review supports this approach for the following reasons:

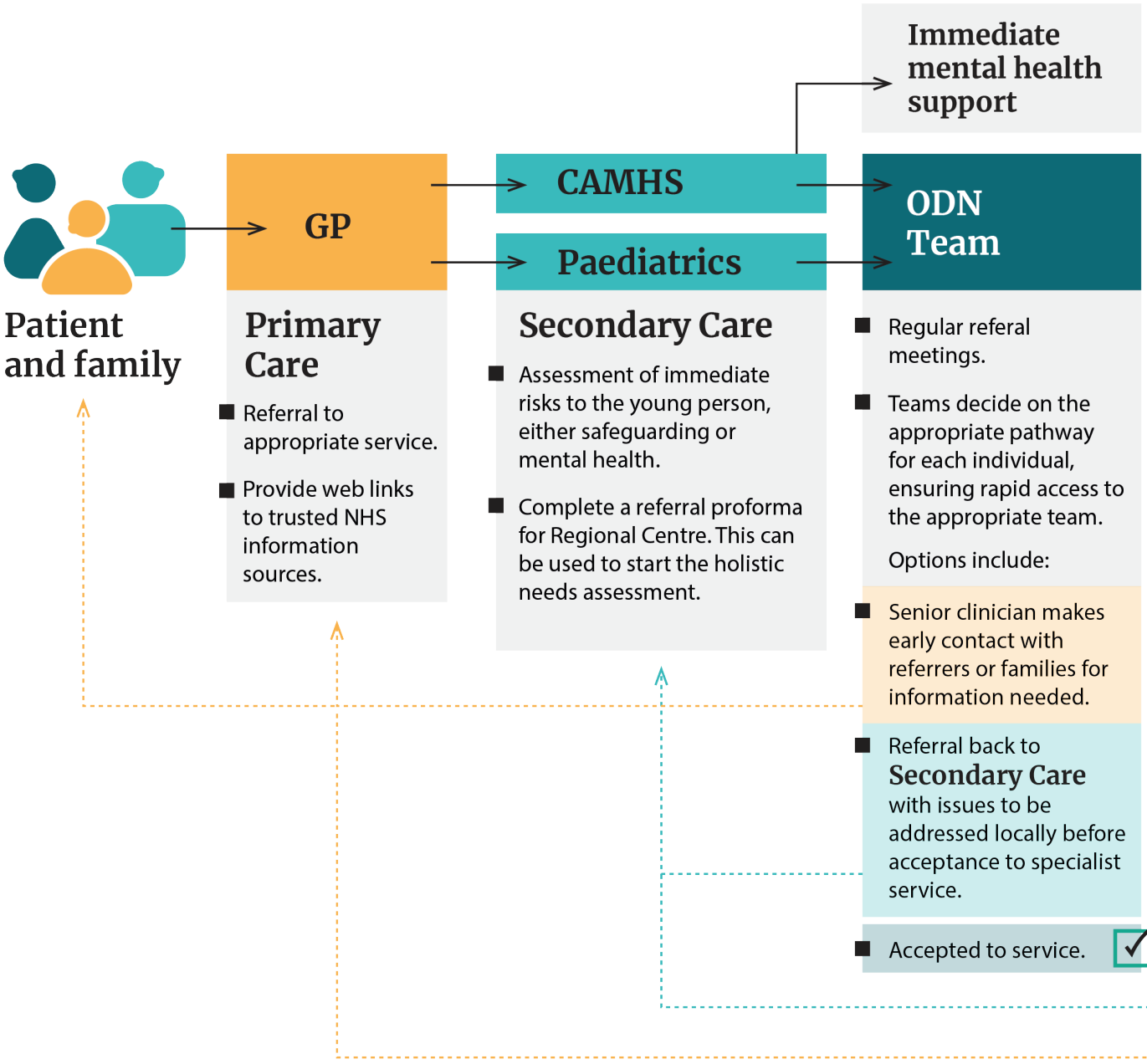
- The Regional Centres need to remain focused on the young people they can best support, and in common with other tertiary services, an initial local assessment ensures that referrals that reach the tertiary centre are appropriate, and are those whose needs cannot be met locally.
- Any immediate safeguarding or mental health risk issues can be identified and addressed, with ongoing local responsibility for this aspect of care.



Recommended referral pathway

19.8 Taking the new service model, described previously, the process for referral would be as follows:

Figure 42: Referral pathway



Specialist Gender Service

Tertiary Care

- Allocated a specific pathway within the service.
- Allocated a specific clinical team, including relevant skills for that person's identified needs (e.g. ASD expertise, occupational therapy to address issues of participation etc.).
- Holistic needs assessment and individualised care plan to meet their identified needs.

Other pathways may emerge over time.

Adolescent pathway

Pre-pubertal pathway



Discharge

- To other NHS services as appropriate to ensure the best care that meets individual needs.
- Back to primary care.
- Transfer to adult services for those for whom it is determined best to continue on a gender pathway towards transition.

Role of Primary Care

19.9 Initial consultation should be with the GP, who should make an initial assessment as they would with any other adolescent. They will have a record of any relevant past medical history and of family context.

19.10 If they consider that the young person may need to be referred to a Regional hub, they should make a referral in the first instance to a secondary Centre service. If the young person reaches the referral threshold for CAMHS, they should be referred to that service, or otherwise they should referred to paediatrics. This should have an immediate effect on reducing the length of time children and young people are waiting to be seen by NHS services.

19.11 The GP should also share weblinks to trusted NHS information sources with the child or young person. In the longer-term these sources should be overseen by the National Provider Collaborative. In the interim, MindEd (2023) provides initial information for frontline staff, parents and teachers.

Role of Secondary Care

19.12 The responsibility of secondary care services is to make an assessment of immediate risks to the young person - either safeguarding or mental health. If there are significant concerns, these will need a local management plan.

19.13 The secondary care service will also need to complete a referral pro forma for the Regional Centre. This will document basic information including a brief history of the young person's gender presentation, family history, any co-existing conditions, and a list of any other services or agencies involved in the young person's care.

19.14 This information should be used to inform/start to complete the information for the assessment framework described in Part 4, so that individuals are not repeating information unless necessary.

Role of the Operational Delivery Networks

19.15 The ODN should hold a regular referral management meeting. Members should include clinical staff from the tertiary service, as well as the DLSS. The team should also include a referral data manager, and may include representatives from social care, education and any other relevant team members at the discretion of the ODN.

19.16 It is essential that information about referrals be collected on a core database in order to improve understanding about the characteristics of the referred population, which is currently weak both nationally and internationally.

19.17 The referral management group will make a decision about the appropriate pathway of care for that young person, ensuring the fastest access to the appropriate team. This decision should be communicated to the young person/child's parents. The ODN should operate a 'transparent walls' approach between the tertiary centre and DLSS, so that initial assessment takes place with the most appropriate team. This will allow flexibility of capacity and skill mix between the DLSS and the tertiary team.

19.18 Options may be as follows:

- a senior clinician may make early contact with referrers or families to gain any further information needed to make decisions about the appropriate referral pathway
- referral to secondary care with advice about issues that may need to be addressed locally before the young person can be seen in the specialist service
- accepted to the specialist service.

19.19 This change should ensure that children and young people are appropriately engaged within the health system and that the NHS has clear responsibility for their care, including support whilst on the waiting list. It will need to be underpinned by access to support and information for referrers, so the whole heath system better understands the needs of this population.

Pathways within the service

19.20 Discussions with clinicians have highlighted the importance of differentiating the subgroups within the referred population who may be at risk and/or need more urgent support, assessment or intervention; there may also be subgroups for whom early advice to parents or school staff may be a more appropriate first step.

19.21 If accepted to the specialist service the child/young person should:

- be allocated to the specific pathway within the service (for example, pre-pubertal pathway or adolescent pathway, other specific pathways may emerge over time)
- be allocated to a specific clinical team either within the DLSS or the tertiary team, to include relevant skills for that person's identified needs (for example, ASD expertise, occupational therapy to address issues of participation etc.).
- receive a full assessment and holistic plan to meet their identified needs.

19.22 Children and young people should be able to move flexibly between different elements of the service in a step-up or step-down model, allowing them and their parents/carers to make decisions at their own pace without requiring rereferral into the system. This could reduce the sense of urgency a young person may feel when first accessing the service.

19.23 The current evidence base suggests that children who present with gender incongruence at a young age are most likely to desist before puberty, although for a small number the incongruence will persist. Parents and families need support and advice about how best to support their children in a balanced and non-judgemental way.

19.24 In reviewing cases put forward for puberty blockers, the MPRG noted that children who had socially transitioned early and completely were likely to approach puberty in a fearful and anxious state because of living 'in stealth'. Helping parents and families to ensure that options remain open and flexible for the child, whilst ensuring that the child is able to function well in school and socially is an important aspect of care provision and there should be no lower age limit for accessing such help and support.

19.25 Importantly some children within this group who remain gender incongruent into puberty may benefit from puberty blockers and will be able to enter the specialist component of the service and access the puberty blocker trial in a timely way, if already under the supervision of the regional network.

Recommendation 22:

Within each regional network, a separate pathway should be established for pre-pubertal children and their families. Providers should ensure that pre-pubertal children and their parents/carers are prioritised for early discussion with a professional with relevant experience.

Discharge

19.26 Children and young people accessing gender services may be discharged as follows:

- to other NHS services according to their individualised care plan
- back to primary care
- a transfer to adult gender services.

Transfer to adult gender services

19.27 Currently, young people may transition [transfer] to adult gender services from the age of 17. These adult services are perceived to be quite different from GIDS, and young people presenting later may therefore not have access to the same holistic care as described in this report.

19.28 There is also concern about the impact on the young person of changing clinicians at a crucial point in their care, particularly for those with neurodiversity/special educational needs or other vulnerabilities.

19.29 The Review considered the wider implications surrounding transition [transfer] from children and young people's gender services to an adult Gender Dysphoria Clinic (GDC), which include:

- the clinical risk at the point of transfer, which includes increased suicidality, loss to follow-up, extended periods on puberty blockers
- that young people are ageing out whilst on the waiting list having not been seen by the children and young people's gender service
- the waiting list challenges within the adult services more generally
- the need for the long-term audit and follow-up research data that are currently lost at the point of transition [transfer] to adult services
- approaches taken by other NHS services: for example, adult congenital heart disease, which is an already established service; 0-25 oncology services, available in some parts of the country; and the aspiration within the NHS Long Term Plan (2019).

19.30 Currently, significant numbers of young people are being transferred from GIDS to adult services. Some will have been under the care of GIDS, but another group who have turned 17 will not have been seen by GIDS, but whose wait for GIDS is being counted towards the wait for adult services. This is increasing waiting lists for adult services and disadvantaging older adults seeking NHS support.

19.31 Taking account of all the above issues, a follow-through service continuing up to age 25 would remove the need for transition at this vulnerable time and benefit both this younger population and the adult population. This will have the added benefit in the longer-term of also increasing the capacity of adult provision across the country as more gender services are established.

19.32 This would be consistent with other service areas supporting young people that are selectively moving to a '0-25 years' service to improve continuity of care.

"Failure to achieve a safe transition can lead to disengagement, failure to take responsibility for their condition and ultimately poorer health outcomes. By 2028 we aim to move towards service models for young people that offer person-centred and age-appropriate care for mental and physical health needs, rather than an arbitrary transition to adult services based on age not need" (NHS Long Term Plan, 2019).

Recommendation 23:

NHS England should ensure that each Regional Centre has a follow-through service for 17-25-year-olds; either by extending the range of the regional children and young people's service or through linked services, to ensure continuity of care and support at a potentially vulnerable stage in their journey. This will also allow clinical, and research follow up data to be collected.

19.33 The Review requested data on the demographics of referrals into adult GDCs, and NHS England requested these data from the clinics on the Review's behalf. The dataset was incomplete (particularly for birth-registered gender) but demonstrates that the majority of referrals (around 70%) were birth-registered females under the age of 25. However, the data related to new referrals only and did not include direct referrals of GIDS patients who had reached the age of 17. Therefore, a conservative estimate would be that 17-25 year olds account for around 75% of referrals to adult gender clinics.

Table 11: Referrals received and referrals accepted by Adult Gender Dysphoria Clinics in England April 2023 - July 2023

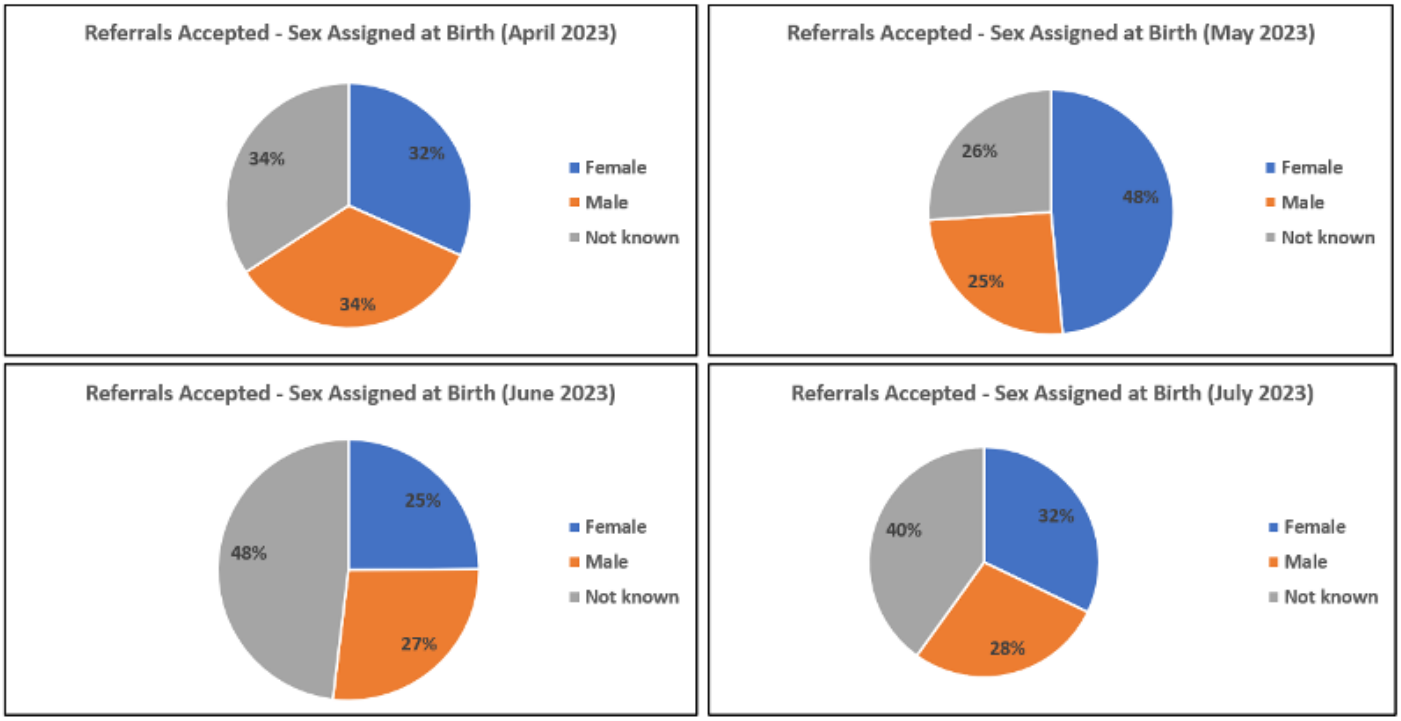
REFERRALS RECEIVED (AGE OF INDIVIDUALS)	APRIL 2023	MAY 2023	JUNE 2023	JULY 2023
Total Aged under 25 years	268	621	503	521
Total Aged 25-49 years	133	150	231	218
Total Aged 50 Years and over	21	21	28	38
Total	**422**	**792**	**762**	**777**

REFERRALS ACCEPTED (AGE OF INDIVIDUALS)	APRIL 2023	MAY 2023	JUNE 2023	JULY 2023
Total Aged under 25 years	245	603	447	496
Total Aged 25-49 years	125	145	218	213
Total Aged 50 Years and over	23	20	24	37
Total	**393**	**768**	**689**	**746**

Source: The Gender Identity Development Service Audit Report, Arden & GEM

NB: All data used has been provided to NHS Arden & GEM CSU by Adult Gender Dysphoria Clinics (GDCs). April 2023 was the first month the GDCs reported activity data using a new template/process. As such data collected/reported in April and May was experimental and data quality has improved since this period.

Figure 43: Referrals received and referrals accepted by adult Gender Dysphoria Clinics in England, April 2023 - July 2023



Source: The Gender Identity Development Service Audit Report, Arden & GEM

NB: All data has been provided to NHS AGEM CSU by GDCs. April 2023 was the first month the GDCs reported activity data using a new template/process. As such data collected/reported in April and May was experimental and data quality has improved since this period. No data was provided by Northampton, Newcastle, Nottingham or Exeter GDCs for referrals received/accepted (sex assigned at birth). AGEM CSU: Arden & GEM Commissioning Support Unit; GDC: Adult Gender Dysphoria Clinic.

19.34 While provision within the NHS adult gender services is outside the scope of this Review, a number of current and past GDC staff have contacted the Review in confidence with concerns about their experiences working in adult gender services. Their experiences covered clinics across different parts of the country, and the Review will set out the main points of concern to NHS England. The consistent messages are represented below.

- Clinicians confirmed the changing demographic as demonstrated by the data above. They described how this changed over a 2-year period between 2017 and 2019, from a mixed age range group with a majority of birth-registered males to 70-80% birth-registered females under the age of 25.
- In terms of complexity, clinicians described a large percentage of the patients having various combinations of confusion about sexuality, psychosis, neurodevelopmental disorders, trauma and deprivation, forensic issues and a range of other undiagnosed conditions.
- There was an expectation that patients would be started on masculinising/ feminising hormones by their second appointment, which was a cause of concern given the complexity of presentations.
- Clinicians reported seeing an increasing number of detransitioners, describing how they often moved between clinics as they preferred not to return to the clinic that had originally treated them.

19.35 As the services for children and young people develop, a strategic approach will be needed to ensure that adult service provision takes account of different population needs and emerging evidence.

Recommendation 24:

Given that the changing demographic presenting to children and young people's services is reflected in a change of presentations to adult services, NHS England should consider bringing forward any planned update of the adult service specification and review the model of care and operating procedures.

Detransition

19.36 The issues around de/retransition have been highlighted in Part 4 in relation to the outcomes of medical interventions and long-term follow-up. There is a need for better services and pathways for this group, many of whom are living with the irreversible effects of transition and no clear way to access services.

19.37 NHS gender services should support all those presenting with gender incongruence and dysphoria, whether that be to transition, detransition or retransition. Those who choose to detransition should be carefully monitored in a supportive setting, particularly when coming off hormone treatments.

19.38 It is also important that services understand and learn from those who choose to detransition as their experience can be used to inform understanding of what services are required earlier in the pathway. There is also the need for more research to understand what factors contribute to the decision to detransition.

19.39 The Review has heard that people experiencing regret may be hesitant to engage with the gender services that supported them through their transition. Consideration should be given to whether existing service specifications need to be adapted to specifically provide for detransition pathways, or whether this should be a separately commissioned service. This should be in consultation with people who have been through detransition.

Recommendation 25:

NHS England should ensure there is provision for people considering detransition, recognising that they may not wish to re-engage with the services they were previously under.

Private provision

19.40 The Review has heard that a number of young people have sought private provision whilst on the waiting list for GIDS, and about families trying to balance the risks of obtaining unregulated and potentially dangerous hormone supplies over the internet with the ongoing trauma of prolonged waits for assessment. Feedback from the lived experience focus groups presents this as "a forced choice (because the NHS provision is not accessible in a timely way) rather than a preference". The ongoing cost of this treatment and the subsequent monitoring can be prohibitive for some.

19.41 Additionally, GPs have expressed concern about being pressurised to prescribe puberty blockers or masculinising/feminising hormones after these have been initiated by private providers and that there is a lack of clarity around their responsibilities in relation to monitoring.

19.42 The Review understands and shares the concerns about the use of unregulated medications and of providers that are not regulated within the UK. Any clinician who ascertains that a young person is being given drugs from an unregulated source should make the young person and their family aware of the risks of such treatment.

19.43 In terms of shared care and prescribing responsibility, this should mirror other areas of practice. Specifically, no clinician should prescribe outside their competence, nor should GPs be expected to enter into a shared care arrangement with a private provider, particularly if that private provider is acting outside NHS guidance. Additionally, pharmacists are responsible for ensuring medications prescribed to patients are suitable (General Pharmaceutical Council, n.d.).

19.44 However, there should be an arrangement to carry out relevant investigations to ensure a young person is not coming to harm (for example, monitoring bone density).

19.45 In terms of funding, NHS England will normally only fund the treatment of a patient who has transferred from privately funded healthcare where their NHS clinician is content that the treatment is clinically indicated. This decision would usually require an individual to join the appropriate waiting list to be assessed by the NHS clinician within NHS protocols before the decision could be made. The prescription could then be continued if the clinician were satisfied that the treatment is clinically indicated and safe.

19.46 In the case of puberty blockers, NHS England has set out that these will only be available under a research protocol (NHS England, 2024). On entering the trial, the young person will have a number of tests to establish their baseline levels for monitoring purposes; for example, in relation to bone density, as well as other initial assessments. If an individual were to have taken puberty blockers outside the study, their eligibility may be affected.

Recommendation 26:

The Department of Health and Social Care and NHS England should consider the implications of private healthcare on any future requests to the NHS for treatment, monitoring and/or involvement in research. This needs to be clearly communicated to patients and private providers.

Recommendation 27:

The Department of Health and Social Care should work with the General Pharmaceutical Council to define the dispensing responsibilities of pharmacists of private prescriptions and consider other statutory solutions that would prevent inappropriate overseas prescribing.

Changing NHS number and access to healthcare

19.47 Currently, when a person requests to change their gender on their NHS record, NHS guidance requires that they are issued with a new NHS number.

19.48 Clinicians have raised concerns about children and young people's NHS numbers being changed inconsistently, as there is no specific guidance for GPs and others as to when this should be done for this population and under what consent.

19.49 This has implications for safeguarding and clinical management of these children and young people, and could affect longer-term health management into adulthood (for example, in terms of screening).

19.50 Safeguarding professionals have described a range of situations where this has put children/young people at risk. These include young people attending hospital after self-harm not being identifiable as a child already on a child protection order; records of previous trauma and/or physical ill health being lost; people who do not have parental responsibility changing a child's name and gender; children being re-registered as the opposite gender in infancy; children on the child protection register being untraceable after moving to a new area.

19.51 The concerns with changing NHS number have also shone a light on the varied experiences and needs of transgender people who are often disadvantaged as they access healthcare (for example, screening services) and risk misdiagnosis.

19.52 It is unclear why an NHS number should need to be changed when the patient is under 18.

19.53 From a research perspective, the issuing of new NHS numbers makes it more difficult to identify the long-term outcomes for a patient population for whom the evidence base is weak.

Recommendation 28:

The NHS and the Department of Health and Social Care needs to review the process and circumstances of changing NHS numbers and find solutions to address the clinical and research implications.

20. Implementation

20.1 The Review recognises that delivery of the aspirations set out in this report will require significant changes. The move to the proposed service model will require a phased approach and it may be several years before the full model is operational across the country. Pragmatic strategic and operational plans are required that set out in a transparent way the steps that will be taken to realise the service transformation. This will be essential to build trust and manage expectations.

20.2 Governance needs to be put in place to oversee implementation of the required changes and provide system-wide leadership. This should be external to the Specialised Commissioning division and draw clinical leadership from professional bodies. Given the level of external interest in these services progress against the implementation plans should be reported.

Recommendation 29:

NHS England should develop an implementation plan with clear milestones towards the future clinical and service model. This should have board level oversight and be developed collaboratively with those responsible for the health of children and young people more generally to support greater integration to meet the wide-ranging needs of complex adolescents.

Recommendation 30:

NHS England should establish robust and comprehensive contract management and audit processes and requirements around the collection of data for the provision of these services. These should be adhered to by the providers responsible for delivering these services for children and young people.

20.3 While the Review has been focused on children and young people with gender incongruence and gender-related distress, the NHS needs to be ambitious in its provision for all children and young people seeking NHS support.

20.4 Consideration should be given to the need to integrate services across health, social care and other sectors, especially for young people with complex and/or multiple needs.

20.5 Through the work of the Review it is clear that the type of holistic service and structures described for gender services could work well for how the NHS supports children and young people more generally.

20.6 NHS provision for adolescents across the board requires greater service and workforce development and sustained investment. Without this we are letting down future generations. NHS England should use this opportunity to integrate investment and development of gender services with the ambitions set out in the NHS Long Term Plan for broader adolescent provision, with consideration given to a complex adolescent pathway.

Wider system learning

20.7 Clinical staff need support and guidance from their professional bodies to apply the evidence-based approaches described in this report. The consortium brought together to develop training resources should also be a vehicle for agreeing professional guidance for their respective clinical groups. This collaborative approach should include processes for listening to the community the service is built for.

20.8 Innovation is important if medicine is to move forward, but there must be a proportionate level of monitoring, oversight and regulation that does not stifle progress, but prevents creep of unproven approaches into clinical practice. Innovation must draw from and contribute to the evidence base.

20.9 Although the GIDS service had set up a research study to evaluate the use of puberty blockers, it failed to publish the results for four years, and continued to act outside of its own findings, and the limitations of the service specification.

Recommendation 31:

Professional bodies must come together to provide leadership and guidance on the clinical management of this population taking account of the findings of this report.

20.10 At a local level regulation of innovation should be integrated with regulation of clinical care. Responsible innovation requires anticipatory governance processes to be put in place, organisational safeguards and submission of innovation to external review. Reporting must include failure as well as success (Centre for Medical Ethics and Law HKU, 2024 [video]).

20.11 At a national level, systems are in place to ensure that any new drug is subjected to rigorous trials, appraisal and approval before unrestricted use on patients. Medical devices are also subject to scrutiny and approval. In response to the lack of such a system being in place for interventional procedures, in 1996 the Safety and Efficacy Register for New Interventional Procedures (SERNIP) was founded by the Royal colleges, and allowed voluntary registration for new procedures. Subsequently the National Institute for Clinical Excellence has taken responsibility for safety and efficacy of interventional procedures (Campbell & Maddern, 2003).

20.12 In the case of use of puberty blockers, there was another system weakness in that an off-label use went beyond the usual level of permissiveness in extending use to a very different indication. NICE may be well placed to lead work to address how this kind of innovation should be managed.

Recommendation 32:

Wider guidance applicable to all NHS services should be developed to support providers and commissioners to ensure that innovation is encouraged but that there is appropriate scrutiny and clinical governance to avoid incremental creep of practice in the absence of evidence.

Final thoughts from the Chair

20.13 It has been a privilege to undertake this important and very necessary Review, but it has, at times, been heartbreaking to hear the struggles that young people and their families face trying to navigate their way to care. Over a number of years, the children and young people at the heart of this review have been bypassed by local services and directed to a single national service that, whilst passionate and wholly committed to their care, had developed a fundamentally different philosophy and approach compared to other paediatric and mental health services.

20.14 While it will take a while to build the whole network of services, I very much hope that with this new approach, that brings these young people back into mainstream care, clinical staff will see this is an important and rewarding area of work. Most importantly I hope that the children and young people will benefit from access to a holistic multi-faceted model of care, along with a research infrastructure that will provide them with more robust evidence-based information on which to make decisions that may have long-term implications.

20.15 Finally, I am aware that this report will generate much discussion and that strongly held views will be expressed. While open and constructive debate is needed, I would urge everybody to remember the children and young people trying to live their lives and the families/carers and clinicians doing their best to support them. All should be treated with compassion and respect.



Glossary



The glossary below sets out a description of some of the terms we have used in the Review.

At times, the Report covers complex scientific concepts and research; the glossary aims to support reader understanding and accessibility.

There is also sometimes no consensus on the best language to use relating to the topic of gender identity. Language changes rapidly and new generations develop varied ways of describing their experiences using different terms and constructs that are relevant to them. The Review tries as far as possible to use language and terms that are respectful and acknowledge diversity, but that also accurately illustrate the complexity of what we are trying to describe and articulate.

The terms we have used may not always feel right to some; nevertheless, it is important to emphasise that the language used is not an indication of a position being taken by the Review.

TERM	ABBREVIATION	DESCRIPTION
Affirmative model		A model of gender healthcare that originated in the USA, which affirms a young person's subjective gender experience while remaining open to fluidity and changes over time (Chen et al., 2021; Ehrensaft et al., 2018; Hidalgo et al., 2013; Olson-Kennedy et al., 2019). This approach is used in some key child and adolescent clinics across the Western world.
Assent		To agree to or approve of something (idea, plan or request), especially after thoughtful consideration.
Attention Deficit Hyperactivity Disorder	ADHD	A neurodevelopmental condition that affects people's behaviour - people with ADHD can seem restless, may have trouble concentrating and may act on impulse. They may also have sleep and anxiety disorders. ADHD is an example of neurodiversity (see below).
Autistic Spectrum Disorder	ASD	The medical name for autism. ASD is a neurological and developmental disorder that affects how people interact with others, communicate, learn and behave. DSM-5 (see below) sets out people with ASD often have: • Difficulty with communication and interaction with other people. • Restricted interests and repetitive behaviours. • Symptoms that affect their ability to function in school, work, and other areas of life. ASD is known as a "spectrum" disorder because there is wide variation in the type and severity of symptoms people experience (National Institute of Mental Health, 2024).

TERM	ABBREVIATION	DESCRIPTION
Autonomy		Personal autonomy is the ability of a person to make their own decisions. In health this refers specifically to decisions about their care.
Best interests		Clinicians and the courts seek to act in the best interests of children and young people. The need to act in someone's best interests is outlined in law. For the Mental Capacity Act (MCA) 2005, decisions for someone who cannot decide for themselves must be made in their best interests. Under the Children Act 1989, in any decision of the court about a child (under 18), the welfare of the child must be paramount. For these purposes, there is little or no material difference between the welfare and best interests, and we have used "best interests" throughout the report. Although there is no standard definition of "best interests of the child," the General Medical Council advises that an assessment of best interests will include what is clinically indicated as well as additional factors such as the child or young person's views, the views of parents and others close to the child or young person and cultural, religious and other beliefs and values of the child or young person (General Medical Council, 2018). The Mental Capacity Act, Section 4 and extensive Court of Protection case law, deals with the approach to best interests under that legislation. Whether in the Court of Protection or the High Court, when the Court is asked to make an assessment of a child or young person's best interests, it will consider their welfare/best interests in the widest sense. This will include not just medical factors but also social and psychological factors.
Binder		A binder is a purpose-built undergarment used to flatten and reduce the appearance of breasts.
Case-mix		The mix of patients (cases) seen by a health service.

TERM	ABBREVIATION	DESCRIPTION
Child and adolescent mental health services	CAMHS	NHS children and young people's mental health services. CAMHS is a secondary care service for children and young people under the age of 18, that assess and treat young people with moderate to severe mental health difficulties. There are local NHS CAMHS services around the UK, with teams made up of nurses, therapists, psychiatrists, psychologists, support workers and social workers, as well as other professionals (Young Minds, n.d.).
Child and/or young person		In law, everyone under 18 years of age is a child (Children Act 1989) but we recognise that it may be more appropriate to refer to those approaching the age of 18 as a young person, and that such young people may not recognise themselves as a "child". In places, we have referred only to "young person", or only to "child", for example where treatment in question is only given towards the later stages of childhood, closer to the age of 18, or in reference to the parent/child relationship, in which they remain the parents' child, regardless of their age. Otherwise, we have used the phrase "child and/or young person" throughout the report for this reason only, and do not intend there to be a material difference between them other than that.
Cisgender		Used to describe a person whose personal identity and gender identity is the same as their birth-registered sex.
Cognitive		Relating to, or involving, the process of thinking and reasoning.
Confidence interval		A range around a measurement that conveys how precise a measurement is. In statistics, a confidence interval is a range of values providing the estimate of an unknown parameter of a population. A confidence interval uses a percentage level to indicate the degree of uncertainty of its construction. This percentage, known as the level of confidence, refers to the proportion of the confidence interval that would capture the true population parameter if the estimate were repeated for numerous samples.

TERM	ABBREVIATION	DESCRIPTION
Confounder		Something that affects the result of an experiment in a way that makes it less clear that one thing causes another, because it has an effect on one of the things being measured (Cambridge Advanced Learner's Dictionary & Thesaurus, n.d.). For example, mortality rates between two groups - one consisting of heavy users of alcohol, one consisting of teetotallers. You may conclude that heavy alcohol use increases the risk of death, however, in reality the situation may be more complex. Alcohol use may not be the only mortality-affecting factor that differs between the two groups, for example, those who consume less alcohol may be more likely to eat a healthier diet, or less likely to smoke, which may in turn affect mortality. These other influencing factors are called confounding variables. Ignoring confounding variables may mean that your results don't reflect reality that well (Ilola, 2018).
Consent		Permission for a clinical intervention (such as an examination, test or treatment) to happen. For consent to be 'informed', information must be disclosed to the person about relevant risks, benefits and alternatives (including the option to take no action), and efforts made to ensure that the information is understood. In legal terms, consent is seen as needing: 1. capacity (or Gillick competence under 16) to make the relevant decision 2. to be fully informed (i.e. the information provided about the available options, the material risks and benefits of each option, and of doing nothing, "material" meaning (per the Montgomery Supreme Court judgment in 2015) what a reasonable patient would want to know, and what this patient actually wants to know, NOT what a reasonable doctor would tell them) 3. to be freely given (that is, without coercion).

TERM	ABBREVIATION	DESCRIPTION
Contraindications		A condition or circumstance that suggests or indicates that a particular technique or drug should not be used in the case in question. For example, having a bleeding disorder is a contraindication for taking aspirin because treatment with aspirin may cause excess bleeding.
Court of Appeal		(England and Wales) The Court of Appeal hears appeals against both civil and criminal judgments from the Crown Courts, High Court and County Court. It is second only to the Supreme Court.
Detransition/ detransitioners		The process of discontinuing or reversing a gender transition, often in connection with a change in how the individual identifies or conceptualises their sex or gender since initiating transition (MacKinnon et al., 2023).
Diagnostic and Statistical Manual of Mental Disorders Fifth edition	DSM-5	The standard classification of mental disorders used by mental health professionals in the UK, and internationally, published by the American Psychiatric Association (2013). The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR) (2022) is the latest version.
Diagnostic formulation		The comprehensive assessment that includes a patient's history, results of psychological tests, and diagnosis of mental health difficulties.
Divisional Court		(England and Wales) When the High Court of Justice of England and Wales hears a case with at least two judges sitting, it is referred to as the Divisional Court. This is typically the case for certain judicial review cases (as well as some criminal cases).

TERM	ABBREVIATION	DESCRIPTION
Dutch Approach		Protocol published in 1998 by the Amsterdam child and adolescent gender identity clinic (de Vries & Cohen-Kettenis, 2012). The protocol set out that young people being considered for treatment for gender dysphoria with the use of puberty blockers must meet the following criteria: • minimum age 12; • life-long gender dysphoria increased around puberty; • psychologically stable without serious comorbid psychiatric disorders that might interfere with the diagnostic process; and • have family support.
Endocrine treatment		Sometimes referred to hormone treatment/therapy. In relation to this clinical area, this term is used to describe the use of gonadotropin-releasing hormones (see below) and feminising and masculinising hormones (see below).
Endocrinologist		An endocrinologist is a medical doctor specialising in diagnosing and treating disorders relating to problems with the body's hormones.
Endocrinology		The study of hormones.
Epidemiology		Epidemiology is the study of how often diseases occur in different groups of people and why. This includes the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems (Centers for Disease Control and Prevention, 2012).
Exploratory approaches		Therapeutic approaches that acknowledge the young person's subjective gender experience, whilst also engaging in an open, curious, non-directive exploration of the meaning of a range of experiences that may connect to gender and broader self-identity (Bonfatto & Crasnow, 2018; Churcher Clarke & Spiliadis, 2019; Di Ceglie, 2009; Spiliadis, 2019).

TERM	ABBREVIATION	DESCRIPTION
Feminising and masculinising hormones (also known as cross-sex hormones, and gender affirming hormones).		Sex hormones given as part of a medical transition for gender dysphoric individuals (testosterone for transgender males and oestrogen for transgender females).
Gender dysphoria		Diagnostic term used by health professionals and found in DSM-5 outlined above (American Psychiatric Association, 2013). Gender dysphoria describes "a marked incongruence between one's experienced/ expressed gender and assigned gender of at least 6 months duration" which must be manifested by a number of criterion.
Gender fluid		An experience of gender that is not fixed, but changes between two or more identities
Gender identity		This term is used to describe an individual's internal sense of being male or female or something else.
Gender identity development		The developmental experience of a child or young person in seeking to understand their gender identity over time.
Gender Identity Development Service	GIDS	The service commissioned by NHS England for children and adolescents with gender dysphoria. NHS England decommissioned GIDS as part of a managed transition of the service, initially to two new nationally networked services (Phase 1 providers) based in specialist children's hospitals.
Gender incongruence		Diagnostic term used by health professionals, found in the WHO International Classification of Diseases ICD-11 (see below). Gender incongruence is characterised by "a marked and persistent incongruence between an individual's experienced gender and the assigned sex".

TERM	ABBREVIATION	DESCRIPTION
Gender-questioning		A broad term used to describe children and young people who are in a process of exploration about their gender.
Gender-related distress		A way of describing distress that may arise from a broad range of experiences connected to a child or young person's gender identity development. Often used for young people whereby any formal diagnosis of gender dysphoria has not yet been made.
General Practitioner	GP	A doctor who provides general medical treatment for people who live in a particular area (Cambridge Advanced Learner's Dictionary & Thesaurus, n.d.). GPs deal with a whole range of health problems and manage the care of their patients, referring onto specialists as appropriate.
Gillick competence/ Fraser guidelines		A term derived from the legal case Gillick v West Norfolk And Wisbech AHA, 1984 that is used to decide whether a child or young person up to the age of 16 years is able to consent to their own medical treatment, without the need for parental permission or knowledge. A child or young person will be 'Gillick competent' for that decision if they have the necessary maturity and understanding to make the decision.
Gonadotropin releasing hormone analogues (also known as hormone blockers and puberty blockers)	GnRH	Taking these hormones stops the progress of puberty. The GnRH analogues (puberty blockers) act by competing with the body's natural gonadotrophin releasing hormone. This competition blocks the release of two gonadotrophin hormones important in puberty called Follicular Stimulating Hormone (FSH) and Luteinising Hormone (LH) from the pituitary gland.
High Court		The third highest court in the UK. It deals with all high value and high importance civil law (non-criminal) cases and appeals of decisions made in lower courts. When the High Court sits with more than one judge, as required for certain kinds of cases, it is called the Divisional Court.

TERM	ABBREVIATION	DESCRIPTION
International Classification of Diseases 11th Revision	ICD-11	The International Classification of Diseases (ICD) is a globally used medical classification of anything that is relevant to health care and is used clinically for medical diagnosis. (https://icd.who.int/en). It is developed and annually updated by the World Health Organization (WHO) and is the mandatory global data standard for recording health information. It is currently in its 11th revision (ICD-11).
Living in stealth		Used to describe a person who is living as a member of their identified gender without others being aware this is different from their birth-registered sex.
Looked after children		Children who are in the care of their Local Authority who may be living with foster parents or in a residential care setting.
Mega-analysis		An analytical process by which raw data is pooled across studies (Eisenhauer, 2020).
Meta-analysis		Meta-analysis is the statistical combination of results from two or more separate research studies that address a similar research question to generate an average result (Higgins et al,. 2023).
Minority stress		Ongoing stress - including discrimination, exclusion, prejudice and violence - experienced by members of minority groups living in a society that stigmatises their identities (Meyer, 2003).
Multi-disciplinary-team	MDT	The identified group of professional staff who provide a clinical service. As a group they provide experience from diverse disciplinary backgrounds.
Neuro-developmental disorders		The World Health Organization criteria (2022b) defines neurodevelopmental disorders as “behavioural and cognitive disorders that arise during the developmental period that involve significant difficulties in the acquisition and execution of specific intellectual, motor, or social functions”.
Neurodiverse		“Neurodiversity” is a popular term that's used to describe differences in the way people's brains work. It is a combination of traits that are seen as both strengths and challenges. ADHD (see above) is an example of neurodiversity.

TERM	ABBREVIATION	DESCRIPTION
Non-binary		A gender identity that does not fit into the traditional gender binary of male and female (Twist & de Graaf, 2018).
Packer		A packer is an item (e.g. prosthetic device, fabric packer) worn to create the appearance of male genitalia.
Paediatrics		The branch of medicine dealing with children and their medical conditions.
Pass/passing		A person's gender being seen and read in the way they identify.
Precocious puberty		This is when a child's body begins changing into that of an adult (puberty) early - before age 8 in girls and before age 9 in boys.
Primary care		Primary care in the UK includes general practice, community pharmacy, dental and optometry (eye health) services. This tends to be the first point of access to healthcare.
Pseudonymised		Patient confidentiality and anonymity is essential. Sometimes to maintain this, patient information and data needs to be presented in a format that ensures a person is not identifiable. This is called pseudonymisation. Pseudonymisation is the de-identification of identifiable patient-centric data item values through the use of substitute values. Pseudonymised data can be linked and used for secondary purposes, such as trend analysis and peer comparison, without using identifiable data items.
Psychological formulation		A structured approach to understanding the factors underlying distressing states in a way that informs the changes needed and the therapeutic intervention for these changes to occur.
Psychosocial		Describes the psychological and social factors that encompass broader wellbeing.
Puberty blockers		See gonadotropin-releasing hormone analogues above.

TERM	ABBREVIATION	DESCRIPTION
Retransition		Resuming a gender transition following detransition. Some people who have detransitioned may use this term to: • indicate restarting hormone therapy for medical reasons, but without re-identifying as transgender • refer to re-identifying since initiating a gender transition such as moving from a binary transgender identity to non-binary • describe stopping or reversing transition (MacKinnon et al., 2023).
Secondary care		Hospital and community health care services that do not provide specialist care and are usually relatively close to the patient. For children this will include Child and Adolescent Mental Health Services (CAMHS), child development and general paediatric services.
Service specification		A service specification clearly defines the standards of care expected from organisations funded by NHS England to provide specialised care. The specifications are developed by specialised clinicians, commissioners, expert patients and public health representatives to describe both core and developmental service standards. Core standards are those that all funded providers should be able to demonstrate, with developmental standards being those which may require further changes in practice over time to provide excellence in the field.
Sex-of-rearing		The gender-specific upbringing by which a child is brought up. In children with Differences in Sex Development (DSD) sex-of-rearing is decided by parents according to the child's biological birth sex (i.e. phenotype).
Social contagion		The spread of ideas, attitudes, or behaviour patterns in a group through imitation and conformity (Colman, 2014).

TERM	ABBREVIATION	DESCRIPTION
Specialised services		NHS specialised services support people with a range of rare and complex conditions. Three factors determine whether NHS England commissions a service as a prescribed specialised service. These are: • The number of individuals who require the service; • The cost of providing the service or facility; The number of people able to provide the service or facility.
Tanner Stage		Tanner Staging, also known as Sexual Maturity Rating, is a classification of puberty by stage of development. This ranges from Stage 1, before physical signs of puberty appear, to Stage 5 at full maturity. The name originates from Professor JM Tanner, a child development expert, was the first to identify the visible stages of puberty.
Tertiary care		Tertiary care is the specialist end of the NHS. These services relate to complex or rare conditions. Services are usually delivered in a number of specialist hospitals/centres.
Transgender	trans	This is an umbrella term that includes a range of people whose gender identity is different from the sex they were registered at birth.
Transition		These are the steps a person may take to live in the gender in which they identify. This may involve different things, such as changing elements of social presentation and role and/or medical intervention for some.
Watchful waiting		An approach by which a child/young person's gender journey is observed (without intervention) to see how their gender identity and expression naturally evolves.

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Appendix 1

Terms of reference

TERMS OF REFERENCE FOR THE REVIEW OF GENDER IDENTITY DEVELOPMENT SERVICES FOR CHILDREN AND ADOLESCENTS

INTRODUCTION

1. NHS England is the responsible commissioner for specialised gender identity services for children and adolescents. The Gender Identity Development Service for children and adolescents is currently managed by the Tavistock and Portman NHS Foundation Trust.

2. In recent years there has been a significant increase in the number of referrals to the Gender Identity Development Service, and this has occurred at a time when the service has moved from a psychosocial and psychotherapeutic model to one that also prescribes medical interventions by way of hormone drugs. This has contributed to growing interest in how the NHS should most appropriately assess, diagnose and care for children and young people who present with gender incongruence and gender identity issues.

3. It is in this context that NHS England and NHS Improvement's Quality and Innovation Committee has asked Dr Hilary Cass to chair an independent review, and to make recommendations on how to improve services for children and young people experiencing issues with their gender identity or gender incongruence, and ensure that the best model/s for safe and effective services are commissioned.

REVIEW SCOPE

The independent review, led by Dr Cass, will be wide ranging in scope and will conduct extensive engagement with all interested stakeholders. The review is expected to set out findings and make recommendations in relation to:

i. Pathways of care into local services, including clinical management approaches for individuals with less complex expressions of gender incongruence who do not need specialist gender identity services;

ii. Pathways of care into specialist gender identity services, including referral criteria into a specialist gender identity service; and referral criteria into other appropriate specialist services;

iii. Clinical models and clinical management approaches at each point of the specialised pathway of care from assessment to discharge, including a description of objectives, expected benefits and expected outcomes for each clinical intervention in the pathway;

iv. Best clinical approach for individuals with other complex presentations;

v. The use of gonadotropin-releasing hormone analogues and gender affirming drugs, supported by a review of the available evidence by the National Institute for Health and Care Excellence; any treatment recommendations will include a description of treatment objectives, expected benefits and expected outcomes, and potential risks, harms and effects to the individual;

vi. Ongoing clinical audit, long term follow-up, data reporting and future research priorities;

vii. Current and future workforce requirements;

viii. Exploration of the reasons for the increase in referrals and why the increase has disproportionately been of natal females, and the implications of these matters; and,

ix. Any other relevant matters that arise during the course of the review.

x. In addition, and with support from the Royal College of Paediatrics and Child Health and other relevant professional associations, the Chair will review current clinical practice concerning individuals referred to the specialist endocrine service. It is expected that findings and any recommendations on this aspect of the review will be reported early in 2021 with the review's wider findings and recommendations delivered later in 2021.

xi. The review will not immediately consider issues around informed consent as these are the subject of an ongoing judicial review. However, any implications that might arise from the legal ruling could be considered by the review if appropriate or necessary.

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Appendix 2



The epidemiology, care pathways, outcomes, and experiences of children and adolescents experiencing gender dysphoria/incongruence: a series of linked systematic reviews and an international survey

AR-000316

The epidemiology, care pathways, outcomes, and experiences of children and adolescents experiencing gender dysphoria/incongruence: a series of linked systematic reviews and an international survey

Introduction

Increasing numbers of children and adolescents experiencing gender dysphoria or incongruence are being referred for care at specialist paediatric gender services. There are several clinical guidelines to support the clinical care of children and adolescents experiencing gender dysphoria or incongruence and their families, however, there are divergent clinical approaches to the management of these children and adolescents. Several countries have or are modifying referral and care pathways and provision in response to increasing numbers of referrals, changing demographics and ongoing uncertainty about the benefits, risks, and long-term effects of medical interventions for these children.

Overall aim: To systematically identify, collate and synthesise the existing evidence on the epidemiology, care pathways, outcomes and experiences for children and adolescents with gender dysphoria/incongruence.

We answered the following questions in the linked series of systematic reviews:

- What are the number of referrals and the characteristics of children and/or adolescents referred to specialist gender identity or endocrinology services that provide healthcare for those experiencing gender dysphoria/incongruence, and have these changed over time?
- What are the range of care pathways for children and/or adolescents referred to specialist paediatric gender or endocrinology services?
- What is the impact of social transition in relation to gender for children and/or adolescents?
- What is the effectiveness of psychosocial support interventions for children and/or adolescents experiencing gender dysphoria/incongruence?
- What is the gender-related, psychosocial, physiological, or cognitive outcomes of puberty suppression in adolescents experiencing gender dysphoria/incongruence?
- What is the gender-related, psychosocial, physiological, or cognitive outcomes of feminising/masculinising hormones in adolescents experiencing gender dysphoria/incongruence?
- What does published guidance on recommendations regarding the care of children and adolescents experiencing gender dysphoria/incongruence include, how were they developed and what is the quality?

The aim for the international survey was to understand the current provision of gender services for children and adolescents across the EU-15+ countries which have comparable high-income healthcare systems, to inform service development in the UK.

Systematic Review Methods

The protocol was registered on PROSPERO (CRD42021289659).

Search strategy

A single search strategy was used to identify studies comprising two combined concepts: 'children', which included all terms for children and adolescents; and 'gender dysphoria', which included associated terms such as gender incongruence and gender-related distress, and gender identity terms including transgender, gender diverse and non-binary. MEDLINE, EMBASE and PsycINFO through OVID, CINAHL Complete through EBSCO, and Web of Science (Social Science Citation Index) were searched (May 2021 updated in April 2022). Reference lists of included studies and relevant systematic reviews were also checked.

Overarching inclusion and exclusion criteria

Each individual review had its own inclusion and exclusion criteria, but studies were first screened against the following broad criteria:

Inclusion Criteria:

- Studies including children <18 years with gender incongruence, gender dysphoria / gender-related distress or referral to a paediatric or adolescent gender identity service.
- Primary studies (including those that involve secondary analysis of previously collected data) of any design, including experimental studies, observational studies, surveys, consensus studies and qualitative studies.

Exclusion Criteria:

- Studies about gender incongruence or gender dysphoria in adulthood.
- Studies of mixed populations unless the results for those with childhood gender incongruence, gender-related distress/dysphoria or those referred to a gender identity service in childhood are presented separately.
- Studies about individuals with differences in sex development (DSD)/ variations in sex characteristics (VSC).
- Single case studies, case series, editorials, or opinion pieces.
- Student dissertations.
- Systematic reviews or other literature reviews.
- Studies reported in conference abstracts.
- Studies not reported in English language.

Selection process

Search results were uploaded to Covidence and screened independently by two reviewers. Full texts for potentially relevant articles were retrieved and reviewed against the inclusion criteria for each review by two reviewers independently. Disagreements were resolved through discussion and involvement of a third reviewer where required.

Risk of Bias (quality) assessment

Where appropriate, the quality of studies included in the individual reviews were appraised using the most appropriate method. The tools used included the Mixed Methods Appraisal Tool (MMAT), modified versions of the Newcastle Ottawa Scale, and the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument. Two researchers rated the studies independently with discussion

to reach consensus. Study quality was not formally assessed in the systematic review that examined the characteristics of children and adolescents referred to paediatric gender services or in the review that examined their care pathways.

Data synthesis

A narrative approach to syntheses was used across reviews. The syntheses were performed by one reviewer and second-checked by another. Depending upon the specific review, proportions were combined in a random-effects meta-analysis using metaprop (Stata v18) with variances stabilised using the Freeman-Tukey double arcsine transformation. Graphs were used to display data visually where appropriate.

International Survey Methods

This was an e-survey of gender services for children and adolescents in the EU15+ countries which was open between September 2022 and April 2023. Contact details for the services were obtained from publicly available data, expert contacts and via snowball sampling. An email was sent to identified clinicians or managers, explaining the survey aims, confidentiality and data protection, and expected completion time. One reminder email was sent after three weeks. The survey contained 34 questions on service structure, care pathways, interventions, and data collection and an additional four questions on staffing and waiting lists. The questions were informed by a review of published papers describing service provision and the content of clinical guidelines. All responses were downloaded into Excel, descriptively analysed, and compared to assess similarity and variation among the services.

Results

Our searches yielded 28,147 records, 3,181 of which were identified as potentially relevant for the linked series of systematic reviews. Across all the reviews, 237 papers (214 studies and 23 guidelines/position statements) including 113,269 children and/or adolescents from 18 countries were reviewed (Figure 1). Included studies were published between 1978 and 2022, with 162 (68%) published from 2017 to the end date of the search in 2022.

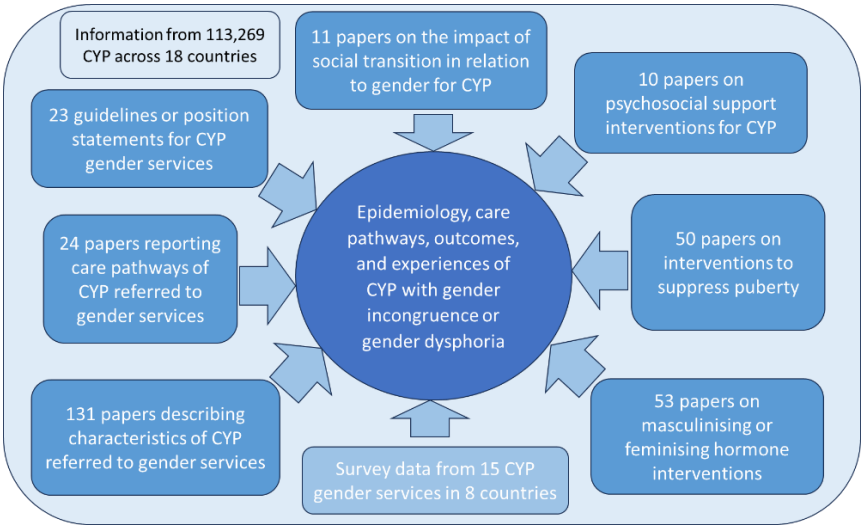

Figure 1: Overview of studies included in the individual reviews.

Overview of the findings

There has been a two to three-fold increase in the number of referrals and an increase in the ratio of birth-registered females to males being referred to specialist paediatric gender services over time across countries. Very few studies report data on gender status (self-reported gender identity, gender dysphoria, age at onset, and social transition) but from the limited data reported, over 60% of those referred were described as having taken steps towards a social transition. The evidence base for outcomes (benefits or harms) of social transition in childhood and adolescence is both limited and of low quality.

Data published to date suggests that presence of mental health challenges such as depression, anxiety, suicidality, self-harm, and eating disorders may be higher in children and adolescents referred to gender services than population estimates. There is limited data reported for other co-occurring mental health conditions. Presence of autism spectrum condition (ASC) and attention deficit hyperactivity disorder (ADHD) may be higher in those referred to gender services than population estimates. It was not possible to make inferences about changes over time for the characteristics explored due to overlapping samples and data being reported over large time-periods in individual studies.

There is very little information about detail or type of psychological care received by children and/or adolescents under the care of a specialist gender service, and there is limited low quality evidence on the outcomes of psychosocial interventions for children and adolescents with gender dysphoria or incongruence. Most analyses of mental health, psychological and/or psychosocial outcomes showed either benefit or no change, with none indicating negative or adverse effects. Only three studies assessed interventions that were specifically designed for children and/or adolescents experiencing gender incongruence, but these interventions varied considerably in content and delivery.

Data published to date suggests that approximately two-thirds of adolescents referred to specialist gender services receive puberty suppression or hormones, although rates for each vary considerably across clinics. There is also variation in the rates of those receiving puberty suppression prior to

starting hormones compared to those receiving hormones alone. There is very little information about children/adolescents who do not complete the assessment process within a specialist gender clinic or who do not receive medical intervention. Studies consistently report small proportions of adolescents who discontinue medical treatment; however, systematic reporting and reasons for discontinuation are rarely provided and follow up periods are limited.

There were no high-quality studies identified that used an appropriate study design to assess the outcomes of puberty suppression in adolescents experiencing gender dysphoria or incongruence. There is insufficient and/or inconsistent evidence about the effects of puberty suppression on gender dysphoria, mental and psychosocial health, cognitive development, cardio-metabolic risk, and fertility. There is consistent moderate-quality evidence, albeit from mainly pre-post studies, that bone density and height may be compromised during treatment.

There is a lack of high-quality research assessing the outcomes of hormones for masculinisation or feminisation in adolescents with gender dysphoria or incongruence and few studies that undertake long-term follow-up. There is little evidence regarding gender dysphoria, body satisfaction, psychosocial and cognitive outcomes, and fertility. There is moderate-quality evidence from mainly pre-post studies that hormone treatment may in the short-term improve some aspects of psychological health. There is inconsistent evidence about the effect of hormones on height/growth, bone health and cardiometabolic effects.

Twenty-three guidelines or position statements were identified that contain recommendations about the management of children and/or adolescents with gender dysphoria or incongruence. Few guidelines are informed by a systematic review of empirical evidence and there is a lack of transparency about how recommendations were developed. Only two of them consulted directly with children and/or adolescents during their development. Most national and regional guidelines have been influenced by the World Professional Association for Transgender Health and Endocrine Society guidelines which themselves lack developmental rigour and are linked through co-sponsorship. There is consensus across guidelines that those requiring specialist gender care should receive a multi-disciplinary assessment, although there is a lack of clarity about who should be involved in this and any differences in assessment for children and adolescents. Similarly, there is consensus that children and adolescents should be offered psychosocial support, but there is limited guidance about the process or approach for this and different recommendations about whether specialist gender clinics or mental health services should provide this. There are differing recommendations about when and on what basis psychological and hormone interventions should be offered, and limited guidance about pre-pubertal children or those with a non-binary gender identity.

The international survey found similar results with areas of common practice across gender services for children and adolescents in eight countries, with most using DSM-V diagnostic criteria and a multidisciplinary team approach. The survey revealed key differences in the composition of teams, the management of co-occurring conditions, pre-pubertal children, and those with a non-binary gender identity, and in the criteria for accessing medical interventions. Referral pathways into gender services for children and adolescents varied, and services reported limited provision of psychological care and a reliance on local mental health services. The survey found a lack of routine

outcome data collection among clinics, and this was evident from the studies included across the systematic reviews.

How the results might affect research, policy, or practice

Services need to respond to the potentially co-occurring complexities of children and adolescents being referred into specialist gender and endocrine services. Information about provision of psychological care and consideration of how this should be delivered is urgently needed considering the higher prevalence of mental health and psychosocial difficulties in this population. Detailed guidance to support psychological care of children and adolescents experiencing gender incongruence/dysphoria, or gender diverse children with psychosocial or mental health difficulties is needed. A better understanding of the care needs and provision for children and adolescents who enter assessment in a gender service but do not go on to receive medical interventions is needed to inform service provision. Prospective studies that follow-up children into adulthood and report information about the range of pathways followed are needed to understand longer term outcomes for those referred to specialist paediatric gender services. There is a lack of evidence and guidelines for those children and/or adolescents identifying as non-binary.

Healthcare services and professionals should take into account the variable quality of published guidelines to support the management of children and young people experiencing gender dysphoria or incongruence. The lack of independence in many national and regional guidelines, and the limited evidence-based underpinning current guidelines, should be considered when utilising these for practice. Practice base guidelines should reflect the limited evidence of the outcome of social transition for children and adolescents. Services and professionals should communicate the limitations of the evidence base surrounding social transition to children and adolescents experiencing gender dysphoria or incongruence and parents/carers.

There is a lack of high-quality evidence to support recommendations for puberty suppression or hormones for masculinisation or feminisation in children/adolescents experiencing gender dysphoria or incongruence. There is a lack of evidence comparing outcomes of adolescents who receive puberty suppression followed by hormones for masculinisation or feminisation to those who receive hormones only. Future guidelines should report the methods of development in full, with greater transparency about the links between evidence and recommendations and how recommendations are made in the absence of evidence.

Robust research is needed to address the significant gaps in our understanding of the potential short- and long-term outcomes of social transition, the risks, and benefits of puberty suppression and hormone interventions, and the appropriateness and effectiveness of different psychosocial interventions. Identification and agreement of core outcomes would help to ensure that what is important to relevant stakeholders is being collected and this would support future aggregation of evidence. High-quality studies using an appropriate study design are needed as is robust reporting. High quality standardised data collection should be routinely undertaken in gender clinics to enable comparison in outcomes for children and adolescents accessing different services.

Strengths and limitations

Strengths include a published protocol with robust search strategies and comprehensive synthesis. A limitation is that the database searches were conducted up until April 2022 and as this is a rapidly evolving area more recent publications would not have been included in the syntheses. We attempted to draw the findings of papers published after April 2022 into the discussion of each review, however as a comprehensive search of this literature was not undertaken more recent publications may have been missed. Due to available resources, only studies published in English were included. The primary research included in the reviews were generally of low quality and there was often inadequate reporting of key information required for the reviews which limited the analyses and conclusions that could be reached. All data relevant to review questions presented within the studies were extracted, summarised, and synthesised.

Caution should be taken when interpreting any of the pooled estimates as they represent data for a wide period of time, reported data were averaged over a large number of years, studies included often overlapping samples from the same clinic, and there were often discrepancies in the individual studies between the referred numbers and those included in the summaries of characteristics, and inadequate and/or unclear reporting of follow-up. Additionally, different tools or instruments were used to measure outcomes which increased heterogeneity. Reliance on publicly available information and known experts may mean some clinics were not identified and contacted to take part in the international survey. The low response rate within the survey means that certain countries are not represented and other potential differences in gender services are still unknown.

Journal publications

There are nine journal articles published in the Archives of Disease in Childhood associated with this overarching summary:

- Impact of social transition in relation to gender for children and adolescents: a systematic review.
- Gender services for children and adolescents across the EU-15+ countries: an online survey.
- Psychosocial support interventions for children and adolescents experiencing gender dysphoria or incongruence: a systematic review.
- Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1).
- Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of recommendations (part 2).
- Interventions to suppress puberty in adolescents experiencing gender dysphoria or incongruence: a systematic review.
- Masculinising and feminising hormone interventions for adolescents experiencing gender dysphoria or incongruence: a systematic review.
- Characteristics of children and adolescents referred to specialist gender services: a systematic review.
- Care pathways of children and adolescents referred to specialist gender services: a systematic review.


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Appendix 3

Qualitative Research Summary

Narrative accounts of gender questioning



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AR-000326

Introduction

In 2020 NHS England appointed Dr Hilary Cass to review gender identity services for children and young people in England. Dr Cass - through NHS England - commissioned independent qualitative research from the University of York to understand:

- children and young people's experiences of gender dysphoria, and the support they found helpful;
- parents' experiences of supporting their child;
- families' experiences of accessing services, including how they make decisions about care;
- experiences of young adults who questioned their gender when younger; and
- the experiences of care professionals who support children and young people, referred to the Gender Identity Development Service (GIDS).

We spoke to young people, aged between 12 and 18 years old (n=14), who sought support from the specialist NHS gender services in England. We also talked to parents (n=12), young adults aged between 19 and 30 years old (n=18) and care professionals (n=23). The research, conducted between March 2022 and August 2023, received NHS ethical approval (IRAS Project Id: 306023). The research protocol is available on the Cass Review website. This short summary introduces what our participants told us. We are currently preparing peer review publications on the basis of further, in-depth analysis. Thank you to everyone, who generously shared their experiences with us.

Doing the research

There is a human imperative to tell our stories and we wished to make use of this, especially as gender identity is a sensitive (and contested) topic, in which public debate can be unsympathetic to diverse experiences. We used narrative interviews, to hear participants' voices and engage with their biographical experiences. We explored how they defined, articulated and negotiated their gender, within the context of social networks.

To ensure we captured diversity, our sampling strategy used different ways of recruiting participants. We recruited 12 young people via the Gender Identity Development Service (GIDS) and two through voluntary organisations. We asked these young people for consent, before inviting their parents to take part. We also recruited three parents,

not related to the young people we spoke to, through private practice and voluntary organisations. Our sample of parents included seven mothers and five fathers.

When recruiting young adults, we contacted six community and voluntary organisations who, in addition to engaging with valuable discussions about the research, circulated invitations to take part in it. We also recruited young adults through an Adult Gender Identity Clinic and interviewed a small number, who had contacted the Cass Review team, asking to take part in the research.

Most care professionals interviewed worked at GIDS. They represented all regional teams; had a variety of different backgrounds (i.e., clinical psychologists, psychological and family therapists, social workers and specialist nurses); varied in the time spent working in the service; and included those with managerial responsibilities. In addition, we interviewed a youth worker and a therapist working in private practice.

When inviting participants to take part in our research, we made no assumptions about how they identify. Our sample of young people included nine young people registered female at birth and five registered as male. Four had begun a medical pathway. Three young people were neurodiverse. Most young people described themselves as trans, although one described themselves as non-binary and several continued to explore labels. Our sample of young adults included eight trans men and four trans women. Four young adults identified as non-binary or gender queer, or for whom labels were not important. Two participants identified as detransitioners. Five young adults were neurodiverse. Three belonged to an ethnic minority.

During our interviews we covered similar topics, to ensure we could compare responses, while creating an environment that enabled participants to reflect on their specific experiences. Topics were developed from relevant literature and through discussions with young gender diverse people as part of our Patient and Public Involvement (PPI) work. These young people also commented on the make-up of the sample and the focus of the study.

Interviews, held online using video conferencing software, lasted between sixty and ninety minutes. With consent, we audio recorded interviews and transcribed them verbatim. We interviewed most participants once but adjusted our approach to support their needs. Those with autistic spectrum conditions, for example, were able to meet with a researcher for shorter periods over several interviews.

Analysis explored the ways in which participants negotiated meaning, within normative expressions of gender identity. This generated narrative themes that enabled us to relate personal and cultural stories to their social context. These themes were then interrogated to highlight similarities and differences among participants.

Doing research on gender identity generates challenges. Some people, for example, expressed a reluctance to take part in research, because of what they regarded as hostile public discussions. We are sorry to miss their voices but understand their concerns. Our voluntary sector colleagues spoke of research fatigue, while the use of GIDS' clinicians to generate our sample of young people may have meant the research did not capture more complex cases. Despite this, our research represents a diverse range of experiences, pathways and outcomes, which provide valuable insights for those planning services.

What we found

Young people

Many young people described an initial sense of difference, which was difficult to explain. They did not fit in and gender norms confused them. Social interactions became fraught with uncertainty and anxiety:

> "I had people telling me constantly, like, why are you acting like this, you're a girl not a boy. Like, I would just be thinking to myself like why are people trying to make me a girl when I'm genuinely not a girl? So yes, that was probably the most confusing time of my life".

Young people explained that they were sometimes made to feel like "freaks" or "outcasts". Many described experiences of bullying. The negative reactions of others caused distress.

They - and their families - initially sought support from primary care and mental health services. Discussing gender in these settings was not always positive. Young people and their parents described a lack of knowledge and understanding. Some also spoke of not being taken seriously:

> "At first, [with a GP] it was not good. He literally had no idea what we were talking about, which was frustrating."

Young people wanted support to help manage potential distress and explore what gender questioning meant for them and their body. Most young people, however,

experienced a long wait before accessing NHS gender services (around three years). Waiting times impact on young people and their families, and the work specialist services provide. Care professionals believe waiting lists represent the biggest challenge facing service delivery. Young people and their parents agree. Families describe the difficulties of understanding gender questioning and managing distress, without formal support. Young people (and their parents) wished professional support was available during the initial stages of gender questioning:

> "Hearing nothing […] was definitely a struggle [...] So maybe like in those waiting times [services should] try providing a bit of support, whether it's just even online or something because you're kind of completely left in the dark and that's quite scary."

Accessing reliable information, a young person could trust and find useful proved challenging for many. While some did find online content helpful, it was described by many as a "minefield". Many expressed a need for balanced and informative online material.

Young people said the lack of support, when waiting, affected their mental health and well-being. They spent the time reflecting and researching. They also took steps to help manage how they felt and most socially transitioned while waiting. The process, although dynamic and flexible, was positively regarded by young people. Many parents, although initially hesitant, come to understand the value of social transitioning. A few, however, remained anxious about its impact. Families would have welcomed advice on how to negotiate social transitioning but many experienced difficulties in accessing support.

Several young people, while waiting, become aware of the ways in which medical pathways could help them. Waiting, they said, provided them with plenty of opportunity to understand how they felt. Many were confident about the next steps, when first accessing NHS gender services. Some young people regard their parents as more cautious. This could be a cause of tension.

Many of the young people we spoke to, however, had not accessed medical pathways. Most were in various stages of assessment, while others were waiting for referral to adult services. The few who had accessed medical pathways described them as having a positive impact.

Young people expressed a range of thoughts and feelings about beginning sessions at GIDS. When accessing specialist services, they learn that "a lot of talking" must be done:

> "At first, it [talking] didn't feel helpful. I didn't really know why […] because they can't really give you a quick-fix […] I feel like when you're a kid, you just want everything to be fixed, and my mum is the same […] so, that was frustrating, but I've, kind of, come to terms with the fact that it's a slow, kind of, like, therapy process, and it's not all about just medication and stuff like that."

Young people respond in different ways, although their hopes remain consistent. They want to feel better about themselves. Some young people looked forward to talking with someone who understood them. Some, however, felt uncomfortable and initially found it difficult to talk about how they felt. Others expressed frustration, disappointment and at times, anger. They believed talking slowed down or prevented access to medical pathways. These young people believed their life was "on hold" and described how they felt unable to plan for the future. Waiting had created a sense of urgency:

> "I expected to do the talking first but I didn't think it'd take long […] [that] they'd want to get me on puberty blockers as soon as possible […] it was just really frustrating because obviously there was nothing I could do about it. Like, it's my body but I have no control over it."

Irrespective of expectations (and any initial frustration or hostility), many young people come to appreciate the opportunity to talk with specialist clinicians. Young people felt listened to and believed. Relationships with clinicians, although not without tension, come to be highly valued. Young people described having access to a relaxed, comfortable and non-threatening, safe space in which they could explore how they feel, as empowering:

> "They give you a safe place to talk as personal as you want and it doesn't go anywhere, you can trust them, and you feel validated and like what you're saying really matters."

Young people remain sensitive to any questioning of who they are. They may, however, become open to talking, when exploring what their gender questioning means for them. Talking, for example, enables them to relieve distress, consider different options

and plan for the future. For young people, successful clinical relationships establish respect, build trust and encourage an openness, when exploring experiences. Young people believe they have a right to be flexible, as they search for an identity, with which they feel comfortable.

Parents

The parents we spoke to represent a diverse range of responses. They support their child in a variety of ways. Parents conduct their own research before seeking support and guidance. They value and prioritise different pathways. Each without doubt, and even when in discord with their child (or with services), acted in what they understood to be the best interests of their child. Maintaining supportive family relationships remained a priority for them. Young people, although mentioning parents' initial confusion and a lack of understanding, felt "lucky" to have such caring parents, even if they do not always agree with them.

Some parents, clear about the next steps, support their child by advocating for access to medical pathways. They express concerns that specialists services are not sufficiently "affirmative" and may act as an inappropriate gatekeeper to medical pathways:

> "[They] felt like the gatekeeper to the endocrinology service [...], so we knew that we had to jump through that hoop [assessment] but in terms of therapeutic support, that's not to say that the therapists weren't skilled because I've got immense amount of respect for [name of clinician] but I think it was just, it's flawed, isn't it, it's an immensely flawed service."

Other parents enter specialist services feeling less certain about what should happen next. These parents wanted help supporting their child, which they hoped would include exploring different options and outcomes. They wanted reliable information and a comprehensive assessment process:

> "I was quite relieved when the counselling with GIDS went on [for] a long time [...] because that just slowed it all down a bit. I think [name of child] wanted to rush, rush, rush, get the diagnosis, get his testosterone, get his top surgery done and then his life would be brilliant again […]. Whereas [...] I wanted it to slow right down and take that time talking, for GIDS to make a proper assessment

and yes, and for me to be able to trust their assessment, [...] which I felt I did at the end of it."

Most parents remain cautious, but open-minded about medical pathways. A few, however, avoided or delayed a referral to GIDS because of worries about an "affirmative" approach, which they believed would rush or prioritise medical pathways.

Parents expressed continuing uncertainties and doubts about what was best for their child. They worry about getting it "wrong". They also worry about the extent services could understand their child and respond appropriately. Some parents explained that healthcare practitioners had raised safeguarding concerns. This included parents advocating for medical pathways and those who adopted a more cautious approach.

Many parents expressed anxieties about the future, including the extent their child would be accepted by a society they regarded as hostile to difference. The long-term consequences of medical interventions also concerned some parents. Parents want their child to be happy but are not always sure how best to achieve this.

Several parents express worries about the extent services can meet holistic needs. Some worry, for example, that mental health and neurodiversity would not be appropriately considered, when exploring their child's gender questioning and any associated distress. Parents of children with autistic spectrum conditions describe positive experiences of specialist support, especially when they help establish networks of support, although some remain unsure if clinicians had the skills or experience to understand and support their child.

Parents' narratives understandably focused on their child's needs. Irrespective of their expectations and hopes for their child, parents found care difficult to negotiate:

> "I think that's part of the problem with this, because the system would like there to be a clear problem to solve and a clear route in which to solve it and I'm afraid it just isn't the case."

They also found caring emotionally challenging and there are times when they feel overwhelmed:

> "I think [we] just need us to swallow our own discomfort and stuff about it, and sit with theirs [their child], and not judge, and not, not tell them how to be or what to do, to just, to standstill with it. And that's really hard for some people I think because it is mind blowing stuff if you let yourself dwell on it."

Some explained that their own mental and physical health had deteriorated because of their caring responsibilities. They rarely received support for this.

Healthcare professionals and clinicians

Clinicians said negotiating assessment (including making decisions about the readiness for medical pathways), while also providing therapeutic support is a defining feature of their role. It was a source of tension too. They explained that before making any assessment, they encouraged the young person to reflect on - and understand - what their gender questioning meant for them. Clinicians worry that current changes, which involve considerable documenting of decision making, reduce the time available for talking to young people and their families.

Clinicians said that increased waiting times meant some young people and their parents come with "fixed" ideas about what they need from specialist provision. This sometimes made it difficult to build positive relationships, at least initially. Working with families, who felt confident in their decision making and wished to move forward quickly, created particular challenges. Clinicians understood that some families regarded them as "gatekeepers" to medical pathways. They believe this can be unhelpful as it could undermine therapeutic intent. Clinicians spent time in initial appointments apologising for the long wait and setting expectations. This may require them to "unpick" what had gone on before. Some families did not like this and it undermined trust.

Clinicians found current clinical language unhelpful. Labels such as "affirmative" or "exploratory", they said, did not reflect the complex and thoughtful work they did. Clinicians felt it possible to "validate" a young person's experience, while seeking to "open up a curiosity" about what this may mean for them. In explaining this, some clinicians said their role was not to make decisions for - or change the mind of - a young person but rather to encourage self-reflection on what would help them to flourish:

> "I think it is really [...] taking a holistic look at the young people that come through the door and a very person-centred approach. I wouldn't claim that any young person that comes through the door would need the same thing as the person who came to the door the hour previous. So really taking that person-centred approach. Looking at what they need to live well, I suppose that's what I see my job as, what does this person need to live well, to be happy, to flourish in the world."

Clinicians say they are "not invested in particular outcomes", when supporting young people. Their role may include facilitating access to medical and/or social pathways, alongside considering other possible outcomes. Successful therapeutic relationships, they say, require carefully listening to what the young person is saying, although this does not preclude a "gentle" questioning of what is said. Clinicians said enabling a young person to articulate an outcome and/or pathway appropriate to their needs, remained their priority:

> "I suppose I see the main purpose of the job as being to develop kind of trusting therapeutic relationships with young people and their families that enable young people to be able to feel safe to explore their experiences [...] thinking about how we can best support people, and that might include physical interventions, it might involve talking, it might involve both, but I think all of that can only really happen if clinicians kind of provide that really like safe listening space."

Some clinicians highlighted the challenges of working with clinical uncertainty and an evidence base that was not as strong as they would have liked, although a few noted that this was not unique to their specialism. More experienced clinicians were better able to negotiate these challenges. Clinicians agreed that puberty blockers and cross sex hormones provide an important pathway, alongside therapeutic support. Ensuring their safe use was important, in addition to understanding their long-term consequences.

Clinicians remarked that there is no agreed fixed point of reference on which to judge the success of an intervention, let alone a societal consensus on the appropriate response to young people who are gender questioning and/or experiencing distress. Responding to changing social and cultural expectations, political interference and regulatory scrutiny, they said, made for a difficult working environment. Clinicians, however, commented on "respecting the anxiety" generated by their role. They agreed, it is a privilege to work with young people. Their work is challenging. They believe it should be. It was also hugely rewarding.

The value of dysphoria as a diagnostic category provides an example of the challenges clinicians face. For many young people - and young adults - dysphoria is a useful medical label, helping to legitimise and explain experience. It also helped justify asking for support. Young people believed it created – at least initially - a possible shared language, which others could understand. Over time, however, some expressed

ambivalence. They continued to understand the value of dysphoria, but thought it could also represent an unhelpful diagnosis, in which their social experience could only be regarded as authentic if a medical label were attached. Young adults are especially sensitive to this. Parents commented on how a diagnosis of dysphoria helped legitimate their child's experiences, while facilitating access to medical pathways. It also helped them make sense of what they were going through, by making it "real". Clinicians understand the importance of diagnosis, particularly when justifying decision making, but remained sensitive to over-medicalisation, especially when a person's dysphoria was socially located.

Young adults

The young adults we spoke to described similar experiences to young people, when managing their distress and like young people, they struggled to access appropriate support. Young adults also spoke of supportive family relationships, although these are not without tension. Several who had initially experienced their parents' questioning as unhelpful, came to recognise its value in enabling them to understand their feelings. A few young adults, however, described less positive relationships, which had deteriorated over time, with both immediate and extended family. This increased their risk of social isolation.

Young adults expressed an incredibly diverse range of experiences and pathways. Many benefitted from access to medical pathways which, they said, enabled them to lead the lives they wanted. Others explored equally empowering options, such as social transitioning and more fluid and non-binary expressions of gender. Some young adults, as they grew older, questioned binary approaches, although for others, gender binaries remain an important reference point. Like young people, young adults highlighted the importance of having access to balanced information that reflected a diverse range of experiences and pathways, from a trusted source, such as the NHS.

Young adults explained how the discovery of gender diversity - and the possibility of transition - generated self-understanding. This included knowledge about the diversity and richness of transition. For many, understanding and expressing their gender occurred gradually and evolved over time:

> "But actually I've learnt that you grow into it and you start to understand yourself more and you begin to love yourself because of it."

Many young adults found transitioning liberating and a source of euphoria. These young adults are proud of their journeys, which they say, have brought them fulfilment, joy and happiness:

> "I started going, oh so what does your euphoria actually want? What are the things that make you happy? And exploring my gender in that way has been just such a joy."

For some, initial gender questioning created a sense of urgency, much of which focused on accessing medical pathways. These young adults acknowledged that their original response was to "fix" the problem. This became less important to them as they grew older. Some explained that discovering different ways to express gender identity was one of the most important things they had learned. They wished this had been explained to them when younger but remain uncertain about the extent they would have listened to such advice.

Young adults believe opening up a space for - and acceptance of - a diversity of 'transition' that does not require them to prove they are "trans enough", is the basis for the successful exploration of gender identity. What young adults dislike is when others try to define - or make assumptions about - who they are. They also dislike the imposition of labels. Young adults are clear. Their gender questioning is not a lifestyle choice or preference. It is who they are.

Two young adults, however, experienced regret. Physical transition had initially helped them. They now felt it was a mistake. Looking back, they would have liked more therapeutic support when considering transition (which they had done outside the NHS). They also described a lack of support available to those who wish to detransition:

> "I felt like it wasn't, you know, acceptable to go back. It wasn't a thing to go back, you know. It wasn't something that was talked about. It didn't feel like an option that they wanted to discuss or even mention […] I want detransition to be something that can be openly talked about, and regret to be openly talked about."

Many young adults, when reflecting on their own experiences of transition, explain that while it can be difficult and uncomfortable, it is important for young people to take their time, ask for support when needed and make decisions that are right for them:

> "Go slow, go calm, just don't rush it. Go at your own pace."

Care, they say, must be timely and validating. Young adults, however, spoke of the difficulties of accessing appropriate care at the time, when you realise you need it.

Young adults (and clinicians) emphasise that diversity should not be used to undermine trans and gender diverse people or the options available to them. Recognising diversity also requires providing access to support for people who may experience regret. Internalised and socially realised transphobia, homophobia and misogyny especially concerned young adults. Young adults feel endlessly judged and held accountable for their difference and believe this closes down discussion and makes it more difficult for a person to take the path that is right for them. Young adults believe a person's capacity to flourish is strongly influenced by the circumstances in which they live. Services should seek to understand and support this:

> I would tell [services] to [...] make it more of a personalised process [that] is really important because not everybody, kind of, falls under this neat little umbrella […] much like gender - it's not confined to little boxes - the service cannot be confined to little boxes because it will then exclude so many more people."

Young adults' experiences suggest that one outcome or pathway should not be prioritised over another. All, they believe, are equally valid. Services should offer opportunities to understand different pathways, consistent with the breadth of experience associated with gender questioning. This, they say, is the basis for the successful exploration of identity. Young adults highlight the need for services to sensitively support young people, reduce distress and help them live well. They recognise the value of open and honest discussions as long as it is done respectfully, in a trusting encounter, in which rapport has been established:

> "It was very in-depth, about every aspect of my life [talking therapy]. In a way, it was good because I'd never really had the chance to talk [...] in-depth about what was going on and piece together why I was feeling the way that I was. Yes. It was difficult, at times, I suppose but I'm glad I had to go through it and I'm glad that they [clinicians] were thorough enough to make sure that transitioning was the right thing for me, at that time."

Concluding thoughts

The needs of those who question their gender identity are not that different from anyone seeking support from healthcare services. They require timely access to appropriate care, consistent with their preferences, in which they are able to make informed choices

about their future. This includes safe and effective treatments, alongside respectful therapeutic support, sensitive to the challenges they face.

Our participants' narratives present rich and varied experiences, although one consistent theme, emerging throughout their accounts, regarded the importance of individual and personalised care. Gender questioning requires an open-minded approach, in which no outcome is presumed or predetermined and where an individual is given space (and time) to reflect on - and understand - what questioning means for them and their bodies. There remains no agreed approach to medical or social transitioning among young people, their parents or young adults. This is perhaps not surprising, given the considerable diversity in how individuals make sense of - and express - their experiences. The range of possible outcomes is similarly diverse. Services are required to respond to this diversity, while respecting the voices of young people. This requires thoughtful and supportive discussions. Those we spoke express a range of hopes, priorities and expectations. This requires transparency when clinicians offer and negotiate support.

Accessing timely support, however, creates considerable challenges for young people, their families and young adults. Participants also reflected on the fraught and politicised nature of current debates. These impacted on their wellbeing and by closing down debate, made it more difficult to pursue options consistent with how they felt.

The possibility of diverse outcomes is refuted by some and not seen as helpful by others. Highlighting diversity, however, does not discredit or devalue those who wish to celebrate their transition and the euphoria it brings them. Nor should it exclude the voices of those who have doubts or regrets. We risk injustice if this diversity and multiplicity is not supported by service delivery. For young people and young adults, their priority is to establish a social context in which they can flourish and feel comfortable. Parents and clinicians share these aspirations. Social inclusion and positive relationships, free from discrimination and in which an individual is accepted, respected and valued, represent an important priority for those - and their families - who seek support from health and social care agencies

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Appendix 4



OVERVIEW OF STUDY DEVELOPMENT

Assessment, Management and Outcomes for Children and Young People Referred to a National Gender Identity Development Service

AR-000342

Assessment, Management and Outcomes for Children and Young People Referred to a National Gender Identity Development Service

Introduction

Some children and young people experience significant levels of gender related distress in their course of their development arising from a persistent mismatch between their gender identity and their registered sex at birth. The numbers of children and young people referred to the Tavistock and Portman's Gender Identity Development Service (GIDS) - the NHS funded service for young people with gender related distress in England and Wales - increased markedly during the 2010s, resulting in lengthy waiting times and uncertainty for young people and their families. There have also been significant changes in the characteristics of young people referred, including an increase in the number of birth registered females and an over representation of young people who have traits or a diagnosis of autistic spectrum conditions. There is therefore an urgent need to understand the characteristics, needs, management options and outcomes of this changing population.

The intention of this study was to use data collected within the NHS - including data from the Tavistock Gender Identity Development Service, hospital wards, outpatient clinics, emergency departments and adult gender identity clinics - to assess the intermediate and longer-term outcomes for children and young people referred to the GIDS service. It would have examined the changing features of these children (including age at referral, co-occurring diagnoses of autism and other mental health difficulties), assessed if some groups of children are more likely to follow a medical approach to managing their gender related distress, and explored patterns of longer-term outcomes including successful transition, detransition and mental health outcomes.

These data would have provided children and their families with vital information on the different options for managing gender related distress and provided evidence for clinicians and policy makers delivering services for these children and young people. Ultimately, the study was not carried out, as the cooperation of all adult gender identity clinics could not be secured.

Overall aim: To examine the changing epidemiology of gender related distress in children and young people, in addition to their appropriate social, clinical, psychological and medical management.

Objectives: 1) To describe the clinical and demographic characteristics of this population of children and their clinical management in the GIDS service; and 2) To assess the intermediate outcomes of this population of children using national healthcare data.

Methods

Patient and public involvement and stakeholder engagement

A series of six online consultation events were held from Feb to June 2022. These events were advertised via GIDS stakeholder groups, the Yellow Door young person's group, Stonewall, Trans Actual, Mermaids and Gendered Intelligence. Across the sessions we spoke to 22 individuals. This was a mix of trans and gender questioning adolescents and young adults (n=12) and the parents of children and young people (n=10) who have been seen, or were waiting to be seen, at GIDS. Two further sessions were held in Autumn 2022, with another 23 individuals attending. Further engagement was planned during the study, following initial data analyses.

A study specific opt out was planned, with patient and carer information produced in both written and animated form. This material would have been advertised via the Tavistock GIDS service, other support organisations, and the University of York websites for 3 months prior to data extraction, directing prospective study participants to contact the Tavistock or their adult clinic if they did not wish their data to be used in the study. Any existing national opt outs would also be upheld.

Research design, participants and sample size

- Retrospective secondary analysis of the Tavistock GIDS data and linked population level datasets available for children and young people referred to the GIDS service.
- All children, teenagers or young adults aged 18 years old or younger at the point of referral to GIDS, who were referred to GIDS between 2009 and 2020.
- A full population cohort (estimated 9,000 participants).

Data Sources

The primary data source is clinical data from the Tavistock GIDS service linked to:

1. Data from the paediatric endocrinology services at University College London Hospital and Leeds Teaching Hospitals Trust.

2. Data from the NHS Gender Identity Clinics for Adults in England:
    - The Tavistock and Portman NHS Foundation Trust, Gender Identity Clinic, London
    - Leeds Gender Identity Clinic, Leeds
    - Northampton Gender Identity Clinic, Daventry
    - Northern Region Gender Dysphoria Service, Newcastle
    - The Nottingham Centre for Transgender Health
    - Porterbrook Clinic Gender Identity Service, Sheffield
    - The Laurels Gender Identity Clinic, Exeter

3. Other healthcare data held by NHS Data and Analytics:
    - Hospital Episodes Data – Accident and Emergency (pre 2019) and Emergency Care (from 2019) datasets
    - Hospital Episodes Data – Admitted Patient Care
    - Hospital Episodes Data – Outpatient
    - Mental Health Minimum data set
    - Community prescribing data
    - Death Registration data

Data Extraction

Demographic data held at the Tavistock GIDS service would be extracted from electronic patient records. Additional clinical data would require manual extraction from paper and/or electronic records. For more recent referrals much of this information will be available on a summary assessment and discharge forms. A unique study ID (pseudonym) would be used to retain the link between the non-identifiable data collected and confidential patient data. The confidential patient data would be retained on the Tavistock system until required for transfer to NHS Data and Analytics for linkage with their datasets. Pseudonymised data would be securely transferred to the Department of Health Sciences server at the University of York.

For assessment of outcomes, confidential patient data required for linkage to other NHS datasets (date of birth, NHS Number, postcode and birth registered sex) would be extracted from electronic records held at the Tavistock clinic and the Adult GIC clinics. To reduce flows of confidential patient data, this would only include those aged up to age 30 years (the oldest young person referred to GIDS in 2009 would be 30 in 2020). All data linkages would be undertaken by NHS Data and Analytics. The University of York team would receive pseudonymised clinical data from the Tavistock, UCLH, NHS Digital and Adult GIC clinics and would be data controller for the study. For both objectives a successful application was made to the Confidentiality Advisory Group (under section 251 of the National Health Service Act 2006 and its current Regulations, the Health Service (Control of Patient Information) Regulations 2002). The NHS Act 2006 and the Regulations enable the common law duty of confidentiality to be temporarily lifted so that confidential patient information can be transferred to an applicant without the discloser being in breach of the common law duty of confidentiality.

Compliance with the Gender Recognition Act (GRA) is required for the second objective. Advice was therefore sought from the National Data Guardian and a request was made to the Secretary of State for Heath to enact Section 22, Point 5 of the GRA as the legal basis for this study. A Statutory Instrument was laid by the Secretary of State for Health for the specific purposes of this study, coming into force on the 28th July 2022 for a duration of 5 years.

Data analysis

Objective 1

A population based retrospective cohort study would have been undertaken using data from electronic and paper records in the GIDS. The population would include all children and young people referred to the Tavistock GIDS resident in England referred from 2009 to 2020. These analyses would aim to:

- Describe the demographics of children referred to GIDS;
- Assess the treatment pathways, including endocrine treatment, of children in GIDS;
- Describe the referral sources of children referred to GIDS;
- Describe the destination of children after GIDS assessment.

The demographic profile of this cohort would be described using counts and percentages for categorical data (e.g., ethnic origin) and means and standard deviation for continuous data (e.g., age at referral). Demographic data would include whether children had begun puberty at the point of referral. Clinical activity data would include numbers of appointments and clinical assessments, source of referral and destination on discharge.

Treatment pathways are an important outcome for this population, so log-binomial or robust (modified) Poisson regression models would be used to assess clinical and demographic associations with likelihood of referral for endocrine treatment. Statistical models would use binary outcomes (referred or not referred to endocrine clinics) with independent variables selected from demographic data (ethnic group, deprivation group, birth sex) and other clinical data (e.g. co-occurring conditions such as autism) and puberty status at referral, based on model fit as assessed by Akaike's Information Criterion and the Bayesian Information Criterion.

Objective 2

Following data linkage, an assessment of data quality and completeness would be undertaken for key clinical and demographic variables. Key outcome data derived from the linked healthcare data would include: surgical and medical management of gender dysphoria; mental health diagnoses and treatment; and co-occurring diagnoses of autistic spectrum disorder. Destinations of young people referred to the Tavistock clinic would be described in terms of the proportion: accessing assessment and psychosocial support only; prescribed hormone blocking treatment only; prescribed hormone blocking treatment followed by cross sex hormone treatment; accessing sex reassignment surgery in adulthood; appearing to have de-transitioned; with a co-occurring mental health diagnosis; with a diagnosis of autistic spectrum disorder; self-harming. Appropriate statistical models would be used to assess whether any clinical or demographic features, including puberty status at referral, are associated with these outcomes.

Regulatory requirements, data protection and patient confidentiality

The ethical aspects of this study were reviewed and approved by a Research Ethics Committee of the Health Research Authority (REF 22/HRA/3277). The use of confidential patient data without consent was approved by the Confidentiality Advisory Group (CAG) of the Health Research Authority. CAG is an independent body which provides expert advice on the use of confidential patient information (REF 22/CAG/0129).

All investigators and research staff would comply with the requirements of The Data Protection Act 2018, the UK's implementation of the General Data Protection Regulation (GDPR), with regards to the collection, storage, processing, and disclosure of personal information. Data storage and handling would comply with data controllers, processers, and University of York policies, including locked storage, password protection, and encryption of the pseudonymised data. Data would be archived for 5 years following the end of the project. Data would be stored in the University of York in accordance with GDPR and the University of York guidelines. At the end of the default retention period (5 years) all data would be confidentially destroyed by a secure method.

Steering group

A Study Steering Committee was established with an independent chair and representation from topic experts and academics. This panel would meet three times per year to assess progress of the study against the defined milestones and deliverables and provide advice and expertise to the Study Management Team.

Stopping the study

Conduct of the study was contingent on gaining access to the relevant patient data and securing the full cooperation of the gender identity clinics. Following study approval by the Health Research Authority, the research team contacted clinical leads at GIDS and each of the Adult Gender Identity Clinics to establish collaborative links and confirm capacity and capability to support the study. Systematic steps were taken to clarify the aims and motivations of the research, understand and address any concerns of clinic staff, and to propose alternative approaches and solutions where appropriate. Negotiations took place between August and November 2023, after which six of the seven adult clinics declined to support the study. Common reasons given by the clinics for non-participation are summarised in **Table 1**. Clinics also rejected the option to conduct the initial data-linkage phase of the study only (i.e. to provide patient name, date of birth and NHS number but no other clinical data). The decision to stop the study was therefore taken on November 30, 2023.

Table 1: Adult gender identity clinics' reasons for non-participation in the data linkage study

Area of concern	Specific issue	University of York response
Accessing patient records	• Paper records started to be replaced by electronic records in 2012, but were still in use in 2020. Identifying eligible patients and extracting data would therefore be labour intensive. • Where available, electronic records may not contain all the required data, and searches of paper records may still be required. • Only a minority of attendees at the adult clinics will have previously attended GIDS, potentially making them more difficult to identify.	• Support is in place to cover clinics' workload in relation to research studies, including extraction of clinical data (see **resource provision**). • The study could be conducted in two phases, with the first phase only requiring clinics to provide patient name, date of birth and NHS number for the purposes of linkage. This would not require an extensive search of paper records. • Clinics would not have to identify patients who previously attended GIDS themselves, as attendance would be established through the data linkage process conducted by NHS Data and Analytics.
Resource provision	• Clinics lack resources and knowledge to answer patient queries in relation to the study. • Some clinics felt obliged to contact all eligible patients directly to inform them of the study (see **ethical considerations**). • Extracting clinical data from notes, even when performed by external researchers, would require supervision by a clinician with epidemiological research experience and local knowledge of the current and historical formatting and archiving of notes.	• Queries about the study would be referred to the dedicated study website, which includes infographics, patient information, opt-out arrangements, a full study protocol and a contact e-mail. • Rigorous patient data safeguards are in place (see **ethical considerations**). • Research support is available to clinics through the Clinical Research Network to cover costs associated with basic data extraction, and researchers employed by the University of York would carry out the most labour-intensive activities relating to detailed data extraction (retrieval of clinical activity data from patient notes). Negotiations between the clinics and the funder (NHS England) could identify additional research support funding to cover the cost of local supervision where appropriate, although it is acknowledged that long-standing workload and recruitment pressures present significant challenges to the provision of support for research in this area.
Data completeness and linkage	• Changes to NHS numbers, postcodes and/or gender would make record linkage between GIDS and adult clinics extremely challenging.	• These are standard challenges for health services research in general and data linkage studies in particular. University of York researchers and analysts based at NHS Data and Analytics have extensive experience in conducting complex

	• Data missingness is likely to be not-at-random, particularly for people who de-transition/re-transition. • Changes in clinical protocols, differences in protocols between clinics and (mis)understanding of those protocols (e.g. whether hormone treatment is required prior to surgery) may confound the study when attempting to associate treatments with outcomes. • Neurodiversity is likely to effect outcomes but may not be well recorded in clinical records, leading to potential confounding.	data linkage studies, addressing issues of missingness and dealing with confounding variables.
Study methodology	• The study outcomes focus on adverse health events, for which the clinics do not feel primarily responsible. • Detailed definitions for study variables were not provided in the protocol, including the conceptualisation and measurement of detransition.	• The purpose of the study is not to audit quality of care but to assess patterns of outcomes in the population. Inevitably, this will include adverse outcomes as these are of concern to both patients and providers. • Detailed definitions would be developed in line with the literature and clinical guidelines, and in consultation with clinic staff.
Ethical considerations	• There was insufficient involvement of clinic staff and service users in study design and development. • People with additional vulnerabilities may be less likely to opt out or may need more support to opt out from the study. • Trust data responsibilities and governance of patient data requires clinics to actively seek consent from all service users before sharing any information, and therefore an opt out (rather than an opt in) was not appropriate.	• The final protocol was developed in consultation with clinicians, service users and international experts in the field. The research team liaised with the adult clinics at the study development stage but there was a general reluctance on the part of the clinics to engage. • Public and patient engagement sessions were conducted in the early stages of protocol development, and participants were generally supportive of the study and the use of their data. Many expected their data to be routinely collated and analysed by the NHS and associated researchers as part of its quality improvement work. • The UK has a stringent series of safeguards covering the use of patient data in research (including Health Research Authority approval, anonymisation of patient data, and General Data Protection Regulations). Additional specific safeguards (including the Statutory Instrument, and the 3 month opt-out period) were put in place for this study. Additional support for vulnerable patients would be discussed with clinics and patient groups.

Concerns about funder motivation and political interference	• The unintended outcome of the study is likely to be a high-profile national report that will be misinterpreted, misrepresented or actively used to harm patients and disrupt the work of practitioners across the gender dysphoria pathway. • Taking part in a study of this kind could bring into question the integrity of clinic staff and the relationships they have with patients. • The study may not be fully independent, and may suffer from interference by NHS England, the Cass Review Team and Government ministers whose interests do not align with those of providers and users of gender identity services.	• Given that there are no existing national level assessments of longer-term outcomes in this patient group, the potential for misinterpretation or misuse of study findings is insufficient reason for not conducting research in this area. • The research team is mindful of the context for the research, having previously conducted systematic reviews and qualitative interviews with service users, and in some cases having direct clinical experience of working with patients. Although it is not possible to control all public responses to published research, the research team would take all reasonable steps to avoid misinterpretation and to ensure study outputs carried clear messaging that reflected the sensitivities surrounding this issue. • Although the study is funded by NHS England, the research team is fully independent and not subject to interference by the Cass Review, NHS England or any other external agency. The research team is experienced in handling sensitive research topics and in publishing research which is critical of funding bodies and government policy.


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Appendix 5



PRELIMINARY REPORT

Epidemiology and Outcomes for Children and Young People with Gender Dysphoria: Retrospective Cohort Study Using Electronic Primary Care Records

AR-000354

Epidemiology and Outcomes for Children and Young People with Gender Dysphoria: Retrospective Cohort Study Using Electronic Primary Care Records

Introduction

The number of children and young people referred to the Tavistock and Portman's Gender Identity Development Service (GIDS) - the NHS funded service for young people with gender related distress in England and Wales - rose markedly during the 2010s, resulting in lengthy waiting times and uncertainty for young people and their families. Additionally, there has been a marked increase in referrals of adolescent birth-registered females and an over-representation of children with autism or autism spectrum traits. Recent reviews by the National Institute for Health & Care Excellence (NICE) on the medical treatment of these children highlighted a lack of evidence of effectiveness and low quality of the published literature. There is also a lack of evidence on outcomes for these children and adolescents, and their presentation in primary care.

Overall aim: To use electronic primary care records to describe the epidemiology of gender dysphoria in people aged 18 and under in England from 2009 to 2021.

Objectives: To estimate for people aged 18 and under with gender dysphoria:

- Changes in incidence and prevalence over time.
- Prevalence of co-occurring autistic spectrum disorders.
- Frequency of primary care prescribing and duration of treatment with puberty blockers and hormones.
- Prevalence of obesity, smoking, self-harm and common mental health conditions compared with people with autism spectrum disorders, eating disorder and no long-term condition.

This preliminary analysis covers the first two objectives; subsequent reports will cover prescribing and co-occurrence of other conditions.

Study population: People aged 18 and under with gender dysphoria and age matched controls with autism and an eating disorder. The final study population consisted of:

- 3,782 people with gender dysphoria;
- 18,740 matched controls with autism spectrum disorder;
- 13,951 matched controls with eating disorder;
- 18,871 matched controls with no recorded long-term condition.

Methods

Data were derived from the Clinical Practice Research Datalink (CPRD), a database of anonymised patient data from general practices across the UK linked to other health-related data, including routine and emergency hospital attendance and Office for National Statistics mortality data. The database holds data for over 18 million currently registered patients. The study population was identified using primary care code lists (READ and SNOMED) covering clinical activities (including diagnosis, symptoms, treatment and referrals) and secondary care codes (Hospital Episode Statistics) indicative of relevant conditions. Co-existing conditions (for example, anxiety and depression) were identified using similar methods. Key covariates included age and local area deprivation (based on the Index of Multiple Deprivation for the postcode of residence). Patient inclusion criteria included:

at least one year of registration with a practice with research-standard data; primary care record linked to secondary care data; and postcode of residence available.

People with gender dysphoria were matched by age to three groups of controls: people with autism spectrum disorders; people with eating disorder; and people with no recorded long-term condition. We aimed to match cases to 5 controls with each condition, but due to low numbers an average of 3.7 controls with eating disorder were matched. Matching was performed on year of birth and index date for controls, on or before index date of cases (i.e. matches must have been diagnosed with the relevant condition before the case was diagnosed with gender dysphoria). Controls were not matched on recorded gender in part due to limitations in the categorization of gender within CPRD. The gender data category allows options of 'male', 'female' and 'other'; as people are first registered at birth if born in the UK, this category generally refers to registered sex, but can subsequently be changed at the patient's request to reflect their gender identity (see **strengths and limitations**). In this study, we use the category term recorded in the CPRD database.

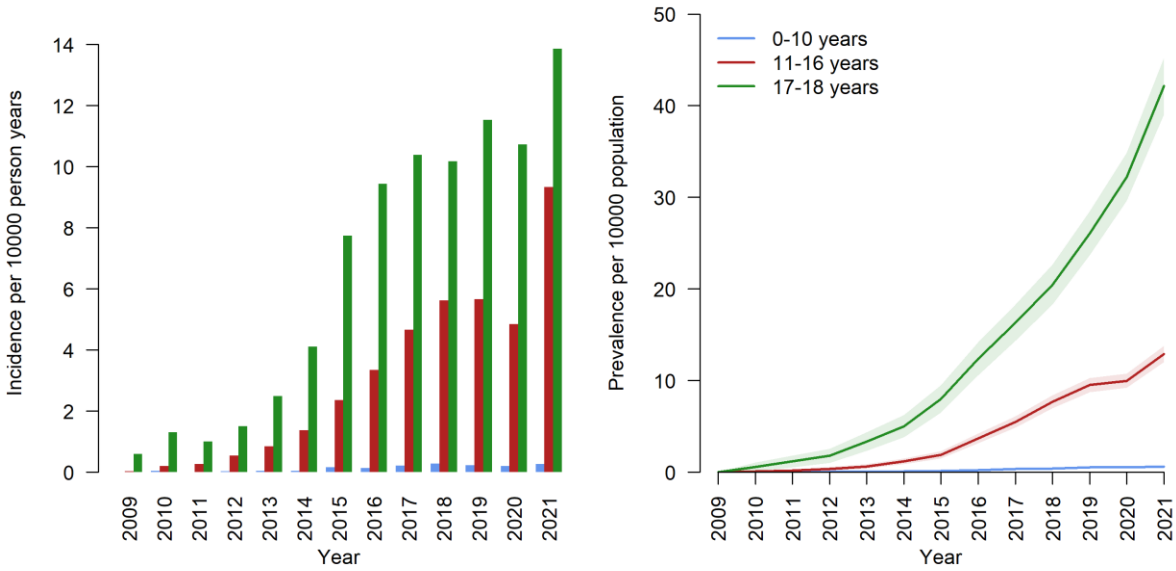
Incidence rates were calculated by dividing the number of new cases in a given year by the person-time at risk. Prevalence was calculated by counting the number of individuals in the dataset registered with practices on 1 July in each year with a diagnosis code recorded on or before that date. This number was divided by the total number of individuals in the dataset registered on 1 July and multiplied by 10,000 to give prevalence per 10,000 people. This method produces an upper limit estimate of recorded prevalence (see **strengths and limitations**). Prescribing data in CPRD were used to assess the proportion of cases and controls receiving relevant medications at each point in time. Comparative analyses of incidence of co-existing conditions and outcomes were calculated using incidence rate ratios, adjusting for common confounders (for example, age and local area deprivation).

To protect patient anonymity, published results are subject to small number suppression and no results for fewer than 10 people are reported. There were few missing data except for month of birth (year of birth was used to calculate age). No attempt was made to impute missing data for demographic information due to the low numbers of missing data (under 1% missing for the deprivation category; zero missing for gender) and the lack of relevant information on which to build an imputation model.

Results

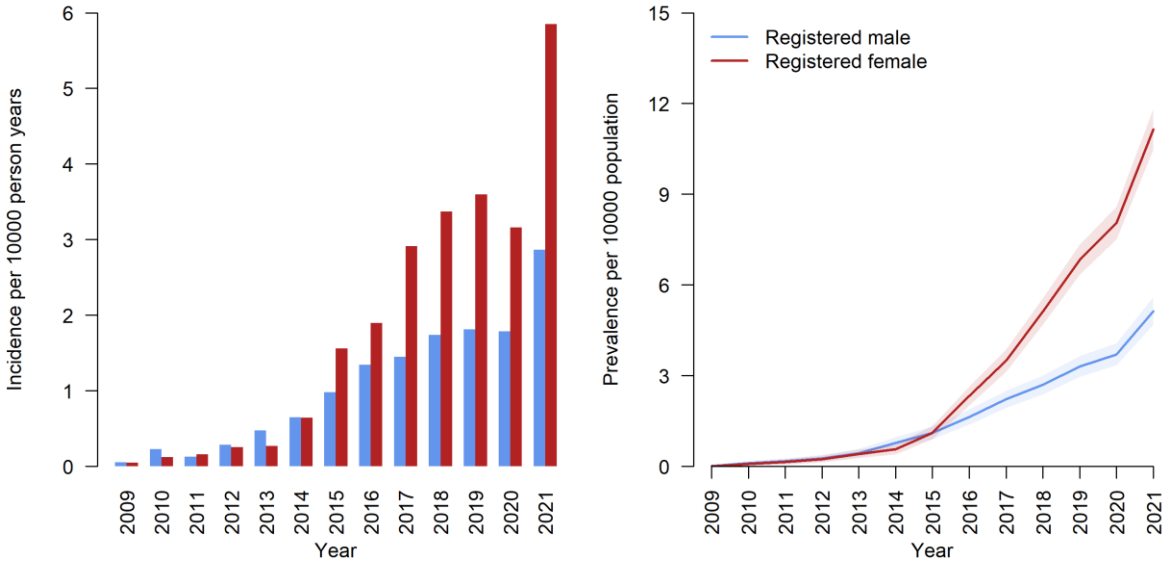
Recording of gender dysphoria was rare before the age of 10, increasing in frequency with each additional year up to age 16, the most common age at diagnosis. New cases for ages 18 and under increased from <0.1 per 10,000 person years in 2009 to 4.4 (95%CI 4.1-4.7) per 10,000 in 2021, with a decline in 2020, the first year of the COVID-19 pandemic (**Figure 1**). Overall recorded prevalence increased from <0.1 per 10,000 persons in 2009 to 8.3 (95%CI 7.9-8.7) per 10,000 in 2021, with the highest recorded prevalence in the 17-18 age group (42.2, 95%CI 39.1-45.2 per 10,000 in 2021). Incidence of new cases was similar for patients registered as male and female up to 2014, after which incidence increased at up to twice the rate for patients registered as female (**Figure 2**).

Figure 1: Incidence and recorded prevalence of gender dysphoria by age group



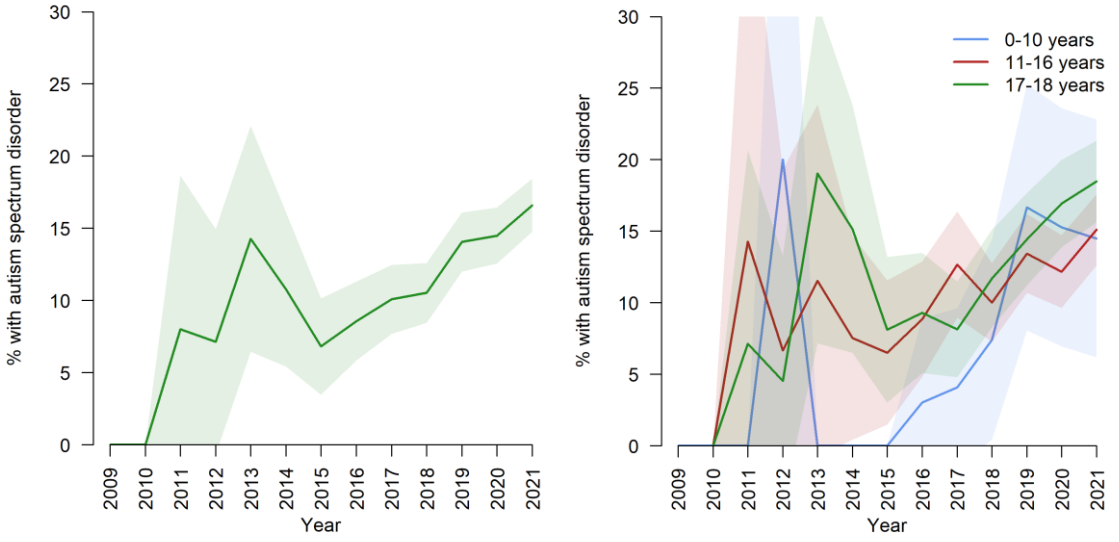
Note: shaded areas on prevalence graph denote 95% confidence intervals.

Figure 2: Incidence and recorded prevalence of gender dysphoria by registered gender



Note: shaded areas on prevalence graph denote 95% confidence intervals.
Patients can request to have their recorded gender changed on their clinical records without undergoing gender reassignment treatment, and CPRD reports the latest recorded gender only.

Figure 3: Co-occurrence of gender dysphoria and autism spectrum disorder, overall and by age group



Note: shaded areas denote 95% confidence intervals.
Due to low numbers of people with gender dysphoria, estimates of the prevalence of co-occurring conditions before 2014 are imprecise, as indicated by the wide confidence intervals.

Figure 4: Co-occurrence of depression, anxiety and gender dysphoria



Note: shaded areas denote 95% confidence intervals.
Due to low numbers of people with gender dysphoria, estimates of the prevalence of co-occurring conditions before 2014 are imprecise, as indicated by the wide confidence intervals.

In 2015, 6.8% (95%CI 3.5-10.1%) of people with gender dysphoria also had a diagnosis of autism spectrum disorder, increasing to 16.6% (95%CI 14.8-18.4%) by 2021. Trends in recorded prevalence did not vary substantially by age group (**Figure 3**). Recorded co-occurrence of depression and anxiety increased over time, reaching 15.0% (95%CI 13.3-16.8%) and 13.8% (95%CI 12.1-15.5%) respectively in 2021 (**Figure 4**).

Overview of the findings

In our sample of general practices, recorded prevalence of gender dysphoria in people aged 18 and under increased over a hundred-fold between 2009 and 2021. This increase occurred in two phases; a gradual increase between 2009 and 2014, followed by an acceleration from 2015 onwards. Increases in this second phase were more rapid for people registered as female, although clinical records do not indicate whether their recorded gender had been changed (see **strengths and limitations**).

Throughout the study period, presentations predominantly occurred in the teenage years, and over half of people with a recorded history of gender dysphoria were in the 17-18 age group. A substantial minority of people with a history of gender dysphoria also had a recorded diagnosis of autism spectrum disorder, and the proportion of people with such a diagnosis increased over time. Depression and anxiety were also more frequently reported over time, approaching 15% of people with gender dysphoria by 2021.

Strengths and limitations

These analyses draw on the complete primary care records of 3,782 children and young adults with a record of gender dysphoria derived from the Clinical Practice Research Datalink database, linked to other relevant health-related datasets. CPRD provides a large, comprehensive and nationally representative cohort covering all aspects of primary care and (through general practices' gatekeeping and care coordination role) secondary and tertiary care. The database facilitates investigation of rare exposures and events, such as gender dysphoria, and minimises selection and information bias as almost all residents in England are registered with a general practitioner soon after birth and practices collect data prospectively.

CPRD data also has several limitations, however, leading to risks of both under-reporting and over-reporting of gender dysphoria. Data are recorded by general practice staff for the purpose of clinical care and not primarily for research, hence key information may be inconsistently recorded, particularly for uncommon conditions such as gender dysphoria, with which individual practitioners may less familiar. Practices may also not record that a long-term condition has resolved, hence our results report the proportion of people at a given point in time with a record of gender dysphoria *at any point* in their history. This will be higher than the proportion of people who currently have gender dysphoria. Conversely, for co-occurring conditions such anxiety and depression, the analyses presented in this preliminary report are restricted to those with a recorded diagnosis, which may underestimate the number of people with symptoms of anxiety and depression, or receiving treatment.

Studies based on primary care records also face challenges with respect to classifying patient sex and gender, and this presents a particular problem for studies of gender dysphoria. Patients can request

to have their recorded gender category changed on their clinical records without undergoing gender reassignment treatment, and are then registered as a new patient with their previous medical information transferred to their new record. CPRD reports the latest recorded gender category only, so it is not possible to assess complete gender histories or to make definitive statements about patient sex. In our results, ‘male’ and ‘female’ refer to the gender recorded by the practice.



AR-000361

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Appendix 6

The Cass Review

Independent review into gender identity services for children and young people

Dr Hilary Cass
Chair
Independent Review of Gender Identity Services for Children and Young People

John Stewart
National Director
Specialised Commissioning
NHS England

Sent by email

19 July 2022

Dear John

INDEPENDENT REVIEW OF GENDER IDENTITY SERVICES FOR CHILDREN AND YOUNG PEOPLE – FURTHER ADVICE

In my interim report I provided advice that in order to meet current demand and provide a more holistic and localised approach to care, gender identity services for children and young people need to move from a single national provider to a regional model.

I have since met with potential providers, Royal Colleges and support and advocacy groups to discuss the essential components of the proposed new model. I will continue with these conversations, including a programme of engagement with service users and their families, but wanted to share the outcome of discussions to date.

Essential components of a new model

A comprehensive patient and family centred service and package of care is needed to ensure children and young people who are questioning their gender identity or experiencing gender dysphoria get on the right pathway for them as an individual. A shared care arrangement is needed to enable children and young people to receive supportive care and appropriate treatment as close to home as possible. This would also improve integration between different children's services, facilitate appropriate access to local community support services, improve the experience of care, and support the transition between children's and adult services that are appropriate for the individual.

Regional centres

Regional centres should be commissioned as specialist centres to manage the caseload of children requiring support around their gender identity. The regional centres should be experienced providers of tertiary paediatric care to ensure a focus on child health and development, with strong links to mental health services. They should have established academic and education functions to ensure that ongoing research and training is embedded within the service delivery model. The centres should have an appropriate multi-professional workforce to enable them to manage the holistic needs of this population, as well as the ability to provide essential related services or be able to access such services through provider collaborations. These should include, but not be limited to: mental health services; services for children and young people with autism and other neurodiverse presentations; and for the subgroup for whom medical treatment may be considered appropriate, access to endocrinology services and fertility services. There should also be expertise in safeguarding, support of looked-after children and children who have experienced trauma. Staff should maintain a broad clinical perspective by working across related services within the tertiary centre and between tertiary and secondary centres in order to embed the care of children and young people with gender-related distress within a broader child and adolescent health context.

Designated local specialist services

The regional centres will need to work collaboratively with local services within their geography. However, recognising that not all local services will have the capacity, capability and/or aspiration to support the care of children and young people with gender-related distress, I would recommend initially identifying a smaller number of secondary services within Child and Adolescent Mental Health Services (CAMHS) and paediatrics to act as **designated local specialist services** within each area. This would give the opportunity to provide targeted training, upskilling and additional staffing to a more manageable number of centres within a geography. Similar models exist in the provision of children's cancer services where there are designated Paediatric Oncology Shared Care Units (POSCUs)[1] and in neonatal care where there are designated Local Neonatal Units (LNUs).[2]

Operational delivery network

The regional centres should be responsible for overseeing the shared care model, working through an **operational delivery network (ODN)** or similar mechanism that can fulfil the stated purposes of ODNs[3] which include:

- ensuring effective clinical flows through the provider system through clinical collaboration for networked provision of services
- taking a whole system, collaborative provision approach to ensure the delivery of safe and effective services across the patient pathway

[1] NHS England (2021). Service Specification: Children's Cancer Network - Principal Treatment Centres
[2] NHS England. Service Specification: Neonatal Critical Care (Intensive Care, HDU and Special Care)
[3] NHS Commissioning Board (2012). Developing Operational Delivery Networks: The Way Forward

- improving cross-organisational, multi-professional clinical engagement to improve pathways of care
- enabling the development of consistent provider guidance and improved service standards, ensuring a consistent patient and family experience
- focusing on quality and effectiveness through the facilitation of comparative benchmarking and auditing of services, with implementation of required improvements
- fulfilling a key role in assuring providers and commissioners of all aspects of quality as well as coordinating provider resources to secure the best outcomes for patients across wide geographical areas
- supporting capacity planning and activity monitoring with collaborative forecasting of demand, and matching of demand and supply

Key to this model is the governance role of the network in maintaining standards of care and ensuring equitable access.

Pathways of care

I would recommend that consideration is given to **intake procedures** that ensure that children and young people referred to these services are able to access the most appropriate package of support at the earliest feasible point in their journey. One model might be that each regional centre would host a regular **intake meeting** involving multi-professional staff from the tertiary centre, the designated local specialist services and other relevant local children's services. Discussions with Gender Identity Development Service clinicians have highlighted the importance of differentiating different subgroups within the referred population who may be at risk and/or need more urgent support, assessment or intervention; there may also be subgroups where early advice to parents or school staff may be a more appropriate first step. Given that it is not always possible to make these judgements based on written referral information, consideration should be given to ring-fencing senior clinical time to make early contact with referrers or families in order to ensure that children and young people are allocated to an appropriate pathway.

There should be a whole system approach to care across the network so that children and young people can access a broad range of services relevant to their individual needs, including supportive exploration and counselling. This is important both for those who go on to medical transition and those who resolve their gender distress in other ways. There should be the ability to move flexibly between different elements of the service in a step-up or step-down model, allowing children and young people and their families/carers to make decisions at their own pace without requiring rereferral into the system.

Stakeholders have raised the need for individuals who are distinct from the professionals that they view as 'gatekeeping' access to the medical treatment to provide support and a safe space for questioning. There is considerable scope for local innovation and partnerships with voluntary sector organisations in developing these services in a range of settings.

The appropriate age for transition to adult services will need further discussion, balancing the workload and capacity of services for children and young people with the need to provide ongoing holistic family-centred care during a critical point in the young person's gender care, particularly for those with neurodiversity/special educational needs or other vulnerabilities.

National provider collaborative/research network

I have already stated that the regional centres should have regular co-ordinated national provider meetings and operate to shared standards and operating procedures. The development of protocols for assessment and treatment to ensure such consistency is an important strand of the work of the Review, and this will be based on best available evidence, the findings from our commissioned research, and expert opinion.

There should also be agreement regarding collection of a core dataset to inform service improvement and research, based on similar approaches already established in other specialities, for example, in paediatric critical care.[4]

To achieve this end, I would recommend that a formal **national provider collaborative** with an **integral research network** is established**,** bringing together clinical and academic representatives from the regional centres. The national provider collaborative should undertake a range of functions including:

- a forum for discussion of complex cases and/or decisions about medical care, and ultimately subsuming the role of the Multi-Professional Review Group
- an ethics forum for cases where there is uncertainty or disagreement about best interests or appropriate care
- providing opportunities for peer review between regional centres
- development of a programme of ongoing Continuing Professional Development for staff at all levels, as well as educational standards for practitioners within the various tiers of service provision
- collation of the national dataset and conduct of national audit
- development of a quality improvement programme to ensure evolving best practice
- ongoing research in areas of weak evidence

Independent oversight of data collection, audit and quality improvement (for example, through a Healthcare Quality Improvement Partnership-commissioned approach) will ensure the highest possible standards of data management and utilisation.

Embedding research in clinical practice

My interim report highlighted the gaps in the evidence base regarding all aspects of gender care for children and young people, from epidemiology through to

[4] PICANet – Paediatric Intensive Care Audit Network for the UK and Ireland

assessment, diagnosis, support, counselling and treatment.[5] NHS England asked me to give some further thought as to how these gaps may be addressed.

The Review has already commissioned a research programme which includes a literature review and both qualitative and quantitative research components. However, I recognise that this programme will not provide all the answers that are needed, and an ongoing programme of work will be required.

Given the particular uncertainties regarding long-term outcomes of medical intervention, and the broader knowledge gaps in this area, there is an imperative to build research capacity into the national network. This research capacity is needed to provide ongoing appraisal of new literature and rapid translation into clinical practice, to continue to identify areas of practice where further research is needed, and to develop a research portfolio that will inform policy on assessment, support and clinical care of children with gender dysphoria, from presentation through to appropriate social, psychological and medical management.

As already highlighted in my interim report, the most significant knowledge gaps are in relation to treatment with puberty blockers, and the lack of clarity about whether the rationale for prescription is as an initial part of a transition pathway or as a 'pause' to allow more time for decision making. For those who will go on to have a stable binary trans identity, the ability to pass in later life is paramount, and many will decide that the trade-offs of medical treatment are a price that is fully justified by the ability to live confidently and comfortably in their identified gender. The widely understood challenge is in determining when a point of certainty about gender identity is reached in an adolescent who is in a state of developmental maturation, identity development and flux.

It is the latter option regarding a 'pause' for decision making about which we have the least information. The rationale for use of puberty blockers at Tanner Stage 2 of development was based on data that demonstrated that children, particularly birth-registered boys who had early gender incongruence, were unlikely to desist once they reached early puberty; this rationale does not necessarily apply to later-presenting young people, including the predominant referral group of birth-registered girls. We do not fully understand the role of adolescent sex hormones in driving the development of both sexuality and gender identity through the early teen years, so by extension we cannot be sure about the impact of stopping these hormone surges on psychosexual and gender maturation. We therefore have no way of knowing whether, rather than buying time to make a decision, puberty blockers may disrupt that decision-making process.

A further concern is that adolescent sex hormone surges may trigger the opening of a critical period for experience-dependent rewiring of neural circuits underlying

[5] Olson-Kennedy, J, Cohen-Kettenis, P. T, Kreukels, B. P, Meyer-Bahlburg, H. F, Garofalo, R, Meyer, W, & Rosenthal, S. M. (2016). Research priorities for gender nonconforming/transgender youth: gender identity development and biopsychosocial outcomes. Current opinion in endocrinology, diabetes, and obesity 23(2), 172–179. DOI:10.1097/MED.0000000000000236.

executive function[6] (i.e. maturation of the part of the brain concerned with planning, decision making and judgement). If this is the case, brain maturation may be temporarily or permanently disrupted by puberty blockers, which could have significant impact on the ability to make complex risk-laden decisions, as well as possible longer-term neuropsychological consequences. To date, there has been very limited research on the short-, medium- or longer-term impact of puberty-blockers on neurocognitive development.

In light of these critically important unanswered questions, I would suggest that consideration is given to the rapid establishment of the necessary research infrastructure to prospectively enrol young people being considered for hormone treatment into a formal research programme with adequate follow up into adulthood, with a more immediate focus on the questions regarding puberty blockers. The appropriate research questions and protocols will need to be developed with input from a panel of academics, clinicians, service users and ethicists.

Without an established research strategy and infrastructure, the outstanding questions will remain unanswered and the evidence gap will continue to be filled with polarised opinion and conjecture, which does little to help the children and young people, and their families and carers, who need support and information on which to make decisions.

I hope this further advice is helpful as you look to develop a detailed service specification. I appreciate you will want some time to consider my advice and am happy to discuss both the longer-term ambition and any interim arrangements that may be necessary, particularly in relation to the development of the clinical and research protocols.

Yours sincerely



Dr Hilary Cass
Chair, Independent Review of Gender Identity Services for Children and Young People

[6] Sisk C L (2017). Development: Pubertal Hormones Meet the Adolescent Brain: Current Biology. 27(14): 706-708. DOI: 10.1016/j.cub.2017.05.092.

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Appendix 7

The Cass Review
Independent review into gender identity services for children and young people

Dr Hilary Cass
Chair
Independent Review of Gender Identity Services for Children and Young People

National Director
Specialised Commissioning
NHS England

Sent by email

31 January 2023

Dear John

As the Review moves into its final phase, I thought it would be helpful to provide an update on progress since my last letter, to outline the Review timetable going forward, and highlight some areas in which NHS England (NHSE) and colleagues across the system may be able to help achieve the Review's objectives.

Over the last few months, the Review has continued to engage with key stakeholders across the statutory and voluntary sectors, as well as leaders of professional organisations, and I have had ongoing listening sessions with individuals who have direct service experience. The Review's commissioned research team is making excellent progress with the systematic reviews, a review of existing guidelines, an international survey of services in countries with comparable healthcare systems, and the qualitative research. We will have outputs from these pieces of work by the spring. I have also established a Clinical Expert Group, including representatives of professional bodies, NHSE's phase one provider units, gender experts and others with expertise in children and young people's care, to help us interpret the findings of this research. Alongside this, the Review is engaging with service users to gain insight into their perspectives on these initial findings.

We have discussed previously the fact that the commissioned data linkage study (part of our quantitative research programme), which represents a unique opportunity to collect longer-term outcome data on this population, has been much more complex than initially envisaged, and is taking longer to establish. However, I am pleased to say that we have now received provisional approvals and will soon be moving into the next phase of the work, which will involve detailed information for service users and the option to opt out before commencement of any data collection. The full protocol will be published on our website.

I anticipate that by the summer, in addition to the strands of work described above, we will have some information on the intermediate outcomes for children and young people with gender dysphoria, as well as the changing characteristics of this group, using data which is already routinely collected within the NHS. However, the complexities encountered in establishing the data linkage study means that the full results of this element will likely not be available before the Review is concluded. As you know, we have already had discussions about the logistics of establishing a formal research network (as described in my letter of July 2022) to receive the results of this study, oversee a clinically informed future research programme and ensure translation into clinical practice.

In the interim, I would like to ask for your help in obtaining some existing data which is of more immediate importance to understanding the needs of this population:

- Firstly, to-date the Review has been working on the understanding that around 20% of children and young people seen by the Gender Identity Development Service (GIDS) enter a hormone pathway. At this stage, it is crucial for us to verify that this is an accurate assumption as it has significant bearing on getting a fuller understanding of the outcomes of the existing clinical approach. I anticipate that it should be relatively straightforward to clarify this through an audit of discharge summaries and would be grateful if this could be arranged as swiftly as possible with colleagues at GIDS.

- Secondly, I understand from discussions with clinicians, that there has been a significant change in the demographic of referrals to adult NHS Gender Dysphoria Clinics (GDCs) – from a more mixed group in terms of age and birth-registered gender to a population base where a significant majority are under 25, with a higher proportion of birth registered females. This obviously comprises a mix of referrals from GIDS and direct referrals to adult clinics. I would be grateful if more robust data on this could be obtained since it is relevant for thinking about both the transition of young people to adult services and potential unmet need within the children and young people's service.

In terms of broader support, there are a number of strands of work which are outside our control, but are crucial to the successful delivery of the Review:

- I would particularly like to thank NHS-Digital for their help to-date in moving forward on the data linkage and look forward to continuing to work with them on this.

- I also look forward to working with the adult NHS GDCs, which are a vital part of understanding the patient journey.

The Review will continue to share information as it becomes available, and I anticipate submitting a final report to NHSE by the end of the year. Within that, I will be making clear those issues we consider to be the sole responsibility of the healthcare system and signposting other issues which fall outside the responsibility of the NHS and require the input of other agencies and organisations and I will make recommendations accordingly.

Yours sincerely



Dr Hilary Cass
Chair, Independent Review of Gender Identity Services for Children and Young People

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Appendix 8

NHS
Arden and
Greater East Midlands
Commissioning Support Unit

The Gender Identity Development Service Audit Report

June 2023



Arden&GEM
Health and social care systems support

AR-000376

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Background

An independent review of gender identity services for children and young people (The Cass Review: Interim Report), has identified a gap in the understanding of treatment pathways once patients are within the Gender Identity Development Service (GIDS) at the Tavistock and Portman NHS Foundation Trust.

As a result of this, a request by the Cass Review team was submitted to NHS England to undertake an audit of discharge notes for patients over a defined period.

NHS England approached NHS Arden and Greater East Midlands Commissioning Support Unit (the CSU) to undertake this audit on behalf of the Cass Review team.

Audit aims and objectives

The aim of the audit was to understand the treatment pathways that children and young people who have entered the GIDS service have received and explore if there are any inconsistencies between GIDS providers.

The key objectives of this study were to:

- Develop a suitable audit template to gather the required information from patients' medical records
- Identify if there are any variations in referrals to endocrinology across the GIDS teams
- Capture information about the proportion of patients entering the GIDS who are subsequently discharged on hormone therapy
- Understand what care patients have received at the point of discharge.

The evidence from this audit will be used to support the next steps of the Cass Review.

Audit scope

The following patients were included in the data collection

- Patients who have attended at least 2 appointments to Tavistock & Portman NHS Foundation Trust GIDS
- Patients who have been discharged from the GIDS between 1 April 2018 and 31 December 2022
- Responsible commissioner is NHS England or NHS Wales

Introduction to methodology

To fulfil the aims and objectives of the study, the CSU developed an audit template in Microsoft Excel® (see Appendix 1) in collaboration with key clinicians at the Tavistock and Portman NHS Foundation Trust, to capture key information that would be extracted from individual patient records. Drop-down lists were utilised where possible to enable standardised information to be captured.

The sections of the audit were grouped into the following themes:

- Patient demographic profile
- Initial referral information
- Endocrinology referral and care pathway
- Discharge information
- Other comments

The CSU identified a clinical workforce to undertake the audit. This ensured that the audit would be to utilise a clinical workforce who:

1) Were bound by their professional registration for patient confidentiality
2) Can understand clinical terminology
3) Can interpret information to undertake the audit
4) Can limit the scope of their tasks to achieve the audit aims

Carenotes system training was provided by the Tavistock and Portman NHS Foundation Trust and individual log-in details were provided to the team. Recognising staff will be required to work within clinical systems at the GIDS which contains highly sensitive confidential patient identifiable information, honorary contracts were put in place between the individual and the trust.

Data extraction methodology



The Tavistock and Portman NHS Foundation Trust provided the CSU with a list of 3466 patients who had been discharged from the service between 1 April 2018 and 31 December 2022, covering the following regional GIDS teams

- GIDS Midlands (incl. Birmingham)
- GIDS Leeds
- GIDS Southeast (incl. London)
- GIDS Southwest (incl. Exeter and Bristol)

The patient list was grouped according to the GIDS team and allocated in batches of between 20-50 patients to the audit team who then reviewed each patient record within Carenotes.

Analysis methodology



To support analysis of the data from the audit, expertise was drawn from across the CSU.

Data from each individual auditor was cleansed and combined into a master Microsoft Excel® spreadsheet. Any patients who did not meet the criteria defined within the audit scope, were excluded from the analysis

Where information was captured as ‘other’, details were provided in the comments section of the audit template, and these were further grouped where possible. For example, several patients had been discharged because they had moved outside of the NHS England and NHS Wales geography.

In context of the Bell v Tavistock High Court Judgement, the date of the judgement, 1st December 2020 was used to undertake the analysis. The terms pre-Bell and post-Bell are used through this report.

Introduction to results

Out of the 3499 patients audited, 3306 were included within the analysis. Of the 193 who were excluded, patients included those who were outside of the NHS England or NHS Wales footprint, non-gender dysphoria patients (for example a patient receiving support due to a family member undergoing gender reassignment), patients who had less than 2 appointments at GIDS and patients who had not been discharged from the service.

The results from the audit are separated into the following themes:

1. Patient demographic profile and referral to GIDs
2. Endocrinology referral and care pathway
3. Discharge from GIDs

Theme 1. Patient demographic profile and referral to GIDs

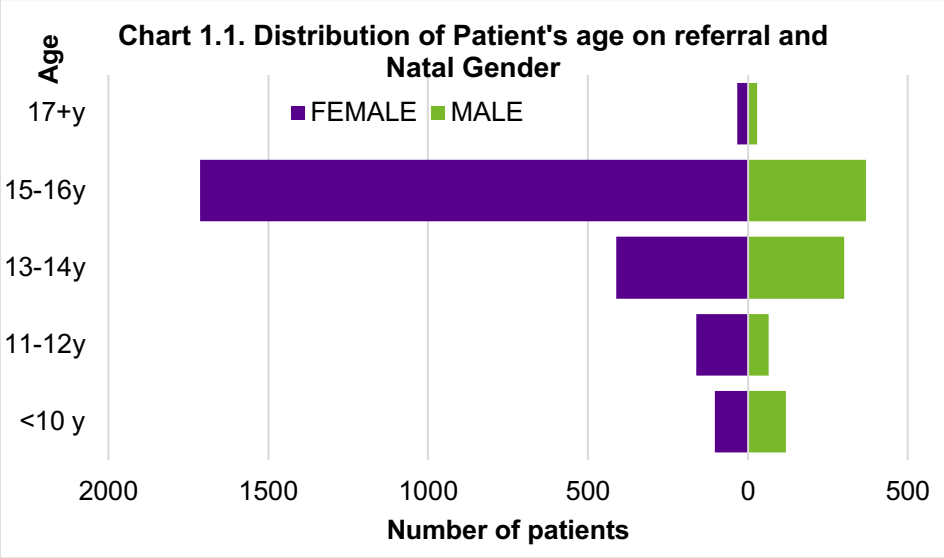
Gender and age profile

The overall natal and current gender of the patients who were audited is detailed within table 1.1. Upon referral into the service, 73% of referrals were for natal female patients, and 27% for those with a natal gender of male. At the point of discharge from the GIDS, the current gender listed within the patients Carenotes record identified a larger proportion, 61% of patients who identified as male.

Table 1.1. Gender profile

	Natal Gender (%)	Current gender (%)
Female	73%	22%
Male	27%	61%
Trans-unspecified/Gender Identity unknown	Not applicable	10%
Non-Binary	Not applicable	5%
Gender questioning	Not applicable	2%

The distribution of patients natal gender and age at the point of referral into the GIDS service is shown in chart 1.1. The minimum age of patients being referred into the GIDS service was 3years, the maximum age was 18years, with a mean and median of 14years.



Referral source

48.6% of patients referred to GIDS were referred by CAMHS/CYP Mental Health Services and 40.68% were referred by their GP practice (see table 1.2). The largest proportion of referrals from CAMHS/CYP Mental Health Services were consistent across the GIDS teams and a full breakdown of the referral source by the GIDS team is provided in appendix 2.

Table 1.2. Referral source	
Referral Source	% of patients
CAMHS / CYP Mental Health	48.6%
GP Practice	40.7%
Children's or Council Service/Local Authority	3.3%
Voluntary sector	3.1%
School	1.8%
Paediatrics	1.6%
Healthcare provider - other	X
Healthcare provider - private	X
Other	X

GIDS team

Table 1.3 shows where patients were assigned their GIDS primary team as identified in the original patient list received from the Tavistock and Portman NHS Foundation Trust.



Table 1.3. Primary GIDS team	
GIDS Team	% of patients
GIDS Leeds	35.27%
GIDS Southeast/London	28.31%
GIDS Midlands/Birmingham	19.87%
GIDS Southwest/Bristol/Exeter	16.55%

Limitations of analysis

- The CSU audit identified that although patients were assigned to a primary GIDS team, often based upon the patient's location, the GIDS team where they received their main assessments and care may have been different to the primary team which has not been analysed.
- There were variations in recorded information between clinics, for example inconsistencies in the information contained within the closing summaries, patient contract information, spells and referral letters. Whilst the CSU team tried to adopt as much consistency as possible, it is recognised that there may be slight variations or inaccuracies in the information that was obtained, such as referral and discharge dates.

Key findings

- 73% of patients are natal female, and 27% natal male when referred into the GIDS.
- The largest proportion of referrals into the GIDS are from CAMHS/CYP Mental Health (48.6%) and GP Practices (40.7%).

Theme 2. Endocrinology referral and care pathway

Across the patients audited, 27% were referred to endocrinology. Analysis against the Bell judgement was not possible due to the methodology of the data collection (refer to limitations within this section). The breakdown of patients by GIDS team is provided in table 2.1.

Table 2.1. Percentage of patients under the care of each GIDS team, referred to endocrinology	
GIDS Team	% of patients
All teams	**27.0%**
GIDS Leeds	32.7%
GIDS Midlands/Birmingham	11.1%
GIDS Southeast/London	20.9%
GIDS Southwest/Bristol/Exeter	11.7%

Excluding patients who did not attend/engage with the GIDS, the referral rate to endocrinology was 28%. Excluding this same cohort or patients along with those who refused the service, the referral rate to endocrinology was 31%.

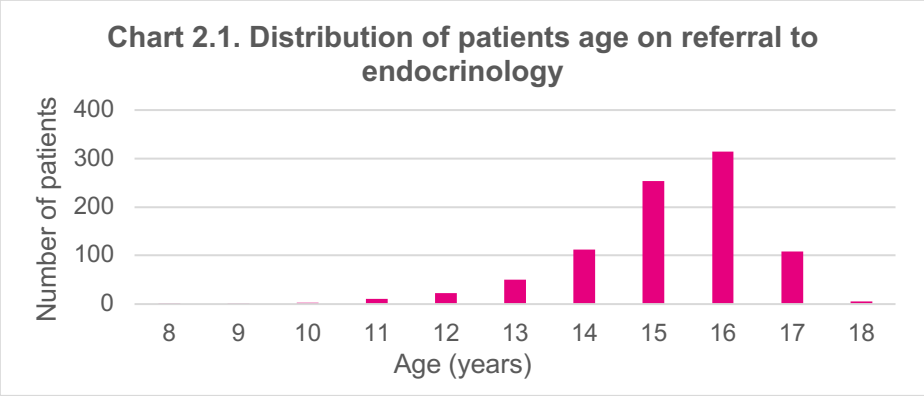
Gender profile on referral to endocrinology

34.6% of natal males were referred to endocrinology, compared to 24.2% of natal females.

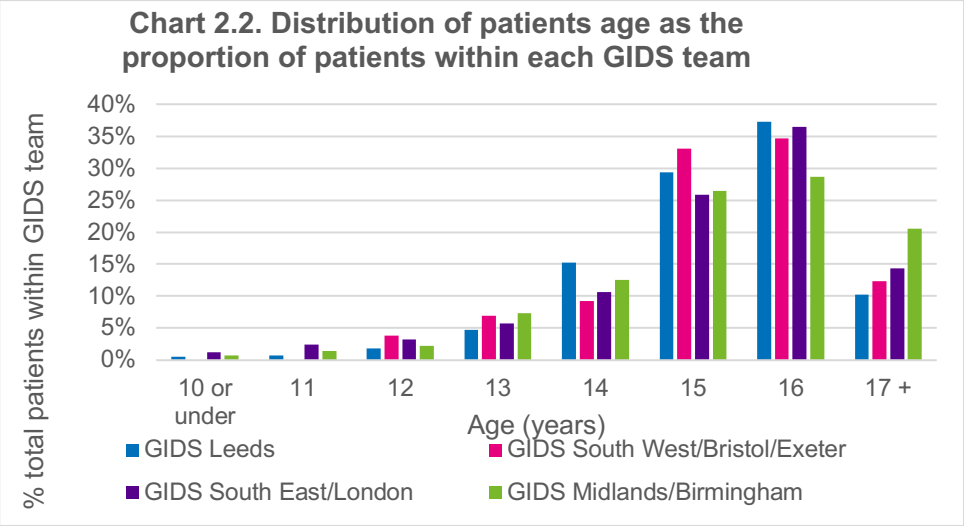
Of the total patients referred into endocrinology, 34% were natal male, and 66% natal female.

Age profile on referral to endocrinology

Patients were referred to endocrinology between the ages of 8 years and 18 years, although the <10 patients referred post-Bell were all 17years. The mean and median age of referral was 15 years. Chart 2.1 shows the distribution of patients age on referral.



The distribution of age broadly similar across the GIDS as shown in chart 2.2. Excluding patients who did not attend/engage or who refused the service had no impact on the distribution of the ages.



Appointments with the GIDS prior to referral to endocrinology

Patients received on average a total of 6.7 appointments with GIDS prior to referral to endocrinology. Analysis against the Bell judgement identified that patients received an average of 6.6 appointments pre-Bell, and 15.8 appointments post-Bell before being referred to endocrinology.

Table 2.2 provides a breakdown of appointments by the GIDS referral team.

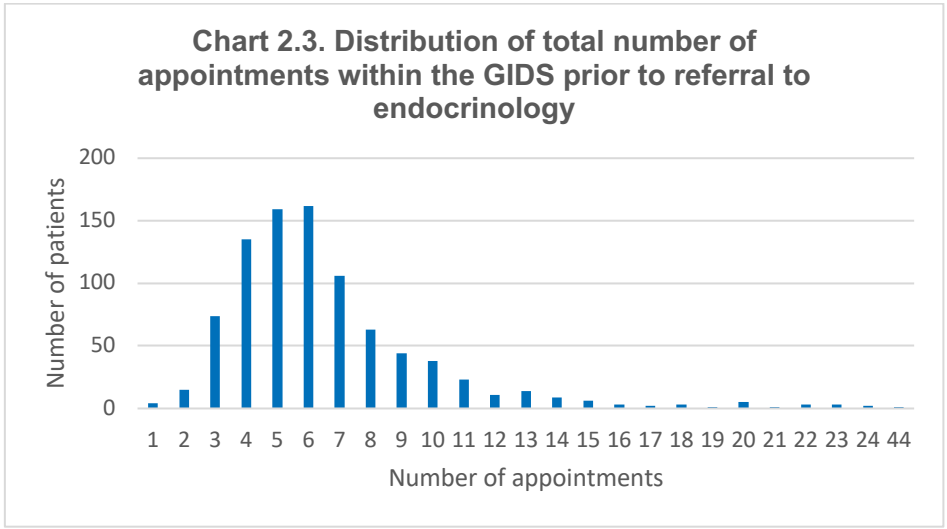
Table 2.2. Total number of appointments with GIDS prior to referral to endocrinology, by GIDS team

GIDS Team	Average	Minimum	Maximum
All teams	**6.7**	**1**	**44**
GIDS Leeds	6.3	1	23
GIDS Midlands/Birmingham	6.4	2	22
GIDS Southeast/London	7.8	1	44
GIDS Southwest/Bristol/Exeter	5.8	1	14

<10 patients seen by the GIDS Leeds team were referred to endocrinology after the first appointment due to transfer of care and were already receiving puberty blocker treatment.

The distribution of appointments is shown in chart 2.3. There was a similar distribution of appointments according to the GIDS team, full details are provided in appendix 3.

Post-Bell, <10 patients were referred to endocrinology had 12 or more appointments with the GIDS prior to the referral.



Limitations of analysis

- The date of referral to endocrine was captured as part of the audit collection tool. The audit did not capture the date which the patient was then seen by endocrinology. Recognising the waiting times into the service, it was not possible to undertake analysis against the Bell judgement upon referral into endocrinology.
- The audit criteria focussed on patients who had been discharged from the GIDS. Therefore there is potentially a cohort who have not been considered as part of this audit and thereby referrals into endocrine could be higher than indicated in this audit.

Key findings

- Overall, 27% of patients were referred to endocrinology. This was slightly increased when excluding patients who did not attend/engage with the service or declined the service.
- The largest proportion of patients referred to endocrinology are seen by GIDS Leeds (32.7%) and GIDS Southeast/London (20.9%).
- 34.6% of natal males were referred to endocrinology, compared to 24.2% of natal females.
- A higher proportion of patients referred to endocrinology are aged 15-16years.
- Patients receive and average of 6.7 appointments prior to referral to endocrinology, with a range of 1 to 44.

First interventions within endocrinology

- **First intervention type overview**

Table 2.3 shows the first interventions received by patients upon referral to endocrinology. Please note, the first intervention was not necessarily the first appointment, where treatment was recommended there were often a number of appointments required to determine the patients' suitability for treatment (e.g., DEXA scans and blood tests prior to commencing puberty blocker treatment).

There was little variation in the first intervention following endocrinology referral when analysed by GIDS team (see appendix 4).

Of the <10 patients referred post-Bell, X received a puberty blocker only, X patients were discharged to the Gender Identity Clinic (GIC) and the other patients decided to access treatment privately. These patients were aged 16 to 17years of age upon referral.

Table 2.3. First intervention received by patients referred to endocrinology

First intervention type	% of patients
Puberty Blockers ONLY	81.5%
Patient declined treatment	7.1%
Puberty assessment ONLY	5.6%
Other*	X
DNA	X
Accessed treatment outside NHS protocols	X
Puberty blockers AND cross-sex hormones	X
Puberty Blocker not started due to JR	X
Did not access physical treatment	X
Cross-sex hormones ONLY	X

Puberty blocker (NHS before GIDS) AND cross-sex hormones	X
Puberty blockers (privately before GIDS) AND cross-sex hormones	X

Other – first interventions captured as other represent a small proportion of patients for reasons which include; referral on hold, other opinion required, discharged to GIC, notes incomplete, puberty blocker advised but unclear if started, treatment not advised on professional advice, patient moved from abroad on puberty blocker and referred on first appointment, puberty blocker not started due to patient misunderstanding about treatment regime, treatment recommended but supply issues (GP prescribing or pharmacy).

- **First intervention type by natal gender**

The first intervention patients received according to their natal gender was broadly similar (see appendix 5).

- **Treatment type and patients' age**

Appendix 6 shows the intervention types by age at the point of referral, against the total proportion of patients referred into endocrinology. 52.5% of patients between 15-16 years received puberty blockers, followed by those aged 13-14 years of age (16.5%).

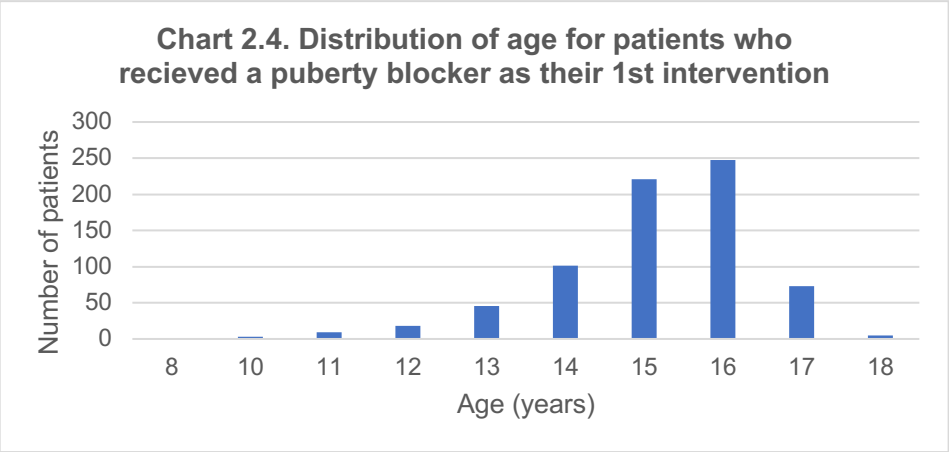
For patients receiving puberty blockers and/or cross-sex hormones upon referral to endocrinology (excluding those who have received clinical treatments outside of the GIDS), table 2.4 provides information about the age at which the patients were upon referral, although the patient may have been older at the point of receiving treatment due to waiting times to be seen by endocrinology.

Table 2.4. Treatment type and patients age at referral, by GIDS team

	Average age	Minimum age	Maximum age
Puberty-blockers ONLY			
All teams	**15**	**8**	**18**
GIDS Leeds	15	8	18
GIDS Midlands/Birmingham	15	10	17
GIDS Southeast/London	15	10	18
GIDS Southwest/Bristol/Exeter	15	12	17
Cross-sex hormones ONLY			
GIDS Leeds	N/A	N/A	N/A
GIDS Midlands/Birmingham	N/A	N/A	N/A
GIDS Southeast/London	<10 patients aged 15 years		
GIDS Southwest/Bristol/Exeter	<10 patients aged 17 years		
Puberty-blocker and cross-sex hormones			
GIDS Leeds	<10 patients aged 15 years <10 patients aged 16 years		
GIDS Midlands/Birmingham	<10 patients aged 14 years		
GIDS Southeast/London	<10 patients aged 16 and 17 years		
GIDS Southwest/Bristol/Exeter	N/A	N/A	N/A



Chart 2.4 shows the distribution of patients ages for those who received a puberty blocker as their first intervention.



Limitations of analysis

- The date that the patient started treatment as part of their first intervention whilst under the care of the endocrinology team was not captured, as it was difficult to capture this accurately and was not part of the audit tool design. The age of the patient upon referral into endocrinology was therefore used for the analysis.

Key findings

- 81.5% of patients referred into endocrinology received puberty blockers, of which 52.5% were between 15-16 years old.
- A small number of patients received cross-sex hormones (<10 patients) or both puberty blockers and cross-sex hormones (<10 patients), as their 1st intervention within the endocrinology service.
- <10 patients who were initially advised to start puberty blockers did not start treatment due to the Bell judgement. All patients were aged 16-17years on referral.
- Post-Bell, <10 patients received a puberty blocker, <10 patients were discharged to the GIC and <10 patients decided to access treatment privately.
- Patients were on average 15 years old when referred for puberty blocker treatment.

Final interventions within endocrinology upon discharge from the GIDS

Table 2.5 shows the end point intervention upon patients discharge from the GIDS, with 54.8% ending up on both puberty blockers and cross-sex hormones.

Of the <10 patients who were referred to endocrinology post-Bell, <10 patients who subsequently received puberty blockers remained on the puberty blocker, but treatment was withdrawn for other patients on professional advice due to side effects. <10 patients was discharged to the GIC and did not access physical treatment whilst under the care of the GIDS, and the final patients decided to access treatment privately.

Table 2.5. Final intervention received by patients referred to endocrinology	
First intervention type	**% of patients**
Puberty blockers AND cross-sex hormones	54.8%
Puberty Blockers ONLY	19.9%
Patient declined treatment	11.4%
Accessed treatment outside NHS protocols	3.9%
Did not access physical treatment	3.3%
Puberty assessment ONLY	2.0%
Treatment withdrawn - DNA	1.5%
Detransitioned/detransitioning	X
Unknown/unclear	X
Puberty Blocker not started due to JR	X
Treatment recommended but supply issues (GP prescribing or pharmacy)	X
Treatment withdrawn - professional advice/side effects	X
Cross-sex hormones ONLY	X
Puberty blockers AND cross-sex hormones (privately)	X

Appendix 7 shows the final intervention types by age against the total proportion of patients referred into endocrinology.

The final intervention patients received according to their natal gender as shown in appendix 8 shows that a higher proportion of natal females (57.9%) ended up on both puberty blockers and cross-sex hormones compared to natal males (47.7%). A higher proportion of natal males (24.7%) ended up on puberty blockers alone compared to natal females (17.4%).

- **First intervention puberty blockers: Final intervention type**

As shown in table 2.6, 64% of patients who were initially started on a puberty blocker at their first intervention pre-Bell, ended up on both a puberty blocker and cross sex-hormone through the GIDS (this does not include 1 patient who was on both interventions however was accessing cross-sex hormones privately). 23% of patients remained on a puberty blocker alone.

Table 2.6. Final intervention received by patients referred to endocrinology	
First intervention type	**% of patients**
Puberty blockers AND cross-sex hormones	64.0%
Puberty Blockers ONLY	23.0%
Patient declined treatment	7.3%
Accessed treatment outside NHS protocols	2.1%
Treatment withdrawn - DNA	1.4%
Unknown/unclear	X
Detransitioned/detransitioning	X
Treatment withdrawn - professional advice/side effects	X
Puberty blockers AND cross-sex hormones (privately)	X
Treatment recommended but supply issues (GP prescribing or pharmacy)	X



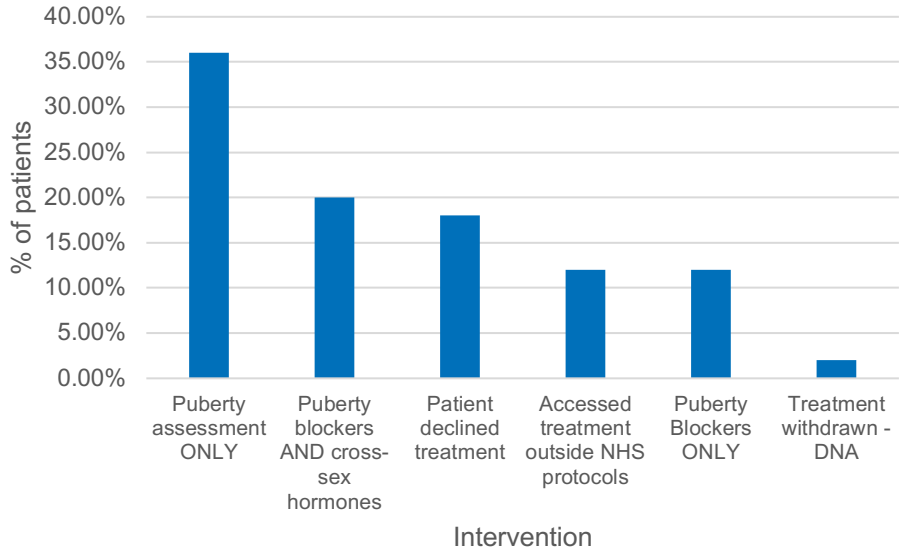
- **First intervention puberty blockers and cross-sex hormones: Final intervention type**

100% of pts (n=<10) who were started on a puberty blocker and cross-sex hormone, remained on the same treatment

- **First intervention initial assessment only: Final intervention type**

Where patients were referred to endocrinology and only received a puberty assessment at their first intervention, chart 2.5 shows the final intervention that the patient had following discharge from the GIDS.

Chart 2.5. Final intervention type for patients who initially only had a puberty assessment on referral into endocrinology



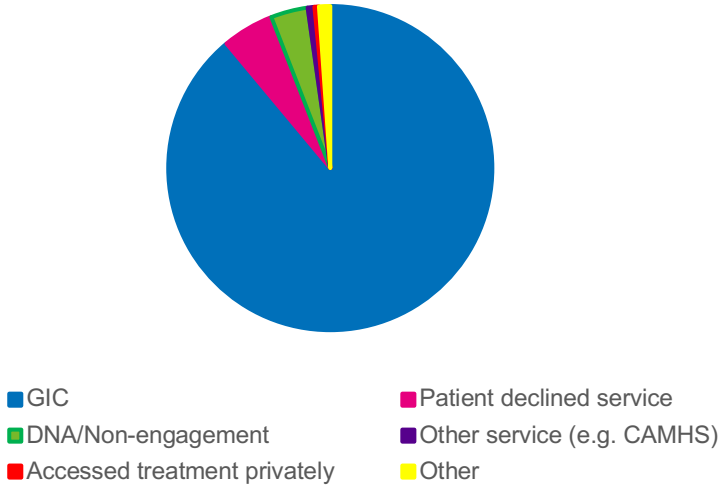
- **Detransitioned/detransitioning patients**

<10 patients who went on to detransition back to their natal gender, all were female. <10 patients had received puberty blockers as their first intervention following endocrinology referral, however it was not clear from the records of the final patient what interventions they had received. They had received an average of 6.5 appointments prior to referral to endocrinology (range 3-10 appointments).

Discharge destination for patients referred to endocrinology

For patients who were referred to endocrinology, 89% of patients were referred to a GIC following discharge from the GIDS (see chart 2.6), 5% of patients declined the GIDS, and 3% did not attend or engage with the service. Other reasons for discharge included to different services, accessed treatment privately, moved outside of the NHS England or NHS Wales footprint, or where the discharge destination was unknown.

Chart 2.6. Patients referred to endocrinology, discharge destination from the GIDS



Limitations of analysis

- Although first intervention and final intervention at discharge from the GIDS was captured, the audit did not gather any information about any interventions which the patient may have received between these time periods.

Key findings

- 54.8% of patients referred to endocrinology ended up on both puberty blockers and cross-sex hormones.
- 57.9% of natal females ended up on both puberty blockers and cross-sex hormones compared to 47.7% for natal males.
- 24.7% of natal males ended up on puberty blockers alone compared to 17.4% of natal females.
- For patients who initially received a puberty blocker upon referral to endocrinology, 64% went on to receive both a puberty blocker and cross-sex hormone.
- All patients who started on both a puberty blocker and cross-sex hormone, remained on the same treatment upon discharge from the GIDS.
- Of the patients who only initially had a puberty assessment, 12% went on to have puberty blockers and a further 20% went on to have both puberty blockers and cross-sex hormones.
- 89% of patients were discharged to a GIC.
- 9% of patients declined, did not attend or engage with the service.
- <10 patients detransitioned back to their natal gender, all of whom were female, and <10 patients were confirmed as having received puberty blockers as their first intervention.

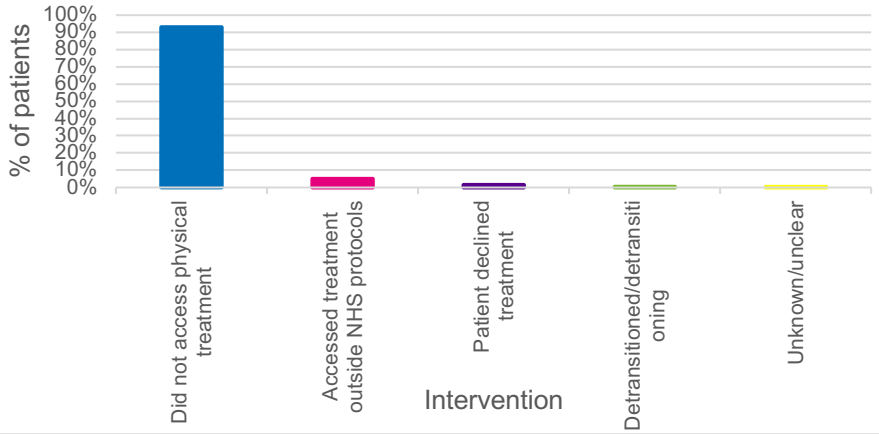
Theme 3. Patients not referred to endocrinology pathway

Across the 3306 patients' audits, 2415 patients were not referred to endocrinology by the GIDS team.

Final interventions for patients not referred to endocrinology

Chart 3.1 shows final intervention patients received upon discharge from the GIDS. 93.0% of patients did not access any physical treatment whilst under the GIDS. 5.0% of patients accessed treatment outside of NHS protocols, 1.5% declined treatment and 0.5% of patients detransitioned or were detransitioning back to their natal gender.

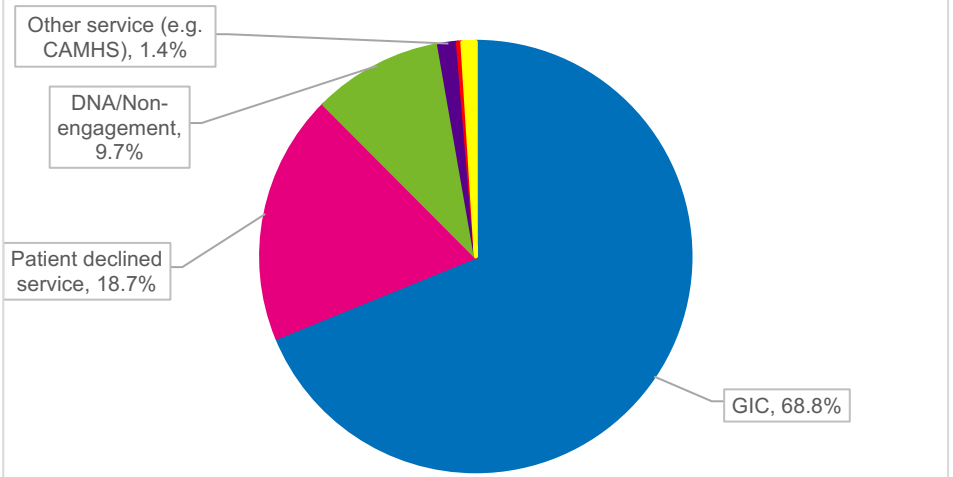
Chart 3.1. Final intervention type for patients who were not referred to endocrinology



Discharge destination for patients not referred to endocrinology

For patients who were not referred to endocrinology, 69% were referred to a GIC following discharge from the GIDS (see chart 3.2), 19% of patients declined the GIDS, and 10% did not attend or engage with the service. Other reasons for discharge included to different services, patient death, or where the discharge destination was unknown.

Chart 3.2. Patients not referred to endocrinology, discharge destination from the GIDS



Key findings

- 93% of patients who were not referred to endocrinology did not access any physical treatment, and 5% accessed treatment outside of NHS protocols.
- 69% of patients were referred to a GIC.
- 29% of patients declined, did not attend or engage with the service.

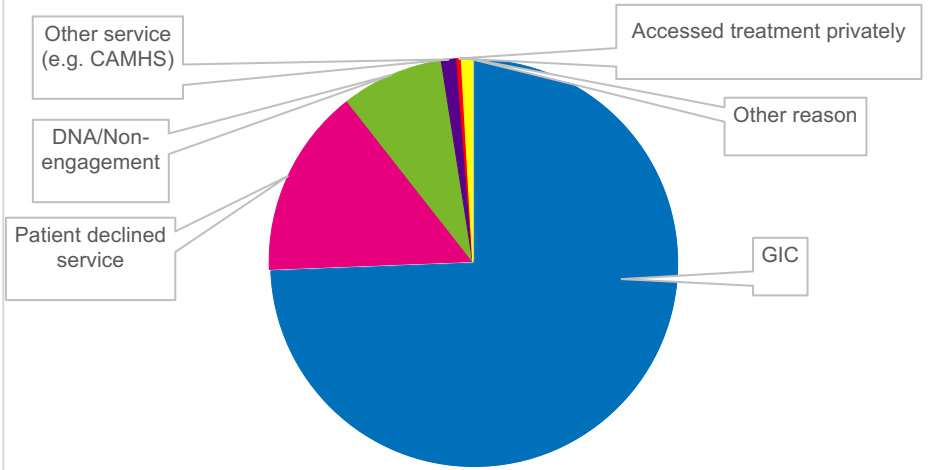


Theme 4. Discharge from GIDs – all patients summary

Discharge destination

Over 70% of patients were referred to a GIC following discharge from the GIDS (see Chart 4.1). Approximately 15% of patients declined the GIDS, and 8% did not attend (DNA) or did not engage with the service. This was similar when comparing the discharge destination pre-Bell and post-Bell. Other reasons for discharge included discharge to other services, moving outside of the NHS England or NHS Wales geographies, patient deaths or where the discharge destination was unknown.

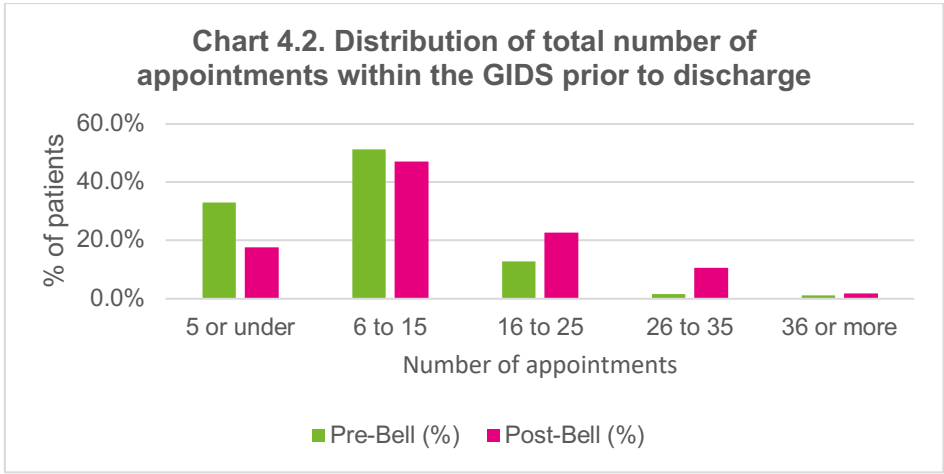
Chart 4.1. Patients discharge destination from GIDS



Appointments with the GIDS prior to discharge

Patients received on average a total of 11 appointments with GIDS prior to discharge, with an average of 10 appointments pre-Bell and 14 appointments post-Bell, which included any relevant endocrinology appointments where the patient was under the care of the endocrinology team. The distribution of appointments pre-Bell and post-Bell are shown in Chart 4.2.

Chart 4.2. Distribution of total number of appointments within the GIDS prior to discharge



Limitations of analysis

- There was inconsistency in the date recorded for discharge within the patients notes, with there being a delay in the processing of the discharge for the patient. The CSU audit team attempted to have consistency in the date used by utilising the closing summary as the first reference point, however this was not always possible where closing summaries were incomplete.

Key findings

- 70% of patients are referred to a GIC upon discharge from the GIDS.
- 8% of patients did not attend/engage or declined the service and were therefore subsequently discharged.
- Patients received an average of 11 appointments with the GIDS prior to discharge.



Arden & GEM CSU would like to thank colleagues at the Tavistock and Portman NHS Foundation Trust for their support provided during the audit process.

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Arden&GEM
Health and social care systems support

References

Dr Hilary Cass. (2022, February). The Cass Review: *Independent review of gender identity services for children and young people: Interim Report.* Retrieved from https://cass.independent-review.uk/wp-content/uploads/2022/03/Cass-Review-Interim-Report-Final-Web-Accessible.pdf

Dame Victoria Sharp P., Lord Justice Lewis, Lieven J. (2020, December). Bell v Tavistock Approved Judgement.. Retrieved from https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf

Appendices

Appendix 1a. Audit Template questions: Patient demographics and initial referral information

Patient ID	Date of Birth	Natal gender (sex assigned at birth)	Current gender	Date of Referral to the GIDS	Referral Source	Gender Identify Development Service (GIDS) team	Lead clinician at initial assessment	Current Lead Clinician
Do not enter NHS number	*Date (01/01/2023)*	*Male (M) or Female (F)*	*Male, Female, Non-Binary or other*	*Date (01/01/2023)*	*CAMHS / CYP Mental Health, Childrens or Council Service/Local Authority, GP Practice, Paediatrics, Private Healthcare, School, Voluntary sector, Other*	*London/Leeds/ Birmingham/Midlands Bristol/ Exeter, South East,South West, Other*	*Full Name*	*Full Name*

Appendix 1b. Audit Template questions: Endocrinology referral and care pathway

Has the patient been referred to the endocrine clinic	If YES (Y), what was their 1st intervention?	If YES (Y), date of referral to endocrine?	If YES (Y), Number of appointments patient has attended pre referral to endocrine	Is patient discharged from the GIDS on referral to endocrine clinic
Yes or No *If No - move to column U*	*1. **ONLY** Puberty Blockers ONLY (PB),* *2. **ONLY** x-sex hormones /gender afirming hormones (SH/GAH)* *3. **BOTH** PB and SH/GAH (PB + SH/GAH)* *4. Puberty assessment ONLY* *5. Pt declined treatment* *6. Other*	*Date (01/01/2023)*	*5* *(**INCLUDE:** 1-2-1 appts with clinicians, network/professional meetings, Child Protection/Children in Need meetings* ***EXCLUDE** : Support meetings such as summer groups, family days, parents and siblings groups)*	*Yes or No* *If No - move to column T*

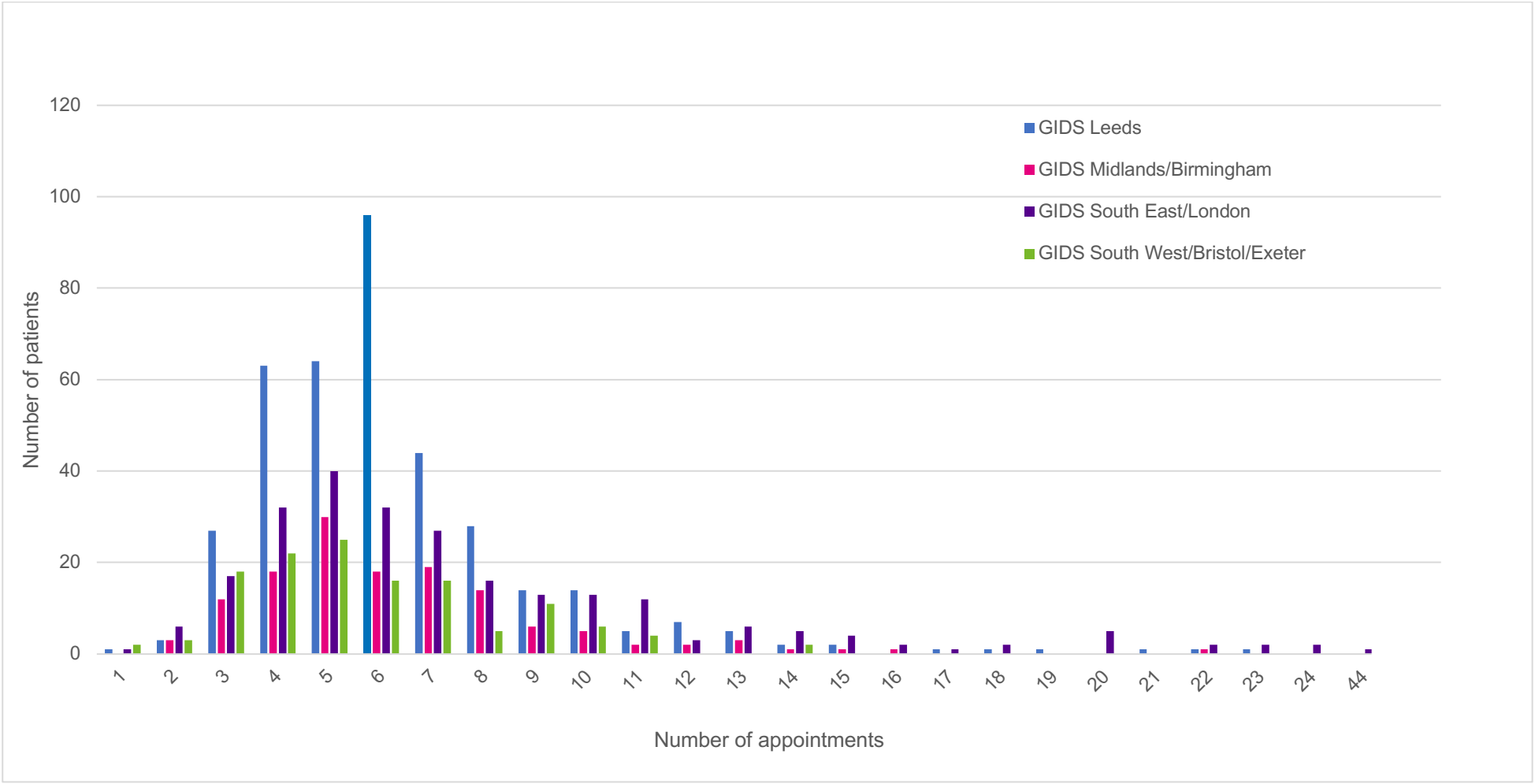
Appendix 1c. Audit Template questions: Discharge information and other comments

Has the patient been discharged for any other reason?	If YES (Y), Discharge reason on patients case file	If YES (Y), Number of appointments patient has attended at GIDS before discharge	If YES (Y), Date of discharge	Does the patient remain on the following at the point of dicharge?	Other comments
Yes or No (If No, data capture for this patient is complete)	*Select drop down (GDC, patient declined service, other service e.g. CAMHS, patient deceased, other reason)*	*5 (**INCLUDE**: 1-2-1 appts with clinicians, network/professional meetings, Child Protection/Children in Need meetings **EXCLUDE:** Support meetings such as summer groups, family days, parents and siblings groups)*	*Date (01/01/2023)*	*1. ONLY Puberty Blockers ONLY (PB), 2. ONLY x-sex hormones /gender afirming hormones (SH/GAH) 3. BOTH PB and SH/GAH (PB + SH/GAH) 4. Puberty assessment ONLY 5. Pt declined hormonal treatment 6. Other*	*Please do not include PID Ensure any relevant information is captured. Where you have selected 'other' in a column, please indicate the specifics along with which column question it related to. e.g. Column V - patient moved abroad*

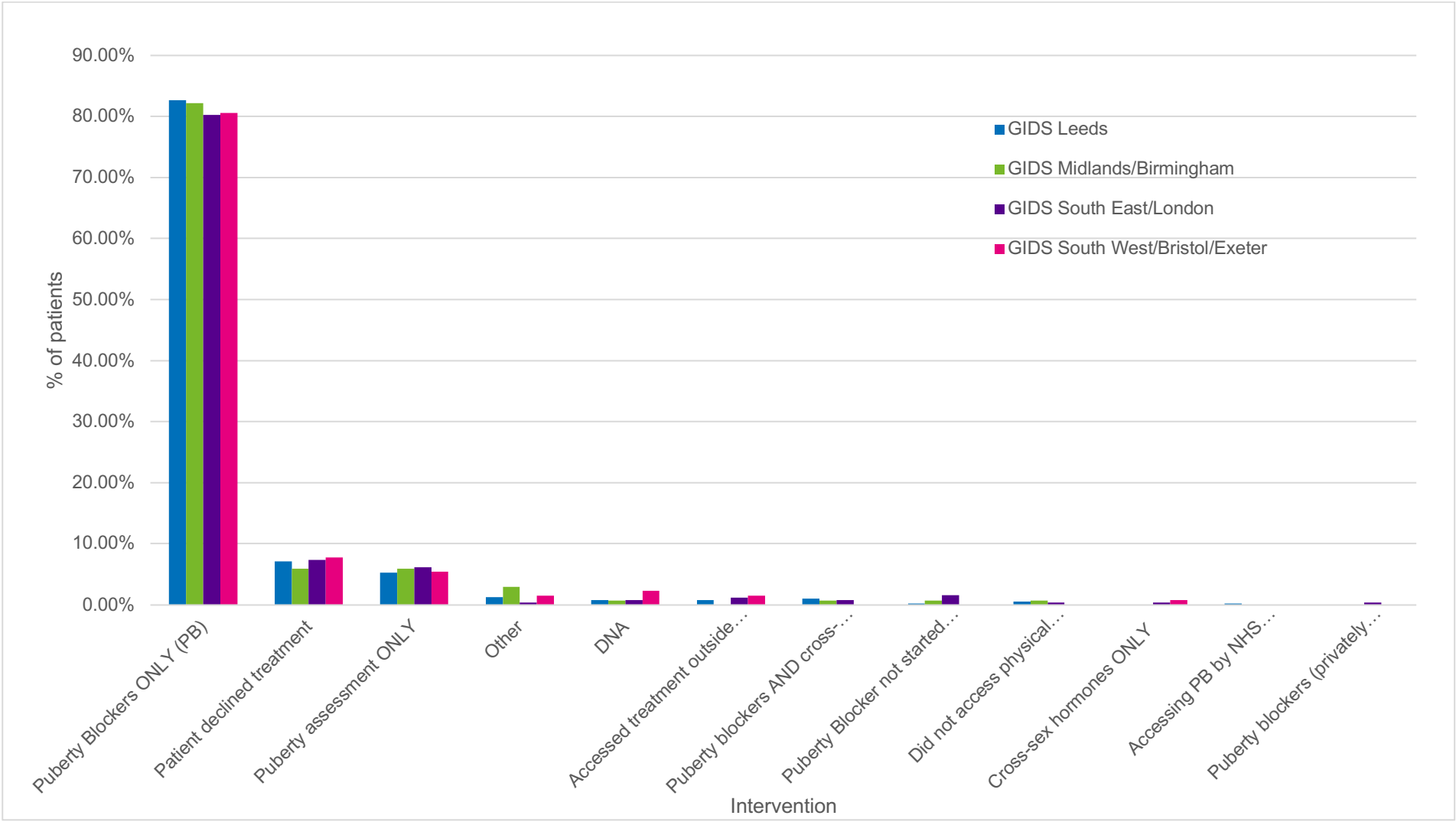
Appendix 2. Breakdown of referral source by GIDS team

	GIDS Leeds	GIDS Midlands/Birmingham	GIDS Southeast/London	GIDS Southwest/Bristol/Exeter	Grand Total
CAMHS / CYP Mental Health	47.34%	44.44%	50.43%	53.02%	48.58%
GP Practice	41.85%	46.27%	37.93%	36.20%	40.68%
Children's or Council Service/Local Authority	X	X	X	X	3.27%
Voluntary sector	X	X	X	X	3.09%
School	X	X	X	X	1.85%
Paediatrics	X	X	X	X	1.57%
Healthcare provider - other	X	X	X	X	X
Healthcare provider - private	X	X	X	X	X
Other	X	X	X	X	X

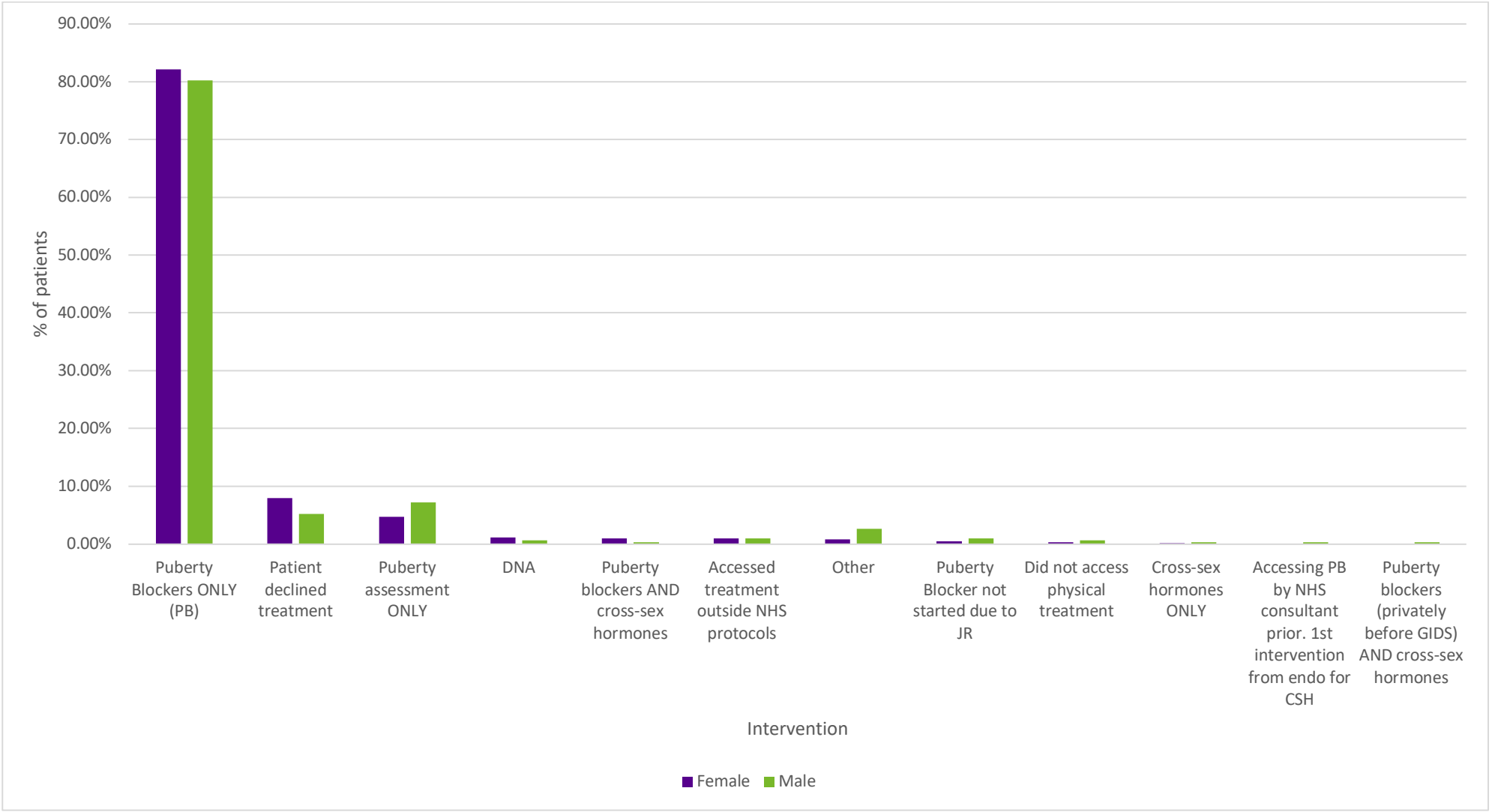
Appendix 3. Distribution of total number of appointments within the GIDS prior to referral to endocrinology, by GIDS team



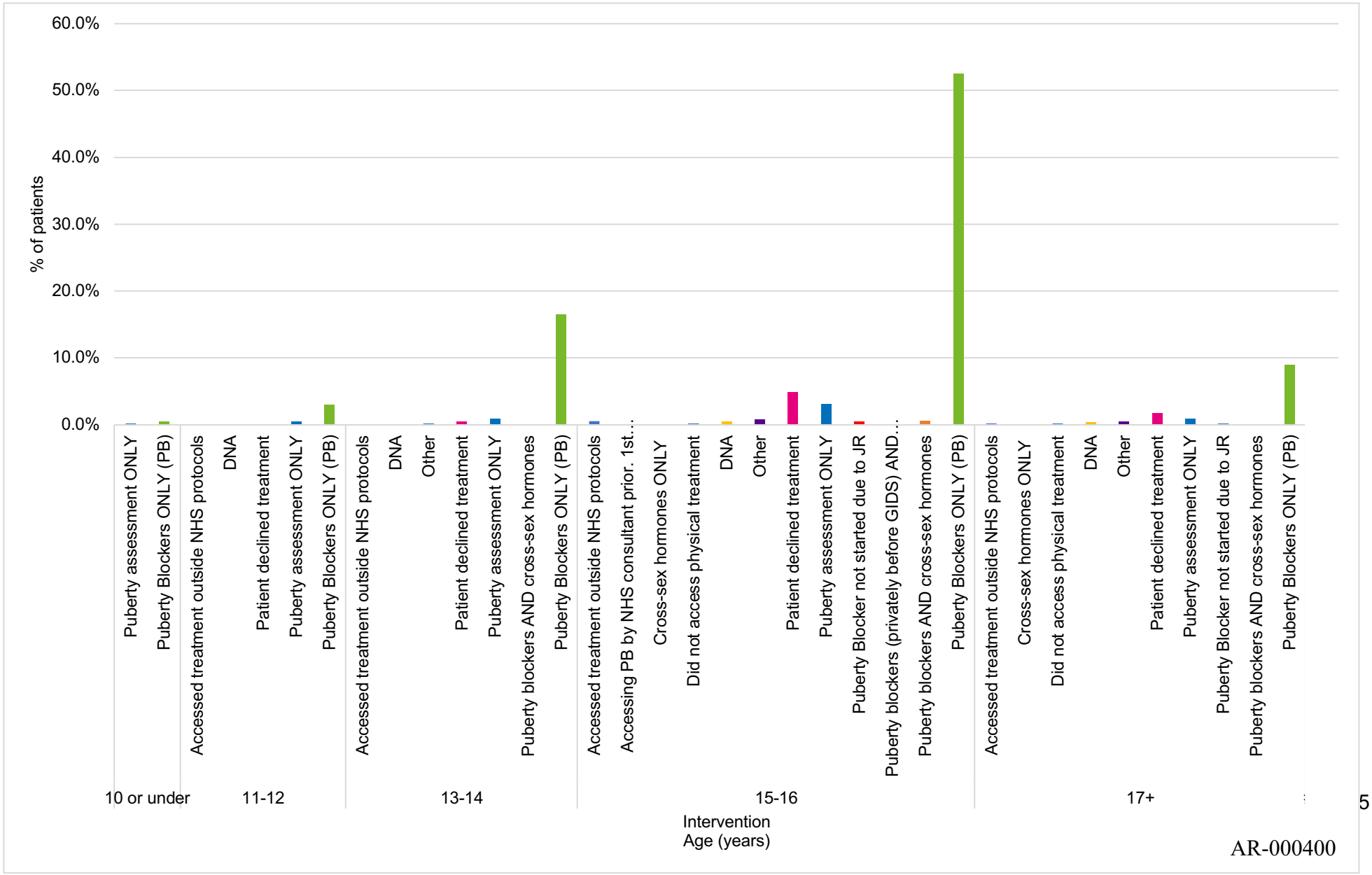
Appendix 4. First intervention for patients referred to endocrinology, by GIDS team



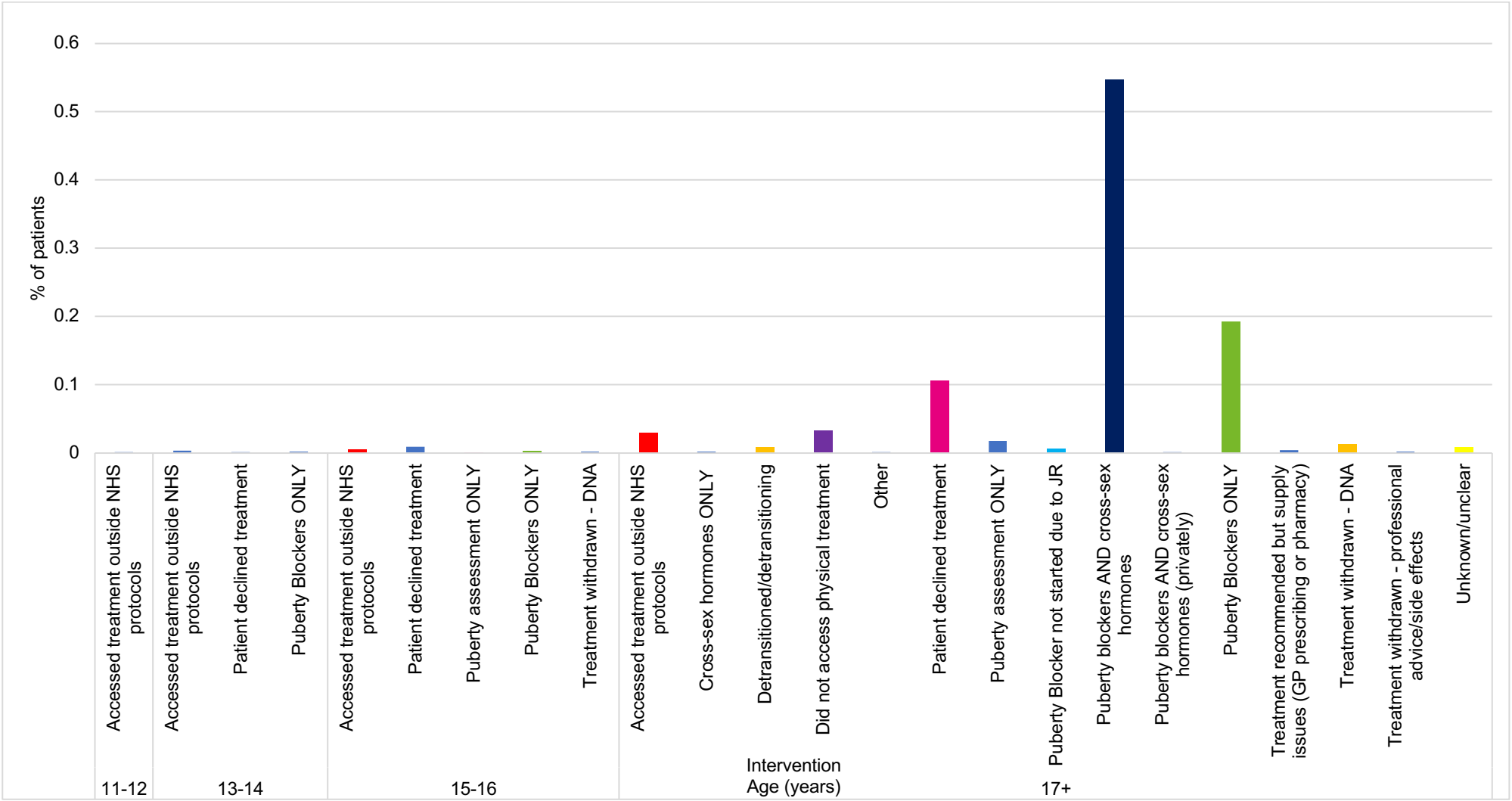
Appendix 5. First intervention following endocrinology referral by natal gender



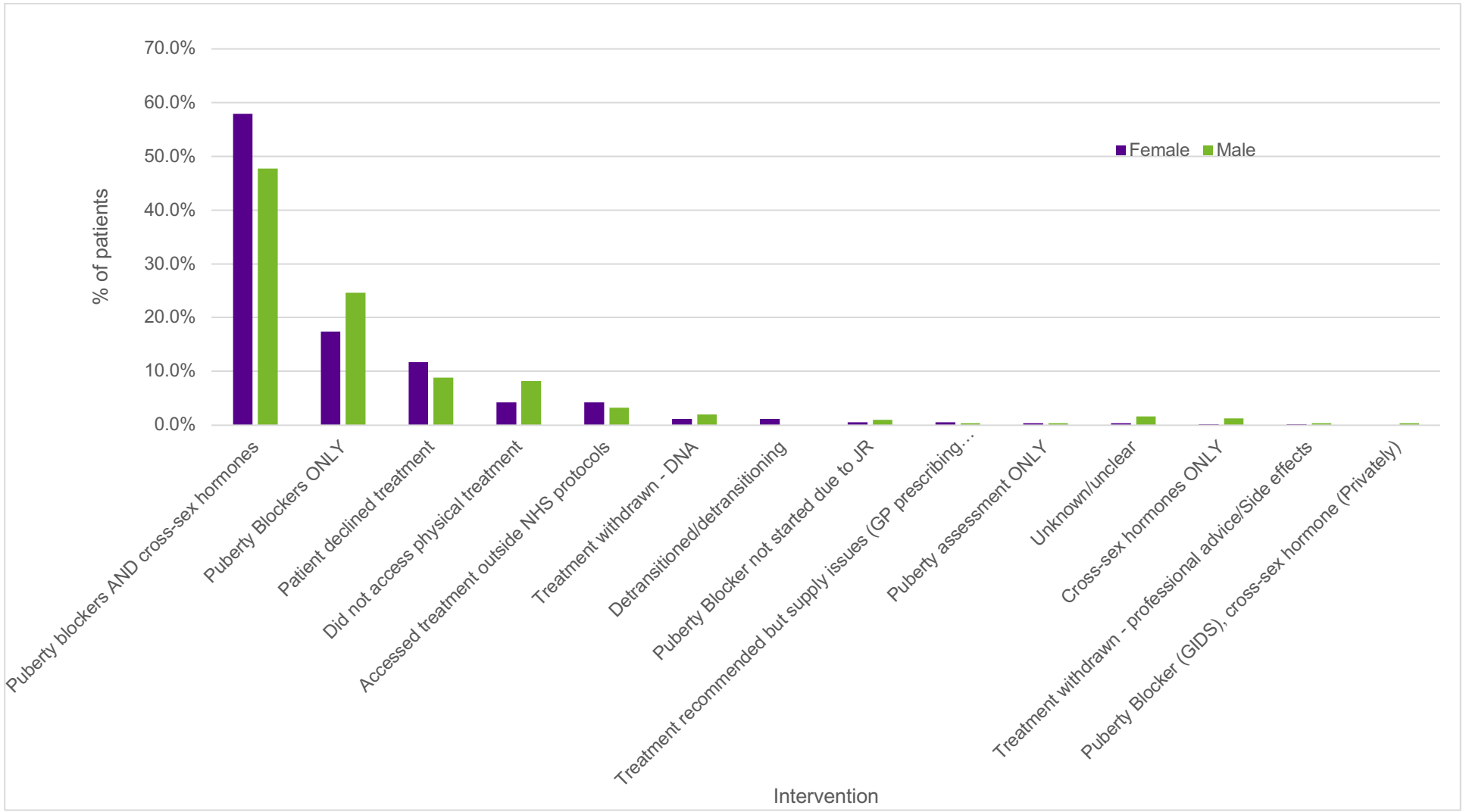
Appendix 6. First intervention following endocrinology referral by age as percent of all patients referred



Appendix 7. Final intervention at discharge from GIDS following endocrinology referral by age as percent of all patients referred



Appendix 8. Final intervention at discharge from GIDS for patients referred to endocrinology, by natal gender



Appendix 9

Date:
Summer 2023

Report:
Learning points from the Gender Dysphoria Multi-Professional Review Group (MPRG).

Provided by: Professor Judith Ellis OBE, Chair MPRG and all members of the MPRG.

Submitted to: John Stewart

Section	**Topic**	**Page numbers**
A	**Background**	2
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C	**MPRG Outcome Options**	3
D	**MPRG Membership**	3
E	**MPRG Model of work**	3-4
F	**MPRG Activity**	4
G	**Outcomes**	4-5
H	**GIDS, Tavistock & Portman NHSFT Response**	5
I	**MPRG Reflections**	5-14
J	**MPRG Impact**	15
K	**Moving Forward**	15
L	**MPRG Summary learning points**	15-16

A. Background:

MPRG was established in August 2021 on an interim basis following CQC and NHSE concerns about GIDS.

CQC concerns included:

- Lack of clearly demonstrated and validated assessment tools for staff
- Lack of structured plans for care,
- Decision-making records unclear,
- Teams not always including all specialists necessary for good care,
- Informed child consent procedures not in line with NHS & GMC requirements
  - Consistency of records on competency, capacity and consent
- Inadequate safeguarding

B. MPRG:

B. i: GIDS review

In summer 2021 a decision was taken for NHSE to establish a Multi-Professional Review Group to decide, if assured, whether appropriate process (according to the NHSE Standard Operating Procedure (SOP)) had been followed in order for the requesting clinician to arrive at a request to refer a child (under 16 years) for consideration of endocrine treatment. This included assurance that:

- the assessment and diagnosis are compliant with requirements of the Service Specification
- the child meets the eligibility criteria for referral to the endocrine clinic
- there is a written record of consent by those with parental/guardian responsibility
- clinicians have explained all necessary information to the parents/guardians, in a balanced way, with opportunity for discussion, and parental/guardian concerns have been addressed appropriately, with evidence that they have understood
- there has been opportunity for parents/guardians to discuss with GIDS clinicians without the child being present
- the capacity or ability of a child's parents/guardians to give consent has been explored and confirmed
- there is a written record of consent by the child
- clinicians have explained all necessary information to the child, in an appropriate and balanced way (tailored to developmental needs (e.g. age, ASD, ADHD, etc)), with opportunity for discussion, and the child's concerns have been addressed appropriately, with evidence that they have understood
- there has been opportunity for the child to discuss with GIDS clinicians without the parents/guardians being present
- the capacity or ability of the child to give consent has been explored and confirmed
- child safeguarding and child protection issues have been fully considered by the Tavistock clinicians in line with their statutory and professional duties.

B ii Endocrine Audit:

For the endocrine clinics, which were rated 'good' by the CQC, the MPRG retrospectively undertook a 'light touch' audit of a sample of endocrine assessments (puberty rating and baseline hormone profiles), to confirm confidence in the whole pathway of care.

This supports assurance to Trust executives that a consistent decision-making process is being followed.

C. MPRG Outcome Options:

There are two outcome options available to the MPRG:

- agree that the appropriate process has been followed and assurance given on all counts
- agree that there is insufficient information on which to be assured on one or all of the elements (see 2.1)

If not fully assured, the MPRG seek and the GIDS team are asked to provide, further information. Where this is the case the MPRG via the Chair clearly outlines the information required /action to be taken and the timeline for receipt of the additional information. Further information supplied is considered by the Chair and if necessary, by specific or all MPRG members, and a decision re assurance taken and communicated to GIDS.
N.B. MPRG reports an assurance that a process has been followed – it does not endorse or refuse treatment.

D. MPRG Membership:

- Chair
- Consultant Child & Adolescent Mental Health Psychiatrist
- Senior Paediatric Nurse with Safeguarding experience
- Professor of Paediatric Endocrinology
- Consultant Paediatrician
- Consultant Psychologists x 2
- Senior Social Worker
- Youth Development Worker (In initial cases)

Management and administrative support and Secretariat are provided by the Clinical Effectiveness, Specialised Services team at NHSE

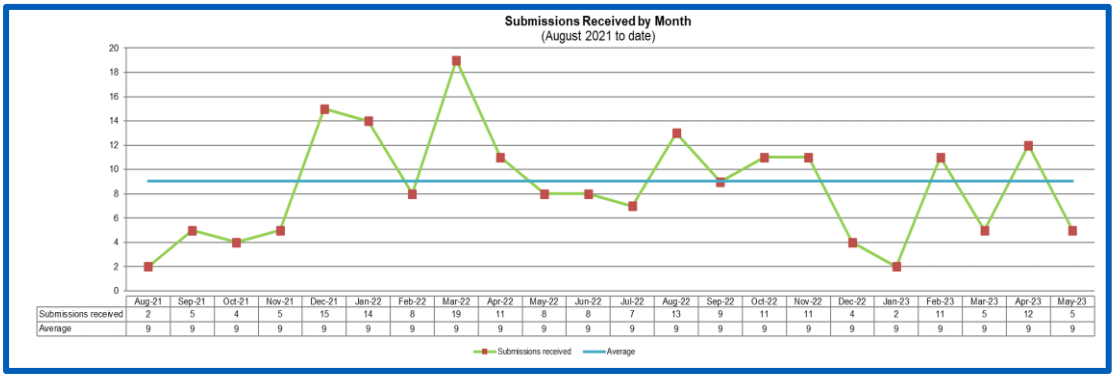
E. MPRG Model of work:

- MPRG meet via an online meeting platform for 4 hrs each week.
- Meetings require 4 members to be quorate (Meetings have never been cancelled due to being inquorate)
- All received documentation is redacted for family names and personal identifiable information
- Meetings are cancelled if no cases have been submitted by the Tavistock or if the NHSE secretariat identify that further redaction or clarification is required before the case is presented to the MPRG for consideration
- Submissions to MPRG have for each case been between 90 to 210 pages in length and vary in quality, from succinct to disorganised and repetitive.
- One MPRG member leads on each case but all members read and consider the complete file.

- Discussions are challenging and probing, remaining professional, respectful, and sympathetic to both the children, families and professional colleagues. As the clinical material can be distressing, the Chair and group seek to maintain psychological safety for participants during the discussions.
- Discussions/ decision documents are typed up by NHSE Admin team and direct quotes from the documentation are used to illustrate points made.
- The Chair reviews and signs off all decision documents.
- All case documentation received is deleted by MPRG members after the weekly discussion and by the Chair once the decision document is signed off.
- N.B. Although in their terms of reference the MPRG are allowed to meet the children and their families, in addition to accepting the importance of client confidentiality and the need for members anonymity, the MPRG have never considered that it would be appropriate or helpful to request a one-off face to face meeting between the young people/family and unfamiliar MPRG members. MPRG have however occasionally required GIDS staff to have additional meetings with the child/family to provide assurance required, particularly around assurance that the child's voice has been heard.

F. MPRG Activity:

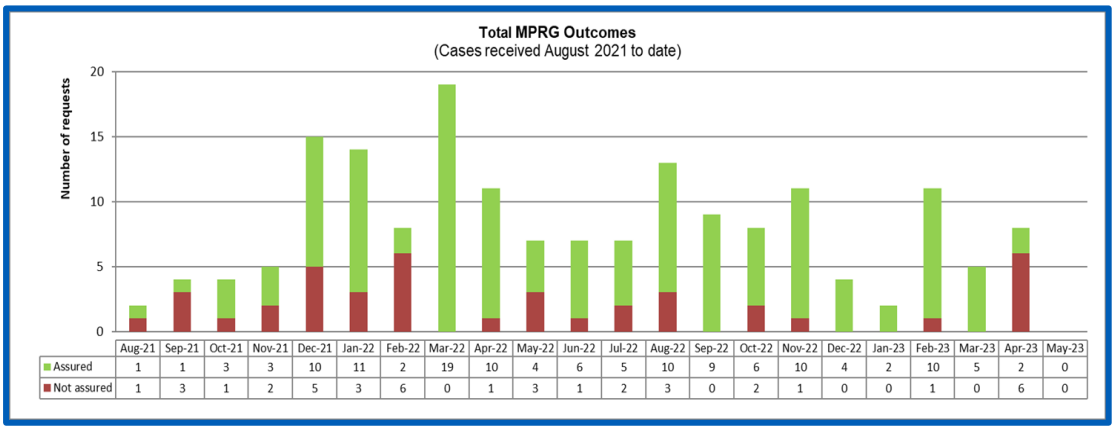
- Submissions received per month (average 9)



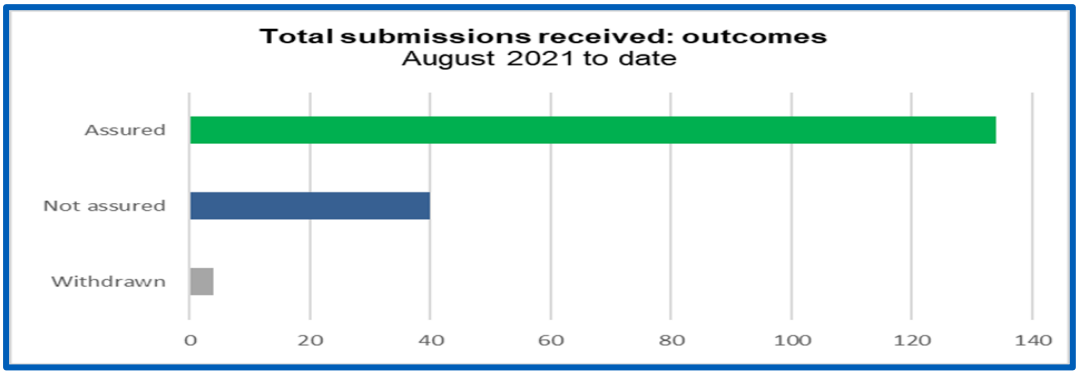
	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23
Submissions received	2	5	4	5	15	14	8	19	11	8	8	7	13	9	11	11	4	2	11	5	12	5
Average	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9

G. Outcomes:

- By July 2023 there have been 179 outcome decisions.



	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23
Assured	1	1	3	3	10	11	2	19	10	4	6	5	10	9	6	10	4	2	10	5	2	0
Not assured	1	3	1	2	5	3	6	0	1	3	1	2	3	0	2	1	0	0	1	0	6	0



- N.B. The MPRG have always met the 20-day review timeline (100%) with a mean time of 10 days.

H. GIDS, Tavistock & Portman NHSFT Response

There have been mixed responses from the GIDS and T & P NHST leadership to the role of the MPRG, shared directly and indirectly with NHSE and the Chair.
Some responses were of expressed relief and indicated that the MPRG process is supportive and that an independent review is valued.
Some responses have, however, included:

- annoyance, due to the increased workload (preparing submissions)
- feeling professionally insulted and not accepting of the need for independent professional review
- the view, sometimes directly shared with children and families, that the MPRG process introduces an additional unnecessary and delaying step in the process of referral to Endocrinology.
- rejecting the need to improve safeguarding practice

I. MPRG reflections

(This section provides overall reflections from the MPRG with no numerical analysis possible as all documents are deleted immediately after a decision document is signed off by the Chair). It is worth noting that the vast majority of documentation provided appears disjointed and unstructured and this makes it vital for the MPRG to examine every page submitted to ensure vital points are not overlooked.

Once documentation is received the MPRG consider the following:

1. **Age:**
   NHSE have analysed the age of children referred to MPRG, at various stages of the patient journey:

	Youngest	**Oldest**	**Average**
Age at time of referral to GIDS	4 years 1 month	12 years 5 months	8 years 5 months

Age at first GIDS appointment	5 years 1 month	14 years 6 months	9 years 9 months
Age at submission to MPRG	12 years 0 months	15 years 9 months	14 years 3 months

	Shortest	**Longest**	**Average**
Time from initial referral to GIDS to submission to MPRG	3 years 1 month	9 years 1 month	5 years 6 months

1.1 The MPRG are fully aware of the difficulties and delays children and their families experience accessing health services, the prolonged GIDS patient journey, including time from initial referral to GIDS to a case being considered by the MPRG. Frustration is evident in the statements received from children and families

1.2 MPRG work as a team to try and ensure that the MPRG review does not unduly add to their frustration. The MPRG have always met the 20-day review timeline (100%) with a mean time of 10 days.

1.3 The MPRG have noted that assigned girls present to GIDS, and therefore to MPRG later than assigned boys, with the start of menses often the main contributing factor for the increase in desire for medical intervention

1.4 Where sexuality was discussed, most cases are of same sex, opposite-gender attracted children. An increasing number of young people described themselves as 'straight' or 'not trans', just a boy/girl.

1.5 All cases referred had met or surpassed the 6 GIDS sessions required in the SOP and in many cases children and families had been seen far more frequently.

1.6 What has not been clearly evidenced is how thoroughly *'gender identity and consideration of different options for gender expression'* and '*different treatment options/choices'* (SOP) were explored.

1.7 MPRG also have a concern that the period between referral and first appointment at GIDS (early-stage delay), has resulted in children and parents having already adopted an affirmative approach. In all but one case, social transition had commenced or completed. There is inconsistent evidence of the individual impact of social transition being explore with children and their families with GIDS tending to affirm the presenting social transition.

1.8 It appears to MPRG from the submissions, that in most cases children and parents were asking to progress on to puberty blockers from the very first appointment with GIDS (see section 3).

2. Physical Medical history:

The GIDS notes supplied to the MPRG rarely provide a structured history or physical assessment, however the submissions to the MPRG suggest that the children have a wide range of childhood, familial and congenital conditions. MPRG has not identified prevalence of specific physical diagnoses in the cohort, including differences in sex development (DSD).

2.1 In a small number of cases parents/ guardians were notably disappointed when an 'intersex' (DSD) diagnosis was not applicable to the child.

3. Gender journey

3.1 Assigned and current gender are identified to the MPRG.

3.2 It is noted by the MPRG that although the Cass interim report shows a large increase in assigned female to male cases this has not been reflected in the cases referred to the MPRG, which remain predominantly assigned male to female cases (NHSE analysis: From August 2021 to April 2023 MPRG had considered 49 Assigned Female cases and 117 Assigned Male cases).

3.3 Information about the child's gender journey is provided by GIDS and it is notable that until the child and family's first appointment at GIDS they have received little, if any, support from health, social care, or education professionals. Most children and parents have felt isolated and desperate for support and have therefore turned for information to the media and online resources, with many accessing LGBTQ+ and GD support groups or private providers which appear to be mainly affirmative in nature and children and families have moved forward with social transition.

3.4 Evidence of adequate exploration of gender identity journey is, therefore, difficult to assure as prior to MPRG consideration, many children have already fully socially transitioned. Most children have changed their names by deed-poll, attend school in their chosen gender and some have changed NHS numbers and passports. (See section 1.4). This history/journey is rarely examined closely by GIDS for signs of difficulty, regret or wishes to alter any aspect of the child's gender journey trajectory.

3.5 Using the documents presented by GIDS to the MPRG it is difficult to assess whether GIDS clinicians have taken an exclusively affirmative stance with the child and family.

3.6 Although a diagnosis of gender dysphoria *DSM-5* (children with consideration of adolescent and adults criteria for older children) is required by the SOP, the MPRG acknowledges that the DSM-5 diagnostic criteria for gender

dysphoria has a low threshold based on overlapping criteria , and is likely to create false positives, i.e. young people who do not go on to have an enduring cross-sex gender identity may have met the criteria in childhood and early – mid childhood social transition may be influential in maintaining adherence to the criteria. Sex role and gender expression stereotyping is present within the diagnostic criteria e.g., preferred toys, clothes etc., not reflecting that many toys, games and activities for children and young people are less exclusively gendered than in previous decades. Retrospective assessment of distress and poor social functioning in a child or young person is fraught with difficulty.

3.7 As stated in 1.4 and 3.4 in the cases considered by the MPRG social transition has occurred. The MPRG is concerned that some children are continuing to live in stealth, with a common, genuine fear of "being found out", suffering rejection either due to having not taking friends in to their confidence (with holding personal information regarding biological sex or specific sex based experiences), or due to trans-prejudice or phobia. . MPRG observe that living in stealth appears to increase a child's level of stress and anxiety with resultant behaviour and mental health problems, including social withdrawal, with children becoming increasingly isolated, including resorting to home-schooling or tutoring, with some distressing descriptions of children rarely leaving their house.

3.8 MPRG have noted both excellent examples of good practice by families and schools in supporting children as they socially transitioned and some worrying examples of unhelpful practices and restrictions.

4. Mental Health:

4.1 Some of the children have had contact with CAMHS at some stage on their GD journey or are on a long waiting list for a CAMHS review (mention of 2-6 year waiting times). In most cases once GIDS were engaged in care, CAMHS were no longer involved. However, MPRG note some examples of great quality collaborative parallel working with CAMHS, school-based therapists or private counsellors.

4.2 The most prevalent mental health issues appear to be social anxiety and the threat of self-harm (including children threatening to cut off their penis), with many families reporting actual self-harm behaviour and injuries having occurred (e.g. eating disorders, cutting, etc.).

4.3 A considerable number of children appear to express suicidal thoughts, particularly at the first signs of puberty, but there has been limited evidence in the MPRG cases of suicidal behaviour.

5. Neurodevelopmental:

5.1 In the majority of cases considered by the MPRG, there is mention of possible ASD or ADHD traits or diagnoses.

5.2 Confirmation of appropriate and complete assessment is rarely available, and there remains some confusion as to how or whether formal diagnosis has been made and whether formal assessments have used sex or gender related psychometric tools to assess children with gender dysphoria and neurodevelopmental concerns. For example, the continuous performance test (Qb) used as part of the ADHD assessment has a sample of children identified at birth as male and a sample identified at birth as female. While the correct use of pronouns and names is key, this is a computer-based programme which does not provide a sample of children with gender dysphoria.

5.3 There appears to be a prolonged waiting time from identification of neurodivergent traits to formal assessment (2- 4 years).

5.4 It is of most concern that where a neurodevelopmental disorder is suspected, but not confirmed because a formalised assessment is not available, there is often limited evidence of GIDS professionals ensuring that options and care has been explained to ensure the child's understanding so that valid consent can be obtained. There was often insufficient evidence of how GIDS make decisions made about the use of appropriate assessment tools for children with additional needs.

6. Psychosocial

6.1 No genograms / family trees were made available and it was difficult to ascertain family structure and relationships from the documentation provided due to redaction.

6.2 The psychosocial background of the children considered by MPRG was rarely uncomplicated and usually complex. MPRG were frequently concerned about the lack of evidence of professional curiosity as to how a child's specific social circumstances may be impacting on their Gender Dysphoria journey and decisions, for example; physical or mental illness within the family, abusive or addictive environments, bereavement, cultural or religious background, etc..

6.3 The children in many of the cases reviewed by the MPRG were residing with one parent but in most cases, there was shared parental responsibility and GIDS had made marked effort to engage with both parents.

6.4 MPRG members considered the impact that each child's home psychosocial situation may have been having on their gender journey, for example, their exploration of options, affirmative or transphobic beliefs and experiences and any possible coercion, family to child or child to family.

6.5 MPRG found it extremely useful to receive external organisation reports, for example from a child's school, that gave some indication of a child's social and psychological state e.g. peer group interactions and relationships and

acceptance, expression of gender identity and wellbeing, school attendance, academic achievement. Furthermore, there were frequent occasions where school reports were significantly out of date.

6.6 MPRG were particularly concerned and interested to understand why a child might be living in stealth and/or was socially isolated, for example being home schooled, taking into account the difficulties enhanced by Covid restrictions. The evidence provided by GIDS frequently failed to provide adequate explanation.

7 Multi-professional Teams

7.1 The Multi-professional nature of the MPRG is a definite benefit with all professionals approaching consideration of the same case from a particular expert standpoint, with constructive challenge from interested and supportive colleagues leading to comprehensive clarity in overall MPRG decision making.

7.2 The Pre MDCR meetings introduced by GIDS over the last year has gone some way to provide this multi-professional consideration of cases and notes from this meeting often identify the same concerns as are raised by the MPRG. The meeting notes from MCDR frequently show that questions or actions were raised, but it is very rare that evidence of answers or resolution of the action is documented.

7.3 It was rare to see appropriate referral of cases for consideration at Complex Case Panels and where this occurred the multi-professional membership, conclusions and actions were unclear.

7.4 A recurrent problem noted by the MPRG was the lack of routine endocrinology involvement during the GIDS process.

7.4.1 A paediatric endocrinologist would have been able to ascertain whether the child has entered puberty and if the Tanner stage reached met the SOP requirement for referral to endocrinology.
In most cases puberty staging depended upon child and family reported changes being interpreted by professionals with no endocrine training. Essentially, the GIDS team was undertaking the layperson's approach to when puberty starts. In summary: Male puberty was based on voice 'breaking' (in reality this occurs between Tanner stages 3-4), some hair 'down below', spontaneous erections described by a variety of terminology, squaring of the shoulders, some facial hair growth, height growth spurt. A key early sign of the onset of male puberty is the increase in testis volume from 3ml to 4ml. Clearly this can only be confirmed by examination. Female puberty was based on 'chest development', aka breast development which an early sign of puberty in girls (equivalent to the testis volume sign in boys). However, the 'chest development' may not represent true breast enlargement but be due to fatty tissue from obesity. Hair 'down below' is akin to pubic hair growth. The definitive marker of puberty well advanced in girls is the onset of menses. This is a late event female puberty, occurring after the growth spurt and equivalent to Tanner stage 4. There is no equivalent in boys, although

nocturnal ‘wet dreams’ would be approximately the same puberty state i.e., late, and well beyond the Tanner 2 stage.

The GIDS members were also involved in counselling about puberty blockers work, their potential side effects, and the need to be judicious in their use in assigned males in order to optimise penile growth to use for subsequent genitoplasty. The team was also involved in detailed discussions about future fertility and technical aspects of gamete preservation.

7.4.2 A recurrent concern for the MPRG was the inadequacy and on occasions inaccuracy of answers given to children and their families by GIDS and their failure to correct child and parental misconceptions about puberty, puberty blockers and hormones. These misconceptions were often evident in the Child and parental statements made at the end of the period of assessment after which the GIDS service had deemed the child appropriate for referral for physical intervention. Examples included:

a. Failing to explain that puberty blocker use in GD cases is unlicensed and off label
b. Correcting parents when they quoted use in GD to be the same as licensed use in precocious puberty
c. Covering known side effects but minimising that a lot is still unknown about short- and long-term side effects,
d. Discussing the permanent and reversible impact of puberty blockers on fertility,
e. Not sharing figures around how many children who start puberty blockers go on to hormone treatment.
f. Rarely is a possible pause or slowing of psychosocial development discussed in relation to the use of puberty blockers.

7.5 MPRG were always provided with a copy of a completed Hormone Blocker Checklist and a Hormone Blocker Referral consent form signed by the child, parent/guardian and GIDS clinician. It was noted that although counterintuitive in most cases the checklist was completed after the consent form.

It would have been far more reassuring if in all cases an endocrinologist had been involved in the completion of this checklist, and early involvement of an endocrinologist would streamline the patient journey as currently after referral a further checklist is completed and a further consent for treatment form is signed by the child and parents and the prescribing endocrinologist. An endocrinologist as a member of the GIDS multi-professional team could ensure informed consent in relation to puberty blockers as well as assuring themselves as the prescriber, of the gender dysphoria diagnosis.

8 Private Puberty Blockers (PPB)

8.1 An increasing concern for the MPRG is the number of children who have commenced private puberty blockers (PPB).

8.2 Private providers do not follow the prescribing, administration and investigation/ monitoring protocols agreed and followed by the NHS.

8.3 It is apparent that children and parents seek this option due to their frustration with NHS delays and that parents believe that they are acting in the 'best interest' of their child.

8.4 When the MPRG was established in 2021 the GIDS team negated their responsibility to discuss any clinical concerns about private treatment with children and families but have since accepted their responsibility as stated in the SOP to discourage families from accessing treatment that is not being delivered according to NHS protocols. GPs have also been advised against prescribing these unlicensed, off label drugs and PPB's are more likely to be delivered by post from overseas.

8.5 As children and families face the increasing worry of further delay due to changes to GIDS provision, MPRG are now having cases presented where parents have, or are threatening to commence PPB's even though the treatment is not as identified in NHS protocols, the families have received no information about side effects or the impact on fertility, and no or limited baseline tests (e.g. bloods, dexa scan) have been done. It is suspected that this is an attempt by parents/guardians to put pressure on the MPRG and NHS that for the child's safety they should be immediately referred for NHS treatment. This safety argument is particularly challenging in cases where PPB's were commenced with temporary charity funding which has now been withdrawn, and the cessation of treatment that the child believes is helping would potentially cause the child significant distress.

9 Consent

9.1 MPRG confirm that consent for referral to endocrinology has been signed and dated by the child, parent/guardian and clinician and generally this has been easy to locate in the documentation, with the MPRG required to accept redacted signatures are the child's and the signature of the parent/s/guardian/s who hold parental responsibility, and the unknown professional's signature.

9.2 For assurance the MPRG consider all information provided to confirm that: Clinicians have explained all necessary information, giving opportunities for discussion, confirming understanding, and that concerns have been addressed appropriately including:

- Exploration/ consideration gender identity/ expression and treatment options
- Purpose and nature PBs: advantages and disadvantages
- Evolving research and understanding of the known implications and short and long term consequences of treatment' PLUS many unknowns.
- Fertility treatment options
- 98% expectation progress to hormone treatment, surgery, etc

9.2.1 For children, clinicians are required to explain the information in an appropriate and balanced way, tailored to the child's developmental needs, which includes neurodevelopmental needs.

This was an area carefully considered by the MPRG and although the range of approaches to explain information and to confirm understanding directly used by GIDS in sessions has generally been impressive, in a number of cases additional information was requested by the MPRG.

9.2.2 As described in 1.4 and 3.4 due to the delay in access to GIDS, and the affirmative stance already evident at first appointments, the MPRG carefully sought evidence of consideration of gender identity and treatment options.

9.2.3 Fertility treatment options were generally well covered, with appropriate consideration of age-related decision making but by non-specialists in this area. However, the discussion of childhood interruption of the development of organs that reach mature function in adulthood is rarely evidenced.

9.2.4 Advantages and disadvantages of PB's were generally covered but the MPRG often requested further confirmation that evolving research, unknown consequences and the 98% expectation of progress to hormone treatment had been adequately discussed and understood.

9.2.5 As stated in 7.4 there was concern from MPRG that the absence of endocrinology input did raise concerns about adequacy of some of the information given and handling of questions and the addressing of concerns before the signing of the consent for referral form although it is acknowledged that a further consent form is signed once a child is under endocrinology and this consent is audited as part of the MPRG light touch endocrine audit

9.3 The MPRG looked for confirmation of the child and parent/guardian's capacity and ability to consent, that the parents/guardians and children:

- Understood and retained relevant information long enough to make a decision
- Used the information as part of the process of making a decision
- Were able to communicate decision to others
- And that there was no evidence of coaching /coercion of parents/child

9.3.1 MPRG were mainly reliant on the GIDS clinicians' assessment of the parent guardians' capacity and ability to consent.

9.3.2 Written statements from parents were provided. Many were moving and helpful, but some were used by parents to praise GIDS staff and to complain about the MPRG process. Many betrayed grave misunderstandings of the nature of gender dysphoria and the outcome of physical treatments.

9.3.3 MPRG occasionally had concerns that parents were being encouraged to move forward to consent by others, but this was difficult to confirm.

9.3.4 There were occasional cases where the parents appeared to be fearful of what they anticipated might be their child's response if they did not consent, (for example child threats of self-harm, suicide, or aggressive behaviour). On these occasions the MPRG carefully considered the notes of meetings when parents were seen alone.

9.3.5 MPRG were provided with an impressive array of resources to demonstrate the children's understanding and exploration of information including verbatim transcripts of discussion with children. While noting that

clinical practice evolves over time and many of the cases presented were seen over an extended period, MPRG were sometimes surprised to see the marked differences in approach and clinician choice of assessment and information giving materials.

9.3.6 In an attempt to hear the child's voice children were asked to write a short statement for MPRG. A few were extremely helpful and informative, but most were extremely brief and unhelpful and on occasions there was suspicious concern due to the language used that they had been rehearsed, written, or dictated by others. Often they included worrying misunderstanding of the outcome of physical interventions.

9.3.7 School reports, when thoughtfully completed were extremely useful in confirming whether the child had capacity and ability to consent.

9.3.8 If the MPRG were unconvinced that they were hearing the child's voice, or if there was concern that there may be coercion from others, the notes from the meetings when the child had been seen alone were carefully considered and on a number of occasions, especially if the child had not been seen alone for some time (e.g. for over a year), the GIDS team were requested by MPRG to organise a 1:1 review and update with the child and resubmit notes from this meeting to the MPRG.

10 Safeguarding & Child protection

When the MPRG began reviewing cases the Tavistock team were unwilling to comply with MPRG safeguarding reporting requirements, but this situation has been partially resolved.

10.1 The MPRG now see Confirmation from Social Services as to whether at the point of referral to the endocrine clinic the child is the subject of a statutory order e.g. a current Child Protection Plan or a Child in Need Plan.

10.2 A Tavistock Risk and Safeguarding assessment form is included in documentation received by the MPRG which is meant to indicate if GIDS are aware of any non-statutory safeguarding concerns including any that have been raised by any health, education, police or social care professionals involved in the child's care.

Although very occasionally a TRSA form is continuously and comprehensively completed, in most cases it has been completed just before the submission is sent to the MPRG and is incomplete when considered alongside issues noted by the MPRG whilst reviewing documentation received. Examples of issues identified by the MPRG include increased psychosocial vulnerability (including complex family relationships/situations/illness/addiction/domestic abuse), transphobic bullying, online abuse/ grooming, isolation, self-harm, suicidality, etc.)

Incomplete forms are returned to GIDS for reconsideration and resubmission.

10.3 MPRG continue to be very concerned about the GIDS teams lack of apparent professional curiosity or concern in relation to risk and safeguarding.

J. MPRG Impact

Positives:

- When established it was estimated that around 4,000 cases were being prepared by Tavistock GIDS for referral to the endocrine service. The MPRG have only received around 180 cases for review, and it is likely that these were cases that the GIDS team considered ready for referral. As shown in section G MPRG were not assured on all counts in 42 of these cases and additional information and action was requested prior to reconsideration. 2 of the 42 cases were withdrawn, 5 are still awaiting resubmission but in the remaining cases further information provided was found to be sufficient to provide assurance on all counts, allowing referral to endocrinology. The figure unknown to MPRG is the number of the remaining 3,820 cases originally stated to be in the system were not submitted to the MPRG due to MPRG requirements for assurance.
- Safeguarding practice has been transformed and strengthened.
- Vast amount of learning to inform Cass Review and support establishment of new centers

Perceived negatives:

- Further perceived delay due to MPRG process (NB MPRG achieved 100% compliance with NHSE agreed timeline)
- GIDS clinicians spending time preparing documentation for the MPRG, time that could have been spent with patients
- NHSE budget required for MPRG activity

(These were all unavoidable as required to deliver the NHSE brief)

K. Moving forward

The MPRG assure GIDS compliance with the SOP in place in 2021. When a new SOP and Service Specification are agreed and new services are established MPRG will be stood down. MPRG members envisage that the service provider's internal governance structures will have the oversight and be responsible for monitoring the quality and functioning of the service against the new service specifications standards and KPI's, with the opportunity for internal and cross-provider safe, respectful and supportive peer review.

The MPRG team members could be called upon to provide a supportive, advisory role as new services are developed and stabilised.

L. MPRG summary learning points:

a. **Essential need for early outreach, including possible direct and indirect support to parents with flexible support for the gender dysphoric child**

b. **Develop first point of access support to help explore *gender identity and consideration of different options for gender expression'.***

c. **Improve on *DSM-5* diagnostic criteria Acknowledgement that a child meeting diagnostic criteria (DSMV or ICD 11) may reject a cross sex gender identity in later years**

d. Need A full psychosocial assessment

e. **Need to increase the availability of ASD or ADHD assessments appropriate for age and gender identity, and for the powerful platform developed in this process to be used to ensure that wording and tools can fit all gender and sexual identities.**
f. **Prioritise hearing child's voice with facility for a developing supportive conversation as the child learns about the complexities of cross-sex gender expression**
g. **Liaise with schools, directing them to information and offer consultation/ support to staff**
h. **Adequate safeguarding and risk management**
i. **Each professional act within their area of expertise**
j. **Endocrinologist part of GIDS MDT**
k. **Different treatment option/choices explored 'including the advantages and disadvantages of treatments, risks and complications of management options including medical intervention. .**
l. **Ensure the child, parents and guardians understand Information on the purpose, nature and physical consequences of puberty blockers (**e.g., menopause, osteoporosis and impact on fertility**) including consideration of unknowns (**to include for example: wellness during period without sex hormones, sexual function, fertility, Psychosocial development and cognitive function), **'evolving research and understanding of the implications and long-term physical consequences of treatment', and that 98% of children would progress to taking sex hormones.**
m. **parents/guardians should periodically meet GIDS clinicians without the child being present'**
n. **child should periodically meet with GIDS clinicians without the parents/guardians being present'**
o. **the capacity or ability of child and parents/guardians to give consent are adequately explored**
p. **Standard Operating Procedures should be agreed and implemented, clearly outlining the decision-making process / pathways that need to be followed to lead to a referral decision, with built in check points.**
q. **A structured decision-making framework should be followed and documented when considering each case**

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Appendix 10

Diagnostic criteria for gender dysphoria

DSM-5-TR diagnostic criteria for gender dysphoria

Gender Dysphoria in Children

The DSM-5-TR defines gender dysphoria in children as a marked incongruence between one's experienced/expressed gender and assigned gender, lasting at least 6 months, as manifested by at least six of the following (one of which must be the first criterion):

- A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender)
- In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing
- A strong preference for cross-gender roles in make-believe play or fantasy play
- A strong preference for the toys, games or activities stereotypically used or engaged in by the other gender
- A strong preference for playmates of the other gender
- In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities
- A strong dislike of one's sexual anatomy
- A strong desire for the physical sex characteristics that match one's experienced gender

As with the diagnostic criteria for adolescents and adults, the condition must also be associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Gender Dysphoria in Adolescents and Adults

The DSM-5-TR defines gender dysphoria in adolescents and adults as a marked incongruence between one's experienced/expressed gender and their assigned gender, lasting at least 6 months, as manifested by at least two of the following:

- A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
- A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
- A strong desire for the primary and/or secondary sex characteristics of the other gender
- A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
- A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)
- A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)

In order to meet criteria for the diagnosis, the condition must also be associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

ICD-11: HA60 Gender incongruence of adolescence or adulthood

Gender Incongruence of Adolescence and Adulthood is characterised by a marked and persistent incongruence between an individual´s experienced gender and the assigned sex, which often leads to a desire to 'transition', in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual´s body align, as much as desired and to the extent possible, with the experienced gender. The diagnosis cannot be assigned prior the onset of puberty. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis.

Exclusions:

Paraphilic disorders. Independent review of gender identity services for children and young people

ICD-11: HA61 Gender incongruence of childhood

Gender incongruence of childhood is characterised by a marked incongruence between an individual's experienced/ expressed gender and the assigned sex in pre-pubertal children. It includes a strong desire to be a different gender than the assigned sex; a strong dislike on the child's part of his or her sexual anatomy or anticipated secondary sex characteristics and/or a strong desire for the primary and/ or anticipated secondary sex characteristics that match the experienced gender; and make-believe or fantasy play, toys, games, or activities and playmates that are typical of the experienced gender rather than the assigned sex. The incongruence must have persisted for about 2 years. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis.

Exclusions:

Paraphilic disorders.

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Appendix 11

To: Dr Hilary Cass

NHS England
Wellington House
133-155 Waterloo Road
London
SE1 8UG

By Email

17 January 2024

Dear Hilary

INDEPENDENT REVIEW OF GENDER IDENTITY SERVICES FOR CHILDREN AND YOUNG PEOPLE – QUANTITATIVE RESEARCH PROGRAMME

With the Review now entering its final stages, I wanted to confirm an approach for handing over to NHS England certain aspects of the Review's research programme which will need to continue beyond delivery of your final report.

The Review's interim report highlighted that one of the challenges with understanding how best to improve NHS services for this group of children and young people is the lack of high quality data. A good example is that little is known about the medium and longer-term outcomes for children and young people who were seen by the Gender Identity Development Service (GIDS) at the Tavistock and Portman NHS Foundation Trust.

The Review's quantitative research programme, led by the University of York, aimed to improve the evidence and provide a better understanding of the treatment approaches for this population of children and young people. The research aimed to do this by tracking the journeys of young people who were seen by GIDS into NHS adult gender dysphoria clinics and the wider health system, to provide a population-level evidence base of the different pathways.

The Secretary of State for Health and Social Care granted an order under s22(5) of the Gender Recognition Act to enable data to be disclosed for a time-limited period for the sole purpose of the study. Like all NHS research, the study was subject to strict ethical and legal controls with an 'opt out' option for individuals who did not wish to have their data used as part of the study.

NHS England was fully supportive of the proposed approach; and the research received full approval from the Health Research Authority.

As you know, the study relied upon the seven NHS trusts in England that host adult Gender Dysphoria Clinics and the GIDS fully cooperating with the University of York in support of the research and NHS England wrote to the Chief Executives and Medical Directors of those organisations accordingly. Regrettably, it is now clear that despite the best efforts of the research team, the necessary cooperation from the clinical leads within those services has

not been forthcoming, and consequently the University of York has advised that as things currently stand, it is not appropriate to yet begin the next stage of the study.

This is clearly very disappointing and if left this way would represent a missed opportunity for the NHS to lead the way internationally in gathering high quality evidence that can, for the first time, present a better understanding of the longer-term outcomes for individuals who have received clinical or medical intervention for gender dysphoria / gender incongruence in childhood or adolescence.

I am sure you will agree that the NHS should not lose the opportunity to make further use of the statutory instrument that was passed by Parliament, which enables the collection of the data for use in an approved research study until 2027. As such, I am writing to confirm that NHS England will take over responsibility for realising the ambitions of the study and the NHS National Research Oversight Board for Children and Young People's Gender Services, chaired by Professor Sir Simon Wessely, is well placed to support us in this task. In your letter of 31st January 2023 you flagged that there would be a need for continued oversight of this work beyond the life of the Review, so I hope this approach reassures you that this aspect of the Review's work will not be lost.

As part of the handover process, I would be grateful if you could carefully document the work completed so far, including the circumstances that led the University of York to reach the conclusion that it was not yet possible to move ahead with the next stages of the research study. I would also welcome any specific recommendations you might wish to make for NHS England's consideration as we look to regain momentum with this important study.

I want to thank you for your vitally important ongoing work in improving services for this group of children and young people, and I look forward to receiving your final advice early in 2024.

Yours sincerely



John Stewart
National Director, Specialised Commissioning

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Appendix 12

The Cass Review

Independent review into gender identity services for children and young people

Dr Hilary Cass
Chair
Review of GIDS for Children and Young People

John Stewart
National Director
Specialised Commissioning
NHS England and NHS Improvement

Sent by email

20 March 2024

Dear John

INDEPENDENT REVIEW OF GENDER IDENTITY SERVICES FOR CHILDREN AND YOUNG PEOPLE – QUANTITATIVE RESEARCH PROGRAMME

I am writing in response to your letter of 17 January regarding the Review's commissioned quantitative research programme, advising that, despite your welcomed efforts to obtain cooperation, most of the NHS gender clinics have refused to take part in this research.

It has not been at all straightforward trying to get this research off the ground. It has absorbed a considerable amount of time and attention from the Review and the researchers at the University of York, as well as from NHS England and the Department of Health and Social Care, all of which has delayed our work.

The study follows usual NHS research practice, it is only novel because of the sensitivity of the subject matter and the issue of changing NHS Numbers, which was overcome by the Statutory Instrument. It is therefore hugely disappointing that the NHS gender services have decided not to participate with this research. I am frustrated on behalf of the young people and their families that the opportunity to reduce some of the uncertainties around care options has not been taken.

Ultimately, the NHS is an evidence-based service with a responsibility to maintain the safety of those in its care. Understanding more about what support people who attended the Gender Identity Development Service (GIDS) received, and whether this helped them, will provide vital evidence to assist young people, their families, and the clinicians working with them to make informed decisions about the right pathway for them. As a single integrated

health service, which for the period in question had one provider of care for children and young people, this was a world leading opportunity to look at outcomes for c.9000 young adults and add to the evidence base.

We had hoped to have some early findings to inform the Review. However, as outlined in my letter to you of 31 January 2023, it had become evident that the full outputs from the study, including resulting peer-reviewed papers, would not be available in time to be published alongside my final report.

I asked that NHS England give consideration as to how the ambitions of this study could be realised beyond the life of the Review. I am grateful for your confirmation that the National Research Oversight Board will support this going forward.

To assist the Oversight Board, I attach detail on the circumstances that led the University of York to reach the conclusion that it was not yet possible to move ahead with the next stages of the research study (Annex A).

I look forward to submitting my final report and recommendations in the coming weeks. In the meantime, my recommendations on this specific issue are that NHS England:

1. Work with the University of York to take forward phase one of the data linkage study without delay.
2. Work with Department of Health and Social Care to mandate the data exchange from the clinics to facilitate this.
3. Undertake a case note audit of record keeping in the adult clinics to assess the feasibility of phase 2 of the data linkage study.

Yours sincerely



Dr Hilary Cass
Chair, Independent Review into Gender Identity Services for Children and Young People

Annex A - Data linkage study: Assessment, Management and Outcomes for children and young people referred to a National Gender Identity Development Service

1.1. Little is known about what happens to the children and young people who have accessed the Gender Identity Development Service (GIDS) in relation to the support and interventions they have received and their outcomes.

1.2. Whilst a considerable amount of research has been published in this field, systematic reviews conducted for this Review and internationally have demonstrated the poor quality of the published studies, meaning there is not a reliable evidence base upon which to base clinical decisions.

1.3. The Review has tried to plug this gap through its commissioned research programme, which included an ambitious data linkage study. The study approach was proposed by the University of York as part of its response to a national open procurement process.

1.4. The research study plans to use existing data held by the NHS - including data from GIDS, hospital wards, outpatient clinics, emergency departments and adult Gender Dysphoria Clinics (GDCs) - to track the journeys of all young people (approximately 9,000) referred to the GIDS service through the system to provide a population-level evidence base of the different pathways people take and different outcomes people experience.

1.5. This study aims to improve the level and quality of evidence on the treatment and care of this population of children and young people:

- enabling the Review and the NHS to have a better understanding of the best treatment approaches for this population of children and young people;
- ensuring clinicians had the best possible evidence when providing care; and
- supporting children and young people and their parents/carers in making better informed decisions.

1.6. This research study offers a real opportunity to contribute to the international evidence base for this service area as it would access what is thought to be the single largest data set available for the presenting population.

1.7. Healthcare data on populations of children, young people and adults are routinely used to determine outcomes of care for the purpose of improving NHS services. This has not been the case for gender questioning children and young people – the aim is that this research would go some way to address this imbalance.

1.8. As with the other studies, the study protocol was subject to Research Ethics Committee (REC) and Confidentiality Advisory Group (CAG) processes prior to achieving full Health Research Authority (HRA) approval. These approvals were required before the study could commence.

1.9. It took over a year to gain the necessary approvals from the Health Research Authority's Research Ethics Committee and Confidentiality Advisory Group. While the methodology proposed for the research is not particularly unusual, the robust scrutiny and consideration the committees applied to the study was entirely appropriate given the sensitivity of the subject matter.

1.10. The approach to governance, data protection and confidentiality was consistent with other research undertaken by the NHS or when using NHS data. In addition, the research team was careful to ensure compliance with any special rules and sensitivities that may apply to information about transgender people, including those with Gender Recognition Certificates (GRCs), as in some cases the individuals whose data would have formed part of the research would have obtained a GRC.

1.11. The Gender Recognition Act (GRA) creates an offence of unlawfully disclosing information about individuals who have obtained a GRC. To ensure an offence could not be inadvertently committed, a 'statutory instrument' was passed through Parliament, permitting the handling of information about people with GRC for the very limited purpose of this research. This was required before REC and CAG would consider the research protocol, and before NHS England and the NHS Data and Analytics team would support the research.

1.12. While the Statutory Instrument took some time to pass, and the public reporting of this caused some concern among the trans and gender diverse community, it was important to do this so that as full a picture as possible was established through the study, and the data of people, who potentially have some of the most successful outcomes, was not automatically excluded.

1.13. In addition, the ethics approval process required the researchers to seek the views of those affected to show that there was a need for the study and that patients were content with the planned approach.

1.14. The PPI sessions found that, while some participants were initially sceptical about the research based on what they had heard in the press or on social media, when the study was explained the majority understood the approach, the reason for the research and how their data would be used. Some participants were surprised that outcomes were not routinely collected and measured, and there was generally a high level of support for the research.

1.15. Another important consideration was the need to provide the opportunity to opt out for those that did not wish for their data to be included. Because the University of York needed to look at a large number of records, it was not feasible to get individual consent. Instead, individuals not wishing to take part in the study would have been able to opt out via their clinical team, based at GIDS or one of the seven adult NHS Gender Dysphoria Clinics (GDCs). The opt out period was to be the first step in the study, to be followed by a standard secure transfer of basic demographic data.

1.16. Despite the rigor applied in meeting HRA requirements, the University of York received significant opposition from all but one of the adult GDCs including refusal to facilitate the initial opt out stage of the study. The concerns cited by the adult GDCs included:

- ethical considerations, which had already been considered and met through the stringent and lengthy HRA process to achieve the relevant approvals;
- availability of/access to data, although the initial stage of the study asked for basic demographic data, which would not be an unusual request for NHS research and raises questions in relation to GDC record management; and
- resource impacts, even though the GDCs are contractually required to take part in research and appropriate costs would have been met by NHS England.

1.17. This was disappointing as at an early stage of protocol development, the research team had met with representatives from three of the clinics to discuss the proposed approach.

1.18. Additionally, prior to final REC and CAG approval, a workshop was held with the adult gender clinics to talk through the study, data requirements and technical aspects and to identify any logistical challenges, where some concerns were highlighted. Following the workshop, the University of York met with the clinics to discuss the issues raised.

1.19. It was agreed to phase the project, building in feasibility steps, which would be overseen by a further National Institute for Heath and Care Research (NIHR) independent panel. Additionally, NHS England was willing to discuss resource implications to address provider concerns about the potential impact on clinical services.

1.20. The team had developed the patient notifications and communications resources to explain the research and provide information about how to opt-out of the study should an individual chose to do so. It was at the point of trying to launch the three-month opt-out period that the clinics confirmed their unwillingness to participate.

1.21. In January 2024, NHS England wrote to inform the Review that it had written to the Chief Executives and Medical Directors of the NHS trusts that host adult GDCs and GIDS to ask them to fully cooperate with the University of York in support of the research. Despite this, the necessary cooperation from the services has not been forthcoming and as a consequence, the University of York advised that it was not appropriate to begin the next stage of the study.

1.22. The Review is disappointed that the study has not progressed to even the first stage during its lifetime. Despite this setback, it is pleasing that NHS England has stated a clear commitment to realising the ambitions of this study beyond the life of the Review.

1.23. The statutory instrument is in place until 2027, and oversight of the study will transfer to the NHS National Research Oversight Board for Children and Young People's Gender Services.

The Cass Review

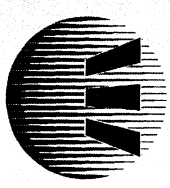
Independent review of gender identity services for children and young people

The Endocrine Society's

CLINICAL GUIDELINES

Endocrine Treatment of Transsexual Persons:

An Endocrine Society Clinical Practice Guideline



THE ENDOCRINE SOCIETY®

THE JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM

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Abstract

Objective: The aim was to formulate practice guidelines for endocrine treatment of transsexual persons.

Participants: An Endocrine Society-appointed Task Force of experts, a methodologist, and a medical writer.

Evidence: This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence, which was low or very low.

Consensus Process: Committees and members of The Endocrine Society, European Society of Endocrinology, European Society for Paediatric Endocrinology, Lawson Wilkins Pediatric Endocrine Society, and World Professional Association for Transgender Health commented on preliminary drafts of these guidelines.

Conclusions: Transsexual persons seeking to develop the physical characteristics of the desired gender require a safe, effective hormone regimen that will 1) suppress endogenous hormone secretion determined by the person's genetic/biologic sex and 2) maintain sex hormone levels within the normal range for the person's desired gender. A mental health professional (MHP) must recommend endocrine treatment and participate in ongoing care throughout the endocrine transition and decision for surgical sex reassignment. The endocrinologist must confirm the diagnostic criteria the MHP used to make these recommendations. Because a diagnosis of transsexualism in a prepubertal child cannot be made with certainty, we do not recommend endocrine treatment of prepubertal children. We recommend treating transsexual adolescents (Tanner stage 2) by suppressing puberty with GnRH analogues until age 16 years old, after which cross-sex hormones may be given. We suggest suppressing endogenous sex hormones, maintaining physiologic levels of gender-appropriate sex hormones and monitoring for known risks in adult transsexual persons.

(J Clin Endocrinol Metab 94: 3132–3154, 2009)

Abbreviations: BMD, Bone mineral density; FTM, female-to-male; GID, gender identity disorder; MHP, mental health professional; MTF, male-to-female; RLE, real-life experience.

SUMMARY OF RECOMMENDATIONS

1.0. DIAGNOSTIC PROCEDURE

1.1. We recommend that the diagnosis of gender identity disorder (GID) be made by a mental health professional (MHP). For children and adolescents the MHP should also have training in child and adolescent developmental psychopathology. (1 | ⊕◯◯◯)

1.2. Given the high rate of remission of GID after the onset of puberty, we recommend against a complete social role change and hormone treatment in prepubertal children with GID. (1 | ⊕⊕◯◯)

1.3. We recommend that physicians evaluate and ensure that applicants understand the reversible and irreversible effects of hormone suppression (*e.g.*, GnRH analogue treatment) and cross-sex hormone treatment before they start hormone treatment.

1.4. We recommend that all transsexual individuals be informed and counseled regarding options for fertility prior to initiation of puberty suppression in adolescents and prior to treatment with sex hormones of the desired sex in both adolescents and adults.

2.0. TREATMENT OF ADOLESCENTS

2.1. We recommend that adolescents who fulfill eligibility and readiness criteria for gender reassignment initially undergo treatment to suppress pubertal development. (1 | ⊕◯◯◯)

2.2. We recommend that suppression of pubertal hormones start when girls and boys first exhibit physical changes of puberty (confirmed by pubertal levels of estradiol and testosterone, respectively), but no earlier than Tanner stages 2–3. (1 | ⊕⊕◯◯)

2.3. We recommend that GnRH analogues be used to achieve suppression of pubertal hormones. (1 | ⊕⊕◯◯)

2.4. We suggest that pubertal development of the desired opposite sex be initiated at about the age of 16 years, using a gradually increasing dose schedule of cross-sex steroids. (2 | ⊕◯◯◯)

2.5. We recommend referring hormone-treated adolescents for surgery when 1) the real-life experience (RLE) has resulted in a satisfactory social role change; 2) the individual is satisfied about the hormonal effects; and 3) the individual desires definitive surgical changes. (1 | ⊕◯◯◯)

2.6. We suggest deferring surgery until the individual is at least 18 years old. (2 | ⊕◯◯◯)

3.0. HORMONAL THERAPY FOR TRANSSEXUAL ADULTS

3.1. We recommend that treating endocrinologists confirm the diagnostic criteria of GID or transsexualism and the eligibility and readiness criteria for the endocrine phase of gender transition. (1 | ⊕⊕⊕◯)

3.2. We recommend that medical conditions that can be exacerbated by hormone depletion and cross-sex hormone treatment be evaluated and addressed prior to initiation of treatment (See Table 11: Medical conditions that can be exacerbated by cross-sex hormone therapy). (1 | ⊕⊕⊕◯)

3.3. We suggest that cross-sex hormone levels be maintained in the normal physiologic range for the desired gender. (2 | ⊕⊕◯◯)

3.4. We suggest that endocrinologists review the onset and time course of physical changes induced by cross-sex hormone treatment. (2 | ⊕⊕◯◯)

4.0. ADVERSE OUTCOME PREVENTION AND LONG-TERM CARE

4.1. We suggest regular clinical and laboratory monitoring every 3 months during the first year and then once or twice yearly. (2 | ⊕⊕◯◯)

4.2. We suggest monitoring prolactin levels in male-to-female transsexual persons treated with estrogens. (2 | ⊕⊕◯◯)

4.3. We suggest that transsexual persons treated with hormones be evaluated for cardiovascular risk factors (2 | ⊕⊕◯◯)

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4.4. We suggest that bone mineral density (BMD) measurements be obtained if risk factors for osteoporosis exist, specifically in those who stop hormone therapy after gonadectomy. (2 | ⊕⊕◯◯)

4.5. We suggest that male-to-female (MTF) transsexual persons, who have no known increased risk of breast cancer, follow breast screening guidelines recommended for biological women. (2 | ⊕⊕◯◯)

4.6. We suggest that MTF transsexual persons treated with estrogens follow screening guidelines for prostatic disease and prostate cancer recommended for biological men. (2 | ⊕◯◯◯)

4.7. We suggest that female-to-male (FTM) transsexual persons evaluate the risks and benefits of including total hysterectomy and oophorectomy as part of sex reassignment surgery. (2 | ⊕◯◯◯)

5.0. SURGERY FOR SEX REASSIGNMENT

5.1. We recommend that transsexual persons consider genital sex reassignment surgery only after both the physician responsible for endocrine transition therapy and the MHP find surgery advisable. (1 | ⊕◯◯◯)

5.2. We recommend that genital sex reassignment surgery be recommended only after completion of at least 1 year of consistent and compliant hormone treatment. (1 | ⊕◯◯◯)

5.3. We recommend that the physician responsible for endocrine treatment medically clear transsexual individuals for sex reassignment surgery and collaborate with the surgeon regarding hormone use during and after surgery. (1 | ⊕◯◯◯)

METHOD OF DEVELOPMENT OF EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES

The Clinical Guidelines Subcommittee of The Endocrine Society deemed the diagnosis and treatment of transsexual individuals a priority area in need of practice guidelines and appointed a Task Force to formulate evidence-based recommendations. The Task Force followed the approach recommended by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) group, an international group with expertise in development and implementation of evidence-based guidelines (19). A detailed description of the grading scheme has been published elsewhere (20). The Task Force used the best available research evidence that Task Force members identified and two commissioned systematic reviews (21, 22) to develop some of the recommendations. The Task Force also used consistent language and graphical descriptions of both the strength of a recommendation and the quality of evidence. In terms of the strength of the recommendation, strong recommendations use the phrase "we recommend" and the number 1, and weak recommendations use the phrase "we suggest" and the number 2. Cross-filled circles indicate the quality of the evidence, such that ⊕◯◯◯ denotes very low quality evidence; ⊕⊕◯◯ low quality; ⊕⊕⊕◯ moderate quality; and ⊕⊕⊕⊕ high quality. The Task Force has confidence that persons who receive care according to the strong recommendations will derive, on average, more good than harm. Weak recommendations require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action. Linked to each *recommendation* is a description of the *evidence* and the *values* that panelists considered in making the recommendation; in some instances, there are *remarks*, a section in which panelists offer technical suggestions for testing conditions, dosing and monitoring. These technical comments reflect the best available evidence applied to a typical person being treated. Often this evidence comes from the unsystematic observations of the panelists and their values and preferences; therefore, these remarks should be considered suggestions. Some statements in this guideline (1.3. and 1.4.) are not graded. These are statements the task force felt necessary to make, and it considers them matters about which no sensible healthcare professional could possibly consider advocating the contrary (*e.g.*, clinicians should conduct an adequate history taking and physical examination, clinicians should educate patients about

their condition). These statements have not been subject to structured review of the evidence and are thus not graded.

INTRODUCTION

Men and women have experienced the confusion and anguish resulting from rigid, forced conformity to sexual dimorphism throughout recorded history. Aspects of gender variance have been part of biological, psychological, and sociological debates among humans in modern history. The twentieth century marked the beginning of a social awakening for men and women "trapped" in the wrong body (1). Harry Benjamin and Magnus Hirschfeld, who met in 1907, pioneered the medical responses to those who sought relief from and resolution of their profound discomfort, enabling the "transsexual," a term coined by Hirschfeld in 1923, to live a gender-appropriate life, occasionally facilitated by surgery (2).

Endocrine treatment of transsexual persons (note: In the current psychiatric classification system, the Diagnostic and Statistical Manual of Mental Disorders-IV-TR, the term *gender identity disorder* is used instead of *transsexualism* (3)), previously limited to ineffective elixirs, creams, and implants, became reasonable with the availability of diethylstilbestrol in 1938 and following the isolation of testosterone in 1935. Personal stories of role models, treated with hormones and sex reassignment surgery, appeared in the press during the second half of the twentieth century. The Harry Benjamin International Gender Dysphoria Association (HBIGDA) was founded in September 1979; it is now known as the World Professional Association of Transgender Health (WPATH). The Association's "Standards of Care" was first published by HBIGDA in 1979, and its sixth edition is currently being revised. These carefully prepared documents have provided mental health and medical professionals with general guidelines for the evaluation and treatment of transsexual persons.

Prior to 1975, few peer-reviewed articles were published concerning endocrine treatment of transsexual persons. Since that time, more than 800 articles about various aspects of transsexual care have appeared. It is the purpose of this guideline to make detailed recommendations and suggestions, based on existing medical literature and clinical experience, that will enable endocrinologists to provide safe and effective endocrine treatment for individuals diagnosed with GID or transsexualism by MHPs. In the future, rigorous evaluation of the effectiveness and safety of endocrine protocols is needed. What will be required is the careful assessment of 1) the effects of prolonged delay of puberty on bone growth and development among adolescents, 2) in adults, the effects on outcome of both endogenous and cross-sex hormone levels during treatment, 3) the requirement for and the effects of anti-androgens and progestins during treatment, and 4) long-term medical and psychological risks of sex reassignment. These needs can be met only by a commitment of mental health and endocrine investigators to collaborate in long-term, large-scale studies across countries that employ the same diagnostic and inclusion criteria, medications, assay methods, and response assessment tools.

Terminology and its use vary and continue to evolve. Table 1 contains definitions of terms as they are used throughout the Guideline.

Etiology of Gender Identity Disorders

One's self-awareness as male or female evolves gradually during infant life and childhood. This process of cognitive and affective learning happens in interaction with parents, peers, and environment, and a fairly accurate timetable exists of the steps in this process (4). Normative psychological literature, however, does not address when gender identity becomes crystallized and what factors contribute to the development of an atypical gender identity. Factors that have been reported in clinical studies may well enhance or perpetuate rather than originate a GID (for an overview, see Ref. 5). Behavioral genetic studies suggest that, in children, atypical gender identity and role development has a heritable component (6, 7). Since, in most cases, GID does not persist into adolescence or adulthood, findings in children with GID cannot be extrapolated to adults.

TABLE 1. Definitions of terms used in this guideline

SEX refers to attributes that characterize biological maleness or femaleness; the best known attributes include the sex-determining genes, the sex chromosomes, the H-Y antigen, the gonads, sex hormones, internal and external genitalia and secondary sex characteristics.
GENDER IDENTITY is used to describe a person's fundamental sense of being men, women, or of indeterminate sex.
GENDER IDENTITY DISORDER (GID) is a DSM-IV-TR diagnosis. This psychiatric diagnosis is given when a strong and persistent cross-gender identification, combined with a persistent discomfort with one's sex or sense of inappropriateness in the gender role of that sex, causes clinically significant distress.
GENDER ROLE is used to refer to behaviors, attitudes, and personality traits that a society, in a given culture and historical period, designates as masculine or feminine, that is, more "appropriate" to, or typical of, the social role as men or as women.
GENDER DYSPHORIA is the distress and unease experienced if gender identity and sex are not completely congruent.
SEXUAL ORIENTATION can be defined by a person's relative responsiveness to sexual stimuli. The most salient dimension of sexual orientation is the sex of the person to whom one is attracted sexually; sexual orientation is not entirely similar to SEXUAL IDENTITY; a person may, for example, be predominantly aroused by homoerotic stimuli, yet not regard himself or herself to be gay or lesbian.
SEX REASSIGNMENT refers to the complete treatment procedure for those who want to adapt their bodies to the desired sex.
SEX REASSIGNMENT SURGERY refers only to the surgical part of this treatment.
TRANSSEXUAL people identify as, or desire to live and be accepted as, a member of the gender opposite to that assigned at birth; the term MALE-TO-FEMALE (MTF) TRANSSEXUAL PERSON refers to a biological male who identifies as, or desires to be, a member of the female gender; FEMALE-TO-MALE (FTM) TRANSSEXUAL PERSON refers to a biological female who identifies as, or desires to be, a member of the male gender.
TRANSITION refers to the period of time during which transsexual persons change their physical, social, and legal characteristics to the gender opposite that of their biologic sex. Transition may also be regarded as an ongoing process of physical change and psychological adaptation.

Note: In this Guideline, we have chosen to use the term "transsexual" throughout as defined by the ICD-10 Diagnostic Code (see Table 3). We recognize that "transsexual" and "transgender" are terms often used interchangeably. However, since "transgender" may also be used to identify individuals whose gender identity does not conform to the conventional gender roles of either male or female and who may not seek endocrine treatment as described herein, we prefer to use "transsexual" as an adjective (e.g., when referring to persons, individuals, men, or women and, when appropriate, referring to subjects in research studies).

In adults, psychological studies investigating etiology hardly exist. Studies that have investigated potential causal factors are retrospective and rely on self-report, making the results intrinsically unreliable.

Most attempts to identify biological underpinnings of gender identity in humans have investigated effects of sex steroids on the brain (functions) (for a review, see Ref. 8). Prenatal androgenization may predispose to development of a male gender identity. However, most 46,XY female-raised children with disorders of sex development and a history of prenatal androgen exposure do not develop a male gender identity (9, 10), whereas 46,XX subjects exposed to prenatal androgens show marked behavioral masculinization, but this does not necessarily lead to gender dysphoria (11–13). Male-to-female (MTF) transsexual individuals, with a male androgen exposure prenatally, develop a female gender identity through unknown mechanisms, apparently overriding the effects of prenatal androgens. There is no comprehensive understanding of hormonal imprinting on gender identity formation. It is of note that, in addition to hormonal factors, genetic mechanisms may bear on psychosexual differentiation (14).

Maternal immunization against the H-Y antigen has been proposed (15, 16). This hypothesis states that the repeatedly reported fraternal birth order effect reflects the progressive immunization of some mothers to Y-linked minor histocompatibility antigens (H-Y antigens) by each succeeding male fetus and the increasing effects of such immunization on the future sexual orientation of each succeeding male fetus. Sibling sex ratio studies have not been experimentally supported (17).

Studies have also failed to find differences in circulating levels of sex steroids between transsexual and non-transsexual individuals (18).

In summary, neither biological nor psychological studies provide a satisfactory explanation for the intriguing phenomenon of GIDs. In both disciplines, studies have been able to correlate certain findings to GIDs, but the findings are not robust and cannot be generalized to the whole population.

1.0. DIAGNOSTIC PROCEDURE

Sex reassignment is a multidisciplinary treatment. It requires five processes: diagnostic assessment, psychotherapy or counseling, real-life experience, hormone therapy, and surgical therapy. The focus of this Guideline is hormone therapy, although collaboration with appropriate professionals responsible for each process maximizes a successful outcome. It would be ideal if care could be given by a multidisciplinary team at one treatment center, but this is not always possible. It is essential that all caregivers be aware of and understand the contributions of each discipline and that they communicate throughout the process.

Diagnostic Assessment and Psychotherapy

Because GID may be accompanied with psychological or psychiatric problems (*see Refs. 23–27*), it is necessary that the clinician making the GID diagnosis be able 1) to make a distinction between GID and conditions that have similar features, 2) to diagnose accurately psychiatric conditions, and 3) to undertake appropriate treatment thereof. Therefore, the Standards of Care (SOC) guidelines of the WPATH recommend that the diagnosis be made by a MHP (28). For children and adolescents, the MHP should also have training in child and adolescent developmental psychopathology.

MHPs usually follow the WPATH's SOC. The main aspects of the diagnostic and psychosocial counseling are described below, and evidence supporting the SOC guidelines is given, whenever available.

During the diagnostic procedure, the MHP obtains information from the applicants for sex reassignment and, in the case of adolescents, the parents or guardians regarding various aspects of their general and psychosexual development and current functioning. On the basis of this information the MHP:

1. Decides whether the applicant fulfills DSM-IV-TR or ICD-10 criteria (see Tables 2 and 3) for GID;
2. Informs the applicant about the possibilities and limitations of sex reassignment and other kinds of treatment to prevent unrealistically high expectations; and
3. Assesses potential psychological and social risk factors for unfavorable outcomes of medical interventions.

In cases in which severe psychopathology or circumstances, or both, seriously interfere with the diagnostic work or make satisfactory treatment unlikely, management of the other issues should be addressed first. Literature on postoperative regret suggests that severe psychiatric comorbidity and lack of support may interfere with good outcome (30–33).

For adolescents, the diagnostic procedure usually includes a complete psychodiagnostic assessment (34) and, preferably, a child psychiatric evaluation (by a clinician other than the diagnostician). DiCeglie *et al.* (35) showed that 75% of the adolescents referred to their Gender Identity clinic in the United Kingdom reported relationship problems with parents. Therefore, a family evaluation to assess the family's ability to endure stress, give support, and deal with the complexities of the adolescent's situation should be part of the diagnostic procedure.

The Real-Life Experience

WPATH's SOC states that "the act of fully adopting a new or evolving gender role or gender presentation in everyday life is known as the RLE. The RLE is essential to the transition to the gender role that is congruent with the patient's gender identity. The RLE tests the person's resolve, the capacity to function in the preferred gender, and the adequacy of social, economic, and psychological supports. It assists both the patient and the MHP in their

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TABLE 2. DSM-IV-TR diagnostic criteria for GID (3)

A. A strong and persistent cross-gender identification (not merely a desire for any perceived cultural advantages of being the other sex).
In children, the disturbance is manifested by four (or more) of the following:
1. Repeatedly stated desire to be, or insistence that he or she is, the other sex.
2. In boys, preference for cross-dressing or simulating female attire; in girls, insistence on wearing only stereotypical masculine clothing.
3. Strong and persistent preferences for cross-sex roles in make-believe play or persistent fantasies of being the other sex.
4. Intense desire to participate in the stereotypical games and pastimes of the other sex.
5. Strong preference for playmates of the other sex.
In adolescents and adults, the disturbance is manifested by symptoms such as a stated desire to be the other sex, frequent passing as the other sex, desire to live or be treated as the other sex, or the conviction that he or she has the typical feelings and reactions of the other sex.
B. Persistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex.
In children, the disturbance is manifested by any of the following:
1. In boys, assertion that his penis or testes are disgusting or will disappear or assertion that it would be better not to have a penis or aversion toward rough-and-tumble play and rejection of male stereotypical toys, games, and activities.
2. In girls, rejection of urinating in a sitting position, assertion that she has or will grow a penis, assertion that she does not want to grow breasts or menstruate, or marked aversion toward normative feminine clothing.
In adolescents and adults, the disturbance is manifested by symptoms such as preoccupation with getting rid of primary and secondary sex characteristics (e.g., request for hormones, surgery, or other procedures to physically alter sexual characteristics to simulate the other sex) or belief that he or she was born the wrong sex.
C. The disturbance is not concurrent with a physical intersex condition.
D. The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
Code based on current age:
302.6 GID in Children
302.85 GID in Adolescents or Adults
Specify whether (for sexually mature individuals):
Sexually Attracted to Males
Sexually Attracted to Females
Sexually Attracted to Both
Sexually Attracted to Neither

judgments about how to proceed" (28). During the RLE, the person should fully experience life in the desired gender role before irreversible physical treatment is undertaken. Living 12 months full-time in the desired gender role is recommended (28). Testing an applicant's ability to function in the desired gender assists the applicant, the MHP and the endocrinologist in their judgments about how to proceed. During the RLE, the person's feelings about the social transformation, including coping with the responses of others, is a major focus of the counseling. Applicants increasingly start the RLE long before they are referred for hormone treatment.

Eligibility and Readiness Criteria

The WPATH SOC document requires that both adolescents and adults applying for hormone treatment and surgery satisfy two sets of criteria—eligibility and readiness—before proceeding (28). There are eligibility and readiness criteria for hormone therapy for adults (Table 4) and eligibility criteria for adolescents (Table 5). Eligibility and

TABLE 3. ICD-10 criteria for transsexualism and GID of childhood (29)

TRANSSEXUALISM (F64.0) criteria:
1. The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatments.
2. The transsexual identity has been present persistently for at least 2 years.
3. The disorder is not a symptom of another mental disorder or a genetic, intersex, or chromosomal abnormality.
GID OF CHILDHOOD (F64.2) has separate criteria for girls and for boys.
FOR GIRLS:
1. The individual shows persistent and intense distress about being a girl and has a stated desire to be a boy (not merely a desire for any perceived cultural advantages of being a boy) or insists that she is a boy.
2. Either of the following must be present:
a. Persistent marked aversion to normative feminine clothing and insistence on wearing stereotypical masculine clothing.
b. Persistent repudiation of female anatomical structures, as evidenced by at least one of the following:
i. An assertion that she has, or will grow, a penis.
ii. Rejection of urination in a sitting position.
iii. Assertion that she does not want to grow breasts or menstruate.
3. The girl has not yet reached puberty.
4. The disorder must have been present for at least 6 months.
FOR BOYS:
1. The individual shows persistent and intense distress about being a boy and has a desire to be a girl or, more rarely, insists that he is a girl.
2. Either of the following must be present:
a. Preoccupation with stereotypic female activities, as shown by a preference for either cross-dressing or simulating female attire or by an intense desire to participate in the games and pastimes of girls and rejection of stereotypical male toys, games, and activities.
b. Persistent repudiation of male anatomical structures, as evidenced by at least one of the following repeated assertions:
i. That he will grow up to become a woman (not merely in the role).
ii. That his penis or testes are disgusting or will disappear.
iii. That it would be better not to have a penis or testes.
3. The boy has not reached puberty.
4. The disorder must have been present for at least 6 months.

readiness criteria for sex reassignment surgery in adults and adolescents are the same (see Section 5.0.). Although the eligibility criteria have not been evaluated in formal studies, a few follow-up studies on adolescents who fulfilled these criteria, and had started cross-sex hormone treatment from the age of 16, indicate good postoperative results (36–38).

One study on MTF transsexual subjects reports that outcome was not associated with minimum eligibility requirements of the WPATH's SOC. However, this study was performed among a group of individuals with a relatively high socioeconomic background (39). One study investigating the need for psychotherapy for sex-reassignment applicants, based on questionnaire scores, suggests that 'classical' forms of psychotherapy prior to medical interventions are not needed in about two thirds of the applicants (40).

Recommendations for those involved in the hormone treatment of applicants for sex reassignment

Recommendation

1.1. We recommend that the diagnosis of GID be made by a MHP. For children and adolescents the MHP must also have training in child and adolescent developmental psychopathology. (1 | ⊕⊕○○)

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TABLE 4. Hormone therapy for adults

Adults are *eligible* for cross-sex hormone treatment if they (28):
1. Fulfill DSM IV-TR or ICD-10 criteria for GID or transsexualism (See Tables 2 and 3);
2. Do not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
3. Demonstrate knowledge and understanding of the expected outcomes of hormone treatment, as well as the medical and social risks and benefits; and
4. Have experienced a documented RLE of at least 3 months duration OR had a period of psychotherapy (duration specified by the MHP after the initial evaluation, usually a minimum of 3 months).
Adults should fulfill the following *readiness criteria* before the cross-sex hormone treatment. The applicant:
1. Has had further consolidation of gender identity during a RLE or psychotherapy;
2. Has made some progress in mastering other identified problems leading to improvement or continuing stable mental health; and
3. Is likely to take hormones in a responsible manner.

TABLE 5. Hormone therapy for adolescents

Adolescents are *eligible* and ready for GnRH treatment if they:
1. Fulfill DSM IV-TR or ICD-10 criteria for GID or transsexualism;
2. Have experienced puberty to at least Tanner stage 2;
3. Have (early) pubertal changes have resulted in an increase of their gender dysphoria;
4. Do not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Have adequate psychological and social support during treatment; and
6. Demonstrate knowledge and understanding of the expected outcomes of GnRH analogue treatment, cross-sex hormone treatment, and sex reassignment surgery, as well as the medical and the social risks and benefits of sex reassignment.
Adolescents are *eligible* for cross-sex hormone treatment if they:
1. Fulfill the criteria for GnRH treatment AND
2. Are 16 years or older.
Readiness criteria for adolescents eligible for cross-sex hormone treatment are the same as those for adults.

1.1. Evidence

GID may be accompanied with psychological or psychiatric problems (*see Refs. 23–27*). It is therefore necessary that the clinician making the GID diagnosis be able to make a distinction between GID and conditions that have similar features, to accurately diagnose psychiatric conditions, and to ensure that any such conditions are treated appropriately. One condition with similar features is body dysmorphic disorder or Skoptic syndrome, a condition in which a person is preoccupied with or engages in genital self-mutilation, such as castration, penectomy, or clitoridectomy (41).

1.1. Values and Preferences

The Task Force placed a very high value on avoiding harm from hormone treatment to individuals who have conditions other than GID and who may not be ready for the physical changes associated with this treatment, and placed a low value on any potential benefit these persons believe they may derive from hormone treatment. This justifies the strong recommendation in the face of low quality evidence.

Recommendation

1.2. Given the high rate of remission of GID after the onset of puberty, we recommend against a complete social role change and hormone treatment in prepubertal children with GID. (1 | ⊕⊕◯◯)

1.2. Evidence

In most children with GID, the GID does not persist into adolescence. The percentages differ between studies, probably dependent upon which version of the DSM was used in childhood, ages of children, and perhaps culture factors. However, the large majority (75-80%) of prepubertal children with a diagnosis of GID in childhood do not turn out to be transsexual in adolescence (42–44); for a review of seven older studies (see Ref. 45). Clinical experience suggests that GID can be reliably assessed only after the first signs of puberty.

This recommendation, however, does not imply that children should be entirely denied to show cross-gender behaviors or should be punished for exhibiting such behaviors.

1.2. Values and Preferences

This recommendation places a high value on avoiding harm with hormone therapy in prepubertal children who may have GID that will remit after the onset of puberty and places a relatively lower value on foregoing the potential benefits of early physical sex change induced by hormone therapy in prepubertal children with GID. This justifies the strong recommendation in the face of very low quality evidence.

Recommendation

1.3. We recommend that physicians evaluate and ensure that applicants understand the reversible and irreversible effects of hormone suppression (*e.g.*, GnRH analogue treatment) and of cross-sex hormone treatment before they start hormone treatment.

1.3. Remarks

In all treatment protocols, compliance and outcome are enhanced by clear expectations concerning the effects of the treatment. The lengthy diagnostic procedure (GnRH analogue treatment included, as this reversible treatment is considered to be a diagnostic aid) and long duration of the period between the start of the hormone treatment and sex reassignment surgery give the applicant ample opportunity to make balanced decisions about the various medical interventions. Clinical evidence shows that applicants react in a variety of ways to this treatment phase. The consequences of the social role change are sometimes difficult to handle, increasing understanding of treatment aspects may be frightening, and a change in gender dysphoric feelings may lead to confusion. Significant adverse effects on mental health can be prevented by a clear understanding of the changes that will occur and the time course of these changes.

Recommendation

1.4. We recommend that all transsexual individuals be informed and counseled regarding options for fertility prior to initiation of puberty suppression in adolescents and prior to treatment with sex hormones of the desired sex in both adolescents and adults.

1.4. *Remarks*

Persons considering hormone use for sex reassignment need adequate information about sex reassignment in general and about fertility effects of hormone treatment in particular to make an informed and balanced decision about this treatment. Because early adolescents may not feel qualified to make decisions about fertility and may not fully understand the potential effects of hormones, consent and protocol education should include parents, the referring MHP(s), and other members of the adolescent's support group. To our knowledge, there are no formally evaluated decision aids available to assist in the discussion and decision regarding future fertility of adolescents or adults beginning sex reassignment treatment.

Prolonged pubertal suppression using GnRH analogues is reversible and should not prevent resumption of pubertal development upon cessation of treatment. Although sperm production and development of the reproductive tract in early adolescent biological males with GID are insufficient for cryopreservation of sperm, they should be counseled that sperm production can be initiated following prolonged gonadotropin suppression, prior to estrogen treatment. This sperm production can be accomplished by spontaneous gonadotropin (both LH and FSH) recovery after cessation of GnRH analogs or by gonadotropin treatment and will probably be associated with physical manifestations of testosterone production. It should be noted that there are no data in this population concerning the time required for sufficient spermatogenesis to collect enough sperm for later fertility. In adult men with gonadotropin deficiency, sperm are noted in seminal fluid by 6–12 months of gonadotropin treatment, although sperm numbers at the time of pregnancy in these patients is far below the normal range (46, 47).

Girls can expect no adverse effects when treated with pubertal suppression. They should be informed that no data are available regarding timing of spontaneous ovulation or response to ovulation induction following prolonged gonadotropin suppression.

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All referred subjects who satisfy eligibility and readiness criteria for endocrine treatment, at age 16 or as adults, should be counseled regarding the effects of hormone treatment on fertility and available options that may enhance the chances of future fertility, if desired (48, 49). The occurrence and timing of potentially irreversible effects should be emphasized. Cryopreservation of sperm is readily available and techniques for cryopreservation of oocytes, embryos, and ovarian tissue are being improved (50).

In biological males, when medical treatment is started in a later phase of puberty or in adulthood, spermatogenesis is sufficient for cryopreservation and storage of sperm. Prolonged exposure of the testes to estrogen has been associated with testicular damage (51–53). Restoration of spermatogenesis after prolonged estrogen treatment has not been studied.

In biological females, the effect of prolonged treatment with exogenous testosterone upon ovarian function is uncertain. Reports of an increased incidence of polycystic ovaries in FTM transsexual persons, both prior to and as a result of androgen treatment, should be acknowledged (54, 55). Pregnancy has been reported in FTM transsexual persons who have had prolonged androgen treatment, but no genital surgery (56). Counsel from a gynecologist before hormone treatment regarding potential fertility preservation after oophorectomy will clarify available and future options (57).

2.0. TREATMENT OF ADOLESCENTS

Over the past decade, clinicians have progressively acknowledged the suffering of young transsexual adolescents that is caused by their pubertal development. Indeed, an adolescent with GID often considers the pubertal physical changes to be unbearable. As early medical intervention may prevent this psychological harm, various clinics have decided to start treating young adolescents with GID with puberty-suppressing medication (a GnRH analogue). As compared with starting sex reassignment long after the first phases of puberty, a benefit of pubertal suppression is relief of gender dysphoria and a better psychological and physical outcome.

The physical changes of pubertal development are the result of maturation of the hypothalamo-pituitary-gonadal axis and development of the secondary sex characteristics. Gonadotropin secretion increases with a day-night rhythm with higher levels of LH during the night. The nighttime LH increase in boys is associated with a parallel testosterone increase. Girls do not show a day-night rhythm, although in early puberty, the highest estrogen levels are observed during the morning as a result of a delayed response by the ovaries (58).

In girls the first physical sign of the beginning of puberty is the start of budding of the breasts followed by an increase in breast and fat tissue. Breast development is also associated with the pubertal growth spurt, with menarche occurring approximately 2 years later. In boys the first physical change is testicular growth. A testicular volume equal to or above 4 ml is seen as the first pubertal increase. From a testicular volume of 10 ml, daytime testosterone levels increase, leading to virilization (59).

Recommendations

2.1. We recommend that adolescents who fulfill eligibility and readiness criteria for gender reassignment initially undergo treatment to suppress pubertal development. (1 | ⊕◯◯◯)

2.2. We recommend that suppression of pubertal hormones start when girls and boys first exhibit physical changes of puberty (confirmed by pubertal levels of estradiol and testosterone, respectively), but no earlier than Tanner stages 2–3. (1 | ⊕⊕◯◯)

2.1.–2.2. Evidence

Pubertal suppression aids in the diagnostic and therapeutic phase, in a manner similar to the RLE (60, 61). Management of gender dysphoria usually improves. In addition, the hormonal changes are fully reversible, enabling full pubertal development in the

biologic gender if appropriate. Therefore, we advise starting suppression of puberty before irreversible development of sex characteristics.

The experience of full biologic puberty, an undesirable condition, may seriously interfere with healthy psychological functioning and well-being. Suffering from gender dysphoria without being able to present socially in the desired social role or to stop the development of secondary sex characteristics may result in an arrest in emotional, social, or intellectual development.

Another reason to start sex reassignment early is that the physical outcome following intervention in adulthood is far less satisfactory than intervention at age 16 (36, 38). Looking like a man (woman) when living as a woman (man) creates difficult barriers with enormous life-long disadvantages.

Pubertal suppression maintains end-organ sensitivity to sex steroids observed during early puberty, enabling satisfactory cross-sex body changes with low doses and avoiding irreversible characteristics that occur by mid-puberty.

The protocol of suppression of pubertal development can also be applied to adolescents in later pubertal stages. In contrast to effects in early pubertal adolescents, physical sex characteristics, such as breast development in girls and lowering of the voice and outgrowth of the jaw and brow in boys, will not regress completely.

Unlike the developmental problems observed with delayed puberty, this protocol requires a MHP skilled in child and adolescent psychology to evaluate the response of the adolescent with GID after pubertal suppression. Adolescents with GID should experience the first changes of their biologic, spontaneous puberty because their emotional reaction to these first physical changes has diagnostic value. Treatment in early puberty risks limited growth of the penis and scrotum that may make the surgical creation of a vagina from scrotal tissue more difficult.

2.1.–2.2. Values and Preferences

These recommendations place a high value on avoiding the increasing likelihood of an unsatisfactory physical change when secondary sexual characteristics have become manifest and irreversible, as well as a high value on offering the adolescent the experience of the desired gender. These recommendations place a lower value on avoiding potential harm from early hormone therapy.

2.1.–2.2. Remarks

Tanner stages of breast and male genital development are given in Table 6. Blood levels of sex steroids during Tanner stages of pubertal development are given in Table 7. Careful documentation of hallmarks of pubertal development will ensure precise timing of initiation of pubertal suppression.

Irreversible and, for transsexual adolescents, undesirable sex characteristics in female puberty are large breasts and short stature and in male puberty are Adam's apple, low voice, male bone configuration such as large jaws, big feet and hands, tall stature, and male hair pattern on the face and extremities.

2.3. We recommend that GnRH analogues be used to achieve suppression of pubertal hormones. (1 | ⊕⊕◯◯)

2.3. Evidence

Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with GnRH analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion (64, 65). Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option.

During treatment with the GnRH analogues, slight development of sex characteristics will regress and, in a later phase of pubertal development, will be halted. In girls, breast development will become atrophic and menses will stop; in boys, virilization will stop and testicular volume will decrease (61).

An advantage of using GnRH analogues is the reversibility of the intervention. If, after extensive exploring of his/her reassignment wish, the applicant no longer desires sex reassignment, pubertal

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TABLE 6. Description of Tanner stages of breast development and male external genitalia

For breast development:
1. Preadolescent.
2. Breast and papilla elevated as small mound; areolar diameter increased.
3. Breast and areola enlarged, no contour separation.
4. Areola and papilla form secondary mound.
5. Mature; nipple projects, areola part of general breast contour.
For penis and testes:
1. Preadolescent.
2. Slight enlargement of penis; enlarged scrotum, pink texture altered.
3. Penis longer, testes larger.
4. Penis larger, glans and breadth increase in size; testes larger, scrotum dark.
5. Penis and testes adult size.

Adapted from Ref. 62

TABLE 7. Estradiol levels in female puberty and testosterone levels in male puberty during night and day

Tanner stage	Nocturnal estradiol	Diurnal estradiol
Estradiol (pmol/liter)[a]		
B1	<37	<37
B2	38.5	56.3
B3	81.7	107.3
B4	162.9	132.3
B5	201.6	196.7
Testosterone (nmol/liter)[b]		
G1	<0.25	<0.25
G2	1.16	0.54
G3	3.76	0.62
G4	9.83	1.99
G5	13.2	7.80
Adult	18.8	17.0

Data represent median of hourly measurements from 2400–0600 h (nocturnal) and 1200–1800 h (diurnal).
a Adapted from Ref. 63.
b Adapted from Ref. 59.

suppression can be discontinued. Spontaneous pubertal development will resume immediately (66).

Men with delayed puberty have decreased bone mineral density (BMD). Treatment of adults with GnRH analogues results in loss of BMD (67). In children with central precocious puberty, bone density is relatively high for age. Suppressing puberty in these children using GnRH analogues will result in a further increase in BMD and stabilization of BMD standard deviation scores (68). Initial data in transsexual subjects demonstrate no change of bone density during GnRH analogue therapy (61). With cross-hormone treatment, bone density increases. The long-term effects on bone density and peak bone mass are being evaluated.

GnRH analogues are expensive and not always reimbursed by insurance companies. Although there is no clinical experience in this population, financial considerations may require treatment with progestins as a less effective alternative. They suppress gonadotropin secretion and exert a mild peripheral anti-androgen effect in boys. Depo-medroxyprogesterone will suppress ovulation and progesterone production for long periods of time, although residual estrogen levels vary. In high doses, progestins are relatively effective in suppression of menstrual cycling in girls and women and androgen levels in boys and men. However, at these doses, side effects such as suppression of adrenal function and suppression of bone growth may occur (69). Anti-estrogens in girls and anti-androgens in boys can be used to delay the progression of puberty (70, 71). Their efficacy, however, is far less than that of the GnRH analogues.

2.3. Values and Preferences

For persons who can afford the therapy, our recommendation of GnRH analogues places a higher value on the superior efficacy, safety, and reversibility of the pubertal hormone suppression achieved, as compared with the alternatives, and a relatively lower value on limiting the cost of therapy. Of the available alternatives, a depot progestin preparation may be partially effective, but is not as safe (69, 72); its lower cost may make it an acceptable treatment for persons who cannot afford GnRH.

2.3. Remarks

Measurements of gonadotropin and sex steroid levels give precise information about suppression of the gonadal axis. If the gonadal axis is not completely suppressed, the interval of GnRH analogue injections should be shortened. During treatment, adolescents should be monitored for negative effects of delaying puberty, including a halted growth spurt and impaired bone accretion. The clinical protocol to be used is shown in Table 8.

Glucose and lipid metabolism, complete blood counts, and liver and renal function should be monitored during suppression and cross-sex hormone substitution. For the evaluation of growth, anthropometric measurements are informative. To assess bone density, dual energy X-ray absorptiometry (DXA) scans can be performed.

2.4. We suggest that pubertal development of the desired, opposite sex be initiated at the age of 16 years, using a gradually increasing dose schedule of cross-sex steroids. (2 | ⊕◯◯◯)

2.4. Evidence

In many countries, 16-year-olds are legal adults with regard to medical decision making. This is probably because, at this age, most adolescents are able to make complex cognitive decisions. Although parental consent may not be required, obtaining it is preferred since the support of parents should improve the outcome during this complex phase of the adolescent's life (61).

For the induction of puberty, we use a similar dose scheme of induction of puberty in these hypogonadal transsexual adolescents as in other hypogonadal individuals (Table 9). We do not advise the use of sex steroid creams or patches since there is little experience for induction of puberty. The transsexual adolescent is hypogonadal and may be sensitive to high doses of cross-sex steroids, causing adverse effects of striae and abnormal breast shape in girls and cystic acne in boys.

In FTM transsexual adolescents, suppression of puberty may halt the growth spurt. To achieve maximum height, slow introduction of androgens will mimic a "pubertal" growth spurt. If the patient is relatively short, one may treat with oxandrolone, a growth-stimulating anabolic steroid also successfully applied in women with Turner syndrome (73–75).

TABLE 8. Follow-up protocol during suppression of puberty

EVERY 3 MONTHS
Anthropometry: height, weight, sitting height, Tanner stages
Laboratory: LH, FSH, estrodiol/testosterone
EVERY YEAR
Laboratory: renal and liver function, lipids, glucose, insulin, glycosylated hemoglobin
Bone density using DXA
Bone age on X-ray of the left hand

In MTF transsexual adolescents, extreme tall stature is often a genetic probability. The estrogen dose may be increased by more rapid increments in the schedule. Estrogens may be started before the age of 16 (in exceptional cases), or estrogens can be prescribed in growth-inhibiting doses (61).

We suggest that treatment with GnRH analogues be continued during treatment with cross-sex steroids to maintain full suppression of pituitary gonadotropin levels and, thereby, gonadal steroids. When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion (Table 7). The estrogen doses used may result in reactivation of gonadotropin secretion and endogenous production of testosterone that can interfere with the effectiveness of the treatment. GnRH analogue treatment is advised until gonadectomy.

2.4. Values and Preferences

Identifying an age at which pubertal development is initiated will be by necessity arbitrary, but the goal is to start this process at a time when the individual will be able to make informed mature decisions and engage in the therapy, while at the same time developing along with his or her peers. Growth targets reflect personal preferences, often shaped by societal expectations. Individual preferences

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TABLE 9. Protocol induction of puberty

Induction of female puberty with oral 17β, estradiol, increasing the dose every 6 months;
5 μg/kg/day
10 μg/kg/day
15 μg/kg/day
20 μg/kg/day
adult dose = 2 mg per day
Induction of male puberty with intramuscular testosterone esters, increasing the dose every 6 months:
25 mg/m^2/2 weeks im
50 mg/m^2/2 weeks im
75 mg/m^2/2 weeks im
100 mg/m^2/2 weeks im

TABLE 10. Follow-up protocol during induction of puberty

EVERY 3 MONTHS
Anthropometry: height, weight, sitting height, Tanner stages
Laboratory: endocrinology: LH, FSH, estrodiol/testosterone
EVERY YEAR
Laboratory: renal and liver function, lipids, glucose, insulin, glycosylated hemoglobin
Bone density using DXA
Bone age on X-ray of the left hand
These parameters should be measured also at long term. For bone development until the age of 25–30 years or until peak bone mass has been reached.

should be the key determinant, rather than the professional's deciding a priori that MTF transsexuals should be shorter than FTM transsexuals.

2.4. Remarks

Protocols for induction of puberty can be found in Table 9.

We recommend monitoring clinical pubertal development as well as laboratory parameters (Table 10). Sex steroids of the desired sex will initiate pubertal development, which can be (partially) monitored using Tanner stages. In addition, the sex steroids will affect growth and bone development, as well as insulin sensitivity and lipid metabolism, as in normal puberty (76, 77).

2.5. We recommend referring hormone-treated adolescents for surgery when 1) the RLE has resulted in a satisfactory social role change, 2) the individual is satisfied about the hormonal effects, and 3) the individual desires definitive surgical changes. (1 | ⊕◯◯)

2.6. We suggest deferring for surgery until the individual is at least 18 years old. (2 | ⊕◯◯).

2.5.–2.6. Evidence

Surgery is an irreversible intervention. The WPATH SOC (28) emphasizes that the "threshold of 18 should be seen as an eligibility criterion and not an indication in itself for active intervention." If the RLE supported by sex hormones of the desired sex has not resulted in a satisfactory social role change, if the person is not satisfied with or is ambivalent about the hormonal effects, or if the person is ambivalent about surgery, then the applicant should not be referred for surgery (78, 79).

3.0. HORMONAL THERAPY FOR TRANSSEXUAL ADULTS

The two major goals of hormonal therapy are: 1) to reduce endogenous hormone levels and, thereby, the secondary sex characteristics of the individual's biological (genetic) sex and assigned gender and 2) to replace endogenous sex hormone levels with those of the reassigned sex by using the principles of hormone replacement treatment of hypogonadal patients. The timing of these two goals and the age at which to begin treatment with cross-sex hormones is co-determined in collaboration with both the person pursuing sex change and the MHP who made the diagnosis, performed psychological evaluation, and recommended sex reassignment. The physical changes induced by this sex hormone transition are usually accompanied by an improvement in mental well-being.

Recommendations

3.1. We recommend that treating endocrinologists confirm the diagnostic criteria of GID or transsexualism and the eligibility and readiness criteria for the endocrine phase of gender transition. (1 | ⊕◯◯)

3.2. We recommend that medical conditions that can be exacerbated by hormone depletion and cross-sex hormone treatment be evaluated and addressed prior to initiation of treatment (Table 11. Medical conditions that can be exacerbated by cross-sex hormone therapy). (1 | ⊕⊕◯◯)

3.3. We suggest that cross-sex hormone levels be maintained in the normal physiologic range for the desired gender. (2 | ⊕⊕◯◯)

3.1.–3.3. Evidence

Although the diagnosis of GID or transsexualism is made by an MHP, the referral for endocrine treatment implies fulfillment of the eligibility and readiness criteria (See Section 1) (28). It is the responsibility of the physician to whom the transsexual person has been referred to confirm that the person fulfills these criteria for treatment. This task can be accomplished by the physician's becoming familiar with the terms and criteria presented in Tables 1–5, taking a thorough history from the person recommended for treatment, and discussing these criteria with the MHP. Continued evaluation of the transsexual person by the MHP, in collaboration with the treating endocrinologist, will ensure that the desire for sex change is appropriate, that the consequences, risks, and benefits of treatment are well understood, and that the desire for sex change persists.

Female-to-male transsexual persons

Clinical studies have demonstrated the efficacy of several different androgen preparations to induce masculinization in FTM transsexual persons (80–84). Regimens to change secondary sex characteristics follow the general principle of hormone replacement treatment of male hypogonadism (85). Either parenteral or transdermal preparations can be used to achieve testosterone values in the normal male range (320–1000 ng/dl) (Table 12). Sustained supraphysiologic levels of testosterone increase the risk of adverse reactions (see Section 4.0.).

TABLE 11. Medical conditions that can be exacerbated by cross-sex hormone therapy

TRANSSEXUAL FEMALE (MTF) – ESTROGEN
Very high risk of serious adverse outcomes
• thromboembolic disease
Moderate to high risk of adverse outcomes
• macroprolactinoma
• severe liver dysfunction (transaminases > 3x upper limit of normal)
• breast cancer
• coronary artery disease
• cerebrovascular disease
• severe migraine headaches
TRANSSEXUAL MALE (FTM) – TESTOSTERONE
Very high risk of serious adverse outcomes
• breast or uterine cancer
• erythrocytosis (hematocrit >50%)
Moderate to high risk of adverse outcomes
• severe liver dysfunction (transaminases > 3x upper limit of normal)

Similar to androgen therapy in hypogonadal men, testosterone treatment in the FTM individual results in increased muscle mass and decreased fat mass, increased facial hair and acne, male pattern baldness, and increased libido (86). Specific to the FTM transsexual person, testosterone will result in clitoromegaly, temporary or permanent decreased fertility, deepening of the voice, and, usually, cessation of menses. Cessation of menses may occur within a few months with testosterone treatment alone, although high doses of testosterone may be required. If uterine bleeding continues, addition of a progestational agent or endometrial ablation may be considered (87, 88). Gonadotropin-releasing hormone analogues or depot medroxyprogesterone may also be used to stop menses prior to testosterone treatment and to reduce estrogens to levels found in biological males.

TABLE 12. Hormone regimens in the transsexual persons

	Dosage
MTF TRANSSEXUAL PERSONS[a]	
Estrogen	
Oral: estradiol	2.0–6.0 mg/d
Transdermal: estradiol patch	0.1– 0.4 mg twice weekly
Parenteral: estradiol	5–20 mg im every 2 wk
valerate or cypionate	2–10 mg im every week
Antiandrogens	
Spironolactone	100–200 mg/d
Cyproterone acetate[b]	50–100 mg/d
GnRH agonist	3.75 mg sc monthly
FTM TRANSSEXUAL PERSONS	
Testosterone	
Oral: testosterone	160–240 mg/d
undecanoate[b]	
Parenteral	
Testosterone enanthate	100–200 mg im every
or cypionate	2 wk or 50% weekly
Testosterone	1000 mg every 12 wk
undecanoate[b,c]	
Transdermal	
Testosterone gel 1%	2.5–10 g/d
Testosterone patch	2.5–7.5 mg/d

a Estrogens used with or without antiandrogens or GnRH agonist.
b Not available in the United States.
c 1000 mg initially, followed by an injection at 6 wk, then at 12-wk intervals

Male-to-female transsexual persons

The hormone regimen for MTF transsexual individuals is more complex than the FTM regimen. Most published clinical studies report the use of an anti-androgen in conjunction with an estrogen (80, 82–84, 89).

The anti-androgens shown to be effective reduce endogenous testosterone levels, ideally to levels found in adult biological women, to enable estrogen therapy to have its fullest effect. Two categories of these medications are progestins with anti-androgen activity and gonadotropin-releasing hormone agonists (90). Spironolactone has anti-androgen properties by directly inhibiting testosterone secretion and by inhibiting androgen binding to the androgen receptor (83, 84). It may also have estrogenic activity (91). Cyproterone acetate, a progestational compound with anti-androgenic properties (80, 82), is widely used in Europe. Flutamide blocks binding of androgens to the androgen receptor, but it does not lower serum testosterone levels; it has liver toxicity, and its efficacy has not been demonstrated.

Dittrich (90), reporting a series of 60 MTF transsexual persons who used monthly the GnRH agonist goserelin acetate in combination with estrogen, found this regimen to be effective in reducing testosterone levels with low incidence of adverse reactions.

Estrogen can be given orally as conjugated estrogens, or 17β-estradiol, as transdermal estrogen or parenteral estrogen esters (Table 12).

Measurement of serum estradiol levels can be used to monitor oral, transdermal, and intramuscular estradiol or its esters. Use of conjugated estrogens or synthetic estrogens cannot be monitored by blood

tests. Serum estradiol should be maintained at the mean daily level for pre-menopausal women (<200 pg/ml), and the serum testosterone level should be in the female range (<55 ng/dl). The transdermal preparations may confer an advantage in the older transsexual women who may be at higher risk for thromboembolic disease (92).

Venous thromboembolism may be a serious complication. A 20-fold increase in venous thromboembolic disease was reported in a large cohort of Dutch transsexual subjects (93). This increase may have been associated with the use of ethinyl estradiol (92). The incidence decreased upon cessation of the administration of ethinyl estradiol (93). Thus, the use of synthetic estrogens, especially ethinyl estradiol, is undesirable because of the inability to regulate dose by measurement of serum levels and the risk of thromboembolic disease. Deep vein thrombosis occurred in 1 of 60 MTF transsexual persons treated with a GnRH analog and oral estradiol (90). The patient was found to have a homozygous C677 T mutation. Administration of cross-sex hormones to 162 MTF and 89 FTM transsexual persons was not associated with venous thromboembolism despite an 8.0% and 5.6% incidence of thrombophilia (94). Thombophilia screening of transsexual persons initiating hormone treatment should be restricted to those with a personal or family history of venous thromboembolism (94). Monitoring D-dimer levels during treatment is not recommended (95).

3.1.–3.3. Values and Preferences

Our recommendation to maintain levels of cross-sex hormones in the normal adult range places a high value on the avoidance of the long-term complications of pharmacologic doses. Those receiving endocrine treatment who have relative contraindications to hormones (*e.g.*, persons who smoke, have diabetes, have liver disease, etc.) should have an in-depth discussion with their physician to balance the risks and benefits of therapy.

3.1.–3.3. Remarks

All endocrine-treated individuals should be informed of all risks and benefits of cross-sex hormones prior to initiation of therapy. Cessation of tobacco use should be strongly encouraged in MTF transsexual persons to avoid increased risk of thromboembolism and cardiovascular complications.

Recommendation

3.4. We suggest that endocrinologists review with persons treated the onset and time course of physical changes induced by cross-sex hormone treatment. (2 | ⊕⊕◯◯)

3.4. Evidence

Female-to-male transsexual persons

Physical changes that are expected to occur during the first 3 months of initiation of testosterone therapy include cessation of menses, increased libido, increased facial and body hair, increased oiliness of skin, increased muscle, and redistribution of fat mass. Changes that occur within the first year of testosterone therapy include deepening of the voice, clitoromegaly, and, in some individuals, male pattern hair loss (83, 96, 97) (Table 13).

Male-to-female transsexual persons

Physical changes that may occur in the first 3–6 months of estrogen and anti-androgen therapy include decreased libido, decreased facial and body hair, decreased oiliness of skin, breast tissue growth, and redistribution of fat mass (82–84, 96–97) (Table 14). Breast development is generally maximal at 2 years after initiation of hormones (82–84). Over a long period of time, the prostate gland and testicles will undergo atrophy.

Although the time course of breast development in MTF transsexual persons has been studied (97), precise information about other changes induced by sex hormones is lacking. There is a great deal of variability between individuals, as evidenced during pubertal development.

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TABLE 13. Masculinizing effects in FTM transsexual persons

EFFECT	ONSET[a] (months)	MAXIMUM[a] (years)
Skin oiliness/acne	1 – 6	1 – 2
Facial/body hair growth	6 – 12	4 – 5
Scalp hair loss	6 – 12	b
Increased muscle mass/strength	6 – 12	2 – 5
Fat redistribution	1 – 6	2 – 5
Cessation of menses	2 – 6	c
Clitoral enlargement	3 – 6	1 – 2
Vaginal atrophy	3 – 6	1 – 2
Deepening of voice	6 – 12	1 – 2

a Estimates represent clinical observations. See Refs 81, 92, 93.
b Prevention and treatment as recommended for biological men.
c Menorrhagia requires diagnosis and treatment by a gynecologist.

TABLE 14. Feminizing effects in MTF transsexual persons

EFFECT	ONSET[a]	MAXIMUM[a]
Redistribution of body fat	3 – 6 months	2 – 3 years
Decrease in muscle mass and strength	3 – 6 months	1 – 2 years
Softening of skin/decreased oiliness	3 – 6 months	Unknown
Decreased libido	1 – 3 months	3 – 6 months
Decreased spontaneous erections	1 – 3 months	3 – 6 months
Male sexual dysfunction	Variable	Variable
Breast growth	3 – 6 months	2 – 3 years
Decreased testicular volume	3 – 6 months	2 – 3 years
Decreased sperm production	Unknown	> 3 years
Decreased terminal hair growth	6 – 12 months	> 3 years[b]
Scalp hair	No regrowth	c
Voice changes	None	d

a Estimates represent clinical observations. See Refs 81, 92, 93.
b Complete removal of male sexual hair requires electrolysis or laser treatment or both.
c Familial scalp hair loss may occur if estrogens are stopped.
d Treatment by speech pathologists for voice training is most effective.

3.4. Values and Preferences

Transsexual persons have very high expectations regarding the physical changes of hormone treatment and are aware that body changes can be enhanced by surgical procedures (*e.g.*, breast, face, and body habitus). Clear expectations for the extent and timing of sex-hormone-induced changes may prevent the potential harm and expense of unnecessary procedures.

4.0. ADVERSE OUTCOME PREVENTION AND LONG-TERM CARE

Cross-sex hormone therapy confers the same risks associated with sex hormone replacement therapy in biological males and females. The risk of cross-sex hormone therapy arises from and is worsened by inadvertent or intentional use of supraphysiologic doses of sex hormones or inadequate doses of sex hormones to maintain normal physiology (81, 89).

Recommendation

4.1. We suggest regular clinical and laboratory monitoring every 3 months during the first year and then once or twice yearly. (2 | ⊕◯◯◯)

4.1. Evidence

Pretreatment screening and appropriate regular medical monitoring is recommended for both FTM and MTF transsexual persons during the endocrine transition and periodically thereafter (13, 97). Monitoring of weight and blood pressure, directed physical exams, routine health questions focused on risk factors and medications, complete blood counts, renal and liver function, lipid and glucose metabolism should be carried out.

Female-to-male transsexual persons

A standard monitoring plan for individuals on testosterone therapy is found in Table 15. Key issues include maintaining testosterone levels in the physiologic normal male range and avoidance of adverse events resulting from chronic testosterone therapy, particularly erythrocytosis, liver dysfunction, hypertension, excessive weight gain, salt retention, lipid changes, excessive or cystic acne, and adverse psychological changes (85).

Since oral 17-alkylated testosterone is not recommended, serious hepatic toxicity is not anticipated with the use parenteral or transdermal testosterone (98, 99). Still, periodic monitoring is recommended given that up to 15% of FTM persons treated with testosterone have transient elevations in liver enzymes (93).

Male-to-female transsexual persons

A standard monitoring plan for individuals on estrogens, gonadotropin suppression, or anti-androgens is found in Table 16. Key issues include avoiding supraphysiologic doses or blood levels of estrogen, which may lead to increased risk for thromboembolic disease, liver dysfunction, and development of hypertension.

TABLE 15. Monitoring of MTF transsexual persons on cross-hormone therapy

1. Evaluate patient every 2–3 months in the first year and then 1–2 times per year to monitor for appropriate signs of feminization and for development of adverse reactions.
2. Measure serum testosterone and estradiol every 3 months. a. Serum testosterone levels should be <55 ng/dl. b. Serum estradiol should not exceed the peak physiologic range for young healthy females, with ideal levels, 200 pg/ml. c. Doses of estrogen should be adjusted according to the serum levels of estradiol.
3. For individuals on spironolactone, serum electrolytes particularly potassium should be monitored every 2–3 months initially in the first year.
4. Routine cancer screening recommended in non-transsexual individuals (breasts, colon, prostate).
5. Consider BMD testing at baseline if risk factors for osteoporotic fracture are present (e.g., previous fracture, family history, glucocorticoid use, prolonged hypogonadism). In individuals at low risk, screening for osteoporosis should be conducted at age 60 or in those who are not compliant with hormone therapy.

6. Annual Prolactin Levels

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Recommendation

4.2. We suggest monitoring prolactin levels in male-to-female transsexual persons treated with estrogens. (2 | ⊕⊕◯◯)

4.2. Evidence

Estrogen therapy can increase the growth of pituitary lactotroph cells. There have been several reports of prolactinomas occurring after long-term estrogen therapy (100–102). Up to 20% of transsexual women treated with estrogens may have elevations in prolactin levels associated with enlargement of the pituitary gland (103). In most cases, the serum prolactin levels will return to the normal range with a reduction or discontinuation of the estrogen therapy (104).

The onset and time course of hyperprolactinemia during estrogen treatment are not known. Prolactin levels should be obtained at baseline and then at least annually during the transition period and biannually thereafter. Given that prolactinomas have been reported only in a few case reports and were not reported in large cohorts of estrogen-treated transsexual persons, the risk of prolactinoma is likely to be very low. Since the major presenting findings of micro-prolactinomas (hypogonadism and sometimes gynecomastia) are not apparent in MTF transsexual persons, radiologic examination of the pituitary may be carried out in those whose prolactin levels persistently increase despite stable or reduced estrogen levels.

Because transsexual persons are diagnosed and followed throughout sex reassignment by an MHP, it is likely that some will receive psychotropic medications that can increase prolactin levels.

Recommendation

4.3. We suggest that transsexual persons treated with hormones be evaluated for cardiovascular risk factors. (2 | ⊕⊕◯◯)

TABLE 16. Monitoring of FTM transsexual persons on cross-hormone therapy

1. Evaluate patient every 2–3 months in the first year and then 1–2 times per year to monitor for appropriate signs of virilization and for development of adverse reactions.
2. Measure serum testosterone every 2–3 months until levels are in the normal physiologic male range:*
a. For testosterone enanthate/cypionate injections, the testosterone level should be measured mid-way between injections. If the level is >700 ng/dl or <350 ng/dl, adjust dose accordingly.
b. For parenteral testosterone undecanoate, testosterone should be measured just before the following injection.
c. For transdermal testosterone, the testosterone level can be measured at any time after 1 week.
d. For oral testosterone undecanoate, the testosterone level should be measured 3–5 hours after ingestion.
e. Note: During the first 3–9 months of testosterone treatment, total testosterone levels may be high although free testosterone levels are normal due to high sex hormone binding globulin levels in some biological women.
3. Measure estradiol levels during the first 6 months of testosterone treatment or until there has been no uterine bleeding for 6 months. Estradiol levels should be <50 pg/ml.
4. Measure CBC and liver function tests at baseline and every 3 months for the first year and then 1–2 times a year. Monitor weight, blood pressure, lipids, fasting blood sugar (if family history of diabetes) and hemoglobin A1c (if diabetic) at regular visits.
5. Consider BMD testing at baseline if risk factors for osteoporotic fracture are present (e.g., previous fracture, family history, glucocorticoid use, prolonged hypogonadism). In individuals at low risk, screening for osteoporosis should be conducted at age 60 or in those who are not compliant with hormone therapy.
6. If cervical tissue is present, an annual pap smear is recommended by the American College of Obstetricians and Gynecologists.
7. If mastectomy is not performed, then consider mammograms as recommended by the American Cancer Society.

* *Adapted from Refs. 83, 85*

4.3. Evidence

Female-to-male transsexual persons

Testosterone administration to FTM transsexual persons will result in a more atherogenic lipid profile with lowered HDL cholesterol and higher triglyceride values (21, 105–107). Studies of the effect of testosterone on insulin sensitivity have mixed results (106, 108). A recent randomized, open-label uncontrolled safety study of FTM transsexual persons treated with testosterone undecanoate demonstrated no insulin resistance after 1 year (109). Numerous studies have demonstrated effects of cross-sex hormone treatment on the cardiovascular system (107, 110–112). Long-term studies from The Netherlands found no increased risk for cardiovascular mortality (93). Likewise, a meta-analysis of 19 randomized trials in men examining testosterone replacement showed no increased incidence of cardiovascular events (113). A systematic review of the literature found that data were insufficient, due to very low quality evidence, to allow meaningful assessment of patient important outcomes such as death, stroke, MI, or venous thromboembolism in FTM transsexual persons (21). Future research is needed to ascertain harms of hormonal therapies (21). Cardiovascular risk factors should be managed as they emerge according to established guidelines (114).

Male-to-female transsexual persons

A prospective study of MTF subjects found favorable changes in lipid parameters with increased HDL and decreased LDL concentrations (106). However, these favorable lipid changes were attenuated by increased weight, blood pressure, and markers of insulin resistance. The largest cohort of MTF subjects (with a mean age of 41) followed for a mean of 10 years showed no increase in cardiovascular mortality despite a 32% rate of tobacco use (93). Thus, there is limited evidence to determine whether estrogen is protective or detrimental in MTF transsexual persons (21). With aging there is usually an increase of body weight and therefore, as with non-transsexual individuals, glucose and lipid metabolism and blood pressure should be monitored regularly and managed according to established guidelines (114).

Recommendation

4.4. We suggest that bone mineral density measurements be obtained if risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. (2 | ⊕⊕◯◯)

4.4. Evidence

Female-to-male transsexual persons

Adequate dosing of testosterone is important to maintain bone mass in FTM transsexual persons (115, 116). In one study (116), serum LH levels were inversely related to bone mineral density, suggesting that low levels of sex hormones were associated with bone loss. Thus, LH levels may serve as an indicator of the adequacy of sex steroid administration to preserve bone mass. The protective effect of testosterone may be mediated by peripheral conversion to estradiol both systemically and locally in the bone.

Male-to-female transsexual persons

Studies in aging genetic males suggest that serum estradiol more positively correlates with BMD than does testosterone (117–119) and is more important for peak bone mass (120). Estrogen preserves BMD in MTF transsexuals who continue on estrogen and anti-androgen therapies (116, 121, 122).

Fracture data in transsexual men and women are not available. Transsexual persons who have undergone gonadectomy may not continue consistent cross-sex steroid treatment after hormonal and surgical sex reassignment, thereby becoming at risk for bone loss.

Recommendations

4.5. We suggest that male-to-female transsexual persons, who have no known increased risk of breast cancer, follow breast screening guidelines recommended for biological women. (2 | ⊕⊕◯◯)

4.6. We suggest that male-to-female transsexual persons treated with estrogens follow screening

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guidelines for prostatic disease and prostate cancer recommended for biological men. (2 | ⊕○○○)

4.5.–4.6. Evidence

Breast cancer is a concern in transsexual women. A few cases of breast cancer in MTF transsexual persons have been reported in the literature (123–125). In the Dutch cohort of 1800 transsexual women followed for a mean of 15 years (range 1 to 30 years), only one case of breast cancer was found. The Women's Health Initiative study reported that women taking conjugated equine estrogen without progesterone for 7 years did not have an increased risk of breast cancer as compared with women taking placebo (126). Women with primary hypogonadism (XO) treated with estrogen replacement exhibited a significantly decreased incidence of breast cancer as compared with national standardized incidence ratios (127, 128). These studies suggest that estrogen therapy does not increase the risk of breast cancer in the short term (<20–30 years). Long-term studies are required to determine the actual risk and the role of screening mammograms. Regular exams and gynecologic advice should determine monitoring for breast cancer.

Prostate cancer is very rare, especially with androgen deprivation therapy, before the age of 40 (129). Childhood or pubertal castration results in regression of the prostate and adult castration reverses benign prostate hypertrophy (BPH) (130). Although van Kesteren (131) reported that estrogen therapy does not induce hypertrophy or pre-malignant changes in the prostate of MTF transsexual persons, cases of BPH have been reported in MTF transsexual persons treated with estrogens for 20–25 years (132, 133). Three cases of prostate carcinoma have been reported in MTF transsexual persons (134–136). However, these individuals initiated cross-hormone therapy after age 50, and whether these cancers were present before the initiation of therapy is unknown.

MTF transsexual persons may feel uncomfortable scheduling regular prostate examinations. Gynecologists are not trained to screen for prostate cancer or to monitor prostate growth. Thus, it may be reasonable for MTF transsexual persons who transitioned after age 20 to have annual screening digital rectal exams after age 50 and PSA tests consistent with the United States Preventive Services Task Force Guidelines Guidelines (137).

Recommendation

4.7. We suggest that female-to-male transsexual persons evaluate the risks and benefits of including a total hysterectomy and oophorectomy as part of sex reassignment surgery. (2 | ⊕○○○)

4.7. Evidence

Although aromatization of testosterone to estradiol in FTM transsexual persons has been suggested as a risk factor for endometrial cancer (138), no cases have been reported. When FTM transsexual persons undergo hysterectomy, the uterus is small and there is endometrial atrophy (139, 140). The androgen receptor has been reported to increase in the ovaries after long-term administration of testosterone, which may be an indication of increased risk of ovarian cancer (141). Cases of ovarian cancer have been reported (142, 143). The relative safety of laparoscopic total hysterectomy argues for preventing the risks of reproductive tract cancers and other diseases through surgery (144).

4.7. Values and Preferences

Given the discomfort that FTM transsexual persons experience accessing gynecologic care, our recommendation for total hysterectomy and oophorectomy places a high value on eliminating the risks of female reproductive tract disease and cancer and a lower value on avoiding the risks of these surgical procedures (related to the surgery and to the potential undesirable health consequences of oophorectomy) and their associated costs.

4.7. Remarks

The sexual orientation and type of sexual practices will determine the need and types of gynecologic care required following transition. In addition, approval of birth certificate change of sex for FTM transsexual persons may be dependent upon having a complete hysterectomy; each patient should be assisted in

researching and counseled concerning such non-medical administrative criteria.

5.0. SURGERY FOR SEX REASSIGNMENT

For many transsexual adults, genital sex reassignment surgery may be the necessary step towards achieving their ultimate goal of living successful in their desired gender role. Although surgery on several different body structures is considered during sex reassignment, the most important issue is the genital surgery and removal of the gonads. The surgical techniques have improved markedly during the past 10 years. Cosmetic genital surgery with preservation of neurological sensation is now the standard. The satisfaction rate with surgical reassignment of sex is now very high (22). In addition, the mental health of the individual seems to be improved by participating in a treatment program that defines a pathway of gender identity treatment that includes hormones and surgery (24). The person must be both eligible and ready for such a procedure (Table 17).

Sex reassignment surgeries available to the MTF transsexual persons consist of gonadectomy, penectomy, and creation of a vagina (145, 146). The skin of the penis is often inverted to form the wall of the vagina. The scrotum becomes the labia majora. Cosmetic surgery is used to fashion the clitoris and its hood, preserving the neurovascular bundle at the tip of the penis as the neurosensory supply to the clitoris. Most recently, plastic surgeons have developed techniques to fashion labia minora. Endocrinologists should encourage the transsexual person to use their tampon dilators to maintain the depth and width of the vagina throughout the postoperative period until the neovagina is being used frequently in intercourse. Genital sexual responsivity and other aspects of sexual function should be preserved following genital sex reassignment surgery (147).

Ancillary surgeries for more feminine or masculine appearance are not within the scope of this guideline. When possible, less surgery is desirable. For instance, voice therapy by a speech language pathologist is preferred to current surgical methods designed to change the pitch of the voice (148).

Breast size in genetic females exhibits a very broad spectrum. For the transsexual person to make the best-informed decision, breast augmentation surgery should be delayed until at least 2 years of estrogen therapy have been completed given that the breasts continue to grow during that time with estrogen stimulation (90, 97).

Another major effort is the removal of facial and masculine-appearing body hair using either electrolysis or laser treatments. Other feminizing surgery, such as that to feminize the face, is now becoming more popular (149–151).

TABLE 17. Sex reassignment surgery eligibility and readiness criteria

Individuals treated with cross-sex hormones are considered eligible for sex reassignment surgery if they:
1. Are of the legal age of majority in their nation.
2. Have used cross-sex hormones continuously and responsibly during 12 months (if they have no medical contraindication).
3. Had a successful continuous full-time RLE during 12 months.
4. Have (if required by the MHP) regularly participated in psychotherapy throughout the RLE at a frequency determined jointly by the patient and the MHP.
5. Have shown demonstrable knowledge of all practical aspects of surgery (e.g., cost, required lengths of hospitalizations, likely complications, postsurgical rehabilitation, etc.).
Individuals, treated with cross-sex hormones, should fulfill the following readiness criteria prior to sex reassignment surgery:
1. Demonstrable progress in consolidating one's gender identity.
2. Demonstrable progress in dealing with work, family, and interpersonal issues resulting in a significantly better state of mental health.

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Sex reassignment surgeries available to the FTM transsexual persons have been less satisfactory. The cosmetic appearance of a neopenis is now very good, but the surgery is multistage and very expensive (152, 153). Neopenile erection can be achieved only if some mechanical device is imbedded in the penis, *e.g.*, a rod or some inflatable apparatus (154). Many choose a metadoioplasty that exteriorizes or brings forward the clitoris and allows for voiding while standing. The scrotum is created from the labia majora with a good cosmetic effect, and testicular prostheses can be implanted. These procedures, as well as oophorectomy, vaginectomy, and complete hysterectomy, are undertaken after a few years of androgen therapy and can be safely performed vaginally with laparoscopy.

The ancillary surgery for the female-to-male transition that is extremely important is the mastectomy. Breast size only partially regresses with androgen therapy. In adults, discussion about mastectomy usually takes place after androgen therapy is begun. Since some FTM transsexual adolescents present after significant breast development has occurred, mastectomy may be considered before age 18.

Recommendations

5.1. We recommend that transsexual persons consider genital sex reassignment surgery only after both the physician responsible for endocrine transition therapy and the MHP find surgery advisable. (1 | ⊕◯◯◯)

5.2. We recommend that genital sex reassignment surgery be recommended only after completion of at least 1 year of consistent and compliant hormone treatment. (1 | ⊕◯◯◯)

5.3. We recommend that the physician responsible for endocrine treatment medically clear transsexual individuals for sex reassignment surgery and collaborate with the surgeon regarding hormone use during and after surgery. (1 | ⊕◯◯◯)

5.1.–5.3. Evidence

When a transsexual individual decides to have sex reassignment surgery, both the endocrinologist and the MHP must certify that he or she satisfies the eligibility and readiness criteria of the SOC (28) (Table 17).

There is some concern that estrogen therapy may cause an increased risk for venous thrombosis during or following surgery (21). For this reason, the surgeon and the endocrinologist should collaborate in making a decision about the use of hormones during the month before surgery.

Although one study suggests that preoperative factors such as compliance are less important for patient satisfaction than are the physical postoperative results (39), other studies and clinical experience dictate that individuals who do not follow medical instructions and work with their physicians toward a common goal do not do achieve treatment goals (155) and experience higher rates of postoperative infections and other complications (156, 157). It is also important that the person requesting surgery feel comfortable with the anatomical changes that have occurred during hormone therapy. Dissatisfaction with social and physical outcomes during the hormone transition may be a contraindication to surgery (78).

Transsexual individuals should be monitored by an endocrinologist after surgery. Those who undergo gonadectomy will require hormone replacement therapy or surveillance or both to prevent adverse effects of chronic hormone deficiency.

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WPATH WORLD PROFESSIONAL ASSOCIATION for TRANSGENDER HEALTH

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Standards of Care

for the Health of Transsexual, Transgender, and Gender-Nonconforming People

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The World Professional Association for Transgender Health

Version 7

AR-000469

WPATH WORLD PROFESSIONAL ASSOCIATION for TRANSGENDER HEALTH

Standards of Care

for the Health of Transsexual, Transgender, and Gender-Nonconforming People

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Purpose and Use of the *Standards of Care*

The World Professional Association for Transgender Health (WPATH)[I] is an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, advocacy, public policy, and respect in transsexual and transgender health. The vision of WPATH is a world wherein transsexual, transgender, and gender-nonconforming people benefit from access to evidence-based health care, social services, justice, and equality.

One of the main functions of WPATH is to promote the highest standards of health care for individuals through the articulation of *Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People*. The *SOC* are based on the best available science and expert professional consensus.[II] Most of the research and experience in this field comes from a North American and Western European perspective; thus, adaptations of the *SOC* to other parts of the world are necessary. Suggestions for ways of thinking about cultural relativity and cultural competence are included in this version of the *SOC*.

The overall goal of the *SOC* is to provide clinical guidance for health professionals to assist transsexual, transgender, and gender-nonconforming people with safe and effective pathways to achieving lasting personal comfort with their gendered selves, in order to maximize their overall health, psychological well-being, and self-fulfillment. This assistance may include primary care, gynecologic and urologic care, reproductive options, voice and communication therapy, mental health services (e.g., assessment, counseling, psychotherapy), and hormonal and surgical treatments. While this is primarily a document for health professionals, the *SOC* may also be used by individuals, their families, and social institutions to understand how they can assist with promoting optimal health for members of this diverse population.

WPATH recognizes that health is dependent upon not only good clinical care but also social and political climates that provide and ensure social tolerance, equality, and the full rights of citizenship. Health is promoted through public policies and legal reforms that promote tolerance and equity

I Formerly the Harry Benjamin International Gender Dysphoria Association

II The *Standards of Care (SOC), Version 7,* represents a significant departure from previous versions. Changes in this version are based upon significant cultural shifts, advances in clinical knowledge, and appreciation of the many health care issues that can arise for transsexual, transgender, and gender-nonconforming people beyond hormone therapy and surgery (Coleman, 2009a, b, c, d).

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for gender and sexual diversity and that eliminate prejudice, discrimination, and stigma. WPATH is committed to advocacy for these changes in public policies and legal reforms.

The *Standards of Care* Are Flexible Clinical Guidelines

The *SOC* are intended to be flexible in order to meet the diverse health care needs of transsexual, transgender, and gender-nonconforming people. While flexible, they offer standards for promoting optimal health care and guiding the treatment of people experiencing gender dysphoria—broadly defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics) (Fisk, 1974; Knudson, De Cuypere, & Bockting, 2010b).

As in all previous versions of the *SOC*, the criteria put forth in this document for hormone therapy and surgical treatments for gender dysphoria are clinical guidelines; individual health professionals and programs may modify them. Clinical departures from the *SOC* may come about because of a patient's unique anatomic, social, or psychological situation; an experienced health professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies. These departures should be recognized as such, explained to the patient, and documented through informed consent for quality patient care and legal protection. This documentation is also valuable for the accumulation of new data, which can be retrospectively examined to allow for health care—and the *SOC*—to evolve.

The *SOC* articulate standards of care but also acknowledge the role of making informed choices and the value of harm-reduction approaches. In addition, this version of the *SOC* recognizes and validates various expressions of gender that may not necessitate psychological, hormonal, or surgical treatments. Some patients who present for care will have made significant self-directed progress towards gender role changes, transition, or other resolutions regarding their gender identity or gender dysphoria. Other patients will require more intensive services. Health professionals can use the *SOC* to help patients consider the full range of health services open to them, in accordance with their clinical needs and goals for gender expression.

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Global Applicability of the *Standards of Care*

While the *SOC* are intended for worldwide use, WPATH acknowledges that much of the recorded clinical experience and knowledge in this area of health care is derived from North American and Western European sources. From place to place, both across and within nations, there are differences in all of the following: social attitudes towards transsexual, transgender, and gender-nonconforming people; constructions of gender roles and identities; language used to describe different gender identities; epidemiology of gender dysphoria; access to and cost of treatment; therapies offered; number and type of professionals who provide care; and legal and policy issues related to this area of health care (Winter, 2009).

It is impossible for the *SOC* to reflect all of these differences. In applying these standards to other cultural contexts, health professionals must be sensitive to these differences and adapt the *SOC* according to local realities. For example, in a number of cultures, gender-nonconforming people are found in such numbers and living in such ways as to make them highly socially visible (Peletz, 2006). In settings such as these, it is common for people to initiate a change in their gender expression and physical characteristics while in their teens or even earlier. Many grow up and live in a social, cultural, and even linguistic context quite unlike that of Western cultures. Yet almost all experience prejudice (Peletz, 2006; Winter, 2009). In many cultures, social stigma towards gender nonconformity is widespread and gender roles are highly prescriptive (Winter et al., 2009). Gender-nonconforming people in these settings are forced to be hidden and, therefore, may lack opportunities for adequate health care (Winter, 2009).

The *SOC* are not intended to limit efforts to provide the best available care to all individuals. Health professionals throughout the world—even in areas with limited resources and training opportunities—can apply the many core principles that undergird the *SOC*. These principles include the following: Exhibit respect for patients with nonconforming gender identities (do not pathologize differences in gender identity or expression); provide care (or refer to knowledgeable colleagues) that affirms patients' gender identities and reduces the distress of gender dysphoria, when present; become knowledgeable about the health care needs of transsexual, transgender, and gender-nonconforming people, including the benefits and risks of treatment options for gender dysphoria; match the treatment approach to the specific needs of patients, particularly their goals for gender expression and need for relief from gender dysphoria; facilitate access to appropriate care; seek patients' informed consent before providing treatment; offer continuity of care; and be prepared to support and advocate for patients within their families and communities (schools, workplaces, and other settings).

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Terminology is culture- and time-dependent and is rapidly evolving. It is important to use respectful language in different places and times, and among different people. As the *SOC* are translated into other languages, great care must be taken to ensure that the meanings of terms are accurately translated. Terminology in English may not be easily translated into other languages, and vice versa. Some languages do not have equivalent words to describe the various terms within this document; hence, translators should be cognizant of the underlying goals of treatment and articulate culturally applicable guidance for reaching those goals.

III

The Difference Between Gender Nonconformity and Gender Dysphoria

Being Transsexual, Transgender, or Gender-Nonconforming Is a Matter of Diversity, Not Pathology

WPATH released a statement in May 2010 urging the de-psychopathologization of gender nonconformity worldwide (WPATH Board of Directors, 2010). This statement noted that "the expression of gender characteristics, including identities, that are not stereotypically associated with one's assigned sex at birth is a common and culturally diverse human phenomenon [that] should not be judged as inherently pathological or negative."

Unfortunately, there is stigma attached to gender nonconformity in many societies around the world. Such stigma can lead to prejudice and discrimination, resulting in "minority stress" (I. H. Meyer, 2003). Minority stress is unique (additive to general stressors experienced by all people), socially based, and chronic, and may make transsexual, transgender, and gender-nonconforming individuals more vulnerable to developing mental health concerns such as anxiety and depression (Institute of Medicine, 2011). In addition to prejudice and discrimination in society at large, stigma can contribute to abuse and neglect in one's relationships with peers and family members, which in turn can lead to psychological distress. However, these symptoms are socially induced and are not inherent to being transsexual, transgender, or gender-nonconforming.

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Gender Nonconformity Is Not the Same as Gender Dysphoria

Gender nonconformity refers to the extent to which a person's gender identity, role, or expression differs from the cultural norms prescribed for people of a particular sex (Institute of Medicine, 2011). *Gender dysphoria* refers to discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics) (Fisk, 1974; Knudson, De Cuypere, & Bockting, 2010b). Only *some* gender-nonconforming people experience gender dysphoria at *some* point in their lives.

Treatment is available to assist people with such distress to explore their gender identity and find a gender role that is comfortable for them (Bockting & Goldberg, 2006). Treatment is individualized: What helps one person alleviate gender dysphoria might be very different from what helps another person. This process may or may not involve a change in gender expression or body modifications. Medical treatment options include, for example, feminization or masculinization of the body through hormone therapy and/or surgery, which are effective in alleviating gender dysphoria and are medically necessary for many people. Gender identities and expressions are diverse, and hormones and surgery are just two of many options available to assist people with achieving comfort with self and identity.

Gender dysphoria can in large part be alleviated through treatment (Murad et al., 2010). Hence, while transsexual, transgender, and gender-nonconforming people may experience gender dysphoria at some points in their lives, many individuals who receive treatment will find a gender role and expression that is comfortable for them, even if these differ from those associated with their sex assigned at birth, or from prevailing gender norms and expectations.

Diagnoses Related to Gender Dysphoria

Some people experience gender dysphoria at such a level that the distress meets criteria for a formal diagnosis that might be classified as a mental disorder. Such a diagnosis is not a license for stigmatization or for the deprivation of civil and human rights. Existing classification systems such as the *Diagnostic Statistical Manual of Mental Disorders (DSM)* (American Psychiatric Association, 2000) and the *International Classification of Diseases* (*ICD*) (World Health Organization, 2007) define hundreds of mental disorders that vary in onset, duration, pathogenesis, functional disability, and treatability. All of these systems attempt to classify clusters of symptoms and conditions, not the individuals themselves. A disorder is a description of something with which a person might struggle, not a description of the person or the person's identity.

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Thus, transsexual, transgender, and gender-nonconforming individuals are not inherently disordered. Rather, the distress of gender dysphoria, when present, is the concern that might be diagnosable and for which various treatment options are available. The existence of a diagnosis for such dysphoria often facilitates access to health care and can guide further research into effective treatments.

Research is leading to new diagnostic nomenclatures, and terms are changing in both the *DSM* (Cohen-Kettenis & Pfäfflin, 2010; Knudson, De Cuypere, & Bockting, 2010b; Meyer-Bahlburg, 2010; Zucker, 2010) and the *ICD*. For this reason, familiar terms are employed in the *SOC* and definitions are provided for terms that may be emerging. Health professionals should refer to the most current diagnostic criteria and appropriate codes to apply in their practice areas.

IV
Epidemiologic Considerations

Formal epidemiologic studies on the incidence[III] and prevalence[IV] of transsexualism specifically or transgender and gender-nonconforming identities in general have not been conducted, and efforts to achieve realistic estimates are fraught with enormous difficulties (Institute of Medicine, 2011; Zucker & Lawrence, 2009). Even if epidemiologic studies established that a similar proportion of transsexual, transgender, or gender-nonconforming people existed all over the world, it is likely that cultural differences from one country to another would alter both the behavioral expressions of different gender identities and the extent to which gender dysphoria—distinct from one's gender identity—is actually occurring in a population. While in most countries, crossing normative gender boundaries generates moral censure rather than compassion, there are examples in certain cultures of gender-nonconforming behaviors (e.g., in spiritual leaders) that are less stigmatized and even revered (Besnier, 1994; Bolin, 1988; Chiñas, 1995; Coleman, Colgan, & Gooren, 1992; Costa & Matzner, 2007; Jackson & Sullivan, 1999; Nanda, 1998; Taywaditep, Coleman, & Dumronggittigule, 1997).

For various reasons, researchers who have studied incidence and prevalence have tended to focus on the most easily counted subgroup of gender-nonconforming individuals: transsexual individuals who experience gender dysphoria and who present for gender-transition-related care at specialist gender clinics (Zucker & Lawrence, 2009). Most studies have been conducted in European countries such as Sweden (Wålinder, 1968, 1971), the United Kingdom (Hoenig & Kenna, 1974),

III **incidence**—the number of new cases arising in a given period (e.g., a year)
IV **prevalence**—the number of individuals having a condition, divided by the number of people in the general population

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the Netherlands (Bakker, Van Kesteren, Gooren, & Bezemer, 1993; Eklund, Gooren, & Bezemer, 1988; van Kesteren, Gooren, & Megens, 1996), Germany (Weitze & Osburg, 1996), and Belgium (De Cuypere et al., 2007). One was conducted in Singapore (Tsoi, 1988).

De Cuypere and colleagues (2007) reviewed such studies, as well as conducted their own. Together, those studies span 39 years. Leaving aside two outlier findings from Pauly in 1965 and Tsoi in 1988, ten studies involving eight countries remain. The prevalence figures reported in these ten studies range from 1:11,900 to 1:45,000 for male-to-female individuals (MtF) and 1:30,400 to 1:200,000 for female-to-male (FtM) individuals. Some scholars have suggested that the prevalence is much higher, depending on the methodology used in the research (e.g., Olyslager & Conway, 2007).

Direct comparisons across studies are impossible, as each differed in their data collection methods and in their criteria for documenting a person as transsexual (e.g., whether or not a person had undergone genital reconstruction, versus had initiated hormone therapy, versus had come to the clinic seeking medically supervised transition services). The trend appears to be towards higher prevalence rates in the more recent studies, possibly indicating increasing numbers of people seeking clinical care. Support for this interpretation comes from research by Reed and colleagues (2009), who reported a doubling of the numbers of people accessing care at gender clinics in the United Kingdom every five or six years. Similarly, Zucker and colleagues (2008) reported a four- to five-fold increase in child and adolescent referrals to their Toronto, Canada clinic over a 30-year period.

The numbers yielded by studies such as these can be considered minimum estimates at best. The published figures are mostly derived from clinics where patients met criteria for severe gender dysphoria and had access to health care at those clinics. These estimates do not take into account that treatments offered in a particular clinic setting might not be perceived as affordable, useful, or acceptable by all self-identified gender dysphoric individuals in a given area. By counting only those people who present at clinics for a specific type of treatment, an unspecified number of gender dysphoric individuals are overlooked.

Other clinical observations (not yet firmly supported by systematic study) support the likelihood of a higher prevalence of gender dysphoria: (i) Previously unrecognized gender dysphoria is occasionally diagnosed when patients are seen with anxiety, depression, conduct disorder, substance abuse, dissociative identity disorders, borderline personality disorder, sexual disorders, and disorders of sex development (Cole, O'Boyle, Emory, & Meyer III, 1997). (ii) Some crossdressers, drag queens/kings or female/male impersonators, and gay and lesbian individuals may be experiencing gender dysphoria (Bullough & Bullough, 1993). (iii) The intensity of some people's gender dysphoria fluctuates below and above a clinical threshold (Docter, 1988). (iv) Gender nonconformity among FtM individuals tends to be relatively invisible in many cultures, particularly to Western health

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professionals and researchers who have conducted most of the studies on which the current estimates of prevalence and incidence are based (Winter, 2009).

Overall, the existing data should be considered a starting point, and health care would benefit from more rigorous epidemiologic study in different locations worldwide.

V

Overview of Therapeutic Approaches for Gender Dysphoria

Advancements in the Knowledge and Treatment of Gender Dysphoria

In the second half of the 20th century, awareness of the phenomenon of gender dysphoria increased when health professionals began to provide assistance to alleviate gender dysphoria by supporting changes in primary and secondary sex characteristics through hormone therapy and surgery, along with a change in gender role. Although Harry Benjamin already acknowledged a spectrum of gender nonconformity (Benjamin, 1966), the initial clinical approach largely focused on identifying who was an appropriate candidate for sex reassignment to facilitate a physical change from male to female or female to male as completely as possible (e.g., Green & Fleming, 1990; Hastings, 1974). This approach was extensively evaluated and proved to be highly effective. Satisfaction rates across studies ranged from 87% of MtF patients to 97% of FtM patients (Green & Fleming, 1990), and regrets were extremely rare (1–1.5% of MtF patients and <1% of FtM patients; Pfäfflin, 1993). Indeed, hormone therapy and surgery have been found to be medically necessary to alleviate gender dysphoria in many people (American Medical Association, 2008; Anton, 2009; World Professional Association for Transgender Health, 2008).

As the field matured, health professionals recognized that while many individuals need both hormone therapy and surgery to alleviate their gender dysphoria, others need only one of these treatment options and some need neither (Bockting & Goldberg, 2006; Bockting, 2008; Lev, 2004). Often with the help of psychotherapy, some individuals integrate their trans- or cross-gender feelings into the gender role they were assigned at birth and do not feel the need to feminize or masculinize their body. For others, changes in gender role and expression are sufficient to alleviate

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gender dysphoria. Some patients may need hormones, a possible change in gender role, but not surgery; others may need a change in gender role along with surgery, but not hormones. In other words, treatment for gender dysphoria has become more individualized.

As a generation of transsexual, transgender, and gender-nonconforming individuals has come of age—many of whom have benefitted from different therapeutic approaches—they have become more visible as a community and demonstrated considerable diversity in their gender identities, roles, and expressions. Some individuals describe themselves not as gender-nonconforming but as unambiguously cross-sexed (i.e., as a member of the other sex; Bockting, 2008). Other individuals affirm their unique gender identity and no longer consider themselves to be either male or female (Bornstein, 1994; Kimberly, 1997; Stone, 1991; Warren, 1993). Instead, they may describe their gender identity in specific terms such as transgender, bigender, or genderqueer, affirming their unique experiences that may transcend a male/female binary understanding of gender (Bockting, 2008; Ekins & King, 2006; Nestle, Wilchins, & Howell, 2002). They may not experience their process of identity affirmation as a "transition," because they never fully embraced the gender role they were assigned at birth or because they actualize their gender identity, role, and expression in a way that does not involve a change from one gender role to another. For example, some youth identifying as genderqueer have always experienced their gender identity and role as such (genderqueer). Greater public visibility and awareness of gender diversity (Feinberg, 1996) has further expanded options for people with gender dysphoria to actualize an identity and find a gender role and expression that are comfortable for them.

Health professionals can assist gender dysphoric individuals with affirming their gender identity, exploring different options for expression of that identity, and making decisions about medical treatment options for alleviating gender dysphoria.

Options for Psychological and Medical Treatment of Gender Dysphoria

For individuals seeking care for gender dysphoria, a variety of therapeutic options can be considered. The number and type of interventions applied and the order in which these take place may differ from person to person (e.g., Bockting, Knudson, & Goldberg, 2006; Bolin, 1994; Rachlin, 1999; Rachlin, Green, & Lombardi, 2008; Rachlin, Hansbury, & Pardo, 2010). Treatment options include the following:

- Changes in gender expression and role (which may involve living part time or full time in another gender role, consistent with one's gender identity);
- Hormone therapy to feminize or masculinize the body;

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- Surgery to change primary and/or secondary sex characteristics (e.g., breasts/chest, external and/or internal genitalia, facial features, body contouring);
- Psychotherapy (individual, couple, family, or group) for purposes such as exploring gender identity, role, and expression; addressing the negative impact of gender dysphoria and stigma on mental health; alleviating internalized transphobia; enhancing social and peer support; improving body image; or promoting resilience.

Options for Social Support and Changes in Gender Expression

In addition (or as an alternative) to the psychological- and medical-treatment options described above, other options can be considered to help alleviate gender dysphoria, for example:

- In-person and online peer support resources, groups, or community organizations that provide avenues for social support and advocacy;
- In-person and online support resources for families and friends;
- Voice and communication therapy to help individuals develop verbal and non-verbal communication skills that facilitate comfort with their gender identity;
- Hair removal through electrolysis, laser treatment, or waxing;
- Breast binding or padding, genital tucking or penile prostheses, padding of hips or buttocks;
- Changes in name and gender marker on identity documents.

VI

Assessment and Treatment of Children and Adolescents With Gender Dysphoria

There are a number of differences in the phenomenology, developmental course, and treatment approaches for gender dysphoria in children, adolescents, and adults. In children and adolescents, a rapid and dramatic developmental process (physical, psychological, and sexual) is involved and

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there is greater fluidity and variability in outcomes, particularly in prepubertal children. Accordingly, this section of the *SOC* offers specific clinical guidelines for the assessment and treatment of gender dysphoric children and adolescents.

Differences Between Children and Adolescents with Gender Dysphoria

An important difference between gender dysphoric children and adolescents is in the proportion for whom dysphoria persists into adulthood. Gender dysphoria during childhood does not inevitably continue into adulthood.[V] Rather, in follow-up studies of prepubertal children (mainly boys) who were referred to clinics for assessment of gender dysphoria, the dysphoria persisted into adulthood for only 6–23% of children (Cohen-Kettenis, 2001; Zucker & Bradley, 1995). Boys in these studies were more likely to identify as gay in adulthood than as transgender (Green, 1987; Money & Russo, 1979; Zucker & Bradley, 1995; Zuger, 1984). Newer studies, also including girls, showed a 12–27% persistence rate of gender dysphoria into adulthood (Drummond, Bradley, Peterson-Badali, & Zucker, 2008; Wallien & Cohen-Kettenis, 2008).

In contrast, the persistence of gender dysphoria into adulthood appears to be much higher for adolescents. No formal prospective studies exist. However, in a follow-up study of 70 adolescents who were diagnosed with gender dysphoria and given puberty-suppressing hormones, all continued with actual sex reassignment, beginning with feminizing/masculinizing hormone therapy (de Vries, Steensma, Doreleijers, & Cohen-Kettenis, 2010).

Another difference between gender dysphoric children and adolescents is in the sex ratios for each age group. In clinically referred, gender dysphoric children under age 12, the male/female ratio ranges from 6:1 to 3:1 (Zucker, 2004). In clinically referred, gender dysphoric adolescents older than age 12, the male/female ratio is close to 1:1 (Cohen-Kettenis & Pfäfflin, 2003).

As discussed in section IV and by Zucker and Lawrence (2009), formal epidemiologic studies on gender dysphoria—in children, adolescents, and adults—are lacking. Additional research is needed to refine estimates of its prevalence and persistence in different populations worldwide.

V Gender-nonconforming behaviors in children may continue into adulthood, but such behaviors are not necessarily indicative of gender dysphoria and a need for treatment. As described in section III, gender dysphoria is not synonymous with diversity in gender expression.

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Phenomenology in Children

Children as young as age two may show features that could indicate gender dysphoria. They may express a wish to be of the other sex and be unhappy about their physical sex characteristics and functions. In addition, they may prefer clothes, toys, and games that are commonly associated with the other sex and prefer playing with other-sex peers. There appears to be heterogeneity in these features: Some children demonstrate extremely gender-nonconforming behavior and wishes, accompanied by persistent and severe discomfort with their primary sex characteristics. In other children, these characteristics are less intense or only partially present (Cohen-Kettenis et al., 2006; Knudson, De Cuypere, & Bockting, 2010a).

It is relatively common for gender dysphoric children to have coexisting internalizing disorders such as anxiety and depression (Cohen-Kettenis, Owen, Kaijser, Bradley, & Zucker, 2003; Wallien, Swaab, & Cohen-Kettenis, 2007; Zucker, Owen, Bradley, & Ameeriar, 2002). The prevalence of autism spectrum disorders seems to be higher in clinically referred, gender dysphoric children than in the general population (de Vries, Noens, Cohen-Kettenis, van Berckelaer-Onnes, & Doreleijers, 2010).

Phenomenology in Adolescents

In most children, gender dysphoria will disappear before, or early in, puberty. However, in some children these feelings will intensify and body aversion will develop or increase as they become adolescents and their secondary sex characteristics develop (Cohen-Kettenis, 2001; Cohen-Kettenis & Pfäfflin, 2003; Drummond et al., 2008; Wallien & Cohen-Kettenis, 2008; Zucker & Bradley, 1995). Data from one study suggest that more extreme gender nonconformity in childhood is associated with persistence of gender dysphoria into late adolescence and early adulthood (Wallien & Cohen-Kettenis, 2008). Yet many adolescents and adults presenting with gender dysphoria do not report a history of childhood gender-nonconforming behaviors (Docter, 1988; Landén, Wålinder, & Lundström, 1998). Therefore, it may come as a surprise to others (parents, other family members, friends, and community members) when a youth's gender dysphoria first becomes evident in adolescence.

Adolescents who experience their primary and/or secondary sex characteristics and their sex assigned at birth as inconsistent with their gender identity may be intensely distressed about it. Many, but not all, gender dysphoric adolescents have a strong wish for hormones and surgery. Increasing numbers of adolescents have already started living in their desired gender role upon entering high school (Cohen-Kettenis & Pfäfflin, 2003).

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Among adolescents who are referred to gender identity clinics, the number considered eligible for early medical treatment—starting with GnRH analogues to suppress puberty in the first Tanner stages—differs among countries and centers. Not all clinics offer puberty suppression. If such treatment is offered, the pubertal stage at which adolescents are allowed to start varies from Tanner stage 2 to stage 4 (Delemarre-van de Waal & Cohen-Kettenis, 2006; Zucker et al., 2012). The percentages of treated adolescents are likely influenced by the organization of health care, insurance aspects, cultural differences, opinions of health professionals, and diagnostic procedures offered in different settings.

Inexperienced clinicians may mistake indications of gender dysphoria for delusions. Phenomenologically, there is a qualitative difference between the presentation of gender dysphoria and the presentation of delusions or other psychotic symptoms. The vast majority of children and adolescents with gender dysphoria are not suffering from underlying severe psychiatric illness such as psychotic disorders (Steensma, Biemond, de Boer, & Cohen-Kettenis, published online ahead of print January 7, 2011).

It is more common for adolescents with gender dysphoria to have coexisting internalizing disorders such as anxiety and depression, and/or externalizing disorders such as oppositional defiant disorder (de Vries et al., 2010). As in children, there seems to be a higher prevalence of autistic spectrum disorders in clinically referred, gender dysphoric adolescents than in the general adolescent population (de Vries et al., 2010).

Competency of Mental Health Professionals Working with Children or Adolescents with Gender Dysphoria

The following are recommended minimum credentials for mental health professionals who assess, refer, and offer therapy to children and adolescents presenting with gender dysphoria:

1. Meet the competency requirements for mental health professionals working with adults, as outlined in section VII;

2. Trained in childhood and adolescent developmental psychopathology;

3. Competent in diagnosing and treating the ordinary problems of children and adolescents.

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Roles of Mental Health Professionals Working with Children and Adolescents with Gender Dysphoria

The roles of mental health professionals working with gender dysphoric children and adolescents may include the following:

1. Directly assess gender dysphoria in children and adolescents (see general guidelines for assessment, below).

2. Provide family counseling and supportive psychotherapy to assist children and adolescents with exploring their gender identity, alleviating distress related to their gender dysphoria, and ameliorating any other psychosocial difficulties.

3. Assess and treat any coexisting mental health concerns of children or adolescents (or refer to another mental health professional for treatment). Such concerns should be addressed as part of the overall treatment plan.

4. Refer adolescents for additional physical interventions (such as puberty-suppressing hormones) to alleviate gender dysphoria. The referral should include documentation of an assessment of gender dysphoria and mental health, the adolescent's eligibility for physical interventions (outlined below), the mental health professional's relevant expertise, and any other information pertinent to the youth's health and referral for specific treatments.

5. Educate and advocate on behalf of gender dysphoric children, adolescents, and their families in their community (e.g., day care centers, schools, camps, other organizations). This is particularly important in light of evidence that children and adolescents who do not conform to socially prescribed gender norms may experience harassment in school (Grossman, D'Augelli, & Salter, 2006; Grossman, D'Augelli, Howell, & Hubbard, 2006; Sausa, 2005), putting them at risk for social isolation, depression, and other negative sequelae (Nuttbrock et al., 2010).

6. Provide children, youth, and their families with information and referral for peer support, such as support groups for parents of gender-nonconforming and transgender children (Gold & MacNish, 2011; Pleak, 1999; Rosenberg, 2002).

Assessment and psychosocial interventions for children and adolescents are often provided within a multidisciplinary gender identity specialty service. If such a multidisciplinary service is not available, a mental health professional should provide consultation and liaison arrangements with a pediatric endocrinologist for the purpose of assessment, education, and involvement in any decisions about physical interventions.

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Psychological Assessment of Children and Adolescents

When assessing children and adolescents who present with gender dysphoria, mental health professionals should broadly conform to the following guidelines:

1. Mental health professionals should not dismiss or express a negative attitude towards nonconforming gender identities or indications of gender dysphoria. Rather, they should acknowledge the presenting concerns of children, adolescents, and their families; offer a thorough assessment for gender dysphoria and any coexisting mental health concerns; and educate clients and their families about therapeutic options, if needed. Acceptance, and alleviation of secrecy, can bring considerable relief to gender dysphoric children/adolescents and their families.

2. Assessment of gender dysphoria and mental health should explore the nature and characteristics of a child's or adolescent's gender identity. A psychodiagnostic and psychiatric assessment—covering the areas of emotional functioning, peer and other social relationships, and intellectual functioning/school achievement—should be performed. Assessment should include an evaluation of the strengths and weaknesses of family functioning. Emotional and behavioral problems are relatively common, and unresolved issues in a child's or youth's environment may be present (de Vries, Doreleijers, Steensma, & Cohen-Kettenis, 2011; Di Ceglie & Thümmel, 2006; Wallien et al., 2007).

3. For adolescents, the assessment phase should also be used to inform youth and their families about the possibilities and limitations of different treatments. This is necessary for informed consent, but also important for assessment. The way that adolescents respond to information about the reality of sex reassignment can be diagnostically informative. Correct information may alter a youth's desire for certain treatment, if the desire was based on unrealistic expectations of its possibilities.

Psychological and Social Interventions for Children and Adolescents

When supporting and treating children and adolescents with gender dysphoria, health professionals should broadly conform to the following guidelines:

1. Mental health professionals should help families to have an accepting and nurturing response to the concerns of their gender dysphoric child or adolescent. Families play an important role in the psychological health and well-being of youth (Brill & Pepper, 2008; Lev, 2004). This also applies to peers and mentors from the community, who can be another source of social support.

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2. Psychotherapy should focus on reducing a child's or adolescent's distress related to the gender dysphoria and on ameliorating any other psychosocial difficulties. For youth pursuing sex reassignment, psychotherapy may focus on supporting them before, during, and after reassignment. Formal evaluations of different psychotherapeutic approaches for this situation have not been published, but several counseling methods have been described (Cohen-Kettenis, 2006; de Vries, Cohen-Kettenis, & Delemarre-van de Waal, 2006; Di Ceglie & Thümmel, 2006; Hill, Menvielle, Sica, & Johnson, 2010; Malpas, in press; Menvielle & Tuerk, 2002; Rosenberg, 2002; Vanderburgh, 2009; Zucker, 2006).

   Treatment aimed at trying to change a person's gender identity and expression to become more congruent with sex assigned at birth has been attempted in the past without success (Gelder & Marks, 1969; Greenson, 1964), particularly in the long term (Cohen-Kettenis & Kuiper, 1984; Pauly, 1965). Such treatment is no longer considered ethical.

3. Families should be supported in managing uncertainty and anxiety about their child's or adolescent's psychosexual outcomes and in helping youth to develop a positive self-concept.

4. Mental health professionals should not impose a binary view of gender. They should give ample room for clients to explore different options for gender expression. Hormonal or surgical interventions are appropriate for some adolescents, but not for others.

5. Clients and their families should be supported in making difficult decisions regarding the extent to which clients are allowed to express a gender role that is consistent with their gender identity, as well as the timing of changes in gender role and possible social transition. For example, a client might attend school while undergoing social transition only partly (e.g., by wearing clothing and having a hairstyle that reflects gender identity) or completely (e.g., by also using a name and pronouns congruent with gender identity). Difficult issues include whether and when to inform other people of the client's situation, and how others in their lives might respond.

6. Health professionals should support clients and their families as educators and advocates in their interactions with community members and authorities such as teachers, school boards, and courts.

7. Mental health professionals should strive to maintain a therapeutic relationship with gender-nonconforming children/adolescents and their families throughout any subsequent social changes or physical interventions. This ensures that decisions about gender expression and the treatment of gender dysphoria are thoughtfully and recurrently considered. The same reasoning applies if a child or adolescent has already socially changed gender role prior to being seen by a mental health professional.

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Social Transition in Early Childhood

Some children state that they want to make a social transition to a different gender role long before puberty. For some children, this may reflect an expression of their gender identity. For others, this could be motivated by other forces. Families vary in the extent to which they allow their young children to make a social transition to another gender role. Social transitions in early childhood do occur within some families with early success. This is a controversial issue, and divergent views are held by health professionals. The current evidence base is insufficient to predict the long-term outcomes of completing a gender role transition during early childhood. Outcomes research with children who completed early social transitions would greatly inform future clinical recommendations.

Mental health professionals can help families to make decisions regarding the timing and process of any gender role changes for their young children. They should provide information and help parents to weigh the potential benefits and challenges of particular choices. Relevant in this respect are the previously described relatively low persistence rates of childhood gender dysphoria (Drummond et al., 2008; Wallien & Cohen-Kettenis, 2008). A change back to the original gender role can be highly distressing and even result in postponement of this second social transition on the child's part (Steensma & Cohen-Kettenis, 2011). For reasons such as these, parents may want to present this role change as an exploration of living in another gender role rather than an irreversible situation. Mental health professionals can assist parents in identifying potential in-between solutions or compromises (e.g., only when on vacation). It is also important that parents explicitly let the child know that there is a way back.

Regardless of a family's decisions regarding transition (timing, extent), professionals should counsel and support them as they work through the options and implications. If parents do not allow their young child to make a gender-role transition, they may need counseling to assist them with meeting their child's needs in a sensitive and nurturing way, ensuring that the child has ample possibilities to explore gender feelings and behavior in a safe environment. If parents do allow their young child to make a gender role transition, they may need counseling to facilitate a positive experience for their child. For example, they may need support in using correct pronouns, maintaining a safe and supportive environment for their transitioning child (e.g., in school, peer group settings), and communicating with other people in their child's life. In either case, as a child nears puberty, further assessment may be needed as options for physical interventions become relevant.

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Physical Interventions for Adolescents

Before any physical interventions are considered for adolescents, extensive exploration of psychological, family, and social issues should be undertaken, as outlined above. The duration of this exploration may vary considerably depending on the complexity of the situation.

Physical interventions should be addressed in the context of adolescent development. Some identity beliefs in adolescents may become firmly held and strongly expressed, giving a false impression of irreversibility. An adolescent's shift towards gender conformity can occur primarily to please the parents and may not persist or reflect a permanent change in gender dysphoria (Hembree et al., 2009; Steensma et al., published online ahead of print January 7, 2011).

Physical interventions for adolescents fall into three categories or stages (Hembree et al., 2009):

1. *Fully reversible interventions*. These involve the use of GnRH analogues to suppress estrogen or testosterone production and consequently delay the physical changes of puberty. Alternative treatment options include progestins (most commonly medroxyprogesterone) or other medications (such as spironolactone) that decrease the effects of androgens secreted by the testicles of adolescents who are not receiving GnRH analogues. Continuous oral contraceptives (or depot medroxyprogesterone) may be used to suppress menses.

2. *Partially reversible interventions*. These include hormone therapy to masculinize or feminize the body. Some hormone-induced changes may need reconstructive surgery to reverse the effect (e.g., gynaecomastia caused by estrogens), while other changes are not reversible (e.g., deepening of the voice caused by testosterone).

3. *Irreversible interventions*. These are surgical procedures.

A staged process is recommended to keep options open through the first two stages. Moving from one stage to another should not occur until there has been adequate time for adolescents and their parents to assimilate fully the effects of earlier interventions.

Fully Reversible Interventions

Adolescents may be eligible for puberty-suppressing hormones as soon as pubertal changes have begun. In order for adolescents and their parents to make an informed decision about pubertal delay, it is recommended that adolescents experience the onset of puberty to at least Tanner Stage 2. Some children may arrive at this stage at very young ages (e.g., 9 years of age). Studies

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evaluating this approach have only included children who were at least 12 years of age (Cohen-Kettenis, Schagen, Steensma, de Vries, & Delemarre-van de Waal, 2011; de Vries, Steensma et al., 2010; Delemarre-van de Waal, van Weissenbruch, & Cohen Kettenis, 2004; Delemarre-van de Waal & Cohen-Kettenis, 2006).

Two goals justify intervention with puberty-suppressing hormones: (i) their use gives adolescents more time to explore their gender nonconformity and other developmental issues; and (ii) their use may facilitate transition by preventing the development of sex characteristics that are difficult or impossible to reverse if adolescents continue on to pursue sex reassignment.

Puberty suppression may continue for a few years, at which time a decision is made to either discontinue all hormone therapy or transition to a feminizing/masculinizing hormone regimen. Pubertal suppression does not inevitably lead to social transition or to sex reassignment.

Criteria for Puberty-Suppressing Hormones

In order for adolescents to receive puberty-suppressing hormones, the following minimum criteria must be met:

1. The adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed);

2. Gender dysphoria emerged or worsened with the onset of puberty;

3. Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment;

4. The adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process.

Regimens, Monitoring, and Risks for Puberty Suppression

For puberty suppression, adolescents with male genitalia should be treated with GnRH analogues, which stop luteinizing hormone secretion and therefore testosterone secretion. Alternatively, they may be treated with progestins (such as medroxyprogesterone) or with other medications that block testosterone secretion and/or neutralize testosterone action. Adolescents with female genitalia should be treated with GnRH analogues, which stop the production of estrogens and

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progesterone. Alternatively, they may be treated with progestins (such as medroxyprogesterone). Continuous oral contraceptives (or depot medroxyprogesterone) may be used to suppress menses. In both groups of adolescents, use of GnRH analogues is the preferred treatment (Hembree et al., 2009), but their high cost is prohibitive for some patients.

During pubertal suppression, an adolescent's physical development should be carefully monitored—preferably by a pediatric endocrinologist—so that any necessary interventions can occur (e.g., to establish an adequate gender appropriate height, to improve iatrogenic low bone mineral density) (Hembree et al., 2009).

Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. Intervention in early adolescence should be managed with pediatric endocrinological advice, when available. Adolescents with male genitalia who start GnRH analogues early in puberty should be informed that this could result in insufficient penile tissue for penile inversion vaginoplasty techniques (alternative techniques, such as the use of a skin graft or colon tissue, are available).

Neither puberty suppression nor allowing puberty to occur is a neutral act. On the one hand, functioning in later life can be compromised by the development of irreversible secondary sex characteristics during puberty and by years spent experiencing intense gender dysphoria. On the other hand, there are concerns about negative physical side effects of GnRH analogue use (e.g., on bone development and height). Although the very first results of this approach (as assessed for adolescents followed over 10 years) are promising (Cohen-Kettenis et al., 2011; Delemarre-van de Waal & Cohen-Kettenis, 2006), the long-term effects can only be determined when the earliest-treated patients reach the appropriate age.

Partially Reversible Interventions

Adolescents may be eligible to begin feminizing/masculinizing hormone therapy, preferably with parental consent. In many countries, 16-year-olds are legal adults for medical decision-making and do not require parental consent. Ideally, treatment decisions should be made among the adolescent, the family, and the treatment team.

Regimens for hormone therapy in gender dysphoric adolescents differ substantially from those used in adults (Hembree et al., 2009). The hormone regimens for youth are adapted to account for the somatic, emotional, and mental development that occurs throughout adolescence (Hembree et al., 2009).

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Irreversible Interventions

Genital surgery should not be carried out until (i) patients reach the legal age of majority to give consent for medical procedures in a given country, and (ii) patients have lived continuously for at least 12 months in the gender role that is congruent with their gender identity. The age threshold should be seen as a minimum criterion and not an indication in and of itself for active intervention.

Chest surgery in FtM patients could be carried out earlier, preferably after ample time of living in the desired gender role and after one year of testosterone treatment. The intent of this suggested sequence is to give adolescents sufficient opportunity to experience and socially adjust in a more masculine gender role, before undergoing irreversible surgery. However, different approaches may be more suitable, depending on an adolescent's specific clinical situation and goals for gender identity expression.

Risks of Withholding Medical Treatment for Adolescents

Refusing timely medical interventions for adolescents might prolong gender dysphoria and contribute to an appearance that could provoke abuse and stigmatization. As the level of gender-related abuse is strongly associated with the degree of psychiatric distress during adolescence (Nuttbrock et al., 2010), withholding puberty suppression and subsequent feminizing or masculinizing hormone therapy is not a neutral option for adolescents.

VII
Mental Health

Transsexual, transgender, and gender-nonconforming people might seek the assistance of a mental health professional for any number of reasons. Regardless of a person's reason for seeking care, mental health professionals should have familiarity with gender nonconformity, act with appropriate cultural competence, and exhibit sensitivity in providing care.

This section of the *SOC* focuses on the role of mental health professionals in the care of adults seeking help for gender dysphoria and related concerns. Professionals working with gender dysphoric children, adolescents, and their families should consult section VI.

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Competency of Mental Health Professionals Working with Adults Who Present with Gender Dysphoria

The training of mental health professionals competent to work with gender dysphoric adults rests upon basic general clinical competence in the assessment, diagnosis, and treatment of mental health concerns. Clinical training may occur within any discipline that prepares mental health professionals for clinical practice, such as psychology, psychiatry, social work, mental health counseling, marriage and family therapy, nursing, or family medicine with specific training in behavioral health and counseling. The following are recommended minimum credentials for mental health professionals who work with adults presenting with gender dysphoria:

1. A master's degree or its equivalent in a clinical behavioral science field. This degree, or a more advanced one, should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent for that country.

2. Competence in using the *Diagnostic Statistical Manual of Mental Disorders* and/or the *International Classification of Diseases* for diagnostic purposes.

3. Ability to recognize and diagnose coexisting mental health concerns and to distinguish these from gender dysphoria.

4. Documented supervised training and competence in psychotherapy or counseling.

5. Knowledgeable about gender-nonconforming identities and expressions, and the assessment and treatment of gender dysphoria.

6. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

In addition to the minimum credentials above, it is recommended that mental health professionals develop and maintain cultural competence to facilitate their work with transsexual, transgender, and gender-nonconforming clients. This may involve, for example, becoming knowledgeable about current community, advocacy, and public policy issues relevant to these clients and their families. Additionally, knowledge about sexuality, sexual health concerns, and the assessment and treatment of sexual disorders is preferred.

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Mental health professionals who are new to the field (irrespective of their level of training and other experience) should work under the supervision of a mental health professional with established competence in the assessment and treatment of gender dysphoria.

Tasks of Mental Health Professionals Working with Adults Who Present with Gender Dysphoria

Mental health professionals may serve transsexual, transgender, and gender-nonconforming individuals and their families in many ways, depending on a client's needs. For example, mental health professionals may serve as a psychotherapist, counselor, or family therapist, or as a diagnostician/assessor, advocate, or educator.

Mental health professionals should determine a client's reasons for seeking professional assistance. For example, a client may be presenting for any combination of the following health care services: psychotherapeutic assistance to explore gender identity and expression or to facilitate a coming-out process; assessment and referral for feminizing/masculinizing medical interventions; psychological support for family members (partners, children, extended family); psychotherapy unrelated to gender concerns; or other professional services.

Below are general guidelines for common tasks that mental health professionals may fulfill in working with adults who present with gender dysphoria.

Tasks Related to Assessment and Referral

1. Assess Gender Dysphoria

Mental health professionals assess clients' gender dysphoria in the context of an evaluation of their psychosocial adjustment (Bockting et al., 2006; Lev, 2004, 2009). The evaluation includes, at a minimum, assessment of gender identity and gender dysphoria, history and development of gender dysphoric feelings, the impact of stigma attached to gender nonconformity on mental health, and the availability of support from family, friends, and peers (for example, in-person or online contact with other transsexual, transgender, or gender-nonconforming individuals or groups). The evaluation may result in no diagnosis, in a formal diagnosis related to gender dysphoria, and/or in other diagnoses that describe aspects of the client's health and psychosocial adjustment. The role

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of mental health professionals includes making reasonably sure that the gender dysphoria is not secondary to, or better accounted for, by other diagnoses.

Mental health professionals with the competencies described above (hereafter called "a qualified mental health professional") are best prepared to conduct this assessment of gender dysphoria. However, this task may instead be conducted by another type of health professional who has appropriate training in behavioral health and is competent in the assessment of gender dysphoria, particularly when functioning as part of a multidisciplinary specialty team that provides access to feminizing/masculinizing hormone therapy. This professional may be the prescribing hormone therapy provider or a member of that provider's health care team.

2. Provide Information Regarding Options for Gender Identity and Expression and Possible Medical Interventions

An important task of mental health professionals is to educate clients regarding the diversity of gender identities and expressions and the various options available to alleviate gender dysphoria. Mental health professionals then may facilitate a process (or refer elsewhere) in which clients explore these various options, with the goals of finding a comfortable gender role and expression and becoming prepared to make a fully informed decision about available medical interventions, if needed. This process may include referral for individual, family, and group therapy and/or to community resources and avenues for peer support. The professional and the client discuss the implications, both short- and long-term, of any changes in gender role and use of medical interventions. These implications can be psychological, social, physical, sexual, occupational, financial, and legal (Bockting et al., 2006; Lev, 2004).

This task is also best conducted by a qualified mental health professional, but may be conducted by another health professional with appropriate training in behavioral health and with sufficient knowledge about gender-nonconforming identities and expressions and about possible medical interventions for gender dysphoria, particularly when functioning as part of a multidisciplinary specialty team that provides access to feminizing/masculinizing hormone therapy.

3. Assess, Diagnose, and Discuss Treatment Options for Coexisting Mental Health Concerns

Clients presenting with gender dysphoria may struggle with a range of mental health concerns (Gómez-Gil, Trilla, Salamero, Godás, & Valdés, 2009; Murad et al., 2010) whether related or unrelated to what is often a long history of gender dysphoria and/or chronic minority stress. Possible concerns include anxiety, depression, self-harm, a history of abuse and neglect, compulsivity, substance abuse, sexual concerns, personality disorders, eating disorders, psychotic disorders, and autistic spectrum disorders (Bockting et al., 2006; Nuttbrock et al., 2010; Robinow, 2009). Mental health professionals should screen for these and other mental health concerns and incorporate

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the identified concerns into the overall treatment plan. These concerns can be significant sources of distress and, if left untreated, can complicate the process of gender identity exploration and resolution of gender dysphoria (Bockting et al., 2006; Fraser, 2009a; Lev, 2009). Addressing these concerns can greatly facilitate the resolution of gender dysphoria, possible changes in gender role, the making of informed decisions about medical interventions, and improvements in quality of life.

Some clients may benefit from psychotropic medications to alleviate symptoms or treat coexisting mental health concerns. Mental health professionals are expected to recognize this and either provide pharmacotherapy or refer to a colleague who is qualified to do so. The presence of coexisting mental health concerns does not necessarily preclude possible changes in gender role or access to feminizing/masculinizing hormones or surgery; rather, these concerns need to be optimally managed prior to, or concurrent with, treatment of gender dysphoria. In addition, clients should be assessed for their ability to provide educated and informed consent for medical treatments.

Qualified mental health professionals are specifically trained to assess, diagnose, and treat (or refer to treatment for) these coexisting mental health concerns. Other health professionals with appropriate training in behavioral health, particularly when functioning as part of a multidisciplinary specialty team providing access to feminizing/masculinizing hormone therapy, may also screen for mental health concerns and, if indicated, provide referral for comprehensive assessment and treatment by a qualified mental health professional.

4. If Applicable, Assess Eligibility, Prepare, and Refer for Hormone Therapy

The *SOC* provide criteria to guide decisions regarding feminizing/masculinizing hormone therapy (outlined in section VIII and Appendix C). Mental health professionals can help clients who are considering hormone therapy to be both psychologically prepared (e.g., client has made a fully informed decision with clear and realistic expectations; is ready to receive the service in line with the overall treatment plan; has included family and community as appropriate) and practically prepared (e.g., has been evaluated by a physician to rule out or address medical contraindications to hormone use; has considered the psychosocial implications). If clients are of childbearing age, reproductive options (section IX) should be explored before initiating hormone therapy.

It is important for mental health professionals to recognize that decisions about hormones are first and foremost a client's decisions—as are all decisions regarding healthcare. However, mental health professionals have a responsibility to encourage, guide, and assist clients with making fully informed decisions and becoming adequately prepared. To best support their clients' decisions, mental health professionals need to have functioning working relationships with their clients and sufficient information about them. Clients should receive prompt and attentive evaluation, with the goal of alleviating their gender dysphoria and providing them with appropriate medical services.

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Referral for feminizing/masculinizing hormone therapy

People may approach a specialized provider in any discipline to pursue feminizing/masculinizing hormone therapy. However, transgender health care is an interdisciplinary field, and coordination of care and referral among a client's overall care team is recommended.

Hormone therapy can be initiated with a referral from a qualified mental health professional. Alternatively, a health professional who is appropriately trained in behavioral health and competent in the assessment of gender dysphoria may assess eligibility, prepare, and refer the patient for hormone therapy, particularly in the absence of significant coexisting mental health concerns and when working in the context of a multidisciplinary specialty team. The referring health professional should provide documentation—in the chart and/or referral letter—of the patient's personal and treatment history, progress, and eligibility. Health professionals who recommend hormone therapy share the ethical and legal responsibility for that decision with the physician who provides the service.

The recommended content of the referral letter for feminizing/masculinizing hormone therapy is as follows:

1. The client's general identifying characteristics;

2. Results of the client's psychosocial assessment, including any diagnoses;

3. The duration of the referring health professional's relationship with the client, including the type of evaluation and therapy or counseling to date;

4. An explanation that the criteria for hormone therapy have been met, and a brief description of the clinical rationale for supporting the client's request for hormone therapy;

5. A statement that informed consent has been obtained from the patient;

6. A statement that the referring health professional is available for coordination of care and welcomes a phone call to establish this.

For providers working within a multidisciplinary specialty team, a letter may not be necessary; rather, the assessment and recommendation can be documented in the patient's chart.

5. If Applicable, Assess Eligibility, Prepare, and Refer for Surgery

The *SOC* also provide criteria to guide decisions regarding breast/chest surgery and genital surgery (outlined in section XI and Appendix C). Mental health professionals can help clients who are

considering surgery to be both psychologically prepared (e.g., has made a fully informed decision with clear and realistic expectations; is ready to receive the service in line with the overall treatment plan; has included family and community as appropriate) and practically prepared (e.g., has made an informed choice about a surgeon to perform the procedure; has arranged aftercare). If clients are of childbearing age, reproductive options (section IX) should be explored before undergoing genital surgery.

The *SOC* do not state criteria for other surgical procedures, such as feminizing or masculinizing facial surgery; however, mental health professionals can play an important role in helping their clients to make fully informed decisions about the timing and implications of such procedures in the context of the overall coming-out or transition process.

It is important for mental health professionals to recognize that decisions about surgery are first and foremost a client's decisions—as are all decisions regarding healthcare. However, mental health professionals have a responsibility to encourage, guide, and assist clients with making fully informed decisions and becoming adequately prepared. To best support their clients' decisions, mental health professionals need to have functioning working relationships with their clients and sufficient information about them. Clients should receive prompt and attentive evaluation, with the goal of alleviating their gender dysphoria and providing them with appropriate medical services.

Referral for surgery

Surgical treatments for gender dysphoria can be initiated by a referral (one or two, depending on the type of surgery) from a qualified mental health professional. The mental health professional provides documentation—in the chart and/or referral letter—of the patient's personal and treatment history, progress, and eligibility. Mental health professionals who recommend surgery share the ethical and legal responsibility for that decision with the surgeon.

- One referral from a qualified mental health professional is needed for breast/chest surgery (e.g., mastectomy, chest reconstruction, or augmentation mammoplasty).

- Two referrals—from qualified mental health professionals who have independently assessed the patient—are needed for genital surgery (i.e., hysterectomy/salpingo-oophorectomy, orchiectomy, genital reconstructive surgeries). If the first referral is from the patient's psychotherapist, the second referral should be from a person who has only had an evaluative role with the patient. Two separate letters, or one letter signed by both (e.g., if practicing within the same clinic) may be sent. Each referral letter, however, is expected to cover the same topics in the areas outlined below.

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The recommended content of the referral letters for surgery is as follows:

1. The client's general identifying characteristics;
2. Results of the client's psychosocial assessment, including any diagnoses;
3. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date;
4. An explanation that the criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery;
5. A statement about the fact that informed consent has been obtained from the patient;
6. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this.

For providers working within a multidisciplinary specialty team, a letter may not be necessary, rather, the assessment and recommendation can be documented in the patient's chart.

Relationship of Mental Health Professionals with Hormone-Prescribing Physicians, Surgeons, and Other Health Professionals

It is ideal for mental health professionals to perform their work and periodically discuss progress and obtain peer consultation from other professionals (both in mental health care and other health disciplines) who are competent in the assessment and treatment of gender dysphoria. The relationship among professionals involved in a client's health care should remain collaborative, with coordination and clinical dialogue taking place as needed. Open and consistent communication may be necessary for consultation, referral, and management of postoperative concerns.

Tasks Related to Psychotherapy

1. Psychotherapy Is Not an Absolute Requirement for Hormone Therapy and Surgery

A mental health screening and/or assessment as outlined above is needed for referral to hormonal and surgical treatments for gender dysphoria. In contrast, psychotherapy—although highly recommended—is not a requirement.

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The *SOC* do not recommend a minimum number of psychotherapy sessions prior to hormone therapy or surgery. The reasons for this are multifaceted (Lev, 2009). First, a minimum number of sessions tends to be construed as a hurdle, which discourages the genuine opportunity for personal growth. Second, mental health professionals can offer important support to clients throughout all phases of exploration of gender identity, gender expression, and possible transition—not just prior to any possible medical interventions. Third, clients and their psychotherapists differ in their abilities to attain similar goals in a specified time period.

2. Goals of Psychotherapy for Adults with Gender Concerns

The general goal of psychotherapy is to find ways to maximize a person's overall psychological well-being, quality of life, and self-fulfillment. Psychotherapy is not intended to alter a person's gender identity; rather, psychotherapy can help an individual to explore gender concerns and find ways to alleviate gender dysphoria, if present (Bockting et al., 2006; Bockting & Coleman, 2007; Fraser, 2009a; Lev, 2004). Typically, the overarching treatment goal is to help transsexual, transgender, and gender-nonconforming individuals achieve long-term comfort in their gender identity expression, with realistic chances for success in their relationships, education, and work. For additional details, see Fraser (Fraser, 2009c).

Therapy may consist of individual, couple, family, or group psychotherapy, the latter being particularly important to foster peer support.

3. Psychotherapy for Transsexual, Transgender, and Gender-Nonconforming Clients, Including Counseling and Support for Changes in Gender Role

Finding a comfortable gender role is, first and foremost, a psychosocial process. Psychotherapy can be invaluable in assisting transsexual, transgender, and gender-nonconforming individuals with all of the following: (i) clarifying and exploring gender identity and role, (ii) addressing the impact of stigma and minority stress on one's mental health and human development, and (iii) facilitating a coming-out process (Bockting & Coleman, 2007; Devor, 2004; Lev, 2004), which for some individuals may include changes in gender role expression and the use of feminizing/masculinizing medical interventions.

Mental health professionals can provide support and promote interpersonal skills and resilience in individuals and their families as they navigate a world that often is ill-prepared to accommodate and respect transgender, transsexual, and gender-nonconforming people. Psychotherapy can also aid in alleviating any coexisting mental health concerns (e.g., anxiety, depression) identified during screening and assessment.

For transsexual, transgender, and gender-nonconforming individuals who plan to change gender roles permanently and make a social gender role transition, mental health professionals can facilitate the development of an individualized plan with specific goals and timelines. While the experience of changing one's gender role differs from person to person, the social aspects of the experience are usually challenging—often more so than the physical aspects. Because changing gender role can have profound personal and social consequences, the decision to do so should include an awareness of what the familial, interpersonal, educational, vocational, economic, and legal challenges are likely to be, so that people can function successfully in their gender role.

Many transsexual, transgender, and gender-nonconforming people will present for care without ever having been related to, or accepted in, the gender role that is most congruent with their gender identity. Mental health professionals can help these clients to explore and anticipate the implications of changes in gender role, and to pace the process of implementing these changes. Psychotherapy can provide a space for clients to begin to express themselves in ways that are congruent with their gender identity and, for some clients, overcome fears about changes in gender expression. Calculated risks can be taken outside of therapy to gain experience and build confidence in the new role. Assistance with coming out to family and community (friends, school, workplace) can be provided.

Other transsexual, transgender, and gender-nonconforming individuals will present for care already having acquired experience (minimal, moderate, or extensive) living in a gender role that differs from that associated with their birth-assigned sex. Mental health professionals can help these clients to identify and work through potential challenges and foster optimal adjustment as they continue to express changes in their gender role.

4. Family Therapy or Support for Family Members

Decisions about changes in gender role and medical interventions for gender dysphoria have implications for, not only clients, but also their families (Emerson & Rosenfeld, 1996; Fraser, 2009a; Lev, 2004). Mental health professionals can assist clients with making thoughtful decisions about communicating with family members and others about their gender identity and treatment decisions. Family therapy may include work with spouses or partners, as well as with children and other members of a client's extended family.

Clients may also request assistance with their relationships and sexual health. For example, they may want to explore their sexuality and intimacy-related concerns.

Family therapy might be offered as part of the client's individual therapy and, if clinically appropriate, by the same provider. Alternatively, referrals can be made to other therapists with relevant expertise

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for working with family members or to sources of peer support (e.g., in-person or offline support networks of partners or families).

5. Follow-Up Care Throughout Life

Mental health professionals may work with clients and their families at many stages of their lives. Psychotherapy may be helpful at different times and for various issues throughout the life cycle.

6. E-Therapy, Online Counseling, or Distance Counseling

Online or e-therapy has been shown to be particularly useful for people who have difficulty accessing competent in-person psychotherapeutic treatment and who may experience isolation and stigma (Derrig-Palumbo & Zeine, 2005; Fenichel et al., 2004; Fraser, 2009b). By extrapolation, e-therapy may be a useful modality for psychotherapy with transsexual, transgender, and gender-nonconforming people. E-therapy offers opportunities for potentially enhanced, expanded, creative, and tailored delivery of services; however, as a developing modality it may also carry unexpected risk. Telemedicine guidelines are clear in some disciplines in some parts of the United States (Fraser, 2009b; Maheu, Pulier, Wilhelm, McMenamin, & Brown-Connolly, 2005) but not all; the international situation is even less well-defined (Maheu et al., 2005). Until sufficient evidence-based data on this use of e-therapy is available, caution in its use is advised.

Mental health professionals engaging in e-therapy are advised to stay current with their particular licensing board, professional association, and country's regulations, as well as the most recent literature pertaining to this rapidly evolving medium. A more thorough description of the potential uses, processes, and ethical concerns related to e-therapy has been published (Fraser, 2009b).

Other Tasks of Mental Health Professionals

1. Educate and Advocate on Behalf of Clients Within Their Community (Schools, Workplaces, Other Organizations) and Assist Clients with Making Changes in Identity Documents

Transsexual, transgender, and gender-nonconforming people may face challenges in their professional, educational, and other types of settings as they actualize their gender identity and expression (Lev, 2004, 2009). Mental health professionals can play an important role by educating people in these settings regarding gender nonconformity and by advocating on behalf of their clients (Currah, Juang, & Minter, 2006; Currah & Minter, 2000). This role may involve consultation

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with school counselors, teachers, and administrators, human resources staff, personnel managers and employers, and representatives from other organizations and institutions. In addition, health providers may be called upon to support changes in a client's name and/or gender marker on identity documents such as passports, driver's licenses, birth certificates, and diplomas.

2. Provide Information and Referral for Peer Support

For some transsexual, transgender, and gender-nonconforming people, an experience in peer support groups may be more instructive regarding options for gender expression than anything individual psychotherapy could offer (Rachlin, 2002). Both experiences are potentially valuable, and all people exploring gender issues should be encouraged to participate in community activities, if possible. Resources for peer support and information should be made available.

Culture and Its Ramifications for Assessment and Psychotherapy

Health professionals work in enormously different environments across the world. Forms of distress that cause people to seek professional assistance in any culture are understood and classified by people in terms that are products of their own cultures (Frank & Frank, 1993). Cultural settings also largely determine how such conditions are understood by mental health professionals. Cultural differences related to gender identity and expression can affect patients, mental health professionals, and accepted psychotherapy practice. WPATH recognizes that the *SOC* have grown out of a Western tradition and may need to be adapted depending on the cultural context.

Ethical Guidelines Related to Mental Health Care

Mental health professionals need to be certified or licensed to practice in a given country according to that country's professional regulations (Fraser, 2009b; Pope & Vasquez, 2011). Professionals must adhere to the ethical codes of their professional licensing or certifying organizations in all of their work with transsexual, transgender, and gender-nonconforming clients.

Treatment aimed at trying to change a person's gender identity and lived gender expression to become more congruent with sex assigned at birth has been attempted in the past (Gelder & Marks, 1969; Greenson, 1964), yet without success, particularly in the long-term (Cohen-Kettenis & Kuiper, 1984; Pauly, 1965). Such treatment is no longer considered ethical.

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If mental health professionals are uncomfortable with, or inexperienced in, working with transsexual, transgender, and gender-nonconforming individuals and their families, they should refer clients to a competent provider or, at minimum, consult with an expert peer. If no local practitioners are available, consultation may be done via telehealth methods, assuming local requirements for distance consultation are met.

Issues of Access to Care

Qualified mental health professionals are not universally available; thus, access to quality care might be limited. WPATH aims to improve access and provides regular continuing education opportunities to train professionals from various disciplines to provide quality, transgender-specific health care. Providing mental health care from a distance through the use of technology may be one way to improve access (Fraser, 2009b).

In many places around the world, access to health care for transsexual, transgender, and gender-nonconforming people is also limited by a lack of health insurance or other means to pay for needed care. WPATH urges health insurance companies and other third-party payers to cover the medically necessary treatments to alleviate gender dysphoria (American Medical Association, 2008; Anton, 2009; The World Professional Association for Transgender Health, 2008).

When faced with a client who is unable to access services, referral to available peer support resources (offline and online) is recommended. Finally, harm-reduction approaches might be indicated to assist clients with making healthy decisions to improve their lives.

VIII
Hormone Therapy

Medical Necessity of Hormone Therapy

Feminizing/masculinizing hormone therapy—the administration of exogenous endocrine agents to induce feminizing or masculinizing changes—is a medically necessary intervention for many transsexual, transgender, and gender-nonconforming individuals with gender dysphoria

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(Newfield, Hart, Dibble, & Kohler, 2006; Pfäfflin & Junge, 1998). Some people seek maximum feminization/masculinization, while others experience relief with an androgynous presentation resulting from hormonal minimization of existing secondary sex characteristics (Factor & Rothblum, 2008). Evidence for the psychosocial outcomes of hormone therapy is summarized in Appendix D.

Hormone therapy must be individualized based on a patient's goals, the risk/benefit ratio of medications, the presence of other medical conditions, and consideration of social and economic issues. Hormone therapy can provide significant comfort to patients who do not wish to make a social gender role transition or undergo surgery, or who are unable to do so (Meyer III, 2009). Hormone therapy is a recommended criterion for some, but not all, surgical treatments for gender dysphoria (see section XI and Appendix C).

Criteria for Hormone Therapy

Initiation of hormone therapy may be undertaken after a psychosocial assessment has been conducted and informed consent has been obtained by a qualified health professional, as outlined in section VII of the *SOC*. A referral is required from the mental health professional who performed the assessment, unless the assessment was done by a hormone provider who is also qualified in this area.

The criteria for hormone therapy are as follows:

1. Persistent, well-documented gender dysphoria;

2. Capacity to make a fully informed decision and to consent for treatment;

3. Age of majority in a given country (if younger, follow the *SOC* outlined in section VI);

4. If significant medical or mental health concerns are present, they must be reasonably well-controlled.

As noted in section VII of the *SOC*, the presence of coexisting mental health concerns does not necessarily preclude access to feminizing/masculinizing hormones; rather, these concerns need to be managed prior to, or concurrent with, treatment of gender dysphoria.

In selected circumstances, it can be acceptable practice to provide hormones to patients who have not fulfilled these criteria. Examples include facilitating the provision of monitored therapy using hormones of known quality as an alternative to illicit or unsupervised hormone use or to patients

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who have already established themselves in their affirmed gender and who have a history of prior hormone use. It is unethical to deny availability or eligibility for hormone therapy solely on the basis of blood seropositivity for blood-borne infections such as HIV or hepatitis B or C.

In rare cases, hormone therapy may be contraindicated due to serious individual health conditions. Health professionals should assist these patients with accessing nonhormonal interventions for gender dysphoria. A qualified mental health professional familiar with the patient is an excellent resource in these circumstances.

Informed Consent

Feminizing/masculinizing hormone therapy may lead to irreversible physical changes. Thus, hormone therapy should be provided only to those who are legally able to provide informed consent. This includes people who have been declared by a court to be emancipated minors, incarcerated people, and cognitively impaired people who are considered competent to participate in their medical decisions (Bockting et al., 2006). Providers should document in the medical record that comprehensive information has been provided and understood about all relevant aspects of the hormone therapy, including both possible benefits and risks and the impact on reproductive capacity.

Relationship Between the *Standards of Care* and Informed Consent Model Protocols

A number of community health centers in the United States have developed protocols for providing hormone therapy based on an approach that has become known as the Informed Consent Model (Callen Lorde Community Health Center, 2000, 2011; Fenway Community Health Transgender Health Program, 2007; Tom Waddell Health Center, 2006). These protocols are consistent with the guidelines presented in the WPATH *Standards of Care, Version 7*. The *SOC* are flexible clinical guidelines; they allow for tailoring of interventions to the needs of the individual receiving services and for tailoring of protocols to the approach and setting in which these services are provided (Ehrbar & Gorton, 2010).

Obtaining informed consent for hormone therapy is an important task of providers to ensure that patients understand the psychological and physical benefits and risks of hormone therapy, as well as its psychosocial implications. Providers prescribing the hormones or health professionals recommending the hormones should have the knowledge and experience to assess gender

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dysphoria. They should inform individuals of the particular benefits, limitations, and risks of hormones, given the patient's age, previous experience with hormones, and concurrent physical or mental health concerns.

Screening for and addressing acute or current mental health concerns is an important part of the informed consent process. This may be done by a mental health professional or by an appropriately trained prescribing provider (see section VII of the *SOC*). The same provider or another appropriately trained member of the health care team (e.g., a nurse) can address the psychosocial implications of taking hormones when necessary (e.g., the impact of masculinization/feminization on how one is perceived and its potential impact on relationships with family, friends, and coworkers). If indicated, these providers will make referrals for psychotherapy and for the assessment and treatment of coexisting mental health concerns such as anxiety or depression.

The difference between the Informed Consent Model and *SOC, Version 7,* is that the *SOC* puts greater emphasis on the important role that mental health professionals can play in alleviating gender dysphoria and facilitating changes in gender role and psychosocial adjustment. This may include a comprehensive mental health assessment and psychotherapy, when indicated. In the Informed Consent Model, the focus is on obtaining informed consent as the threshold for the initiation of hormone therapy in a multidisciplinary, harm-reduction environment. Less emphasis is placed on the provision of mental health care until the patient requests it, unless significant mental health concerns are identified that would need to be addressed before hormone prescription.

Physical Effects of Hormone Therapy

Feminizing/masculinizing hormone therapy will induce physical changes that are more congruent with a patient's gender identity.

- In FtM patients, the following physical changes are expected to occur: deepened voice, clitoral enlargement (variable), growth in facial and body hair, cessation of menses, atrophy of breast tissue, and decreased percentage of body fat compared to muscle mass.

- In MtF patients, the following physical changes are expected to occur: breast growth (variable), decreased erectile function, decreased testicular size, and increased percentage of body fat compared to muscle mass.

Most physical changes, whether feminizing or masculinizing, occur over the course of two years. The amount of physical change and the exact timeline of effects can be highly variable. Tables 1a and 1b outline the approximate time course of these physical changes.

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TABLE 1A: EFFECTS AND EXPECTED TIME COURSE OF MASCULINIZING HORMONES [A]

Effect	Expected onset[B]	Expected maximum effect[B]
Skin oiliness/acne	1–6 months	1–2 years
Facial/body hair growth	3–6 months	3–5 years
Scalp hair loss	>12 months[C]	Variable
Increased muscle mass/strength	6–12 months	2–5 years[D]
Body fat redistribution	3–6 months	2–5 years
Cessation of menses	2–6 months	n/a
Clitoral enlargement	3–6 months	1–2 years
Vaginal atrophy	3–6 months	1–2 years
Deepened voice	3–12 months	1–2 years

[A] Adapted with permission from Hembree et al.(2009). Copyright 2009, The Endocrine Society.
[B] Estimates represent published and unpublished clinical observations.
[C] Highly dependent on age and inheritance; may be minimal.
[D] Significantly dependent on amount of exercise.

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TABLE 1B: EFFECTS AND EXPECTED TIME COURSE OF FEMINIZING HORMONES [A]

Effect	Expected onset[B]	Expected maximum effect[B]
Body fat redistribution	3–6 months	2–5 years
Decreased muscle mass/ strength	3–6 months	1–2 years[C]
Softening of skin/decreased oiliness	3–6 months	Unknown
Decreased libido	1–3 months	1–2 years
Decreased spontaneous erections	1–3 months	3–6 months
Male sexual dysfunction	Variable	Variable
Breast growth	3–6 months	2–3 years
Decreased testicular volume	3–6 months	2–3 years
Decreased sperm production	Variable	Variable
Thinning and slowed growth of body and facial hair	6–12 months	> 3 years[D]
Male pattern baldness	No regrowth, loss stops 1–3 months	1–2 years

[A] Adapted with permission from Hembree et al. (2009). Copyright 2009, The Endocrine Society.
[B] Estimates represent published and unpublished clinical observations.
[C] Significantly dependent on amount of exercise.
[D] Complete removal of male facial and body hair requires electrolysis, laser treatment, or both.

The degree and rate of physical effects depends in part on the dose, route of administration, and medications used, which are selected in accordance with a patient's specific medical goals (e.g., changes in gender role expression, plans for sex reassignment) and medical risk profile. There is no current evidence that response to hormone therapy—with the possible exception of voice deepening in FtM persons—can be reliably predicted based on age, body habitus, ethnicity, or family appearance. All other factors being equal, there is no evidence to suggest that any medically approved type or method of administering hormones is more effective than any other in producing the desired physical changes.

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Risks of Hormone Therapy

All medical interventions carry risks. The likelihood of a serious adverse event is dependent on numerous factors: the medication itself, dose, route of administration, and a patient's clinical characteristics (age, comorbidities, family history, health habits). It is thus impossible to predict whether a given adverse effect will happen in an individual patient.

The risks associated with feminizing/masculinizing hormone therapy for the transsexual, transgender, and gender-nonconforming population as a whole are summarized in Table 2. Based on the level of evidence, risks are categorized as follows: (i) likely increased risk with hormone therapy, (ii) possibly increased risk with hormone therapy, or (iii) inconclusive or no increased risk. Items in the last category include those that may present risk, but for which the evidence is so minimal that no clear conclusion can be reached.

Additional detail about these risks can be found in Appendix B, which is based on two comprehensive, evidence-based literature reviews of masculinizing/feminizing hormone therapy (Feldman & Safer, 2009; Hembree et al., 2009), along with a large cohort study (Asscheman et al., 2011). These reviews can serve as detailed references for providers, along with other widely recognized, published clinical materials (Dahl, Feldman, Goldberg, & Jaberi, 2006; Ettner, Monstrey, & Eyler, 2007).

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TABLE 2: RISKS ASSOCIATED WITH HORMONE THERAPY. BOLDED ITEMS ARE CLINICALLY SIGNIFICANT

Risk Level	Feminizing hormones	Masculinizing hormones
Likely increased risk	Venous thromboembolic disease[A] Gallstones Elevated liver enzymes Weight gain Hypertriglyceridemia	Polycythemia Weight gain Acne Androgenic alopecia (balding) Sleep apnea
Likely increased risk with presence of additional risk factors[B]	Cardiovascular disease	
Possible increased risk	Hypertension Hyperprolactinemia or prolactinoma	Elevated liver enzymes Hyperlipidemia
Possible increased risk with presence of additional risk factors[B]	Type 2 diabetes[A]	Destabilization of certain psychiatric disorders[C] Cardiovascular disease Hypertension Type 2 diabetes
No increased risk or inconclusive	Breast cancer	Loss of bone density Breast cancer Cervical cancer Ovarian cancer Uterine cancer

* **Note:** Risk is greater with oral estrogen administration than with transdermal estrogen administration.

A Risk is greater with oral estrogen administration than with transdermal estrogen administration.

B Additional risk factors include age.

C Includes bipolar, schizoaffective, and other disorders that may include manic or psychotic symptoms. This adverse event appears to be associated with higher doses or supraphysiologic blood levels of testosterone.

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Competency of Hormone-Prescribing Physicians, Relationship with Other Health Professionals

Feminizing/masculinizing hormone therapy is best undertaken in the context of a complete approach to health care that includes comprehensive primary care and a coordinated approach to psychosocial issues (Feldman & Safer, 2009). While psychotherapy or ongoing counseling is not required for the initiation of hormone therapy, if a therapist is involved, then regular communication among health professionals is advised (with the patient's consent) to ensure that the transition process is going well, both physically and psychosocially.

With appropriate training, feminizing/masculinizing hormone therapy can be managed by a variety of providers, including nurse practitioners, physician assistants, and primary care physicians (Dahl et al., 2006). Medical visits relating to hormone maintenance provide an opportunity to deliver broader care to a population that is often medically underserved (Clements, Wilkinson, Kitano, & Marx, 1999; Feldman, 2007; Xavier, 2000). Many of the screening tasks and management of comorbidities associated with long-term hormone use, such as cardiovascular risk factors and cancer screening, fall more uniformly within the scope of primary care rather than specialist care (American Academy of Family Physicians, 2005; Eyler, 2007; World Health Organization, 2008), particularly in locations where dedicated gender teams or specialized physicians are not available.

Given the multidisciplinary needs of transsexual, transgender, and gender-nonconforming people seeking hormone therapy, as well as the difficulties associated with fragmentation of care in general (World Health Organization, 2008), WPATH strongly encourages the increased training and involvement of primary care providers in the area of feminizing/masculinizing hormone therapy. If hormones are prescribed by a specialist, there should be close communication with the patient's primary care provider. Conversely, an experienced hormone provider or endocrinologist should be involved if the primary care physician has no experience with this type of hormone therapy, or if the patient has a pre-existing metabolic or endocrine disorder that could be affected by endocrine therapy.

While formal training programs in transgender medicine do not yet exist, hormone providers have a responsibility to obtain appropriate knowledge and experience in this field. Clinicians can increase their experience and comfort in providing feminizing/masculinizing hormone therapy by co-managing care or consulting with a more experienced provider, or by providing more limited types of hormone therapy before progressing to initiation of hormone therapy. Because this field of medicine is evolving, clinicians should become familiar and keep current with the medical literature, and discuss emerging issues with colleagues. Such discussions might occur through networks established by WPATH and other national/local organizations.

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Responsibilities of Hormone-Prescribing Physicians

In general, clinicians who prescribe hormone therapy should engage in the following tasks:

1. Perform an initial evaluation that includes discussion of a patient's physical transition goals, health history, physical examination, risk assessment, and relevant laboratory tests.

2. Discuss with patients the expected effects of feminizing/masculinizing medications and the possible adverse health effects. These effects can include a reduction in fertility (Feldman & Safer, 2009; Hembree et al., 2009). Therefore, reproductive options should be discussed with patients before starting hormone therapy (see section IX).

3. Confirm that patients have the capacity to understand the risks and benefits of treatment and are capable of making an informed decision about medical care.

4. Provide ongoing medical monitoring, including regular physical and laboratory examination to monitor hormone effectiveness and side effects.

5. Communicate as needed with a patient's primary care provider, mental health professional, and surgeon.

6. If needed, provide patients with a brief written statement indicating that they are under medical supervision and care that includes feminizing/masculinizing hormone therapy. Particularly during the early phases of hormone treatment, a patient may wish to carry this statement at all times to help prevent difficulties with the police and other authorities.

Depending on the clinical situation for providing hormones (see below), some of these responsibilities are less relevant. Thus, the degree of counseling, physical examinations, and laboratory evaluations should be individualized to a patient's needs.

Clinical Situations for Hormone Therapy

There are circumstances in which clinicians may be called upon to provide hormones without necessarily initiating or maintaining long-term feminizing/masculinizing hormone therapy. By acknowledging these different clinical situations (see below, from least to highest level of complexity), it may be possible to involve clinicians in feminizing/masculinizing hormone therapy who might not otherwise feel able to offer this treatment.

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1. Bridging

Whether prescribed by another clinician or obtained through other means (e.g., purchased over the Internet), patients may present for care already on hormone therapy. Clinicians can provide a limited (1–6 month) prescription for hormones while helping patients find a provider who can prescribe long-term hormone therapy. Providers should assess a patient's current regimen for safety and drug interactions and substitute safer medications or doses when indicated (Dahl et al., 2006; Feldman & Safer, 2009). If hormones were previously prescribed, medical records should be requested (with the patient's permission) to obtain the results of baseline examinations and laboratory tests and any adverse events. Hormone providers should also communicate with any mental health professional who is currently involved in a patient's care. If a patient has never had a psychosocial assessment as recommended by the *SOC* (see section VII), clinicians should refer the patient to a qualified mental health professional if appropriate and feasible (Feldman & Safer, 2009). Providers who prescribe bridging hormones need to work with patients to establish limits as to the duration of bridging therapy.

2. Hormone Therapy Following Gonad Removal

Hormone replacement with estrogen or testosterone is usually continued lifelong after an oophorectomy or orchiectomy, unless medical contraindications arise. Because hormone doses are often decreased after these surgeries (Basson, 2001; Levy, Crown, & Reid, 2003; Moore, Wisniewski, & Dobs, 2003) and only adjusted for age and comorbid health concerns, hormone management in this situation is quite similar to hormone replacement in any hypogonadal patient.

3. Hormone Maintenance Prior to Gonad Removal

Once patients have achieved maximal feminizing/masculinizing benefits from hormones (typically two or more years), they remain on a maintenance dose. The maintenance dose is then adjusted for changes in health conditions, aging, or other considerations such as lifestyle changes (Dahl et al., 2006). When a patient on maintenance hormones presents for care, the provider should assess the patient's current regimen for safety and drug interactions and substitute safer medications or doses when indicated. The patient should continue to be monitored by physical examinations and laboratory testing on a regular basis, as outlined in the literature (Feldman & Safer, 2009; Hembree et al., 2009). The dose and form of hormones should be revisited regularly with any changes in the patient's health status and available evidence on the potential long-term risks of hormones (See *Hormone Regimens,* below).

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4. Initiating Hormonal Feminization/Masculinization

This clinical situation requires the greatest commitment in terms of provider time and expertise. Hormone therapy must be individualized based on a patient's goals, the risk/benefit ratio of medications, the presence of other medical conditions, and consideration of social and economic issues. Although a wide variety of hormone regimens have been published (Dahl et al., 2006; Hembree et al., 2009; Moore et al., 2003), there are no published reports of randomized clinical trials comparing safety and efficacy. Despite this variation, a reasonable framework for initial risk assessment and ongoing monitoring of hormone therapy can be constructed, based on the efficacy and safety evidence presented above.

Risk Assessment and Modification for Initiating Hormone Therapy

The initial evaluation for hormone therapy assesses a patient's clinical goals and risk factors for hormone-related adverse events. During the risk assessment, the patient and clinician should develop a plan for reducing risks wherever possible, either prior to initiating therapy or as part of ongoing harm reduction.

All assessments should include a thorough physical exam, including weight, height, and blood pressure. The need for breast, genital, and rectal exams, which are sensitive issues for most transsexual, transgender, and gender-nonconforming patients, should be based on individual risks and preventive health care needs (Feldman & Goldberg, 2006; Feldman, 2007).

Preventive Care

Hormone providers should address preventive health care with patients, particularly if a patient does not have a primary care provider. Depending on a patient's age and risk profile, there may be appropriate screening tests or exams for conditions affected by hormone therapy. Ideally, these screening tests should be carried out prior to the start of hormone therapy.

Risk Assessment and Modification for Feminizing Hormone Therapy (MtF)

There are no absolute contraindications to feminizing therapy per se, but absolute contraindications exist for the different feminizing agents, particularly estrogen. These include previous venous thrombotic events related to an underlying hypercoagulable condition, history of estrogen-sensitive neoplasm, and end-stage chronic liver disease (Gharib et al., 2005).

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Other medical conditions, as noted in Table 2 and Appendix B, can be exacerbated by estrogen or androgen blockade, and therefore should be evaluated and reasonably well controlled prior to starting hormone therapy (Feldman & Safer, 2009; Hembree et al., 2009). Clinicians should particularly attend to tobacco use, as it is associated with increased risk of venous thrombosis, which is further increased with estrogen use. Consultation with a cardiologist may be advisable for patients with known cardio- or cerebrovascular disease.

Baseline laboratory values are important to both assess initial risk and evaluate possible future adverse events. Initial labs should be based on the risks of feminizing hormone therapy outlined in Table 2, as well as individual patient risk factors, including family history. Suggested initial lab panels have been published (Feldman & Safer, 2009; Hembree et al., 2009). These can be modified for patients or health care systems with limited resources, and in otherwise healthy patients.

Risk Assessment and Modification for Masculinizing Hormone Therapy (FtM)

Absolute contraindications to testosterone therapy include pregnancy, unstable coronary artery disease, and untreated polycythemia with a hematocrit of 55% or higher (Carnegie, 2004). Because the aromatization of testosterone to estrogen may increase risk in patients with a history of breast or other estrogen dependent cancers (Moore et al., 2003), consultation with an oncologist may be indicated prior to hormone use. Comorbid conditions likely to be exacerbated by testosterone use should be evaluated and treated, ideally prior to starting hormone therapy (Feldman & Safer, 2009; Hembree et al., 2009). Consultation with a cardiologist may be advisable for patients with known cardio- or cerebrovascular disease. (Dhejne et al., 2011).

An increased prevalence of polycystic ovarian syndrome (PCOS) has been noted among FtM patients even in the absence of testosterone use (Baba et al., 2007; Balen, Schachter, Montgomery, Reid, & Jacobs, 1993; Bosinski et al., 1997). While there is no evidence that PCOS is related to the development of a transsexual, transgender, or gender-nonconforming identity, PCOS is associated with increased risk of diabetes, cardiac disease, high blood pressure, and ovarian and endometrial cancers (Cattrall & Healy, 2004). Signs and symptoms of PCOS should be evaluated prior to initiating testosterone therapy, as testosterone may affect many of these conditions. Testosterone can affect the developing fetus (*Physicians' Desk Reference,* 2010), and patients at risk of becoming pregnant require highly effective birth control.

Baseline laboratory values are important to both assess initial risk and evaluate possible future adverse events. Initial labs should be based on the risks of masculinizing hormone therapy outlined in Table 2, as well as individual patient risk factors, including family history. Suggested initial lab panels have been published (Feldman & Safer, 2009; Hembree et al., 2009). These can be modified for patients or health care systems with limited resources, and in otherwise healthy patients.

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Clinical Monitoring During Hormone Therapy for Efficacy and Adverse Events

The purpose of clinical monitoring during hormone use is to assess the degree of feminization/masculinization and the possible presence of adverse effects of medication. However, as with the monitoring of any long-term medication, monitoring should take place in the context of comprehensive health care. Suggested clinical monitoring protocols have been published (Feldman & Safer, 2009; Hembree et al., 2009). Patients with comorbid medical conditions may need to be monitored more frequently. Healthy patients in geographically remote or resource-poor areas may be able to use alternative strategies, such as telehealth, or cooperation with local providers such as nurses and physician assistants. In the absence of other indications, health professionals may prioritize monitoring for those risks that are either likely to be increased by hormone therapy or possibly increased by hormone therapy but clinically serious in nature.

Efficacy and Risk Monitoring During Feminizing Hormone Therapy (MtF)

The best assessment of hormone efficacy is clinical response: Is a patient developing a feminized body while minimizing masculine characteristics, consistent with that patient's gender goals? In order to more rapidly predict the hormone dosages that will achieve clinical response, one can measure testosterone levels for suppression below the upper limit of the normal female range and estradiol levels within a premenopausal female range but well below supraphysiologic levels (Feldman & Safer, 2009; Hembree et al., 2009).

Monitoring for adverse events should include both clinical and laboratory evaluation. Follow-up should include careful assessment for signs of cardiovascular impairment and venous thromboembolism (VTE) through measurement of blood pressure, weight, and pulse; heart and lung exams; and examination of the extremities for peripheral edema, localized swelling, or pain (Feldman & Safer, 2009). Laboratory monitoring should be based on the risks of hormone therapy described above, a patient's individual comorbidities and risk factors, and the specific hormone regimen itself. Specific lab-monitoring protocols have been published (Feldman & Safer, 2009; Hembree et al., 2009).

Efficacy and Risk Monitoring During Masculinizing Hormone Therapy (FtM)

The best assessment of hormone efficacy is clinical response: Is a patient developing a masculinized body while minimizing feminine characteristics, consistent with that patient's gender goals? Clinicians can achieve a good clinical response with the least likelihood of adverse events by maintaining testosterone levels within the normal male range while avoiding supraphysiological

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levels (Dahl et al., 2006; Hembree et al., 2009). For patients using intramuscular (IM) testosterone cypionate or enanthate, some clinicians check trough levels while others prefer midcycle levels (Dahl et al., 2006; Hembree et al., 2009; Tangpricha, Turner, Malabanan, & Holick, 2001; Tangpricha, Ducharme, Barber, & Chipkin, 2003).

Monitoring for adverse events should include both clinical and laboratory evaluation. Follow-up should include careful assessment for signs and symptoms of excessive weight gain, acne, uterine break-through bleeding, and cardiovascular impairment, as well as psychiatric symptoms in at-risk patients. Physical examinations should include measurement of blood pressure, weight, and pulse; and heart, lung, and skin exams (Feldman & Safer, 2009). Laboratory monitoring should be based on the risks of hormone therapy described above, a patient's individual comorbidities and risk factors, and the specific hormone regimen itself. Specific lab monitoring protocols have been published (Feldman & Safer, 2009; Hembree et al., 2009).

Hormone Regimens

To date, no controlled clinical trials of any feminizing/masculinizing hormone regimen have been conducted to evaluate safety or efficacy in producing physical transition. As a result, wide variation in doses and types of hormones have been published in the medical literature (Moore et al., 2003; Tangpricha et al., 2003; van Kesteren, Asscheman, Megens, & Gooren, 1997). In addition, access to particular medications may be limited by a patient's geographical location and/or social or econonomic situations. For these reasons, WPATH does not describe or endorse a particular feminizing/masculinizing hormone regimen. Rather, the medication classes and routes of administration used in most published regimens are broadly reviewed.

As outlined above, there are demonstrated safety differences in individual elements of various regimens. The Endocrine Society Guidelines (Hembree et al., 2009) and Feldman and Safer (2009) provide specific guidance regarding the types of hormones and suggested dosing to maintain levels within physiologic ranges for a patient's desired gender expression (based on goals of full feminization/masculinization). It is strongly recommend that hormone providers regularly review the literature for new information and use those medications that safely meet individual patient needs with available local resources.

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Regimens for Feminizing Hormone Therapy (MtF)

Estrogen

Use of oral estrogen, and specifically ethinyl estradiol, appears to increase the risk of VTE. Because of this safety concern, ethinyl estradiol is not recommended for feminizing hormone therapy. Transdermal estrogen is recommended for those patients with risks factors for VTE. The risk of adverse events increases with higher doses, particular doses resulting in supraphysiologic levels (Hembree et al., 2009). Patients with co-morbid conditions that can be affected by estrogen should avoid oral estrogen if possible and be started at lower levels. Some patients may not be able to safely use the levels of estrogen needed to get the desired results. This possibility needs to be discussed with patients well in advance of starting hormone therapy.

Androgen-reducing medications ("anti-androgens")

A combination of estrogen and "anti-androgens" is the most commonly studied regimen for feminization. Androgen-reducing medications, from a variety of classes of drugs, have the effect of reducing either endogenous testosterone levels or testosterone activity, and thus diminishing masculine characteristics such as body hair. They minimize the dosage of estrogen needed to suppress testosterone, thereby reducing the risks associated with high-dose exogenous estrogen (Prior, Vigna, Watson, Diewold, & Robinow, 1986; Prior, Vigna, & Watson, 1989).

Common anti-androgens include the following:

- Spironolactone, an antihypertensive agent, directly inhibits testosterone secretion and androgen binding to the androgen receptor. Blood pressure and electrolytes need to be monitored because of the potential for hyperkalemia.

- Cyproterone acetate is a progestational compound with anti-androgenic properties. This medication is not approved in the United States because of concerns over potential hepatotoxicity, but it is widely used elsewhere (De Cuypere et al., 2005).

- GnRH agonists (e.g., goserelin, buserelin, triptorelin) are neurohormones that block the gonadtropin-releasing hormone receptor, thus blocking the release of follicle stimulating hormone and luteinizing hormone. This leads to highly effective gonadal blockade. However, these medications are expensive and only available as injectables or implants.

- 5-alpha reductase inhibitors (finasteride and dutasteride) block the conversion of testosterone to the more active agent, 5-alpha-dihydrotestosterone. These medications have beneficial effects on scalp hair loss, body hair growth, sebaceous glands, and skin consistency.

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Cyproterone and spironolactone are the most commonly used anti-androgens and are likely the most cost-effective.

Progestins

With the exception of cyproterone, the inclusion of progestins in feminizing hormone therapy is controversial (Oriel, 2000). Because progestins play a role in mammary development on a cellular level, some clinicians believe that these agents are necessary for full breast development (Basson & Prior, 1998; Oriel, 2000). However, a clinical comparison of feminization regimens with and without progestins found that the addition of progestins neither enhanced breast growth nor lowered serum levels of free testosterone (Meyer et al., 1986). There are concerns regarding potential adverse effects of progestins, including depression, weight gain, and lipid changes (Meyer et al., 1986; Tangpricha et al., 2003). Progestins (especially medroxyprogesterone) are also suspected to increase breast cancer risk and cardiovascular risk in women (Rossouw et al., 2002). Micronized progesterone may be better tolerated and have a more favorable impact on the lipid profile than medroxyprogesterone does (de Lignières, 1999; Fitzpatrick, Pace, & Wiita, 2000).

Regimens for Masculinizing Hormone Therapy (FtM)

Testosterone

Testosterone generally can be given orally, transdermally, or parenterally (IM), although buccal and implantable preparations are also available. Oral testosterone undecanoate, available outside the United States, results in lower serum testosterone levels than nonoral preparations and has limited efficacy in suppressing menses (Feldman, 2005, April; Moore et al., 2003). Because intramuscular testosterone cypionate or enanthate are often administered every 2–4 weeks, some patients may notice cyclic variation in effects (e.g., fatigue and irritability at the end of the injection cycle, aggression or expansive mood at the beginning of the injection cycle), as well as more time outside the normal physiologic levels (Jockenhövel, 2004). This may be mitigated by using a lower but more frequent dosage schedule or by using a daily transdermal preparation (Dobs et al., 1999; Jockenhövel, 2004; Nieschlag et al., 2004). Intramuscular testosterone undecanoate (not currently available in the United States) maintains stable, physiologic testosterone levels over approximately 12 weeks and has been effective in both the setting of hypogonadism and in FtM individuals (Mueller, Kiesewetter, Binder, Beckmann, & Dittrich, 2007; Zitzmann, Saad, & Nieschlag, 2006). There is evidence that transdermal and intramuscular testosterone achieve similar masculinizing results, although the timeframe may be somewhat slower with transdermal preparations (Feldman, 2005, April). Especially as patients age, the goal is to use the lowest dose needed to maintain the desired clinical result, with appropriate precautions being made to maintain bone density.

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Other agents

Progestins, most commonly medroxyprogesterone, can be used for a short period of time to assist with menstrual cessation early in hormone therapy. GnRH agonists can be used similarly, as well as for refractory uterine bleeding in patients without an underlying gynecological abnormality.

Bioidentical and Compounded Hormones

As discussion surrounding the use of bioidentical hormones in postmenopausal hormone replacement has heightened, interest has also increased in the use of similar compounds in feminizing/masculinizing hormone therapy. There is no evidence that custom compounded bioidentical hormones are safer or more effective than government agency-approved bioidentical hormones (Sood, Shuster, Smith, Vincent, & Jatoi, 2011). Therefore, it has been advised by the North American Menopause Society (2010) and others to assume that, whether the hormone is from a compounding pharmacy or not, if the active ingredients are similar, it should have a similar side-effect profile. WPATH concurs with this assessment.

IX
Reproductive Health

Many transgender, transsexual, and gender-nonconforming people will want to have children. Because feminizing/masculinizing hormone therapy limits fertility (Darney, 2008; Zhang, Gu, Wang, Cui, & Bremner, 1999), it is desirable for patients to make decisions concerning fertility before starting hormone therapy or undergoing surgery to remove/alter their reproductive organs. Cases are known of people who received hormone therapy and genital surgery and later regretted their inability to parent genetically related children (De Sutter, Kira, Verschoor, & Hotimsky, 2002).

Health care professionals—including mental health professionals recommending hormone therapy or surgery, hormone-prescribing physicians, and surgeons—should discuss reproductive options with patients prior to initiation of these medical treatments for gender dysphoria. These discussions should occur even if patients are not interested in these issues at the time of treatment, which may be more common for younger patients (De Sutter, 2009). Early discussions are desirable, but not always possible. If an individual has not had complete sex reassignment surgery, it may be possible to stop hormones long enough for natal hormones to recover, allowing

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the production of mature gametes (Payer, Meyer, & Walker, 1979; Van den Broecke, Van der Elst, Liu, Hovatta, & Dhont, 2001).

Besides debate and opinion papers, very few research papers have been published on the reproductive health issues of individuals receiving different medical treatments for gender dysphoria. Another group who faces the need to preserve reproductive function in light of loss or damage to their gonads are people with malignancies that require removal of reproductive organs or use of damaging radiation or chemotherapy. Lessons learned from that group can be applied to people treated for gender dysphoria.

MtF patients, especially those who have not already reproduced, should be informed about sperm-preservation options and encouraged to consider banking their sperm prior to hormone therapy. In a study examining testes that were exposed to high-dose estrogen (Payer et al., 1979), findings suggest that stopping estrogen may allow the testes to recover. In an article reporting on the opinions of MtF individuals towards sperm freezing (De Sutter et al., 2002), the vast majority of 121 survey respondents felt that the availability of freezing sperm should be discussed and offered by the medical world. Sperm should be collected before hormone therapy or after stopping the therapy until the sperm count rises again. Cryopreservation should be discussed even if there is poor semen quality. In adults with azoospermia, a testicular biopsy with subsequent cryopreservation of biopsied material for sperm is possible, but may not be successful.

Reproductive options for FtM patients might include oocyte (egg) or embryo freezing. The frozen gametes and embryo could later be used with a surrogate woman to carry to pregnancy. Studies of women with polycystic ovarian disease suggest that the ovary can recover in part from the effects of high testosterone levels (Hunter & Sterrett, 2000). Stopping the testosterone briefly might allow for ovaries to recover enough to release eggs; success likely depends on the patient's age and duration of testosterone treatment. While not systematically studied, some FtM individuals are doing exactly that, and some have been able to become pregnant and deliver children (More, 1998).

Patients should be advised that these techniques are not available everywhere and can be very costly. Transsexual, transgender, and gender-nonconforming people should not be refused reproductive options for any reason.

A special group of individuals are prepubertal or pubertal adolescents who will never develop reproductive function in their natal sex due to blockers or cross-gender hormones. At this time there is no technique for preserving function from the gonads of these individuals.

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X

Voice and Communication Therapy

Communication, both verbal and nonverbal, is an important aspect of human behavior and gender expression. Transsexual, transgender, and gender-nonconforming people might seek the assistance of a voice and communication specialist to develop vocal characteristics (e.g., pitch, intonation, resonance, speech rate, phrasing patterns) and non-verbal communication patterns (e.g., gestures, posture/movement, facial expressions) that facilitate comfort with their gender identity. Voice and communication therapy may help to alleviate gender dysphoria and be a positive and motivating step towards achieving one's goals for gender role expression.

Competency of Voice and Communication Specialists Working with Transsexual, Transgender, and Gender-Nonconforming Clients

Specialists may include speech-language pathologists, speech therapists, and speech-voice clinicians. In most countries the professional association for speech-language pathologists requires specific qualifications and credentials for membership. In some countries the government regulates practice through licensing, certification, or registration processes (American Speech-Language-Hearing Association, 2011; Canadian Association of Speech-Language Pathologists and Audiologists; Royal College of Speech Therapists, United Kingdom; Speech Pathology Australia).

The following are recommended minimum credentials for voice and communication specialists working with transsexual, transgender, and gender-nonconforming clients:

1. Specialized training and competence in the assessment and development of communication skills in transsexual, transgender, and gender-nonconforming clients.

2. A basic understanding of transgender health, including hormonal and surgical treatments for feminization/masculinization and trans-specific psychosocial issues as outlined in the *SOC*; and familiarity with basic sensitivity protocols such as the use of preferred gender pronoun and name (Canadian Association of Speech-Language Pathologists and Audiologists; Royal College of Speech Therapists, United Kingdom; Speech Pathology Australia).

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3. Continuing education in the assessment and development of communication skills in transsexual, transgender, and gender-nonconforming clients. This may include attendance at professional meetings, workshops, or seminars; participation in research related to gender identity issues; independent study; or mentoring from an experienced, certified clinician.

Other professionals such as vocal coaches, theatre professionals, singing teachers, and movement experts may play a valuable adjunct role. Such professionals will ideally have experience working with, or be actively collaborating with, speech-language pathologists.

Assessment and Treatment Considerations

The overall purpose of voice and communication therapy is to help clients adapt their voice and communication in a way that is both safe and authentic, resulting in communication patterns that clients feel are congruent with their gender identity and that reflect their sense of self (Adler, Hirsch, & Mordaunt, 2006). It is essential that voice and communication specialists be sensitive to individual communication preferences. Communication—style, voice, choice of language, etc.—is personal. Individuals should not be counseled to adopt behaviors with which they are not comfortable or which do not feel authentic. Specialists can best serve their clients by taking the time to understand a person's gender concerns and goals for gender-role expression (American Speech-Language-Hearing Association, 2011; Canadian Association of Speech-Language Pathologists and Audiologists; Royal College of Speech Therapists, United Kingdom; Speech Pathology Australia).

Individuals may choose the communication behaviors that they wish to acquire in accordance with their gender identity. These decisions are also informed and supported by the knowledge of the voice and communication specialist and by the assessment data for a specific client (Hancock, Krissinger, & Owen, 2010). Assessment includes a client's self-evaluation and a specialist's evaluation of voice, resonance, articulation, spoken language, and non-verbal communication (Adler et al., 2006; Hancock et al., 2010).

Voice-and-communication treatment plans are developed by considering the available research evidence, the clinical knowledge and experience of the specialist, and the client's own goals and values (American Speech-Language-Hearing Association, 2011; Canadian Association of Speech-Language Pathologists and Audiologists; Royal College of Speech Therapists, United Kingdom; Speech Pathology Australia). Targets of treatment typically include pitch, intonation, loudness and stress patterns, voice quality, resonance, articulation, speech rate and phrasing, language, and nonverbal communication (Adler et al., 2006; Davies & Goldberg, 2006; de Bruin, Coerts, & Greven, 2000; Gelfer, 1999; McNeill, 2006; Oates & Dacakis, 1983). Treatment may involve individual and/or group sessions. The frequency and duration of treatment will vary according to a client's needs. Existing protocols for voice-and-communication treatment can be considered in

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developing an individualized therapy plan (Carew, Dacakis, & Oates, 2007; Dacakis, 2000; Davies & Goldberg, 2006; Gelfer, 1999; McNeill, Wilson, Clark, & Deakin, 2008; Mount & Salmon, 1988).

Feminizing or masculinizing the voice involves non-habitual use of the voice production mechanism. Prevention measures are necessary to avoid the possibility of vocal misuse and long-term vocal damage. All voice and communication therapy services should therefore include a vocal health component (Adler et al., 2006).

Vocal Health Considerations After Voice Feminization Surgery

As noted in section XI, some transsexual, transgender, and gender-nonconforming people will undergo voice feminization surgery. (Voice deepening can be achieved through masculinizing hormone therapy, but feminizing hormones do not have an impact on the adult MtF voice.) There are varying degrees of satisfaction, safety, and long-term improvement in patients who have had such surgery. It is recommended that individuals undergoing voice feminization surgery also consult a voice and communication specialist to maximize the surgical outcome, help protect vocal health, and learn nonpitch related aspects of communication. Voice surgery procedures should include follow-up sessions with a voice and communication specialist who is licensed and/or credentialed by the board responsible for speech therapists/speech-language pathologists in that country (Kanagalingam et al., 2005; Neumann & Welzel, 2004).

XI
Surgery

Sex Reassignment Surgery Is Effective and Medically Necessary

Surgery – particularly genital surgery – is often the last and the most considered step in the treatment process for gender dysphoria. While many transsexual, transgender, and gender-nonconforming individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender dysphoria (Hage & Karim, 2000). For the latter group, relief from gender dysphoria cannot be achieved

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without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity. Moreover, surgery can help patients feel more at ease in the presence of sex partners or in venues such as physicians' offices, swimming pools, or health clubs. In some settings, surgery might reduce risk of harm in the event of arrest or search by police or other authorities.

Follow-up studies have shown an undeniable beneficial effect of sex reassignment surgery on postoperative outcomes such as subjective well-being, cosmesis, and sexual function (De Cuypere et al., 2005; Gijs & Brewaeys, 2007; Klein & Gorzalka, 2009; Pfäfflin & Junge, 1998). Additional information on the outcomes of surgical treatments are summarized in Appendix D.

Ethical Questions Regarding Sex Reassignment Surgery

In ordinary surgical practice, pathological tissues are removed to restore disturbed functions, or alterations are made to body features to improve a patient's self image. Some people, including some health professionals, object on ethical grounds to surgery as a treatment for gender dysphoria, because these conditions are thought not to apply.

It is important that health professionals caring for patients with gender dysphoria feel comfortable about altering anatomically normal structures. In order to understand how surgery can alleviate the psychological discomfort and distress of individuals with gender dysphoria, professionals need to listen to these patients discuss their symptoms, dilemmas, and life histories. The resistance against performing surgery on the ethical basis of "above all do no harm" should be respected, discussed, and met with the opportunity to learn from patients themselves about the psychological distress of having gender dysphoria and the potential for harm caused by denying access to appropriate treatments.

Genital and breast/chest surgical treatments for gender dysphoria are not merely another set of elective procedures. Typical elective procedures involve only a private mutually consenting contract between a patient and a surgeon. Genital and breast/chest surgeries as medically necessary treatments for gender dysphoria are to be undertaken only after assessment of the patient by qualified mental health professionals, as outlined in section VII of the *SOC*. These surgeries may be performed once there is written documentation that this assessment has occurred and that the person has met the criteria for a specific surgical treatment. By following this procedure, mental health professionals, surgeons, and patients share responsibility for the decision to make irreversible changes to the body.

It is unethical to deny availability or eligibility for sex reassignment surgeries solely on the basis of blood seropositivity for blood-borne infections such as HIV or hepatitis C or B.

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Relationship of Surgeons with Mental Health Professionals, Hormone-Prescribing Physicians (if Applicable), and Patients (Informed Consent)

The role of a surgeon in the treatment of gender dysphoria is not that of a mere technician. Rather, conscientious surgeons will have insight into each patient's history and the rationale that led to the referral for surgery. To that end, surgeons must talk at length with their patients and have close working relationships with other health professionals who have been actively involved in their clinical care.

Consultation is readily accomplished when a surgeon practices as part of an interdisciplinary health care team. In the absence of this, a surgeon must be confident that the referring mental health professional(s), and if applicable the physician who prescribes hormones, is/are competent in the assessment and treatment of gender dysphoria, because the surgeon is relying heavily on his/her/their expertise.

Once a surgeon is satisfied that the criteria for specific surgeries have been met (as outlined below), surgical treatment should be considered and a preoperative surgical consultation should take place. During this consultation, the procedure and postoperative course should be extensively discussed with the patient. Surgeons are responsible for discussing all of the following with patients seeking surgical treatments for gender dysphoria:

- The different surgical techniques available (with referral to colleagues who provide alternative options);
- The advantages and disadvantages of each technique;
- The limitations of a procedure to achieve "ideal" results; surgeons should provide a full range of before-and-after photographs of their own patients, including both successful and unsuccessful outcomes;
- The inherent risks and possible complications of the various techniques; surgeons should inform patients of their own complication rates with each procedure.

These discussions are the core of the informed consent process, which is both an ethical and legal requirement for any surgical procedure. Ensuring that patients have a realistic expectation of outcomes is important in achieving a result that will alleviate their gender dysphoria.

All of this information should be provided to patients in writing, in a language in which they are fluent, and in graphic illustrations. Patients should receive the information in advance (possibly

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via the Internet) and be given ample time to review it carefully. The elements of informed consent should always be discussed face-to-face prior to the surgical intervention. Questions can then be answered and written informed consent can be provided by the patient. Because these surgeries are irreversibile, care should be taken to ensure that patients have sufficient time to absorb information fully before they are asked to provide informed consent. A minimum of 24 hours is suggested.

Surgeons should provide immediate aftercare and consultation with other physicians serving the patient in the future. Patients should work with their surgeon to develop an adequate aftercare plan for the surgery.

Overview of Surgical Procedures for the Treatment of Patients with Gender Dysphoria

For the Male-to-Female (MtF) Patient, Surgical Procedures May Include the Following:

1. Breast/chest surgery: augmentation mammoplasty (implants/lipofilling);

2. Genital surgery: penectomy, orchiectomy, vaginoplasty, clitoroplasty, vulvoplasty;

3. Nongenital, nonbreast surgical interventions: facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal augmentation (implants/lipofilling), hair reconstruction, and various aesthetic procedures.

For the Female-to-Male (FtM) Patient, Surgical Procedures May Include the Following:

1. Breast/chest surgery: subcutaneous mastectomy, creation of a male chest;

2. Genital surgery: hysterectomy/salpingo-oophorectomy, reconstruction of the fixed part of the urethra, which can be combined with a metoidioplasty or with a phalloplasty (employing a pedicled or free vascularized flap), vaginectomy, scrotoplasty, and implantation of erection and/or testicular prostheses;

3. Nongenital, nonbreast surgical interventions: voice surgery (rare), liposuction, lipofilling, pectoral implants, and various aesthetic procedures.

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Reconstructive Versus Aesthetic Surgery

The question of whether sex reassignment surgery should be considered "aesthetic" surgery or "reconstructive" surgery is pertinent not only from a philosophical point of view, but also from a financial point of view. Aesthetic or cosmetic surgery is mostly regarded as not medically necessary and therefore is typically paid for entirely by the patient. In contrast, reconstructive procedures are considered medically necessary—with unquestionable therapeutic results—and thus paid for partially or entirely by national health systems or insurance companies.

Unfortunately, in the field of plastic and reconstructive surgery (both in general and specifically for gender-related surgeries), there is no clear distinction between what is purely reconstructive and what is purely cosmetic. Most plastic surgery procedures actually are a mixture of both reconstructive and cosmetic components.

While most professionals agree that genital surgery and mastectomy cannot be considered purely cosmetic, opinions diverge as to what degree other surgical procedures (e.g., breast augmentation, facial feminization surgery) can be considered purely reconstructive. Although it may be much easier to see a phalloplasty or a vaginoplasty as an intervention to end lifelong suffering, for certain patients an intervention like a reduction rhinoplasty can have a radical and permanent effect on their quality of life, and therefore is much more medically necessary than for somebody without gender dysphoria.

Criteria for Surgeries

As for all of the *SOC*, the criteria for initiation of surgical treatments for gender dysphoria were developed to promote optimal patient care. While the *SOC* allow for an individualized approach to best meet a patient's health care needs, a criterion for all breast/chest and genital surgeries is documentation of persistent gender dysphoria by a qualified mental health professional. For some surgeries, additional criteria include preparation and treatment consisting of feminizing/masculinizing hormone therapy and one year of continuous living in a gender role that is congruent with one's gender identity.

These criteria are outlined below. Based on the available evidence and expert clinical consensus, different recommendations are made for different surgeries.

The *SOC* do not specify an order in which different surgeries should occur. The number and sequence of surgical procedures may vary from patient to patient, according to their clinical needs.

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Criteria for Breast/Chest Surgery (One Referral)

Criteria for mastectomy and creation of a male chest in FtM patients:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country (if younger, follow the *SOC* for children and adolescents);
4. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Hormone therapy is not a prerequisite.

Criteria for breast augmentation (implants/lipofilling) in MtF patients:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country (if younger, follow the *SOC* for children and adolescents);
4. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Although not an explicit criterion, it is recommended that MtF patients undergo feminizing hormone therapy (minimum 12 months) prior to breast augmentation surgery. The purpose is to maximize breast growth in order to obtain better surgical (aesthetic) results.

Criteria for Genital Surgery (Two Referrals)

The criteria for genital surgery are specific to the type of surgery being requested.

Criteria for hysterectomy and salpingo-oophorectomy in FtM patients and for orchiectomy in MtF patients:

1. Persistent, well-documented gender dysphoria;

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2. Capacity to make a fully informed decision and to consent for treatment;

3. Age of majority in a given country;

4. If significant medical or mental health concerns are present, they must be well controlled.

5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless hormones are not clinically indicated for the individual).

The aim of hormone therapy prior to gonadectomy is primarily to introduce a period of reversible estrogen or testosterone suppression, before the patient undergoes irreversible surgical intervention.

These criteria do not apply to patients who are having these procedures for medical indications other than gender dysphoria.

Criteria for metoidioplasty or phalloplasty in FtM patients and for vaginoplasty in MtF patients:

1. Persistent, well-documented gender dysphoria;

2. Capacity to make a fully informed decision and to consent for treatment;

3. Age of majority in a given country;

4. If significant medical or mental health concerns are present, they must be well controlled;

5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless hormones are not clinically indicated for the individual).

6. 12 continuous months of living in a gender role that is congruent with their gender identity.

Although not an explicit criterion, it is recommended that these patients also have regular visits with a mental health or other medical professional.

Rationale for a preoperative, 12-month experience of living in an identity-congruent gender role:

The criterion noted above for some types of genital surgeries—i.e., that patients engage in 12 continuous months of living in a gender role that is congruent with their gender identity—is based on expert clinical consensus that this experience provides ample opportunity for patients to experience and socially adjust in their desired gender role, before undergoing irreversible surgery. As noted in section VII, the social aspects of changing one's gender role are usually challenging—

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often more so than the physical aspects. Changing gender role can have profound personal and social consequences, and the decision to do so should include an awareness of what the familial, interpersonal, educational, vocational, economic, and legal challenges are likely to be, so that people can function successfully in their gender role. Support from a qualified mental health professional and from peers can be invaluable in ensuring a successful gender role adaptation (Bockting, 2008).

The duration of 12 months allows for a range of different life experiences and events that may occur throughout the year (e.g., family events, holidays, vacations, season-specific work or school experiences). During this time, patients should present consistently, on a day-to-day basis and across all settings of life, in their desired gender role. This includes coming out to partners, family, friends, and community members (e.g., at school, work, other settings).

Health professionals should clearly document a patient's experience in the gender role in the medical chart, including the start date of living full time for those who are preparing for genital surgery. In some situations, if needed, health professionals may request verification that this criterion has been fulfilled: They may communicate with individuals who have related to the patient in an identity-congruent gender role, or request documentation of a legal name and/or gender marker change, if applicable.

Surgery for People with Psychotic Conditions and Other Serious Mental Illnesses

When patients with gender dysphoria are also diagnosed with severe psychiatric disorders and impaired reality testing (e.g., psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated. (Dhejne et al., 2011). Reevaluation by a mental health professional qualified to assess and manage psychotic conditions should be conducted prior to surgery, describing the patient's mental status and readiness for surgery. It is preferable that this mental health professional be familiar with the patient. No surgery should be performed while a patient is actively psychotic (De Cuypere & Vercruysse, 2009).

Competency of Surgeons Performing Breast/Chest or Genital Surgery

Physicians who perform surgical treatments for gender dsyphoria should be urologists, gynecologists, plastic surgeons, or general surgeons, and board-certified as such by the relevant national

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and/or regional association. Surgeons should have specialized competence in genital reconstructive techniques as indicated by documented supervised training with a more experienced surgeon. Even experienced surgeons must be willing to have their surgical skills reviewed by their peers. An official audit of surgical outcomes and publication of these results would be greatly reassuring to both referring health professionals and patients. Surgeons should regularly attend professional meetings where new techniques are presented. The internet is often effectively used by patients to share information on their experience with surgeons and their teams.

Ideally, surgeons should be knowledgeable about more than one surgical technique for genital reconstruction so that they, in consultation with patients, can choose the ideal technique for each individual. Alternatively, if a surgeon is skilled in a single technique and this procedure is either not suitable for or desired by a patient, the surgeon should inform the patient about other procedures and offer referral to another appropriately skilled surgeon.

Breast/Chest Surgery Techniques and Complications

Although breast/chest appearance is an important secondary sex characteristic, breast presence or size is not involved in the legal definitions of sex and gender and is not necessary for reproduction. The performance of breast/chest operations for treatment of gender dysphoria should be considered with the same care as beginning hormone therapy, as both produce relatively irreversible changes to the body.

For the MtF patient, a breast augmentation (sometimes called "chest reconstruction") is not different from the procedure in a natal female patient. It is usually performed through implantation of breast prostheses and occasionally with the lipofilling technique. Infections and capsular fibrosis are rare complications of augmentation mammoplasty in MtF patients (Kanhai, Hage, Karim, & Mulder, 1999).

For the FtM patient, a mastectomy or "male chest contouring" procedure is available. For many FtM patients, this is the only surgery undertaken. When the amount of breast tissue removed requires skin removal, a scar will result and the patient should be so informed. Complications of subcutaneous mastectomy can include nipple necrosis, contour irregularities, and unsightly scarring (Monstrey et al., 2008).

Genital Surgery Techniques and Complications

Genital surgical procedures for the MtF patient may include orchiectomy, penectomy, vaginoplasty, clitoroplasty, and labiaplasty. Techniques include penile skin inversion, pedicled colosigmoid

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transplant, and free skin grafts to line the neovagina. Sexual sensation is an important objective in vaginoplasty, along with creation of a functional vagina and acceptable cosmesis.

Surgical complications of MtF genital surgery may include complete or partial necrosis of the vagina and labia, fistulas from the bladder or bowel into the vagina, stenosis of the urethra, and vaginas that are either too short or too small for coitus. While the surgical techniques for creating a neovagina are functionally and aesthetically excellent, anorgasmia following the procedure has been reported, and a second stage labiaplasty may be needed for cosmesis (Klein & Gorzalka, 2009; Lawrence, 2006).

Genital surgical procedures for FtM patients may include hysterectomy, salpingo-oophorectomy, vaginectomy, metoidioplasty, scrotoplasty, urethroplasty, placement of testicular prostheses, and phalloplasty. For patients without former abdominal surgery, the laparoscopic technique for hysterectomy and salpingo-oophorectomy is recommended to avoid a lower-abdominal scar. Vaginal access may be difficult as most patients are nulliparous and have often not experienced penetrative intercourse. Current operative techniques for phalloplasty are varied. The choice of techniques may be restricted by anatomical or surgical considerations and by a client's financial considerations. If the objectives of phalloplasty are a neophallus of good appearance, standing micturition, sexual sensation, and/or coital ability, patients should be clearly informed that there are several separate stages of surgery and frequent technical difficulties, which may require additional operations. Even metoidioplasty, which in theory is a one-stage procedure for construction of a microphallus, often requires more than one operation. The objective of standing micturition with this technique can not always be ensured (Monstrey et al., 2009).

Complications of phalloplasty in FtMs may include frequent urinary tract stenoses and fistulas, and occasionally necrosis of the neophallus. Metoidioplasty results in a micropenis, without the capacity for standing urination. Phalloplasty, using a pedicled or a free vascularized flap, is a lengthy, multi-stage procedure with significant morbidity that includes frequent urinary complications and unavoidable donor site scarring. For this reason, many FtM patients never undergo genital surgery other than hysterectomy and salpingo-oophorectomy (Hage & De Graaf, 1993).

Even patients who develop severe surgical complications seldom regret having undergone surgery. The importance of surgery can be appreciated by the repeated finding that quality of surgical results is one of the best predictors of the overall outcome of sex reassignment (Lawrence, 2006).

Other Surgeries

Other surgeries for assisting in body feminization include reduction thyroid chondroplasty (reduction of the Adam's apple), voice modification surgery, suction-assisted lipoplasty (contour

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modeling) of the waist, rhinoplasty (nose correction), facial bone reduction, face-lift, and blepharoplasty (rejuvenation of the eyelid). Other surgeries for assisting in body masculinization include liposuction, lipofilling, and pectoral implants. Voice surgery to obtain a deeper voice is rare but may be recommended in some cases, such as when hormone therapy has been ineffective.

Although these surgeries do not require referral by mental health professionals, such professionals can play an important role in assisting clients in making a fully informed decision about the timing and implications of such procedures in the context of the social transition.

Although most of these procedures are generally labeled "purely aesthetic," these same operations in an individual with severe gender dysphoria can be considered medically necessary, depending on the unique clinical situation of a given patient's condition and life situation. This ambiguity reflects reality in clinical situations, and allows for individual decisions as to the need and desirability of these procedures.

XII

Postoperative Care and Follow-Up

Long-term postoperative care and follow-up after surgical treatments for gender dysphoria are associated with good surgical and psychosocial outcomes (Monstrey et al., 2009). Follow-up is important to a patient's subsequent physical and mental health and to a surgeon's knowledge about the benefits and limitations of surgery. Surgeons who operate on patients coming from long distances should include personal follow-up in their care plan and attempt to ensure affordable local long-term aftercare in their patients' geographic region.

Postoperative patients may sometimes exclude themselves from follow-up by specialty providers, including the hormone-prescribing physician (for patients receiving hormones), not recognizing that these providers are often best able to prevent, diagnose, and treat medical conditions that are unique to hormonally and surgically treated patients. The need for follow-up equally extends to mental health professionals, who may have spent a longer period of time with the patient than any other professional and therefore are in an excellent position to assist in any postoperative adjustment difficulties. Health professionals should stress the importance of postoperative follow-up care with their patients and offer continuity of care.

Postoperative patients should undergo regular medical screening according to recommended guidelines for their age. This is discussed more in the next section.

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XIII
Lifelong Preventive and Primary Care

Transsexual, transgender, and gender-nonconforming people need health care throughout their lives. For example, to avoid the negative secondary effects of having a gonadectomy at a relatively young age and/or receiving long-term, high-dose hormone therapy, patients need thorough medical care by providers experienced in primary care and transgender health. If one provider is not able to provide all services, ongoing communication among providers is essential.

Primary care and health maintenance issues should be addressed before, during, and after any possible changes in gender role and medical interventions to alleviate gender dysphoria. While hormone providers and surgeons play important roles in preventive care, every transsexual, transgender, and gender-nonconforming person should partner with a primary care provider for overall health care needs (Feldman, 2007).

General Preventive Health Care

Screening guidelines developed for the general population are appropriate for organ systems that are unlikely to be affected by feminizing/masculinizing hormone therapy. However, in areas such as cardiovascular risk factors, osteoporosis, and some cancers (breast, cervical, ovarian, uterine, and prostate), such general guidelines may either over- or underestimate the cost-effectiveness of screening individuals who are receiving hormone therapy.

Several resources provide detailed protocols for the primary care of patients undergoing feminizing/masculinizing hormone therapy, including therapy that is provided after sex reassignment surgeries (Center of Excellence for Transgender Health, UCSF, 2011; Feldman & Goldberg, 2006; Feldman, 2007; Gorton, Buth, & Spade, 2005). Clinicians should consult their national evidence-based guidelines and discuss screening with their patients in light of the effects of hormone therapy on their baseline risk.

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Cancer Screening

Cancer screening of organ systems that are associated with sex can present particular medical and psychosocial challenges for transsexual, transgender, and gender-nonconforming patients and their health care providers. In the absence of large-scale prospective studies, providers are unlikely to have enough evidence to determine the appropriate type and frequency of cancer screenings for this population. Over-screening results in higher health care costs, high false positive rates, and often unnecessary exposure to radiation and/or diagnostic interventions such as biopsies. Under-screening results in diagnostic delay for potentially treatable cancers. Patients may find cancer screening gender affirming (such as mammograms for MtF patients) or both physically and emotionally painful (such as Pap smears offer continuity of care for FtM patients).

Urogenital Care

Gynecologic care may be necessary for transsexual, transgender, and gender-nonconforming people of both sexes. For FtM patients, such care is needed predominantly for individuals who have not had genital surgery. For MtF patients, such care is needed after genital surgery. While many surgeons counsel patients regarding postoperative urogenital care, primary care clinicians and gynecologists should also be familiar with the special genital concerns of this population.

All MtF patients should receive counseling regarding genital hygiene, sexuality, and prevention of sexually transmitted infections; those who have had genital surgery should also be counseled on the need for regular vaginal dilation or penetrative intercourse in order to maintain vaginal depth and width (van Trotsenburg, 2009). Due to the anatomy of the male pelvis, the axis and the dimensions of the neovagina differ substantially from those of a biologic vagina. This anatomic difference can affect intercourse if not understood by MtF patients and their partners (van Trotsenburg, 2009).

Lower urinary tract infections occur frequently in MtF patients who have had surgery because of the reconstructive requirements of the shortened urethra. In addition, these patients may suffer from functional disorders of the lower urinary tract; such disorders may be caused by damage of the autonomous nerve supply of the bladder floor during dissection between the rectum and the bladder, and by a change of the position of the bladder itself. A dysfunctional bladder (e.g., overactive bladder, stress or urge urinary incontinence) may occur after sex reassignment surgery (Hoebeke et al., 2005; Kuhn, Hiltebrand, & Birkhauser, 2007).

Most FtM patients do not undergo vaginectomy (colpectomy). For patients who take masculinizing hormones, despite considerable conversion of testosterone to estrogens, atrophic changes of the vaginal lining can be observed regularly and may lead to pruritus or burning. Examination can be

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both physically and emotionally painful, but lack of treatment can seriously aggravate the situation. Gynecologists treating the genital complaints of FtM patients should be aware of the sensitivity that patients with a male gender identity and masculine gender expression might have around having genitals typically associated with the female sex.

XIV

Applicability of the *Standards of Care* to People Living in Institutional Environments

The *SOC* in their entirety apply to all transsexual, transgender, and gender-nonconforming people, irrespective of their housing situation. People should not be discriminated against in their access to appropriate health care based on where they live, including institutional environments such as prisons or long-/intermediate-term health care facilities (Brown, 2009). Health care for transsexual, transgender, and gender-nonconforming people living in an institutional environment should mirror that which would be available to them if they were living in a non-institutional setting within the same community.

All elements of assessment and treatment as described in the *SOC* can be provided to people living in institutions (Brown, 2009). Access to these medically necessary treatments should not be denied on the basis of institutionalization or housing arrangements. If the in-house expertise of health professionals in the direct or indirect employ of the institution does not exist to assess and/or treat people with gender dysphoria, it is appropriate to obtain outside consultation from professionals who are knowledgeable about this specialized area of health care.

People with gender dysphoria in institutions may also have coexisting mental health conditions (Cole et al., 1997). These conditions should be evaluated and treated appropriately.

People who enter an institution on an appropriate regimen of hormone therapy should be continued on the same, or similar, therapies and monitored according to the *SOC*. A "freeze frame" approach is not considered appropriate care in most situations *(Kosilek v. Massachusetts Department of Corrections/Maloney,* C.A. No. 92–12820-MLW, 2002). People with gender dysphoria who are deemed appropriate for hormone therapy (following the *SOC*) should be started on such therapy. The consequences of abrupt withdrawal of hormones or lack of initiation of hormone therapy when medically necessary include a high likelihood of negative outcomes such as surgical self-treatment by autocastration, depressed mood, dysphoria, and/or suicidality (Brown, 2010).

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Reasonable accommodations to the institutional environment can be made in the delivery of care consistent with the *SOC*, if such accommodations do not jeopardize the delivery of medically necessary care to people with gender dysphoria. An example of a reasonable accommodation is the use of injectable hormones, if not medically contraindicated, in an environment where diversion of oral preparations is highly likely (Brown, 2009). Denial of needed changes in gender role or access to treatments, including sex reassignment surgery, on the basis of residence in an institution are not reasonable accommodations under the *SOC* (Brown, 2010).

Housing and shower/bathroom facilities for transsexual, transgender, and gender-nonconforming people living in institutions should take into account their gender identity and role, physical status, dignity, and personal safety. Placement in a single-sex housing unit, ward, or pod on the sole basis of the appearance of the external genitalia may not be appropriate and may place the individual at risk for victimization (Brown, 2009).

Institutions where transsexual, transgender, and gender-nonconforming people reside and receive health care should monitor for a tolerant and positive climate to ensure that residents are not under attack by staff or other residents.

XV

Applicability of the *Standards of Care* to People With Disorders of Sex Development

Terminology

The term *disorder of sex development* (DSD) refers to a somatic condition of atypical development of the reproductive tract (Hughes, Houk, Ahmed, Lee, & LWPES/ESPE Consensus Group, 2006). DSDs include the condition that used to be called *intersexuality*. Although the terminology was changed to DSD during an international consensus conference in 2005 (Hughes et al., 2006), disagreement about language use remains. Some people object strongly to the "disorder" label, preferring instead to view these congenital conditions as a matter of diversity (Diamond, 2009) and to continue using the terms *intersex* or *intersexuality*. In the *SOC*, WPATH uses the term DSD in an objective and value-free manner, with the goal of ensuring that health professionals recognize this medical term and use it to access relevant literature as the field progresses. WPATH remains

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open to new terminology that will further illuminate the experience of members of this diverse population and lead to improvements in health care access and delivery.

Rationale for Addition to the *SOC*

Previously, individuals with a DSD who also met the *DSM-IV-TR's* behavioral criteria for Gender Identity Disorder (American Psychiatric Association, 2000) were excluded from that general diagnosis. Instead, they were categorized as having a "Gender Identity Disorder - Not Otherwise Specified." They were also excluded from the WPATH *Standards of Care*.

The current proposal for *DSM-5* (www.dsm5.org) is to replace the term *gender identity disorder* with *gender dysphoria*. Moreover, the proposed changes to the *DSM* consider gender dysphoric people with a DSD to have a subtype of gender dysphoria. This proposed categorization—which explicitly differentiates between gender dysphoric individuals with and without a DSD—is justified: In people with a DSD, gender dysphoria differs in its phenomenological presentation, epidemiology, life trajectories, and etiology (Meyer-Bahlburg, 2009).

Adults with a DSD and gender dysphoria have increasingly come to the attention of health professionals. Accordingly, a brief discussion of their care is included in this version of the *SOC*.

Health History Considerations

Health professionals assisting patients with both a DSD and gender dysphoria need to be aware that the medical context in which such patients have grown up is typically very different from that of people without a DSD.

Some people are recognized as having a DSD through the observation of gender-atypical genitals at birth. (Increasingly this observation is made during the prenatal period by way of imaging procedures such as ultrasound.) These infants then undergo extensive medical diagnostic procedures. After consultation among the family and health professionals—during which the specific diagnosis, physical and hormonal findings, and feedback from long-term outcome studies (Cohen-Kettenis, 2005; Dessens, Slijper, & Drop, 2005; Jurgensen, Hiort, Holterhus, & Thyen, 2007; Mazur, 2005; Meyer-Bahlburg, 2005; Stikkelbroeck et al., 2003; Wisniewski, Migeon, Malouf, & Gearhart, 2004) are considered—the newborn is assigned a sex, either male or female.

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Other individuals with a DSD come to the attention of health professionals around the age of puberty through the observation of atypical development of secondary sex characteristics. This observation also leads to a specific medical evaluation.

The type of DSD and severity of the condition has significant implications for decisions about a patient's initial sex assignment, subsequent genital surgery, and other medical and psychosocial care (Meyer-Bahlburg, 2009). For instance, the degree of prenatal androgen exposure in individuals with a DSD has been correlated with the degree of masculinization of gender-related *behavior* (that is, *gender role and expression*); however, the correlation is only moderate, and considerable behavioral variability remains unaccounted for by prenatal androgen exposure (Jurgensen et al., 2007; Meyer-Bahlburg, Dolezal, Baker, Ehrhardt, & New, 2006). Notably, a similar correlation of prenatal hormone exposure with gender *identity* has not been demonstrated (e.g., Meyer-Bahlburg et al., 2004). This is underlined by the fact that people with the same (core) gender identity can vary widely in the degree of masculinization of their gender-related behavior.

Assessment and Treatment of Gender Dysphoria in People with Disorders of Sex Development

Very rarely are individuals with a DSD identified as having gender dysphoria *before* a DSD diagnosis has been made. Even so, a DSD diagnosis is typically apparent with an appropriate history and basic physical exam—both of which are part of a medical evaluation for the appropriateness of hormone therapy or surgical interventions for gender dysphoria. Mental health professionals should ask their clients presenting with gender dysphoria to have a physical exam, particularly if they are not currently seeing a primary care (or other health care) provider.

Most people with a DSD who are born with genital ambiguity do not develop gender dysphoria (e.g., Meyer-Bahlburg, Dolezal, et al., 2004; Wisniewski et al., 2004). However, some people with a DSD will develop chronic gender dysphoria and even undergo a change in their birth-assigned sex and/or their gender role (Meyer-Bahlburg, 2005; Wilson, 1999; Zucker, 1999). If there are persistent and strong indications that gender dysphoria is present, a comprehensive evaluation by clinicians skilled in the assessment and treatment of gender dysphoria is essential, irrespective of the patient's age. Detailed recommendations have been published for conducting such an assessment and for making treatment decisions to address gender dysphoria in the context of a DSD (Meyer-Bahlburg, 2011). Only after thorough assessment should steps be taken in the direction of changing a patient's birth-assigned sex or gender role.

Clinicians assisting these patients with treatment options to alleviate gender dysphoria may profit from the insights gained from providing care to patients without a DSD (Cohen-Kettenis, 2010).

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However, certain criteria for treatment (e.g., age, duration of experience with living in the desired gender role) are usually not routinely applied to people with a DSD; rather, the criteria are interpreted in light of a patient's specific situation (Meyer-Bahlburg, 2011). In the context of a DSD, changes in birth-assigned sex and gender role have been made at any age between early elementary-school age and middle adulthood. Even genital surgery may be performed much earlier in these patients than in gender dysphoric individuals without a DSD if the surgery is well justified by the diagnosis, by the evidence-based gender-identity prognosis for the given syndrome and syndrome severity, and by the patient's wishes.

One reason for these treatment differences is that genital surgery in individuals with a DSD is quite common in infancy and adolescence. Infertility may already be present due to either early gonadal failure or to gonadectomy because of a malignancy risk. Even so, it is advisable for patients with a DSD to undergo a full social transition to another gender role only if there is a long-standing history of gender-atypical behavior, and if gender dysphoria and/or the desire to change one's gender role has been strong and persistent for a considerable period of time. Six months is the time period of full symptom expression required for the application of the gender dysphoria diagnosis proposed for *DSM-5* (Meyer-Bahlburg, 2011).

Additional Resources

The gender-relevant medical histories of people with a DSD are often complex. Their histories may include a great variety of inborn genetic, endocrine, and somatic atypicalities, as well as various hormonal, surgical, and other medical treatments. For this reason, many additional issues need to be considered in the psychosocial and medical care of such patients, regardless of the presence of gender dysphoria. Consideration of these issues is beyond what can be covered in the *SOC*. The interested reader is referred to existing publications (e.g., Cohen-Kettenis & Pfäfflin, 2003; Meyer-Bahlburg, 2002, 2008). Some families and patients also find it useful to consult or work with community support groups.

There is a very substantial medical literature on the medical management of patients with a DSD. Much of this literature has been produced by high-level specialists in pediatric endocrinology and urology, with input from specialized mental health professionals, especially in the area of gender. Recent international consensus conferences have addressed evidence-based care guidelines (including issues of gender and of genital surgery) for DSD in general (Hughes et al., 2006) and specifically for Congenital Adrenal Hyperplasia (Joint LWPES/ESPE CAH Working Group et al., 2002; Speiser et al., 2010). Others have addressed the research needs for DSD in general (Meyer-Bahlburg & Blizzard, 2004) and for selected syndromes such as 46,XXY (Simpson et al., 2003).

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APPENDIX A
GLOSSARY

Terminology in the area of health care for transsexual, transgender, and gender-nonconforming people is rapidly evolving; new terms are being introduced, and the definitions of existing terms are changing. Thus, there is often misunderstanding, debate, or disagreement about language in this field. Terms that may be unfamiliar or that have specific meanings in the *SOC* are defined below for the purpose of this document only. Others may adopt these definitions, but WPATH acknowledges that these terms may be defined differently in different cultures, communities, and contexts.

WPATH also acknowledges that many terms used in relation to this population are not ideal. For example, the terms *transsexual* and *transvestite*—and, some would argue, the more recent term *transgender*—have been applied to people in an objectifying fashion. Yet such terms have been more or less adopted by many people who are making their best effort to make themselves understood. By continuing to use these terms, WPATH intends only to ensure that concepts and processes are comprehensible, in order to facilitate the delivery of quality health care to transsexual, transgender, and gender-nonconforming people. WPATH remains open to new terminology that will further illuminate the experience of members of this diverse population and lead to improvements in health care access and delivery.

Bioidentical hormones: Hormones that are *structurally* identical to those found in the human body (ACOG Committee of Gynecologic Practice, 2005). The hormones used in bioidentical hormone therapy (BHT) are generally derived from plant sources and are structurally similar to endogenous human hormones, but they need to be commercially processed to become bioidentical.

Bioidentical compounded hormone therapy (BCHT): Use of hormones that are prepared, mixed, assembled, packaged, or labeled as a drug by a pharmacist and custom-made for a patient according to a physician's specifications. Government drug agency approval is not possible for each compounded product made for an individual consumer.

Cross-dressing (transvestism): Wearing clothing and adopting a gender role presentation that, in a given culture, is more typical of the other sex.

Disorders of sex development (DSD): Congenital conditions in which the development of chromosomal, gonadal, or anatomic sex is atypical. Some people strongly object to the "disorder" label and instead view these conditions as a matter of diversity (Diamond, 2009), preferring the terms *intersex* and *intersexuality*.

AR-000569

Female-to-Male (FtM): Adjective to describe individuals assigned female at birth who are changing or who have changed their body and/or gender role from birth-assigned female to a more masculine body or role.

Gender dysphoria: Distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics) (Fisk, 1974; Knudson, De Cuypere, & Bockting, 2010b).

Gender identity: A person's intrinsic sense of being male (a boy or a man), female (a girl or woman), or an alternative gender (e.g., boygirl, girlboy, transgender, genderqueer, eunuch) (Bockting, 1999; Stoller, 1964).

Gender identity disorder: Formal diagnosis set forth by the *Diagnostic Statistical Manual of Mental Disorders, 4th Edition, Text Rev (DSM IV-TR)* (American Psychiatric Association, 2000). Gender identity disorder is characterized by a strong and persistent cross-gender identification and a persistent discomfort with one's sex or sense of inappropriateness in the gender role of that sex, causing clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Gender-nonconforming: Adjective to describe individuals whose gender identity, role, or expression differs from what is normative for their assigned sex in a given culture and historical period.

Gender role or expression: Characteristics in personality, appearance, and behavior that in a given culture and historical period are designated as masculine or feminine (that is, more typical of the male or female social role) (Ruble, Martin, & Berenbaum, 2006). While most individuals present socially in clearly masculine or feminine gender roles, some people present in an alternative gender role such as genderqueer or specifically transgender. All people tend to incorporate both masculine and feminine characteristics in their gender expression in varying ways and to varying degrees (Bockting, 2008).

Genderqueer: Identity label that may be used by individuals whose gender identity and/or role does not conform to a binary understanding of gender as limited to the categories of man or woman, male or female (Bockting, 2008).

Internalized transphobia: Discomfort with one's own transgender feelings or identity as a result of internalizing society's normative gender expectations.

Male-to-Female (MtF): Adjective to describe individuals assigned male at birth who are changing or who have changed their body and/or gender role from birth-assigned male to a more feminine body or role.

Natural hormones: Hormones that are derived from natural *sources* such as plants or animals. Natural hormones may or may not be bioidentical.

AR-000570

Sex: Sex is assigned at birth as male or female, usually based on the appearance of the external genitalia. When the external genitalia are ambiguous, other components of sex (internal genitalia, chromosomal and hormonal sex) are considered in order to assign sex (Grumbach, Hughes, & Conte, 2003; MacLaughlin & Donahoe, 2004; Money & Ehrhardt, 1972; Vilain, 2000). For most people, gender identity and expression are consistent with their sex assigned at birth; for transsexual, transgender, and gender-nonconforming individuals, gender identity or expression differ from their sex assigned at birth.

Sex reassignment surgery (gender affirmation surgery): Surgery to change primary and/or secondary sex characteristics to affirm a person's gender identity. Sex reassignment surgery can be an important part of medically necessary treatment to alleviate gender dysphoria.

Transgender: Adjective to describe a diverse group of individuals who cross or transcend culturally defined categories of gender. The gender identity of transgender people differs to varying degrees from the sex they were assigned at birth (Bockting, 1999).

Transition: Period of time when individuals change from the gender role associated with their sex assigned at birth to a different gender role. For many people, this involves learning how to live socially in another gender role; for others this means finding a gender role and expression that are most comfortable for them. Transition may or may not include feminization or masculinization of the body through hormones or other medical procedures. The nature and duration of transition are variable and individualized.

Transsexual: Adjective (often applied by the medical profession) to describe individuals who seek to change or who have changed their primary and/or secondary sex characteristics through femininizing or masculinizing medical interventions (hormones and/or surgery), typically accompanied by a permanent change in gender role.

APPENDIX B
OVERVIEW OF MEDICAL RISKS OF HORMONE THERAPY

The risks outlined below are based on two comprehensive, evidence-based literature reviews of masculinizing/feminizing hormone therapy (Feldman & Safer, 2009; Hembree et al., 2009), along with a large cohort study (Asscheman et al., 2011). These reviews can serve as detailed references for providers, along with other widely recognized, published clinical materials (e.g., Dahl et al., 2006; Ettner et al., 2007).

AR-000571

Risks of Feminizing Hormone Therapy (MtF)

Likely Increased Risk:

Venous thromboembolic disease

- Estrogen use increases the risk of venous thromboembolic events (VTE), particularly in patients who are over age 40, smokers, highly sedentary, obese, and who have underlying thrombophilic disorders.
- This risk is increased with the additional use of third generation progestins.
- This risk is decreased with use of the transdermal (versus oral) route of estradiol administration, which is recommended for patients at higher risk of VTE.

Cardiovascular, cerebrovascular disease

- Estrogen use increases the risk of cardiovascular events in patients over age 50 with underlying cardiovascular risk factors. Additional progestin use may increase this risk.

Lipids

- Oral estrogen use may markedly increase triglycerides in patients, increasing the risk of pancreatitis and cardiovascular events.
- Different routes of administration will have different metabolic effects on levels of HDL cholesterol, LDL cholesterol and lipoprotein(a).
- In general, clinical evidence suggests that MtF patients with pre-existing lipid disorders may benefit from the use of transdermal rather than oral estrogen.

Liver/gallbladder

- Estrogen and cyproterone acetate use may be associated with transient liver enzyme elevations and, rarely, clinical hepatotoxicity.
- Estrogen use increases the risk of cholelithiasis (gall stones) and subsequent cholecystectomy.

AR-000572

Possible Increased Risk:

Type 2 diabetes mellitus

- Feminizing hormone therapy, particularly estrogen, may increase the risk of type 2 diabetes, particularly among patients with a family history of diabetes or other risk factors for this disease.

Hypertension

- Estrogen use may increase blood pressure, but the effect on incidence of overt hypertension is unknown.
- Spironolactone reduces blood pressure and is recommended for at-risk or hypertensive patients desiring feminization.

Prolactinoma

- Estrogen use increases the risk of hyperprolactinemia among MtF patients in the first year of treatment, but this risk is unlikely thereafter.
- High-dose estrogen use may promote the clinical appearance of preexisting but clinically unapparent prolactinoma.

Inconclusive or No Increased Risk:

Items in this category include those that may present risk, but for which the evidence is so minimal that no clear conclusion can be reached.

Breast cancer

- MtF persons who have taken feminizing hormones do experience breast cancer, but it is unknown how their degree of risk compares to that of persons born with female genitalia.
- Longer duration of feminizing hormone exposure (i.e., number of years taking estrogen preparations), family history of breast cancer, obesity (BMI >35), and the use of progestins likely influence the level of risk.

AR-000573

Other Side Effects of Feminizing Therapy:

The following effects may be considered minor or even desired, depending on the patient, but are clearly associated with feminizing hormone therapy.

Fertility and sexual function

- Feminizing hormone therapy may impair fertility.
- Feminizing hormone therapy may decrease libido.
- Feminizing hormone therapy reduces nocturnal erections, with variable impact on sexually stimulated erections.

Risks of Anti-Androgen Medications:

Feminizing hormone regimens often include a variety of agents that affect testosterone production or action. These include GnRH agonists, progestins (including cyproterone acetate), spironolactone, and 5-alpha reductase inhibitors. An extensive discussion of the specific risks of these agents is beyond the scope of the *SOC*. However, both spironolactone and cyproterone acetate are widely used and deserve some comment.

Cyproterone acetate is a progestational compound with anti-androgenic properties (Gooren, 2005; Levy et al., 2003). Although widely used in Europe, it is not approved for use in the United States because of concerns about hepatotoxicity (Thole, Manso, Salgueiro, Revuelta, & Hidalgo, 2004). Spironolactone is commonly used as an anti-androgen in feminizing hormone therapy, particularly in regions where cyproterone is not approved for use (Dahl et al., 2006; Moore et al., 2003; Tangpricha et al., 2003). Spironolactone has a long history of use in treating hypertension and congestive heart failure. Its common side effects include hyperkalemia, dizziness, and gastrointestinal symptoms (*Physicians' Desk Reference*, 2007).

AR-000574

Risks of Masculinizing Hormone Therapy (FtM)

Likely Increased Risk:

Polycythemia

- Masculinizing hormone therapy involving testosterone or other androgenic steroids increases the risk of polycythemia (hematocrit > 50%), particularly in patients with other risk factors.
- Transdermal administration and adaptation of dosage may reduce this risk.

Weight gain/visceral fat

- Masculinizing hormone therapy can result in modest weight gain, with an increase in visceral fat.

Possible Increased Risk:

Lipids

- Testosterone therapy decreases HDL, but variably affects LDL and triglycerides.
- Supraphysiologic (beyond normal male range) serum levels of testosterone, often found with extended intramuscular dosing, may worsen lipid profiles, whereas transdermal administration appears to be more lipid neutral.
- Patients with underlying polycystic ovarian syndrome or dyslipidemia may be at increased risk of worsening dyslipidemia with testosterone therapy.

Liver

- Transient elevations in liver enzymes may occur with testosterone therapy.
- Hepatic dysfunction and malignancies have been noted with oral methyltestosterone. However, methyltestosterone is no longer available in most countries and should no longer be used.

Psychiatric

Masculinizing therapy involving testosterone or other androgenic steroids may increase the risk of hypomanic, manic, or psychotic symptoms in patients with underlying psychiatric disorders that include such symptoms. This adverse event appears to be associated with higher doses or supraphysiologic blood levels of testosterone.

Inconclusive or No Increased Risk:

Items in this category include those that may present risk, but for which the evidence is so minimal that no clear conclusion can be reached.

Osteoporosis

- Testosterone therapy maintains or increases bone mineral density among FtM patients prior to oophorectomy, at least in the first three years of treatment.
- There is an increased risk of bone density loss after oophorectomy, particularly if testosterone therapy is interrupted or insufficient. This includes patients utilizing solely oral testosterone.

Cardiovascular

- Masculinizing hormone therapy at normal physiologic doses does not appear to increase the risk of cardiovascular events among healthy patients.
- Masculinizing hormone therapy may increase the risk of cardiovascular disease in patients with underlying risks factors.

Hypertension

- Masculinizing hormone therapy at normal physiologic doses may increase blood pressure but does not appear to increase the risk of hypertension.
- Patients with risk factors for hypertension, such as weight gain, family history, or polycystic ovarian syndrome, may be at increased risk.

AR-000576

Type 2 diabetes mellitus

- Testosterone therapy does not appear to increase the risk of type 2 diabetes among FtM patients overall, unless other risk factors are present.
- Testosterone therapy may further increase the risk of type 2 diabetes in patients with other risk factors, such as significant weight gain, family history, and polycystic ovarian syndrome. There are no data that suggest or show an increase in risk in those with risk factors for dyslipidemia.

Breast cancer

- Testosterone therapy in FtM patients does not increase the risk of breast cancer.

Cervical cancer

- Testosterone therapy in FtM patients does not increase the risk of cervical cancer, although it may increase the risk of minimally abnormal Pap smears due to atrophic changes.

Ovarian cancer

- Analogous to persons born with female genitalia with elevated androgen levels, testosterone therapy in FtM patients may increase the risk of ovarian cancer, although evidence is limited.

Endometrial (uterine) cancer

- Testosterone therapy in FtM patients may increase the risk of endometrial cancer, although evidence is limited.

Other Side Effects of Masculinizing Therapy:

The following effects may be considered minor or even desired, depending on the patient, but are clearly associated with masculinization.

Fertility and sexual function

- Testosterone therapy in FtM patients reduces fertility, although the degree and reversibility are unknown.

AR-000577

- Testosterone therapy can induce permanent anatomic changes in the developing embryo or fetus.
- Testosterone therapy induces clitoral enlargement and increases libido.

Acne, androgenic alopecia

Acne and varying degrees of male pattern hair loss (androgenic alopecia) are common side effects of masculinizing hormone therapy.

APPENDIX C
SUMMARY OF CRITERIA FOR HORMONE THERAPY AND SURGERIES

As for all previous versions of the *SOC*, the criteria put forth in the *SOC* for hormone therapy and surgical treatments for gender dysphoria are clinical guidelines; individual health professionals and programs may modify them. Clinical departures from the *SOC* may come about because of a patient's unique anatomic, social, or psychological situation; an experienced health professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies. These departures should be recognized as such, explained to the patient, and documented through informed consent for quality patient care and legal protection. This documentation is also valuable to accumulate new data, which can be retrospectively examined to allow for health care—and the *SOC*—to evolve.

Criteria for Feminizing/Masculinizing Hormone Therapy (One Referral or Chart Documentation of Psychosocial Assessment)

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to give consent for treatment;
3. Age of majority in a given country (if younger, follow the *SOC* for children and adolescents);
4. If significant medical or mental concerns are present, they must be reasonably well controlled.

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Criteria for Breast/Chest Surgery (One Referral)

Mastectomy and Creation of a Male Chest in FtM Patients:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to give consent for treatment;
3. Age of majority in a given country (if younger, follow the *SOC* for children and adolescents);
4. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Hormone therapy is not a prerequisite.

Breast Augmentation (Implants/Lipofilling) in MtF Patients:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to give consent for treatment;
3. Age of majority in a given country (if younger, follow the *SOC* for children and adolescents);
4. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Although not an explicit criterion, it is recommended that MtF patients undergo feminizing hormone therapy (minimum 12 months) prior to breast augmentation surgery. The purpose is to maximize breast growth in order to obtain better surgical (aesthetic) results.

Criteria for Genital Surgery (Two Referrals)

Hysterectomy and Salpingo-Oophorectomy in FtM Patients and Orchiectomy in MtF Patients:

1. Persistent, well documented gender dysphoria;
2. Capacity to make a fully informed decision and to give consent for treatment;

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3. Age of majority in a given country;

4. If significant medical or mental health concerns are present, they must be well controlled;

5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless hormones are not clinically indicated for the individual).

The aim of hormone therapy prior to gonadectomy is primarily to introduce a period of reversible estrogen or testosterone suppression, before a patient undergoes irreversible surgical intervention.

These criteria do not apply to patients who are having these surgical procedures for medical indications other than gender dysphoria.

Metoidioplasty or Phalloplasty in FtM Patients and Vaginoplasty in MtF Patients:

1. Persistent, well documented gender dysphoria;

2. Capacity to make a fully informed decision and to give consent for treatment;

3. Age of majority in a given country;

4. If significant medical or mental health concerns are present, they must be well controlled;

5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless hormones are not clinically indicated for the individual);

6. 12 continuous months of living in a gender role that is congruent with their gender identity.

Although not an explicit criterion, it is recommended that these patients also have regular visits with a mental health or other medical professional.

The criterion noted above for some types of genital surgeries—that is, that patients engage in 12 continuous months of living in a gender role that is congruent with their gender identity—is based on expert clinical consensus that this experience provides ample opportunity for patients to experience and socially adjust in their desired gender role, before undergoing irreversible surgery.

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APPENDIX D
EVIDENCE FOR CLINICAL OUTCOMES OF THERAPEUTIC APPROACHES

One of the real supports for any new therapy is an outcome analysis. Because of the controversial nature of sex reassignment surgery, this type of analysis has been very important. Almost all of the outcome studies in this area have been retrospective.

One of the first studies to examine the post-treatment psychosocial outcomes of transsexual patients was done in 1979 at Johns Hopkins University School of Medicine and Hospital (USA) (J. K. Meyer & Reter, 1979). This study focused on patients' occupational, educational, marital, and domiciliary stability. The results revealed several significant changes with treatment. These changes were not seen as positive; rather, they showed that many individuals who had entered the treatment program were no better off or were worse off in many measures after participation in the program. These findings resulted in closure of the treatment program at that hospital/medical school (Abramowitz, 1986).

Subsequently, a significant number of health professionals called for a standard for eligibility for sex reassignment surgery. This led to the formulation of the original *Standards of Care* of the Harry Benjamin International Gender Dysphoria Association (now WPATH) in 1979.

In 1981, Pauly published results from a large retrospective study of people who had undergone sex reassignment surgery. Participants in that study had much better outcomes: Among 83 FtM patients, 80.7% had a satisfactory outcome (i.e., patient self report of "improved social and emotional adjustment"), 6.0% unsatisfactory. Among 283 MtF patients, 71.4% had a satisfactory outcome, 8.1% unsatisfactory. This study included patients who were treated before the publication and use of the *Standards of Care*.

Since the *Standards of Care* have been in place, there has been a steady increase in patient satisfaction and decrease in dissatisfaction with the outcome of sex reassignment surgery. Studies conducted after 1996 focused on patients who were treated according to the *Standards of Care*. The findings of Rehman and colleagues (1999) and Krege and colleagues (2001) are typical of this body of work; none of the patients in these studies regretted having had surgery, and most reported being satisfied with the cosmetic and functional results of the surgery. Even patients who develop severe surgical complications seldom regret having undergone surgery. Quality of surgical results is one of the best predictors of the overall outcome of sex reassignment (Lawrence, 2003). The vast majority of follow-up studies have shown an undeniable beneficial effect of sex reassignment surgery on postoperative outcomes such as subjective well being, cosmesis, and sexual function (De Cuypere et al., 2005; Garaffa, Christopher, & Ralph, 2010; Klein & Gorzalka, 2009), although the specific magnitude of benefit is uncertain from

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the currently available evidence. One study (Emory, Cole, Avery, Meyer, & Meyer, 2003) even showed improvement in patient income.

One troubling report (Newfield et al., 2006) documented lower scores on quality of life (measured with the SF-36) for FtM patients than for the general population. A weakness of that study is that it recruited its 384 participants by a general email rather than a systematic approach, and the degree and type of treatment were not recorded. Study participants who were taking testosterone had typically being doing so for less than 5 years. Reported quality of life was higher for patients who had undergone breast/chest surgery than for those who had not ($p<.001$). (A similar analysis was not done for genital surgery.) In other work, Kuhn and colleagues (2009) used the King's Health Questionnaire to assess the quality of life of 55 transsexual patients at 15 years after surgery. Scores were compared to those of 20 healthy female control patients who had undergone abdominal/pelvic surgery in the past. Quality of life scores for transsexual patients were the same or better than those of control patients for some subscales (emotions, sleep, incontinence, symptom severity, and role limitation), but worse in other domains (general health, physical limitation, and personal limitation).

Two long-term observational studies, both retrospective, compared the mortality and psychiatric morbidity of transsexual adults to those of general population samples (Asscheman et al., 2011; Dhejne et al., 2011). An analysis of data from the Swedish National Board of Health and Welfare information registry found that individuals who had received sex reassignment surgery (191 MtF and 133 FtM) had significantly higher rates of mortality, suicide, suicidal behavior, and psychiatric morbidity than those for a nontranssexual control group matched on age, immigrant status, prior psychiatric morbidity, and birth sex (Dhejne et al., 2011). Similarly, a study in the Netherlands reported a higher total mortality rate, including incidence of suicide, in both pre- and post-surgery transsexual patients (966 MtF and 365 MtF) than in the general population of that country (Asscheman et al., 2011). Neither of these studies questioned the efficacy of sex reassignment; indeed, both lacked an adequate comparison group of transsexuals who either did not receive treatment or who received treatment other than genital surgery. Moreover, transsexual people in these studies were treated as far back as the 1970s. However, these findings do emphasize the need to have good long-term psychological and psychiatric care available for this population. More studies are needed that focus on the outcomes of current assessment and treatment approaches for gender dysphoria.

It is difficult to determine the effectiveness of hormones alone in the relief of gender dysphoria. Most studies evaluating the effectiveness of masculinizing/feminizing hormone therapy on gender dysphoria have been conducted with patients who have also undergone sex reassignment surgery. Favorable effects of therapies that included both hormones and surgery were reported in a comprehensive review of over 3000 patients in 79 studies (mostly observational) conducted between 1961 and 1991 (Eldh, Berg, & Gustafsson, 1997; Gijs & Brewaeys, 2007; Murad et al., 2010; Pfäfflin & Junge, 1998). Patients operated on after 1986 did better than those before 1986; this reflects significant improvement in surgical complications (Eldh et al., 1997). Most patients have reported improved psychosocial outcomes, ranging between 87% for MtF patients and 97% for FtM patients (Green & Fleming, 1990).

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Similar improvements were found in a Swedish study in which "almost all patients were satisfied with sex reassignment at 5 years, and 86% were assessed by clinicians at follow-up as stable or improved in global functioning" (Johansson, Sundbom, Höjerback, & Bodlund, 2010). Weaknesses of these earlier studies are their retrospective design and use of different criteria to evaluate outcomes.

A prospective study conducted in the Netherlands evaluated 325 consecutive adult and adolescent subjects seeking sex reassignment (Smith, Van Goozen, Kuiper, & Cohen-Kettenis, 2005). Patients who underwent sex reassignment therapy (both hormonal and surgical intervention) showed improvements in their mean gender dysphoria scores, measured by the Utrecht Gender Dysphoria Scale. Scores for body dissatisfaction and psychological function also improved in most categories. Fewer than 2% of patients expressed regret after therapy. This is the largest prospective study to affirm the results from retrospective studies that a combination of hormone therapy and surgery improves gender dysphoria and other areas of psychosocial functioning. There is a need for further research on the effects of hormone therapy without surgery, and without the goal of maximum physical feminization or masculinization.

Overall, studies have been reporting a steady improvement in outcomes as the field becomes more advanced. Outcome research has mainly focused on the outcome of sex reassignment surgery. In current practice there is a range of identity, role, and physical adaptations that could use additional follow-up or outcome research (Institute of Medicine, 2011).

APPENDIX E
DEVELOPMENT PROCESS FOR THE *STANDARDS OF CARE,* VERSION 7

The process of developing *Standards of Care, Version 7* began when an initial *SOC* "work group" was established in 2006. Members were invited to examine specific sections of *SOC, Version 6*. For each section, they were asked to review the relevant literature, identify where research was lacking and needed, and recommend potential revisions to the *SOC* as warranted by new evidence. Invited papers were submitted by the following authors: Aaron Devor, Walter Bockting, George Brown, Michael Brownstein, Peggy Cohen-Kettenis, Griet DeCuypere, Petra DeSutter, Jamie Feldman, Lin Fraser, Arlene Istar Lev, Stephen Levine, Walter Meyer, Heino Meyer-Bahlburg, Stan Monstrey, Loren Schechter, Mick van Trotsenburg, Sam Winter, and Ken Zucker. Some of these authors chose to add co-authors to assist them in their task.

Initial drafts of these papers were due June 1, 2007. Most were completed by September 2007, with the rest completed by the end of 2007. These manuscripts were then submitted to the *International*

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Journal of Transgenderism (IJT). Each underwent the regular *IJT* peer review process. The final papers were published in Volume 11 (1–4) in 2009, making them available for discussion and debate.

After these articles were published, an *SOC* Revision Committee was established by the WPATH Board of Directors in 2010. The Revision Committee was first charged with debating and discussing the *IJT* background papers through a Google website. A subgroup of the Revision Committee was appointed by the Board of Directors to serve as the Writing Group. This group was charged with preparing the first draft of *SOC, Version 7* and continuing to work on revisions for consideration by the broader Revision Committee. The Board also appointed an International Advisory Group of transsexual, transgender, and gender-nonconforming individuals to give input on the revision.

A technical writer was hired to (1) review all of the recommendations for revision—both the original recommendations as outlined in the *IJT* articles and additional recommendations that emanated from the online discussion—and (2) create a survey to solicit further input on these potential revisions. From the survey results, the Writing Group was able to discern where these experts stood in terms of areas of agreement and areas in need of more discussion and debate. The technical writer then (3) created a very rough first draft of *SOC, Version 7* for the Writing Group to consider and build on.

The Writing Group met on March 4 and 5, 2011 in a face-to-face expert consultation meeting. They reviewed all recommended changes and debated and came to consensus on various controversial areas. Decisions were made based on the best available science and expert consensus. These decisions were incorporated into the draft, and additional sections were written by the Writing Group with the assistance of the technical writer.

The draft that emerged from the consultation meeting was then circulated among the Writing Group and finalized with the help of the technical writer. Once this initial draft was finalized, it was circulated among the broader *SOC* Revision Committee and the International Advisory Group. Discussion was opened up on the Google website and a conference call was held to resolve issues. Feedback from these groups was considered by the Writing Group, who then made further revisions. Two additional drafts were created and posted on the Google website for consideration by the broader *SOC* Revision Committee and the International Advisory Group. Upon completion of these three iterations of review and revision, the final document was presented to the WPATH Board of Directors for approval. The Board of Directors approved this version on September 14, 2011.

Funding

The *Standards of Care* revision process was made possible through a generous grant from the Tawani Foundation and a gift from an anonymous donor. These funds supported the following:

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1. Costs of a professional technical writer;

2. Process of soliciting international input on proposed changes from gender identity professionals and the transgender community;

3. Working meeting of the Writing Group;

4. Process of gathering additional feedback and arriving at final expert consensus from the professional and transgender communities, the *Standards of Care, Version 7,* Revision Committee, and WPATH Board of Directors;

5. Costs of printing and distributing *Standards of Care, Version 7,* and posting a free downloadable copy on the WPATH website;

6. Plenary session to launch the *Standards of Care, Version 7,* at the 2011 WPATH Biennial Symposium in Atlanta, Georgia, USA.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALISHEA KINGDOM, et al., Plaintiffs, v. DONALD J. TRUMP, et al., Defendants.	Case No. 1:25-cv-00691 **DECLARATION OF DR. CATHY THOMPSON**

I, Cathy Thompson, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

INTRODUCTION AND SCOPE OF WORK

1. I am a licensed clinical psychologist and recently retired Federal law enforcement officer with more than 20 years' experience working in correctional settings. My experience includes providing direct mental health services to incarcerated individuals inside prison and jail facilities. I later served as a national administrator for the Department of Justice's Federal Bureau of Prisons (BOP) and therefore have extensive experience in developing programs and services and drafting and implementing policies specific to the safety and treatment of individuals in BOP custody. I was involved in the development and implementation of BOP's procedures for managing transgender inmates. I retired from federal service effective September 23, 2023, and I now work as a consultant.

2. I have been retained by counsel for Plaintiffs in the class action complaint for declaratory and injunctive relief in *Kingdom v. Trump* (Trump Administration and BOP's categorical ban on gender-affirming health care for people with gender dysphoria in the custody of the Federal Bureau of Prisons), Case No.: 1:25-cv-00691. I have been asked to provide expert testimony about BOP policies and practices for transgender people prior to the executive order, and my expert opinion on the current and future impact of BOP's recent policy changes pertaining to treatment and management of transgender individuals in BOP custody.

3. My opinion, which is explained in further detail below, addresses the history of BOP's approach to managing and treating transgender people and the ways in which the recent guidance and policy issued by the BOP 1) cause harm to both those individuals and the staff who work with them, and 2) are not consistent with standards and accepted practices applicable to BOP.

4. It is my understanding that since January 2025, the BOP has rescinded its policy about transgender individuals, issued guidance prohibiting accommodations for transgender people, and directed medical staff to cease provision of gender affirming care, including hormones for all persons in custody.

5. It is my opinion that (1) a blanket ban on treating individuals who are transgender or have gender dysphoria is neither safe nor consistent with accepted practices, and (2) providing gender affirming care promotes security efforts.

PROFESSIONAL BACKGROUND

6. In 2000, I obtained my doctorate in Clinical Psychology from Texas Tech

University. As part of this degree, I completed an internship with the BOP during 1999-2000. After graduating, I continued my career with the BOP which spanned over 23 years until my retirement in 2023.

7. During more than two decades with BOP, I held positions of increasing responsibility in both prisons and administrative offices across the United States wherein I not only practiced psychology, but worked collaboratively and closely with other disciplines to meet the agency's mission of operating facilities that were safe while also delivering quality, evidence-based services.

8. For approximately the first decade, I promoted through positions located inside prisons. I provided treatment to men and women with a wide range of presenting issues. I provided supportive counseling to individuals struggling with issues of gender identity and more intensive psychological interventions for comorbid gender dysphoria and depressive disorders, posttraumatic stress disorder (PTSD), or anxiety disorders. Consistent with the standards mandated by the Prison Rape Elimination Act (PREA), I conducted assessments and provided treatment to incarcerated victims of sexual abuse.

9. In 2009, I was chosen for my first administrative oversight position within the BOP. In this capacity, I began to not only provide safe treatment and management directly, but to start giving guidance to others on how to create and maintain proper correctional environments through reliance on policy and accepted practices.

10. Five years later, I was promoted to a national level mental health position. My primary responsibility was the oversight, development, and implementation of substance use and mental health treatment programs. My work included ensuring these

services were relevant and beneficial to all individuals in BOP custody and addressing the care of transgender individuals was a large part of that work.

11. I had primary responsibility for ensuring BOPs residential treatment programs operated as modified therapeutic communities (MTCs). This is an evidence-based approach to residential substance use treatment designed to maximize the positive benefits of a supportive community that welcomes all members.[1]

12. While serving in this role, I was asked to be the acting national administrator for psychology services. During this time, BOP's policies regarding transgender inmates advanced significantly, and I was part of those efforts. I advised both my supervisors and institution staff on the accepted practices in caring for this population. I also provided input on policy development, and as it was implemented, I provided consultation and expertise to BOP's Transgender Executive Committee (TEC) regarding placement for transgender people that maximized opportunities for access to mental health treatment, reentry programming, and personal safety. I collaborated with other subject matter experts to develop lesson plans for annual training provided to all BOP staff on a wide range of psychological issues, including the accepted practices in the management of transgender people in secure settings. Most importantly, I was in a national leadership role advising on the importance of providing individualized and affirming services to transgender people, and I saw the benefits of this approach firsthand.

[1] De Leon, George. (2000). *The Therapeutic Community*. Springer Publishing Company.

13. Throughout the course of my BOP career, I remained engaged in scientific research which I published and presented outside the agency. I also taught courses at the college level. I retired in 2023 and do part-time consulting and treatment work. **My resume is attached as Exhibit A**.

14. I am being compensated at the rate of $500 per hour for my time completing this declaration.

BASES FOR OPINIONS

15. In preparing this report, I have relied on my training; my years of experience working in correctional settings and my specific experience within the BOP making care decisions about individuals who are transgender; my knowledge of the policies and practices surrounding these issues in both BOP and other correctional systems; and my knowledge of the relevant literature and standards.

16. In addition, in preparing this report, I have reviewed the following information to inform my opinion: the class action complaint filed March 10, 2025 and the two associated exhibits. I also reviewed publicly available materials as cited in this document.

BRIEF HISTORY OF BOP'S TRANSGENDER PRACTICES AND STANDARDS

17. As part of operating safe facilities, over the last several decades correctional systems have begun to have a better understanding of how to provide care to transgender inmates, just as they have provided care to individuals with any other

medical, mental health, learning, or other need. These efforts are supported by data demonstrating transgender individuals are both more likely to become involved in the justice system, and also more likely to experience sexual assault while incarcerated.[2] [3] Thus, in service to operating a safe facility and meeting the agency mission, sound correctional practices have long included provision of individualized health care and accommodations to transgender or intersex persons.

18. In 2003, the Prison Rape Elimination Act (PREA) was signed into law, and in 2012, the Department of Justice published the PREA Final Rule, which included standards for implementing the statute.[4] [5] PREA drew national attention to the needs of the incarcerated transgender population, and was the first federal law identifying best care practices. Five standards specify requirements addressing transgender persons in carceral settings.

19. One of those standards, PREA standard 115.42(c) establishes the necessity of individualized assessments, stating, "the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems." The Department of Justice

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[2] Grant, Jaime M.; Mottet, Lisa A.; Tanis, Justin; Harrison, Jack; Herman, Jody L.; Keisling, Mara (2011). Injustice at Every Turn: A Report of the National Transgender Discrimination Survey (PDF) (Report). Washington: National Center for Transgender Equality and National Gay and Lesbian Task Force.
[3] Beck, A. J., & Shandler, S. (2013). *Sexual Victimization in Prisons and Jails Reported by Inmates, 2011-2012*. U.S. Department of Justice, Bureau of Justice Statistics.
[4] 28 CFR Part 115 National Standards To Prevent, Detect, and Respond to Prison Rape; Final Rule.
[5] Prison Rape Elimination Act (PREA) of 2003 (P.L. 108-79).

also determined assigning housing to a transgender person based solely on genitalia is a violation of PREA.[6]

20. Mental health and medical treatment of transgender individuals was improving through the establishment of standards or accepted practices while PREA standards were being developed and issued. Research indicates, for example, that transgender individuals are at higher risk for suicide than non-transgender persons.[7] In 2015, the American Psychological Association issued guidance on working with transgender and non-binary individuals, including a key principle that "Psychologists strive to recognize the influence of institutional barriers on the lives of [transgender] people and to assist in developing [transgender]-affirmative environments."[8] [9] Similarly, the American Medical Association has made a number of public statements supporting the importance of and right to access gender affirming interventions.[10]

21. Meanwhile, BOP along with correctional systems across the country and world were developing procedures to ensure appropriate care for transgender inmates.

BOP POLICY AND PROCEDURES IMPACT

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[6] National PREA Resource Center. (2016). *FAQ: Does a policy that houses transgender or intersex inmates based exclusively on external genital anatomy violate Standard 115.42(c) & (e)*.
[7] Marshall E, Claes L, Bouman WP, et al. (2016). *Non-suicidal self-injury and suicidality in trans people: A systematic review of the literature*. Int Rev Psychiatry. 28, 58–69.
[8] American Psychological Association. (2015). *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*. American Psychologist, 70 (9), 832-864. Retrieved from https://www.apa.org/practice/guidelines/transgender.pdf
[9] *Id.,* at 840.
[10] *See* https://transhealthproject.org/resources/medical-organization-statements/american-medical-association-statements/

22. The BOP is the largest correctional system in the United States and operates 122 prison facilities across the country. Facilities are classified into four security-level categories, and men and women are housed in separate units or facilities. Over 35,000 employees work for BOP.

23. BOP, like most correctional systems, utilizes policy and training as dual methods to ensure staff are complying with the law and using the most accepted and safest practices available. Any policy is developed in response to a need for guidance and grounded in science, law, and safety.

24. Going back to the beginning of my BOP career in 1999, BOP has recognized that individuals who are transgender or intersex may not easily fit into BOP's housing structure. Thus, senior officials at the agency have made decisions about the most appropriate housing for these persons, based on the safety of both the individual and others. Yet, BOP did not have a policy, and while transgender people did receive treatment and in some cases were housed in accordance with their gender identity, , the lack of agency directive raised questions as to how to best make such decisions.

25. Following the passage of PREA in 2003, BOP updated its policy on sexual abuse to ensure it was compliant with the statute and standards.[11] In particular, the policy included language from the PREA standards and explained to staff in clear language the importance of individualized decision-making about the safety of transgender inmates.

26. While staff became familiar with these standards and recognized the

[11] DOJ-BOP. (2015). Program Statement 5324.12, Sexually Abusive Behavior Prevention and Intervention.

benefits of the individualized approaches, questions also arose as to how to make the best, fairest, and safest decisions with regard to housing and health care treatment. Many staff, particularly in remote locations, were not well acquainted with transgender terminology, for example, or were not familiar with external guidance documents, such as the standards from the World Professional Association for Transgender Health (WPATH).[12] Further, BOP data demonstrated a significant over-representation of transgender persons in restrictive housing settings, often for safety instead of disciplinary reasons.

27. Individuals with gender dysphoria experience significant clinical distress and, as noted previously, are at increased risk for suicide. Before BOP implemented national policy that was consistent with the accepted practices in the care and management of transgender people in prison settings, it was my experience that transgender individuals in BOP custody were more likely to require services to manage mental health crises than incarcerated individuals who are not transgender. In cases of severe gender dysphoria, risks included attempts at self-surgery and suicide.

28. Thus, in 2016, BOP began to develop national policy and guidance on the management and treatment of transgender persons in custody. This meant that, consistent with BOP labor relationships agreements, agency leadership began meeting with union representatives to develop what would be published in January 2017 as the Transgender

[12] World Professional Association for Transgender Health. Standards of care. Retrieved from https://wpath.org/publications/soc8/

Offender Manual (TOM).[13] [14]

29. Until recently, all policies issued by BOP underwent significant negotiation and review by both management and bargaining unit staff. Following several months of this review, the first TOM provided a great deal of information and direction to BOP staff. In addition to providing definitions, the policy set requirements for training, accommodations, pronoun usage, medical treatment, and housing placement.

30. I worked alongside the person leading TOM policy development, providing input specific to treatment and later helping her ensure implementation. Speaking about policy development, she described it as, "just a safe practice that comported with the law."[15] The key components of the policy were identifying how to implement accepted practices and ensuring any gender affirming services were provided based on individual need.

31. The TOM also established clear parameters around a decision-making body, known as the Transgender Executive Council (TEC). Membership on this body included senior leaders from the Women and Special Populations Branch as well as the senior psychologist, psychiatrist, security expert, and medical administrator in the

[13] DOJ-BOP. (2017, 2018, 2020). Program Statement 5200.08, Transgender Offender Manual.
[14] The TOM was updated two times. The first update clarified factors in placement and the second elucidated surgery processes. The BOP has since deleted all versions of the TOM from its website as a result of President Trump's Executive Order. The most recent version, dated Jan. 13, 2022, is preserved and available at https://perma.cc/4BP6-YWRP and **is attached as Exhibit B**.
[15] Schwartzapfel, B. (January 23, 2025). *Trump's Order Takes Aim at Transgender People in Prison*. The Marshall Project.

agency.

32. Although BOP had provided mental health and medical care before the TOM was issued, once the policy was in place, national administrators began to roll out training and supports for staff to ensure implementation was done with fidelity. Training was delivered to all employees, and advanced continuing education sessions were delivered to clinicians who delivered therapy or prescribe hormones.

33. In keeping with these efforts to ensure treatment was tied to evidence and that guidance was available, the BOP's Health Services Division also created a Transgender Clinical Care Team (TCCT) made of experienced medical professionals who could offer guidance to prescribers working in the prisons who may not have expertise in endocrinology or the prescription of hormones. Importantly, clinical assessments for hormone medication or other medical treatments included assessments by both psychologists and medical providers for the presence of gender dysphoria. In other words, to receive medical treatment, a person must actually have a condition warranting such an approach. Hormones or surgeries were provided only based on individual clinical need. **Attached as Exhibit C** are the most recent version of the clinical guidelines for health care staff, dated June 2023. Again, these guidelines were taken down from the BOP website after President Trump's Executive Order, but are also preserved at https://perma.cc/U5UT-S9PN. These clinical guidelines were an update of the previous guidelines from health care staff that had been operative since December 2016.

34. At the same, mental health procedures were developed to guide psychologists in the best ways to treat transgender people. While psychologists do not

prescribe medication in BOP, they were taught the benefit of gender affirming care, including hormones, in improving safety and wellbeing. This same information was conveyed to all staff because gender affirming care can reduce distress.

35. Support groups and other types of mental health treatment were also developed, eventually becoming part of BOP's list of approved programs under the First Step Act.

36. Accommodations were also described in policy, again as ways to better care for and manage the inmate population. Accommodations included allowing for the use of preferred pronouns and the provision of undergarments to match gender identity. Individuals were also given the option to purchase gender affirming items other than medication and undergarments that were allowed inside prison but required the use of personal funds (such as make-up). As noted, these items were intended to improve individual functioning, decrease crises, and therefore not only improve individuals' health but also make prisons safer.

37. Finally, the TOM created clear processes and benchmarks for a transgender individual to potentially be housed at a facility that aligns with their gender identity. The TOM took an approach grounded in safety where decisions were made by the TEC based on a number of factors and requirements.

38. Within a few years of the TOM's issuance in January 2017, BOP staff had fully implemented the policy. Gender affirming care was consistently available when indicated, and transgender people were afforded greater opportunities for engagement and positive programming that reduced psychological distress, reduced sexual

victimization, increased personal and institutional safety, and improved reentry outcomes. Agency policies direct consistent practice across all components and are reinforced by positive outcomes, and the TOM was no different.

DISCUSSION AND ANALYSIS OF RECENT BOP POLICY CHANGES

39. In early 2025, BOP abruptly rescinded a number of policies, including the TOM, following a Presidential Executive Order. BOP staff were suddenly operating without a policy but no guidance about what services or practices were supposed to replace the policy.

40. On February 21, 2025, Dana DiGiacomo, Acting Assistant Director of the BOP Reentry Services Division, and Shane Salem, Assistant Director of the BOP Correctional Programs Division, two individuals with whom I worked at BOP, issued a memo clarifying that BOP had been temporarily blocked by legal action from removing medical and mental health care from transgender persons in custody, but was proceeding with other restrictions. (This memo is filed with the Court at Docket 1-1.) Specifically, the aforementioned accommodations of gender affirming pronouns, undergarments, and purchased personal items were to cease. Additionally, programs for transgender persons and training on accepted practices with them stopped. Finally, the TEC itself was renamed and repurposed. Despite being authored by two individuals with no professional expertise on transgender care and no clinical degrees, the memo also indicated the TEC would no longer refer people for surgery.

41. A week later, Chris Bina, a pharmacist who leads BOP's Health Services Division, issued a memo stating no BOP funds could be used to treat any transgender

person in a way that validates their gender identity. It specifically states that "no Bureau of Prisons funds are to be expended for any medical procedure, treatment, or drug for the purpose of conforming an inmate's appearance to that of the opposite sex." (This memo is filed with the Court at Docket 1-2.)

42. The blanket ban on gender affirming care, is not only inconsistent with PREA and professional association guidance, it is also unsafe.

43. First, BOP's TOM was consistent with the law and medical standards. It served not only as a guide for BOP, but for other systems because it was effective.[16] The TOM was tied to PREA, whereas the new BOP approach is inconsistent with the individualized approach to housing required under PREA. Similarly, the new BOP approach is not consistent with psychological or medical association positions on the importance of delivering individualized gender affirming care and treatment to transgender persons who have a clinical need for that care.

44. Not only are these new BOP directives incompatible with accepted practices and law, they can cause significant harm and danger. Denying gender-affirming hormones to patients with a clinical need for such treatment has negative consequences, including causing or exacerbating distress and depression. Additionally, denying hormone therapy and access to other accommodations and treatments for gender dysphoria will bring about the return of the dysphoric symptoms, potentially causing

[16]Murphy, M., Et. al. (2023). *Implementing Gender-Affirming Care in Correctional Settings: A Review of Key Barriers and Action Steps for Change*. Journal of Correctional Health, 29(1).

attempts to self-castrate, self-harm, suicide, and aggression. All of these create safety concerns not only for people who are transgender, but for everyone who works or is incarcerated in the entire system. And with BOP's staffing crisis, there simply are not enough clinicians to manage the increased suicide watches and crisis, which could be deadly.[17]

45. Instead, BOP's former approach of providing gender affirming health care when indicated, as well as accommodations that support social transition under the TOM, was effective in maintaining transgender individuals' health and promoting institutional safety. Providing this care improves the agency goals of security and rehabilitation. Prohibiting such care undermines these goals.

CONCLUSION

46. BOP has the responsibility of managing and treating everyone in its custody, which means individuals with all sorts of health issues and conditions, including people who have gender dysphoria.

47. Treatment and care in BOP involves evidence-based approaches, and has

[17] Separate from the changes specific to transgender policies, BOP for years has experienced a crisis of custody and health care staffing shortages. Staffing shortages are evident across every job type, from psychologists to correctional officers. Moreover, under the new Administration, BOP announced that it will "greatly reduce, and in some cases eliminate, retention incentives across the agency, effective March 23, 2025." *See* Testimony of Kathleen Toomey, BOP Associate Deputy Director, before the U.S. House Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies during a hearing on Oversight of the Federal Bureau of Prisons, Feb. 26, 2025, at https://docs.house.gov/meetings/AP/AP19/20250226/117920/HHRG-119-AP19-Wstate-ToomeyK-20250226.pdf. This cut in salaries is likely to worsen staffing problems. As a result of these staffing shortages, all incarcerated individuals – not only those who are transgender - are likely to receive less medical and mental health care than they need.

always been individualized. Not only does it comport with the law, but it is also an accepted practice to provide treatment and accommodations based on individual factors. Prisons that support individual needs are safer and have fewer crises. I have grave concerns about the well-being of transgender individuals in BOP custody and the continued safe operations within BOP, should its ban on providing individualized care to transgender persons continue.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 17th day of March, 2025.

Cathy Thompson, PhD.

Dr. Cathy Thompson

EXHIBIT A

EXHIBIT A – RESUME OF CATHY THOMPSON

EDUCATION

Ph.D. in Clinical Psychology – Texas Tech University (APA Accredited), 2000
Dissertation: Gender Effects, Consistency, and Assessment in Coping
Licensed Clinical Psychologist – Texas State Board of Examiners of Psychologists (Since 2002)

M.A. in Clinical Psychology – Texas Tech University (APA Accredited), 1996

B.A. in Psychology (Summa Cum Laude) – Texas Tech University, 1992
Minor: Family Studies
Member of Psi Chi & National Golden Key Honor Society

PROFESSIONAL EXPERIENCE

2025 - Present
Consultant
AMM Solutions
Washington D.C.

Provide consultation, training and subject matter expertise to include investigative support, litigation support and expert witness testimony on a wide range of correctional and mental health topics. Analyze complaints to develop mitigation reports or strategy guidance. Deliver workshops and design curricula and interventions.

2024 - Present
Clinical Psychologist, Owner
Thompson & Associates Psychological Services, PLLC
North Richland Hills, TX

Provide comprehensive psychological services to a diverse client population. Administer psychological assessments to inform diagnosis and individualized treatment planning. Conduct individual therapy sessions for clients dealing with anxiety, depression, trauma, and relationship issues using evidence-based interventions. Offer expert guidance on substance use treatment, stress management, and behavioral interventions.

2024 - Present
Trainer and Consultant
The Change Companies
Carson City, NV

Develop and deliver training on evidence-based interventions, program fidelity, and best practices in behavioral health treatment. Consult with organizations and professionals to enhance the implementation of evidence-based practices in behavioral health and substance use treatment. Facilitate workshops and provide expert guidance on treatment effectiveness, compliance, and program development strategies.

2018 - 2023
National Chief of Drug Treatment Programs/Acting National Psychology Services Administrator
Federal Bureau of Prisons (Department of Justice)
Washington, D.C.

Responsible for coordinating and evaluating all services and activities of the agency's substance use treatment programs (both residential and non-residential) for federal offenders incarcerated in over 120 correctional facilities. Coordinated a system of technical assistance and training to ensure compliance with policy and best standards of clinical practice as related to all facets of correctional psychology. Analyzed information and provided recommendations for the formulation, establishment, or modification of program objectives, plans, and policies. Managed a $15M+ budget and supervised a diverse team of psychologists, clinicians, and administrative staff. Responded to high-level inquiries from various oversight bodies, including the Government Accountability Office (GAO) and the Office of the Inspector General (OIG). Served as senior agency psychologist on Transgender Executive Committee.

2015 - 2018
Supervisory Psychology Treatment Program Coordinator
Federal Bureau of Prisons (Department of Justice)
Washington, D.C.

Led teams of subject matter experts who provided on-site technical assistance and training to ensure compliance with policy and best standards of clinical practice as related to all facets of correctional psychology. Supervised a multidisciplinary team, including psychologists, clinicians, and administrative personnel. Spearheaded a major update of the agency's data analysis system to enhance tracking and ensure program utilization targets were met.

2013 - 2015 Psychology Treatment Program Coordinator
Federal Bureau of Prisons (Department of Justice)
Annapolis Junction, MD

Provided on-site technical assistance and training to ensure compliance with policy and best standards of clinical practice as related to all facets of correctional psychology. Served as the Employee Assistance Program Coordinator for Regional Office staff,

providing support and resources to enhance employee well-being. Engaged in staff recruitment efforts to attract and retain top talent within the agency.

2009 - 2013
Transitional Drug Abuse Program Coordinator
Federal Bureau of Prisons (Department of Justice)
Annapolis Junction, MD

Responsible for the procurement and administration of over 45 contracts for community-based substance use, mental health, and sex offender treatment, ensuring compliance with regulations, performance standards, and fiscal accountability. Managed a $15M+ budget and supervised a diverse team of clinicians and administrative staff.

1999 - 2009 Additional Roles

Federal Bureau of Prisons (Department of Justice)

Internship Program Coordinator – Developed and implemented a pre-doctoral psychology internship program, gaining agency approval. Coordinated site registration, designed training rotations, and authored the Internship Brochure and Training Manual. Managed application reviews, interview processes, and applicant ranking. Provided clinical and administrative supervision of interns and psychologists.

Challenge Program Coordinator – Managed a large residential treatment program for high- security male offenders, addressing substance use and mental health needs. Provided therapy, crisis intervention, psychological evaluations, and suicide risk assessments for all incarcerated individuals, including women, transgender people, and veterans. Provided clinical and administrative supervision of subordinate staff.

Step-Down Program Coordinator – Managed a large residential treatment program for severely mentally ill male offenders. Provided therapy, crisis intervention, psychological evaluations, and suicide risk assessments for all incarcerated individuals, including special populations such as transgender people and veterans. Provided clinical and administrative supervision of subordinate staff.

Drug Abuse Program Coordinator – Managed a non-residential drug abuse program at a medium-security federal prison. Provided individual and group therapy, crisis intervention, and suicide risk assessments. Served as a Mental Health Consultant for the Hostage Negotiation Team. Provided clinical and administrative supervision of subordinate staff.

Post-Doctoral Psychologist – Conducted individual and group psychotherapy for male offenders. Completed forensic evaluations to determine competency and responsibility.

Managed the Suicide Prevention Program, conducted extensive audits of departmental operations, delivered staff training, and consulted with Human Resources regarding hiring of qualified personnel.

TEACHING EXPERIENCE

Contributing Faculty – Adtalem Global Education (2004–Present)
Responsible for instructing graduate foundational and advanced graduate psychology courses, serving as dissertation committee member, and overseeing practicum/internship field experiences.

Adjunct Instructor – South Plains Junior College (1995–1999)
Responsible for all phases of teaching undergraduate General Psychology and Human Growth and Development courses, including the preparation and administration of lectures, construction and administration of examinations, and the computation and assignment of course grades. Lecture format with approximately 25 undergraduate students per semester. Fourteen sections taught.

Adjunct Instructor – Texas Tech University (1995–1997)
Responsible for all phases of teaching a senior-level undergraduate Abnormal Psychology course, including the preparation and administration of lectures, construction and administration of examinations, and the computation and assignment of course grades. Lecture format with approximately 50 undergraduate students per semester. Five sections taught.

PROFESSIONAL AFFILIATIONS

Member, American Psychological Association (APA) (Since 1995)
Member, APA Division 18: Psychologists in Public Service (Since 2000)

PUBLICATIONS & PRESENTATIONS

Publications:
Cook, S. W., Thompson, C. L., & Coca-Lyle, V. A. (2000). The psychology of stress and coping. In Management of Stress and Eating Disorders for Women and Children
(2nd ed.), CRC Press.

Selected Presentations:
Thompson, C. L. (2023, August). Substance use disorders and treatment options for justice-involved populations. Presentation given at the 2023 National Pretrial Services Leadership Conference.
Thompson, C. L. (2022, August). Meeting the needs of incarcerated women: Best

practices. Presentation given at the American Psychological Association National Convention, Minneapolis, MN.

Thompson, C. L. (2021, November). Treatment of substance use and associated mental illness in the federal prison system in the United States. Presentation given at the United Nations Office on Drugs and Crime technical consultation.

Thompson, C. L. (2019, August). Federal Bureau of Prisons: Drug abuse programs. Presentation given at the American Psychological Association National Convention,
Chicago, IL.

Thompson, C. L. (2012, May). Evolving perspectives on reentry. Presentation given at the 2012 Mid-Atlantic Regional Contractors Conference, Nashville, Tennessee.

Thompson, C. L., & Cook, S. W. (2000, August). Dispositional versus situational assessment, consistency, and gender effects in coping. Poster presentation given at the American Psychological Association National Convention, Washington, DC.

KEY SKILLS & EXPERTISE

Clinical Psychology & Mental Health

Licensed clinical psychologist with over 20 years of experience

Expertise in psychological assessments, therapy, and crisis intervention

Expertise in special populations, including women, veterans, and transgender people

Specialized in substance use treatment, trauma, and evaluations

Corrections & Criminal Justice

Extensive career in the Federal Bureau of Prisons, holding leadership roles

Developed and managed residential and non-residential treatment programs for incarcerated individuals

Expertise in correctional policy, reentry programs, and offender rehabilitation

Program Development & Administration

Designed and implemented large-scale treatment programs for diverse correctional populations and settings

Managed budgets exceeding $15M and supervised multidisciplinary teams

Developed training curricula for behavioral health professionals

Ensured policy compliance and program effectiveness through auditing and technical assistance

Leadership & Executive Management

Served as National Chief of Drug Treatment Programs for the Federal Bureau of Prisons

Led national teams of psychologists, clinicians, and administrative staff

Provided expert consultation and support in correctional psychology
Experienced in soliciting, awarding, and managing federal contracts

Teaching & Academic Contributions
Contributing faculty member for graduate psychology programs since 2004
Extensive experience in curriculum development and dissertation advisement
Taught undergraduate and graduate courses in psychology for multiple institutions

Public Speaking & Expert Testimony
Speaker at national and international conferences on substance use, reentry, and correctional psychology
Presented at the American Psychological Association National Convention and United Nations Office on Drugs and Crime
Provided expert witness testimony and consultation on legal cases involving mental health and corrections

Publications & Research
Published works in psychology and behavioral health, focusing on stress, coping, and substance use disorders
Conducted research on gender effects in coping and correctional psychology

Dr. Thompson's expertise spans clinical psychology, correctional mental health, program administration, and policy development, making her a leader in the field of correctional psychology and behavioral health treatment.

EXHIBIT B

U.S. Department of Justice
Federal Bureau of Prisons

P R O G R A M S T A T E M E N T
OPI: RSD/WASPB
NUMBER: 5200.08
DATE: January 13, 2022

Transgender Offender Manual

/s/
Approved: M.D. Carvajal
Director, Federal Bureau of Prisons

1. PURPOSE AND SCOPE

To ensure the Bureau of Prisons (Bureau) properly identifies, tracks, and provides services to the transgender population.

a. Program Objectives. Expected results of this program are:

- This policy provides guidance to staff in dealing with the unique issues that arise when working with transgender inmates.
- Institutions ensure transgender inmates can access programs and services that meet their needs as appropriate, and prepare them to return to the community.
- Sufficient resources will be allocated to deliver appropriate services to transgender inmates.
- Staff will complete training, enabling them to work effectively with transgender inmates.
- To enhance staff's understanding of the increased risk of suicide, mental health issues and victimization of transgender inmates.

b. Summary of Changes

Rescinded P5200.04 CN-1 Transgender Offender Manual (5/11/2018)

This reissuance incorporates the following modifications:

- Clarified duties and responsibilities of various staff.
- Added an institution requirement for maintaining a copy of the Case Management Activity (CMA) Assignment form BP-A1110, Consent Form for Transgender Inmates. Inmates can no longer request to have a CMA assignment removed, and then re-added at a later date.
- Clarified transfer, consultation, and program requirements.

- Updated guidance regarding initial designation and redesignation procedures for transgender offenders.
- Added information about gender affirming surgery.

c. **Institution Supplement**. None required. Should local facilities make any changes outside changes required in national policy or establish any additional local procedures to implement national policy, the local Union may invoke to negotiate procedures or appropriate arrangements.

2. DEFINITIONS

Gender – a construct used to classify a person as male, female, both, or neither. Gender encompasses aspects of social identity, psychological identity, and human behavior.

Gender identity – a person's sense of their own gender, which is communicated to others by their gender expression.

Gender expression – includes mannerisms, clothing, hairstyle, and choice of activities.

Gender nonconforming – a person whose appearance or manner does not conform to traditional societal gender expectations.

Transgender – the state of one's gender identity not matching one's sex assigned at birth. For the purposes of this policy, a transgender inmate is one who has met with a Bureau Psychologist and signed the form indicating consent to be identified within the agency as transgender. This step allows accommodations to be considered.

Cisgender – the state of one's gender identity matching one's sex assigned at birth.

Sexual orientation – the direction of one's sexual interest towards members of the same, opposite, or both genders (e.g., heterosexual, homosexual, bisexual, asexual). Sexual orientation and gender identity are not related.

Gender Dysphoria (GD) – a mental health diagnosis currently defined by DSM-5 as, "A strong and persistent cross-gender identification. It is manifested by a stated desire to be the opposite sex and persistent discomfort with his or her biologically assigned sex." Not all transgender inmates will have a diagnosis of GD, and a diagnosis of GD is not required for an individual to be provided services.

Intersex – a person whose sexual or reproductive anatomy or chromosomal pattern does not seem to fit typical physiological definitions of male or female. Not all intersex people identify as

transgender; unless otherwise specified, this policy does not apply to intersex people who do not identify as transgender.

Transition – measures that change one's gender expression or body to better reflect a person's gender identity.

Gender Affirming – describes behaviors or interventions that support the gender identity of a person.

3. STAFF RESPONSIBILITIES

The following Bureau components are responsible for ensuring consistent establishment of the programs, services, and resource allocations necessary for transgender offenders.

a. Central Office

(1) The **Women and Special Populations Branch (WASPB)** is the agency's primary source and point of contact on accommodation/transition, classification, management, and intervention/treatment programs and practices for transgender inmates in Bureau custody. The Branch is responsible for the following functions as they relate to transgender inmates:

- Engaging stakeholders, including serving as the primary point of contact on issues affecting transgender inmates with external entities including judges, congress, and advocacy groups.
- Ensuring the Bureau offers appropriate services to transgender inmates.
- Preparing budget requests to deliver national and pilot programs or services affecting transgender inmates.
- Providing guidance and direction to staff and institution, region, and agency leadership on transgender issues.
- Developing and implementing staff training on transgender issues.
- Building a research-based foundation for the Bureau's work with transgender inmates, including implementation support and intervention services.
- Presenting at internal and external conferences/events regarding the agency's transgender inmates' practices.
- Developing and monitoring monthly reports on the transgender population and institutional programs.
- Conducting an annual survey of transgender inmates in the Bureau and sharing results with internal and external stakeholders.
- Providing national oversight of pilot programs and initiatives serving transgender offenders.
- Overseeing the Transgender Executive Council (TEC).
- Ensure that a National Program and Policy Coordinator is assigned to each Region who will meet quarterly to discuss staffing and programming needs of transgender inmates.

(2) The **Health Services Division** oversees all medical and psychiatric guidance and treatment as it applies to transgender inmates. Clinical guidance on the most current research-driven clinical medical and psychiatric care of transgender inmates will be provided at the direction of the Medical Director. The Medical Director only receives referrals from the TEC and determines whether gender affirming surgery requests will be referred to a surgeon.

(3) The **Psychology Services Branch** oversees all mental health programs and services as they apply to transgender inmates, to include providing advice and guidance on identification and evaluation of transgender inmates, and making recommendations for treatment needs of transgender inmates and/or inmates with GD.

(4) **Central Office Branches** of Correctional Services, Psychology Services, Education, Correctional Programs, Reentry Affairs, Residential Reentry Management, Health Programs, Litigation, Chaplaincy Services, Intelligence and Counter Terrorism Branch, and Trust Fund meet annually with the Women and Special Populations Branch to discuss transgender population needs and evaluate current gender-responsive services. The National Union and the Central Office LGBT Special Emphasis Program Manager will be invited to attend these meetings.

(5) The **Transgender Executive Council (TEC)** will consist of senior level staff members (GS-14 and above) from the Women and Special Populations Branch, the Psychology Services Branch, Health Services Division, and the Designation and Sentence Computation Center (DSCC). The team is led by the Senior Deputy Assistant Director, Reentry Services and also includes the Senior Deputy Assistant Director, Correctional Programs Division (DSCC), and the Senior Deputy Assistant Director, Health Services. The TEC is the agency's official decision-making body on all issues affecting the transgender population. It will meet a minimum of monthly to offer advice and guidance on unique measures related to treatment and management needs of transgender inmates and/or inmates with GD, including training, designation issues, and reviewing all transfers for approval. Staff or inmates may raise issues on specific inmates to the TEC through the Women and Special Populations Branch. The Office of General Counsel is consulted as needed.

b. Regional Offices

- Provide oversight to institutions regarding services and other relevant trends managing transgender inmates.

c. Institutions

The Warden will establish a multi-disciplinary approach to the management of transgender inmates. The Associate Warden of Programs is the primary point of contact in the institution for transgender issues and will consult as needed with the Chief Psychologist, Captain, Clinical

Director, Unit Manager, or other individuals as appropriate; and specifically to:

- Ensure transgender inmates have access to services.
- Enter tracking information for self-identified transgender inmates by updating SENTRY CMA assignments and other databases (e.g., PDS).
- Maintain a copy of the Case Management Activity (CMA) SENTRY Assignment Consent Form for Transgender Inmates (BP-A1110) in the Central File and Psychology Data System (PDS).
- Provide appropriate reentry resources that may be specific to the population.
- Advise the Local Union of transgender inmate management issues.
- Consult and refer transgender inmates to the TEC.
- Provide programming developed by the Reentry Services Division for transgender inmates.

4. STAFF TRAINING

Staff are provided specialized training in working with unique issues when managing transgender inmates as part of annual training. Institutions housing transgender inmates should provide additional training.

The Women and Special Populations Branch is responsible for developing training materials and current information on the management of transgender inmates. This information will be made available to staff via the Bureau's intranet.

In addition, the Prison Rape Elimination Act (PREA) regulations incorporated into the BOP Program Statement, **Sexually Abusive Behavior Prevention and Intervention Program** have training requirements concerning pat searches and communication skills for transgender inmates. See 28 C.F.R. § 115.15(f) and 115.31 (a) (9). Please refer to this Program Statement regarding implementation of those training requirements.

Staff will be provided adequate time to complete these trainings during duty hours. Staff will be provided proper relief to complete the training.

5. INITIAL DESIGNATIONS

The PREA regulations (section 28 C.F.R. § 115.42 (c)), incorporated into the Program Statement **Sexually Abusive Behavior Prevention and Intervention Program**, state:

"In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates…the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems."

Upon receipt of information from a Pre-Sentence Report, court order, U.S. Attorney's Office, defense counsel, the offender, or other source that an individual entering BOP custody is

transgender or intersex, designations staff will refer the matter to the TEC.

Institution staff managing pretrial or holdover offenders must also refer cases to the TEC for review. Any TEC recommendations concerning pretrial inmates will be coordinated with the appropriate United States Marshals Service District Office.

The TEC will consider factors including, but not limited to, an inmate's security level, criminal and behavioral/disciplinary history, current gender expression, programming, medical, and mental health needs/information, vulnerability to sexual victimization, and likelihood of perpetrating abuse. The TEC may also consider facility-specific factors, including inmate populations, staffing patterns, and physical layouts (e.g., types of showers available). The TEC will consider the wellbeing of all inmates while exploring appropriate options available to assist with mitigating risk to the inmate, to include but not limited to cell and/or unit assignments, application of management variables, programming missions of the facility, and security of the institution.

It will be documented on all SENTRY designation notes for transgender inmates that the TEC reviewed the inmate for appropriate institution designation.

6. HOUSING AND PROGRAMMING ASSIGNMENTS

During Initial Classification and subsequent Program Reviews, unit management staff will review the inmate's current housing unit status and programming available for transgender inmates. This review will be documented by Unit Management staff in the inmate central file and for holdovers in the holdover file, with institution oversight by the Associate Warden.

The reviews will consider on a case-by-case basis that the inmate placement does not jeopardize the inmate's wellbeing and does not present management or security concerns.

In making housing unit and programming assignments, a transgender or intersex inmate's own views with respect to his/her own safety must be given serious consideration.

Transgender inmates shall be given the opportunity to shower separate from other inmates when individual shower stalls are unavailable.

The agency shall not place transgender or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status. The only exception is if such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

Wardens will consult with WASPB prior to submitting a designation request to the DSCC for the redesignation of transgender inmates when the designation is related to the individual's

transition. The DSCC and Office of Medical Designations will consult with WASPB prior to the designation or redesignation of all transgender inmates.

In situations where the transfer request is related to progressing the individual inmate's transition (i.e., transfer to a different sex facility) the TEC will consider the case. Prior to considering the case, the Warden will submit documentation to the TEC showing the inmate has met the minimum standards of compliance with programs, medications and mental health treatment, and meeting hormone goal levels. Ordinarily, inmates will not be submitted to the TEC for consideration until they have maintained one year clear conduct for 100 and 200 series incident report sanctions, though they may be considered for submission on a case-by-case basis by the Warden, as appropriate.

It will be noted in all SENTRY designation notes that the TEC reviewed the inmate for appropriate institution designation.

7. DOCUMENTATION AND SENTRY ASSIGNMENTS

The PREA regulations in 28 C.F.R. part 115, Subpart A, incorporated into the Program Statement **Sexually Abusive Behavior Prevention and Intervention Program** and the Program Statement **Intake Screening,** address intake screening. Screening of transgender inmates will be conducted in accordance with these policies and all other applicable policies and procedures.

a. Medical and Mental Health Information. Medical and mental health information for transgender inmates will be maintained in the current electronic recordkeeping system or health record system in accordance with the Program Statements **Health Information Management and Psychology Services Manual**. Medical and mental health information is considered confidential, and may only be released in accordance with appropriate laws, rules, and regulations.

b. Initial Screening. For initial designations, staff will assign Case Management Activity (CMA) SENTRY assignments if information in the PSR or other documentation indicates a likely transgender identity. The screening codes are:

SCRN M2F – inmate should be screened for male to female transgender identification.
SCRN F2M – inmate should be screened for female to male transgender identification.

Any inmate arriving at the designated institution with a screening code is to be referred to the Chief Psychologist or designee for review within 14 days. If the code was assigned in error, the screening code will be removed by the Psychologist. If the inmate identifies as transgender, the psychologist will replace the screening code with an identifying code, as indicated below. Holdover facilities are exempt from this initial screening requirement, as limited available

records and brevity of stay do not typically allow for a comprehensive screening.

Any inmate who arrives without a screening code but identifies as transgender during intake, or at any time during the incarceration period, is referred to the Chief Psychologist or designee and interviewed within 14 days of the inmate notification. Inmates in pretrial status at Bureau facilities may also receive a transgender screening CMA SENTRY assignment.

c. Notification to Staff and Tracking. After consultation with Psychology Services, and if the inmate affirms his/her transgender identity, the screening code will be updated to a permanent assignment by a Psychologist:

TRN M2F – inmate identifies as male to female transgender (transgender female).
TRN F2M – inmate identifies as female to male transgender (transgender male).

The inmate must request to Psychology Services staff that the Case Management Activity (CMA) assignment be entered, and the inmate consents that all staff will therefore be notified that the individual is transgender. The inmate's request will be documented on a Case Management Activity (CMA) SENTRY Assignment Consent Form for Transgender Inmates (BP-A1110). Psychology Services shall maintain the form in the electronic mental health record.

Staff should consult the transgender CMA assignment when interacting with the inmate; e.g., use of pronouns and access to accommodations. All inmates have access to transgender treatment, regardless of assignment.

If there are questions about the need to continue a CMA assignment, the Warden will contact the WASPB. Inmates may request in writing to have CMA assignments removed. If this occurs, ordinarily the assignment will not be re-added at a later date.

8. HORMONE THERAPY AND MEDICAL TREATMENT

Hormone therapy or other medical treatment may be provided after an individualized assessment of the requested inmate by institution medical staff. Medical staff will request consultation from Psychology Services regarding the mental health benefits of hormone or other medical treatment. If appropriate for the inmate, hormone treatment will be provided in accordance with the Program Statement **Patient Care** and relevant Clinical Guidance. Questions concerning hormone treatment may be referred to the WASPB or the Health Services Division.

In the event this treatment changes the inmate's appearance to the extent a new identification card is needed, the inmate will not be charged for the identification card as is standard practice.

9. SURGERY

While not all inmates who identify as transgender may be interested in seeking surgical intervention, such a decision does not preclude them from obtaining other accommodations as described in this Program Statement. For transgender inmates in Bureau custody, surgery may be the final stage in the transition process and is generally considered only after one year of clear conduct and compliance with mental health, medical, and programming services at the gender affirming facility. Once that period elapses, an inmate may submit a request to his or her Warden requesting surgical consideration. The Warden will forward the request to the TEC. The TEC is the sole body who may determine that all milestones and individual goals for surgical consideration have been met. When this occurs, the case is referred to the agency's Medical Director for medical consideration. He or she may review existing records and/or interview the inmate, institution staff, and members of the TEC. After this individualized assessment, the Medical Director will determine if the surgery is medically appropriate for referral to a gender affirming surgeon.

10. OTHER MENTAL HEALTH SERVICES

Bureau Psychologists provide assessment and treatment services for transgender inmates, as appropriate. Guidance on assessment procedures is available on the Psychology Services intranet page.

If an inmate identifies as transgender, the Psychologist will provide the inmate with information regarding the range of treatment options available in the Bureau and their implications. In addition, based upon the Psychologist's preliminary assessment and the inmate's expressed interest, a referral to the Clinical Director and/or Chief Psychiatrist may be generated. While the initial interview must be scheduled within 14 days, an assessment may take longer in some instances.

In addition to a referral for medical services, a transgender inmate may be offered individual psychotherapy. Individual psychotherapy goals might include: (1) helping the inmate to live more comfortably within a gender identity and deal effectively with non-gender issues; (2) emphasizing the need to set realistic life goals related to daily living, work, and relationships, including family of origin; (3) seeking to define and address issues that may have undermined a stable lifestyle, such as substance abuse and/or criminality; and (4) addressing any co-occurring mental health issues. Mood disorders, anxiety disorders, substance use disorders, and personality disorders, etc., may also be present; any effective treatment plan will fully address these symptoms. Group treatment may also be recommended.

Common concerns of transgender inmates, which can be addressed effectively in a group setting, include self-esteem issues and relationship issues.

Psychologists who provide mental health treatment for transgender inmates address all mental health needs, including suicide risk, if present. If an inmate who identifies as a transgender harms, attempts to remove, or removes his or her genitalia or other gender-specific anatomy, a suicide risk assessment is conducted consistent with the Program Statement, Suicide Prevention Program. In addition, the treating psychologist notifies the Chief Psychologist who in turn notifies the Regional Psychology Services Administrator and the Psychology Services Branch.

Psychologists working with transgender inmates are encouraged to consult the Reentry Services Division in Central Office for additional resources.

11. SPECIAL POPULATIONS SERVICES

Some facilities have Special Populations Coordinators on staff. These individuals are responsible for delivering First Step Act and other programs, which includes programs developed specifically for inmates who identify as transgender. In the absence of such staff, the Warden will seek consultation from WASPB regarding the delivery of group interventions and services.

12. PRONOUNS AND NAMES

Staff interacting with inmates who have a CMA assignment of transgender, shall either use the authorized gender-neutral communication with inmates (e.g., by the legal last name or "Inmate" last name) or the pronouns associated with the inmate's identified gender. Deliberately and repeatedly mis-gendering an inmate is not permitted.

The name entered on the inmate's Judgment and Commitment Order is the official committed name for all Bureau records (incident reports, progress reviews, sentence calculations, etc.). An official committed name change while in BOP custody must be done consistent with the Program Statement **Correctional Systems Manual.** Any additional names or aliases should be entered into SENTRY, as appropriate.

13. PAT SEARCH ACCOMMODATIONS

Pat searches of transgender inmates will be conducted in accordance with the Program Statement **Searches of Housing Units, Inmates, and Inmate Work Areas**.

Pat search information refers only to individuals at male facilities who identify as female. The Bureau does not offer "male only" pat searches.

Unless there is a history of inappropriate sexual behavior suggesting approval poses risks to staff, requests are ordinarily approved by the Warden's Office. Inmates may request denials be reviewed by the TEC through the Administrative Remedy Program. Inmates who are granted this exception under policy may have it reversed by the Warden if found to have violated

institution rules concerning contraband.

In exigent circumstances, any staff member may conduct a pat search of any inmate consistent with the Program Statement **Searches of Housing Units, Inmates, and Inmate Work Areas**.

14. VISUAL SEARCHES

For purposes of a visual search, inmates will be searched in accordance with the gender of the institution, or housing assignment, to which they are assigned. The visual search shall be made in a manner designed to ensure as much privacy to the inmate as practicable. Staff should consider the physical layout of the institution, and the characteristics of an inmate with a transgender CMA assignment, to adjust conditions of the visual search as needed for the inmate's privacy.

Transgender inmates may also request an exception to be visually searched by a staff member of the inmate's identified gender. The exception must be pre-authorized by the Warden, after consultation with staff from Health Services, Psychology Services, Unit Management, and Correctional Services. Exceptions must be specifically described (e.g., "visual search only by female staff"), clearly communicated to relevant staff through a memorandum, and reflected in SENTRY (or other Bureau database). Inmates should be provided a personal identifier (e.g., notation on identification, etc.) that indicates their individual exception, to be carried at all times and presented to staff prior to visual searches.

Inmates request an exception by submitting an Inmate Request to Staff (BP-A0148) to the Warden. The Warden will consult with the departments listed above, and the memo approving or denying the request will be generated by the Warden's Office. Inmates may request denials be reviewed by the TEC through the Administrative Remedy Program. Inmates who are granted this exception may have it reversed by the Warden if found to have violated institution rules concerning contraband.

Transgender inmates placed at an institution or in a housing unit that does not correspond with their identified gender, and who are granted an exemption as indicated above, will be searched by staff of the inmate's identified gender who consent to participate in the search, or Health Services clinical staff.

Transgender inmates placed at an institution or in a housing unit of their identified gender will be searched by staff of the inmate's identified gender who consent to participate in the search or medical staff.

Institutions should consider using available body scanning technology in lieu of visual searches of transgender inmates.

In exigent circumstances, any staff member may conduct a visual search of any inmate consistent with the Program Statement **Searches of Housing Units, Inmates, and Inmate Work Areas**.

15. CLOTHING, COMMISSARY ITEMS, AND OTHER ACCOMMODATIONS

Consistent with safety and security concerns, inmates with the CMA assignment of transgender will have the opportunity to have undergarments of their identified gender even if they are not housed with inmates of the identified gender. Institutional laundry will have available institutional undergarments that fulfill the needs of transgender inmates. Undergarments will not have metal components.

Standardized lists of Commissary items for transgender inmates are available in accordance with the Program Statement **Trust Fund/Deposit Manual** and the information on the RSD intranet page.

Additional items based on an individualized assessment of the transgender inmate population may be approved by the Warden. Additional items may be provided by the institution or purchased by the inmate, as appropriate. Any concerns regarding such items are directed to the WASPB.

Inmates who purchase and/or are provided items under this section will be subject to disciplinary sanctions, including the removal of these items, if they are found to have violated institution rules relating to the possession of these items.

Any other accommodation requests are discussed with the TEC through the WASPB.

16. REENTRY NEEDS

In accordance with the Program Statement **Release Preparation Program**, institution staff assist transgender inmates in addressing reentry issues prior to release or placement in a Residential Reentry Center/Home Confinement.

During Initial Classification and Program Reviews, unit management formulates a pre-release plan that assists transgender inmates in obtaining identification, finding housing and employment, and providing community resources to assist with reintegration into the community.

The Reentry Affairs Coordinator will assist staff with identifying these resources. Community Treatment Services staff or Institution and/or Regional Social Workers may be contacted concerning the continuity of medical care.

The WASPB can be contacted to provide guidance and resources for any additional reentry

needs of transgender inmates. All accommodation and treatment decisions for inmates in community custody are made by the Residential Reentry Management Branch in consultation with the TEC.

17. ADMINISTRATIVE REMEDIES

Inmates who wish to seek formal review of any issue relating to this policy may use the procedures in the Program Statement **Administrative Remedy Program**.

REFERENCES

Program Statements

P1330.18	Administrative Remedy Program (1/6/14)
P4500.12	Trust Fund/Deposit Fund Manual (3/15/18)
P5100.08	Security Designation and Custody Classification Manual (9/4/19)
P5290.15	Intake Screening (3/30/09)
P5310.17	Psychology Services Manual (08/25/16)
P5310.16	Treatment and Care of Inmates with Mental Illness (5/1/14)
P5322.13	Inmate Classification and Program Review (5/16/14)
P5324.08	Suicide Prevention (4/5/07)
P5324.12	Sexually Abusive Behavior Prevention and Intervention Program (6/4/15)
P5325.07	Release Preparation Program (8/15/19)
P5521.06	Searches of Housing Units, Inmates, and Inmate Work Areas (6/4/15)
P5800.15	Correctional Systems Manual (9/23/16)
P6031.04	Patient Care (6/3/14)
P6090.04	Health Information Management (3/2/15)

Federal Regulations

28 CFR part 115

Additional Resources For Clinicians

Diagnostic and Statistical Manual of Mental Disorders (DSM), most current version. World Professional Association for Transgender Health (WPATH) standards.

ACA Standards

■ American Correctional Association Standards for Adult Correctional Institutions, 5th Edition: 5-ACI-1C-09, 5-ACI-1D-12, 5-ACI-1D-13, 5-ACI-2C-02, 5-ACI-1D-08, 5-ACI-3D-05, 5-ACI-3D-08(M), 5-ACI-3D-09, 5-ACI-3D-10, 5-ACI-3D-11, 5-ACI-3D-12, 5-ACI-3D-13, 5-ACI-3D-14, 5-ACI-3D-15, 5-ACI-3D-16, 5-ACI-6A-21(M), 5-ACI-6A-32(M), 5-ACI-6C-14(M)

■ American Correctional Association Performance Based Standards for Adult Local Detention Facilities, 4th Edition: 4-ALDF-2A-29, 4-ALDF-2A-32, 4-ALDF-2A-34, 4-ALDF-6B-03, 4-ALDF-2C-03, 4-ALDF-4C-22M, 4-ALDF-4C-30M, 4-ALDF-4D-22, 4-ALDF-4D-22-1, 4-

ALDF-4D-22-2, 4-ALDF-4D-22-3, 4-ALDF-4D-22-4, 4-ALDF-4D-22-5, 4-ALDF-4D-22-6M, 4-ALDF-4D-22-7, 4-ALDF-4D-22-8, 4-ALDF-7B-08, 4-ALDF-7B-10, 4-ALDF-7B-10-1.

- American Correctional Association Standards for Administration of Correctional Agencies, 2nd Edition: None.
- American Correctional Association Standards for Correctional Training Academies: None.

Records Retention

Requirements and retention guidance for records and information applicable to this program are available in the Records and Information Disposition Schedule (RIDS) on Sallyport.

EXHIBIT C

GENDER-AFFIRMING CARE OF TRANSGENDER AND GENDER NONBINARY PERSONS

Federal Bureau of Prisons

Clinical Guidance

June 2023

Federal Bureau of Prisons (BOP) Clinical Guidance is made available to the public for informational purposes only. The BOP does not warrant this guidance for any other purpose and assumes no responsibility for any injury or damage resulting from the reliance thereof. Proper medical practice necessitates that all cases are evaluated on an individual basis and that treatment decisions are patient-specific. Consult the BOP Health Management Resources Web page to determine the date of the most recent update to this document: http://www.bop.gov/resources/health_care_mngmt.jsp.

WHAT'S NEW IN THIS DOCUMENT

This guidance on *Gender-Affirming Care of Transgender and Gender Nonbinary Persons* is an update to the BOP Clinical Guidance on *Medical Management of Transgender Inmates*, issued in December 2016. Significant changes were made throughout this document to more closely align with community standards and the World Professional Association for Transgender Health (WPATH) *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8* published in 2022. While WPATH Standards of Care were referenced when updating this guidance, deviations due to the unique correctional environment were made when necessary. The key revisions include:

- Addition of *Transition Pathway for Transgender Inmate Patients* for guidance in patient care decisions found in *Section 4* and *Appendix 1.*
- Added language in *Section 5* to describe the process for requesting designation to a cross/gender reaffirming institution according to BOP policy.
- New sections created with emphasis on care in correctional environment:
  - Preventative Health Screening (*Section 13*)
  - Minimally or Non-Invasive (*Section 14*) and Invasive [Surgical] Procedures (*Section 15*)
    - Information regarding facial hair removal expounded *(Facial Hair Removal)*
    - Including description of the use of Transgender Utilization Review Advisory Group
  - Transitions of Care (*Section 16*)

DOCUMENT ORGANIZATION

- The **ABBREVIATIONS** are now listed in a new section, *Key to Abbreviations*, preceding the appendices. (This list does not replace the list of *Definitions* in *Section 2*.)
- The appendices summarizing **HORMONE TREATMENT** have been renumbered, as follows:
  - *Appendix 2. Summary Charts for Feminizing Hormone Therapy*
  - *Appendix 3. Summary Chart for MASCULINIZING Hormone Therapy*
- The main body of the **MEDICATION MONITORING** guidance is now in two new appendices:
  - *Appendix 4. Monitoring During FEMINIZING Hormone Therapy*
  - *Appendix 5. Monitoring During MASCULINIZING Hormone Therapy*
- The items in the *References* section are now listed alphabetically by author or source.

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1. PURPOSE

The Federal Bureau of Prisons (BOP) Clinical Guidance for *Gender Affirming Care of Transgender and Gender Nonbinary Persons* provides recommendations for the medical management and treatment of transgender and gender nonbinary federal inmates, referred to in this guidance as *transgender* and/or *gender nonbinary* and *individual(s)*, *patient(s)*, or *person(s)*.

2. DEFINITIONS

BISEXUAL: Refers to a person attracted to both sexes.

BIGENDER: Refers to those who identify with two genders or multigender.

BOP TRANSGENDER CLINICAL CARE TEAM: A group of physicians (primary care and psychiatrists), pharmacists, and social workers devoted to advocating and advancing the treatment options for this population. The team provides education and the tools to institutional staff to develop clinical treatment plans for the TG and gender nonbinary population. This team has no authority to review, approve or disapprove gender affirming surgery referrals.

BOP TRANSGENDER EXECUTIVE COUNCIL (TEC): A group of BOP management personnel who mitigate executive level administrative gender affirming issues.

BOP TRANSGENDER UTILIZATION REVIEW ADVISORY GROUP : A group of BOP physicians, psychiatrists, pharmacists, and social workers assigned by the Medical Director to provide clinical review of gender-confirming surgical requests.

CISGENDER: denoting or relating to a person whose sense of personal identity and gender corresponds with their sex assigned at birth.

COMPLEX AND INVASIVE GENDER CONFIRMING PROCEDURES: complex and invasive medical procedures will almost always require general anesthesia, and a surgeon with advanced skills. Most of these procedures carry the inherent risk for blood loss, infection, pain, multi-day hospitalization, and post-operative complications; in this guidance, these terms refer to all procedures listed in *Table 5*, which require the approval of the Medical Director.

FEMALE-TO-MALE (FTM): Refers to a biological female who identifies as, or desires to be, a member of the male gender. The term **transgender male**, or **trans male** for short, is used to refer to the **GENDER IDENTITY** of a person who is **FTM**. (See the definition of **TRANSGENDER** below.)

GAY: Refers to a person who is romantically or sexually attracted to persons of the same gender. The term is mostly used to describe males. (See the definition of **LESBIAN** below.)

GENDER-AFFIRMING HORMONES: Hormonal therapy utilized to facilitate physiological change(s) during **TRANSITION** (see definition below). The term **CROSS-SEX HORMONES** is often utilized in the medical literature, but it is falling out of use.

GENDER-AFFIRMING SURGERY/GENDER-CONFIRMING SURGERY: The surgical component of an individual's **TRANSITION** (see definition below); these terms have replaced the outdated terminology of **SEX REASSIGNMENT SURGERY**.

GENDER BINARY: A system of viewing gender as consisting solely of two, opposite categories of gender, termed "male and female"

GENDER CONFORMITY: Behavior and appearance that adheres to the social expectations of a particular **GENDER**. (See the definition of **GENDER NONCONFORMITY** below.)

GENDER DYSPHORIA (GD): The condition of feeling that one's emotional and psychological identity as male or female is different from one's biological sex assigned at birth. **GD implies that there is a state of distress or anxiety directly related to this conflict.** In the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)*, released in May 2013, people whose assigned sex at birth is contrary to the one they identify with *and* who are experiencing a state of distress should be diagnosed with **GD**.

- *This diagnosis of **GD** is a revision of the criteria in the DSM-IV for **GENDER IDENTITY DISORDER (GID)** and is intended to better characterize the experiences of affected individuals. The DSM-5 no longer uses the term **GID**.*
- *A Gender Dysphoria diagnosis may be necessary in some regions to access transition-related care.*

GENDER EXPRESSION: Includes mannerisms, clothing, hair style, and choice of activities that individuals use to express their **GENDER IDENTITY**.

GENDER FLUID: A changing or "fluid" gender identity.

GENDER IDENTITY: How one identifies oneself: female, male, both, or neither. **GENDER** encompasses aspects of social identity, psychological identity, and human behavior.

GENDER NONBINARY: someone who does not identify as exclusively male or female

GENDER NONCONFORMITY (ALSO KNOWN AS GENDER NONBINARY): Behavior or appearance that does not adhere to the social expectations of a particular **GENDER**.

GENDER QUEER: Denoting or relating to a person who does not subscribe to conventional gender distinctions but identifies with neither, both or a combination of male and female genders.

INFORMED CONSENT: A patient's ability to understand the risks, benefits, alternatives, unknowns, limitations, and risks of treatment pertaining to a specific healthcare intervention.

INTERSEX: Refers to a person whose sexual/reproductive anatomy or chromosomal pattern does not seem to fit the typical biological definition of male or female.

LESBIAN: Refers to a female who is romantically or sexually attracted to other females.

MALE-TO-FEMALE (MTF): Refers to a biological male who identifies as, or desires to be, a member of the female gender. The term **transgender female**, or **trans female** for short, is used to refer to the **GENDER IDENTITY** of a person who is **MTF**. (See the definition of **TRANSGENDER** below.)

MINIMALLY INVASIVE GENDER AFFIRMING PROCEDURES: minimally invasive medical procedures are usually same day office or hospital-based procedures that may require anesthesia and break skin or enter an organ; in this guidance, this term refers to professional facial hair removal services, and other procedures typically labeled as aesthetic in a non-trans population.

NON-INVASIVE GENDER AFFIRMING TREATMENT MODALITIES: non-invasive medical modalities typically do not break skin or enter a body part; in this guidance, this term refers to treatment modalities such as voice and communication training.

PATIENT-CENTERED CARE: Care in which patients are partners with their health care providers and health care decisions are driven by the patient's specific health needs and desired health outcomes.

SEX: A biological classification based on chromosomal composition, reproductive anatomy (primary sex characteristics), and the phenotypic characteristics that develop during pubertal maturation (secondary sex characteristics).

SEXUAL ORIENTATION: The direction of one's sexual interest. It is not defined by the person's gender identity. People of the same gender identity may have different sexual orientations.

TRANSGENDER (TG) (ALSO KNOWN AS TRANSSEXUAL) OR TRANS SPECTRUM: An umbrella term used for individuals whose **GENDER IDENTITY** does not conform to the typical expectations associated with the gender they were assigned at birth. It is important to note that terminology changes often and the latter term is falling out of use.

TRANSPHOBIA: Dislike of or strong prejudice against transgender people with attitudes such as fear, discomfort, distrust, or disdain.

TRANSITION: The period during which **TG** individuals change their physical, social, and legal characteristics to the gender with which they identify. **TRANSITION** may also be regarded as an ongoing process of physical change and psychological adaptation. Individuals may want to proceed to different stages of transition.

3. INTRODUCTION & GENERAL CONSIDERATIONS

TRANSGENDER (**TG**) people are those whose gender identity is different from the sex which they were assigned at birth. **GENDER DYSPHORIA** (**GD**)—previously known as **GENDER IDENTITY DISORDER** (**GID**)—is the *discomfort or distress* caused by a discrepancy between a person's gender identity and that person's gender assigned at birth.

- TG people have many of the same health needs as the general population. They may also have other special healthcare needs.
- Not all TG person(s) will be diagnosed with GD, and a diagnosis of GD is not required for access for all TG services. According to the American Psychological Association's guidelines (see *References* section), an individual's identification as **TG or GENDER NONBINARY** can be healthy and self-affirming and is not considered pathological.
- However, some **TG or GENDER NONBINARY** individuals experience distress associated with their gender identity, their body, or their sex assigned at birth. There is also distress associated with

societal stigma and discrimination. A systematic review of studies by Valentine, et al (2018) indicates significantly higher rates of mental health morbidity compared with the general population—particularly anxiety, depression, and suicidality.

- **Gender-affirming health care involves supporting individuals through social, psychological, behavioral, or medical (including hormonal treatment or surgery) treatments—to support and affirm an individual's experienced gender identity.**

The **BOP TRANSGENDER CLINICAL CARE TEAM** . The team provides education and the tools to institutional staff to develop clinical treatment plans for the TG and gender nonbinary population. This team has no authority to review, approve or disapprove gender affirming surgery referrals. This team is composed of physicians (primary care physicians and psychiatrists), pharmacists, and social workers who are available to help institution providers. For example, when patients have medical contraindications (relative or absolute) to hormone treatments, consultation with the TCCT may be helpful. Institution staff may refer to their Regional Medical Director for a list of current team members and their contact information.

STIGMA

Stigma and prior negative experiences in institutions can contribute to healthcare disparities. Stigma commonly leads to prejudice and discrimination, which may also exacerbate mental health concerns in transgender and gender-nonconforming individuals.

Respect and trust are essential to the provider-patient relationship. Respectful language and terms should always be used, affirming the patient's experienced gender identity. Once an individual has identified as **TG**, use of pronouns or salutations preferred by the **TG** individual is appropriate, especially for those patients with a Case Management Activity (**CMA**) Sentry assignment of **TRANSGENDER** (either TRN M2F or TRN F2M; see ***TABLE 1*** below). This practice is more likely to facilitate a cooperative relationship between the **TG** individual and others, and generally reduces the stress of gender transition.

- *Using this informal approach is distinct from a legal name change while in BOP custody; a legal name change must conform to the policy requirements in the **Program Statement 5800.15 Correctional Systems Manual** (or the most recent version).*

MENTAL HEALTH CONCERNS AND SUICIDALITY

As reported by Valentine, et al (2018), a higher prevalence of depression, anxiety, and suicidality is seen among TG adults compared to the general population. It has been suggested these elevated rates are linked to complex trauma, stigma, violence, and discrimination. A recent study by Baker, et al (2021) suggests that appropriate gender-affirming care, including medical and surgical care, can lessen psychiatric symptoms. Transgender adults with **GD** are at an increased risk of suicidal ideation and suicide prior to initiation of their gender transition, regardless of the clinical endpoint of their transition - whether that endpoint is living as the psychologically identified gender, hormone therapy, cosmetic treatments, breast augmentation/removal, and/or gender-affirming surgery (Wolford-Clevenger et al 2018). For many individuals, the risk of suicide may decrease after receiving the appropriate, individualized treatment (Turban et al 2022).

COMORBID CONDITIONS

- **Anxiety and Depression:** The most common mental health conditions seen in **TG** adults are anxiety and depression. A significant interdisciplinary approach between Psychology and Health Services is always required for **TG** patient care.
  - ➔ *See BOP Program Statement 5310.16, Treatment and Care of Inmates with Mental Illness, available at https://www.bop.gov/policy/progstat/5310_16.pdf.*
- **HIV Infection:** Epidemiologic studies indicate a higher prevalence of HIV in the **TG** populations, specifically among **transgender male** persons. HIV services for TG people should address the specific biological, pathological, and social needs of this population (i.e., antiretroviral therapy, HIV prevention and care programs). Effective risk assessment requires obtaining an accurate sexual risk history, including anatomy-specific sexual behavior.
  - ➔ *See CDC's website on HIV and Transgender People, listed in the References section.*

PATIENT-CENTERED MULTIDISCIPLINARY TREATMENT APPROACH

A patient-centered multidisciplinary team approach is recommended for managing issues associated with the incarceration of TG individuals. Incarcerated individuals may present to an institution with a well-established gender identity or begin their transgender or gender nonbinary journey while incarcerated. It is important to have a system in place to allow for individualized treatment. Individuals requesting care for gender dysphoria should have access to a diverse range of treatment services. Patient-centered care explores individualized therapeutic options, which may differ from person to person.

The BOP offers **TRAUMA-INFORMED CORRECTIONAL CARE (TICC),** which incorporates an understanding that patient attitudes, behaviors, and concerns are likely to be affected by prior traumatic experiences. **TICC** includes both training and treatment programs, emphasizes the recognition of trauma in all forms, and incorporates the principle that all staff may have a role in reducing its impact.

HOUSING ASSIGNMENTS, PROGRAM ASSIGNMENTS, AND PAT SEARCHES

- ➔ *Refer to the current version of BOP **Program Statement 5324.12, Sexually Abusive Behavior Prevention and Intervention Program**, available at https://www.bop.gov/policy/progstat/5324_012.pdf*
- ➔ *Refer also to the BOP **Program Statement 5200.08 Transgender Offender Manual**, available at https://www.bop.gov/policy/progstat/5200-08-cn-1.pdf*

PRISON RAPE ELIMINATION ACT (PREA)

Per the national Prison Rape Elimination Act (PREA) Resource Center, *being transgender is a known risk factor for being sexually victimized in confinement settings.* Consequently, PREA regulations and BOP Program Statements provide ways to protect the transgender population through the following:

- **PREA** regulations, incorporated into **Program Statement 5324.12, Sexually Abusive Behavior Prevention and Intervention Program** (available at *https://www.bop.gov/policy/progstat/5324_012.pdf*), state that the intake screening shall assess the individual's risk of sexual victimization by considering, at a minimum, whether the individual is known or perceived to be gay, lesbian, bisexual, **TG**, intersex, or gender nonconforming.
- According to the PREA (*28 C.F.R. § 115.41 (h)*), *individuals may not be disciplined for refusing to answer, or for not disclosing complete information in response to,* [questions about being gay, lesbian, bisexual, **TG**, intersex, or gender nonconforming].
- According to the PREA (*28 C.F.R. § 115.15 (e)*), *staff shall not search or physically examine a transgender or intersex inmate for the sole purpose of determining the inmate's genital status. If the inmate's genital status is unknown, it may be determined as appropriate during conversations with the inmate, by reviewing medical records, or, if necessary, learning that information as part of a broader medical examination conducted in private by a medical provider.*

4. TRANSITION PATHWAY FOR TRANSGENDER PATIENTS

Appendix 1 summarizes a pathway for TG patients to access gender-affirming mental health and medical care in the BOP. The order depicted in this table is not as important as the provision of individualized treatment, e.g., individuals may approach a medical professional before they approach a mental health professional and this should not preclude them or delay appropriate treatment if the medical provider is qualified in this area.

A gender dysphoria (GD) diagnosis is not necessary for hormone treatment, and TG patients may not be interested in following up with a mental health professional. However, the reverse might also occur: TG patients may seek out a mental health professional for months before they are ready to be referred for a medical evaluation. Not all gender non-binary patients will require gender-affirming hormone treatment and treatment is individualized to the patient's needs.

5. DESIGNATION TO A CROSS/GENDER-AFFIRMING INSTITUTION

In accordance with ***Program Statement 5200.08 Transgender Offender Manual***, transgender individuals may ask their respective warden to be considered for designation to a gender-affirming institution. All requests for designation are reviewed by the Transgender Executive Council (TEC). The memo is submitted from the Warden to the TEC indicating the patient is requesting re-designation to an institution able to provide full-time gender affirming life experiences in identified gender.

6. PRESENTATION OF GENDER NON-CONFORMITY

Gender non-conformity status is based on an individual's experienced gender identity, role, or expression differing from societal norms assigned to a particular sex. When an individual self-identifies as TG and requests referral or evaluation for treatment, an evaluation is conducted according to PS5200.08, and further referrals may be made, as clinically appropriate, to fully evaluate the individual's treatment needs.

Discussion of the following areas may be useful in helping a person describe their gender identity:

- Persistent and marked differences between experienced gender and their biologic or natal sex.
- Strong feelings about primary or secondary sex characteristics.
- Strong feelings about being treated as or becoming another gender.
- Belief that one's actions, feelings, or mannerisms are more characteristic of another gender.

Gender non-conformity often (but not always) presents with gender dysphoria, which denotes the discomfort or distress that is caused by the nonconformity of a person's gender identity, and that person's sex assigned at birth. Gender nonconformity may present in a spectrum of expressed or desired gender affirmation needs. Patients may experience:

- Strong desires to be treated as the identified gender
- Strong convictions that one has feelings and reactions typical of the identified gender
- Strong inclinations to look in a way that affirms the identified gender

Clinicians must accurately assess and document the patient's individual presentation. Attention should be given as to whether the level of distress meets criteria for a formal diagnosis of gender dysphoria, and/or if there are other coexisting mental or medical health disorders.

7. GENDER-AFFIRMING MENTAL HEALTH ASSESSMENT

When TG individuals present to mental health professionals it is important to conduct a thorough mental health evaluation. The mental health professional is encouraged to affirm the individual's experienced gender and whether there is gender dysphoria. The mental health professional should conduct a thorough evaluation including assessing for any mental health diagnosis. The clinician will develop an individualized treatment plan for the TG patient and collaborate with the medical provider.

A mental health assessment for TG individuals typically includes:

- Obtaining a gender identity history and screening for **GD**
- Screening for other mental health disorders related to mood, anxiety, autism, eating, personality, psychosis, and substance use
- Identifying a history of abuse or neglect
- Assessing any current or past self-harm ideations or attempts
- Performing an assessment of affective, cognitive, and psychosocial functioning
- Psychosocial treatment recommendations; and/or
- Medical referral, if indicated.

➔ *Please also refer to the APA's Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, listed in the References section.*

Mental Health Treatment Considerations

The mental health team plays an important role in gender-affirming care. This can include screening for mental health disorders and assisting with treatment planning. Prior to engaging in treatment, conversations regarding the individual's realistic expectations of outcome are encouraged to identify realistic goals for treatment.

➔ *A collaborative approach with both mental health and medical services staff is highly recommended.*

Patients can also be referred to psychiatry services for mental health concerns or medication management of mental illness.

- **Psychotherapy:** This is a general term for treating mental health problems; it includes a broad variety of techniques to help individuals with emotional difficulties or coexisting mental illnesses. Psychotherapy can be used to learn about and treat an individual's moods, thoughts, and behaviors. It can also be supportive to individuals experiencing distressing thoughts, feelings and/or behavior.
- **Psychiatry Services:** Individuals can also be referred to psychiatry services for mental health concerns or medication management of other mental illness in conjunction with **GD**. Appropriate pharmacotherapy is considered when indicated to optimally manage co-existing mental health concerns prior to, or concurrently with, treatment of **GD**.

Gender Dysphoria (GD) Criteria

Individuals identifying as TG or gender nonbinary do not necessarily have GD. Although data regarding the prevalence rates of **GD** in the transgender population is limited, many clinicians anecdotally report that most **TG** individuals experience some degree of dysphoria in the absence of treatment.

Because untreated or under-treated **GD** is associated with increased morbidity and mortality (Jackson et al 2023), screening for **GD** in **TG** individuals is essential. Without treatment, this population may experience higher rates of depression, anxiety, self-harm, and suicidality. Gender-affirming treatment supports TG people throughout their lifespan. Treatment modalities are designed to meet the individual's unique goals and may include social supports, mental health treatment, and medical treatment (including hormone therapy and surgery). These interventions may improve medical and psychological health, increase social support, decrease **GD**, treat mental health comorbidities, and improve TG individuals' overall quality of life**.** The DSM-5 criteria may be used to make the diagnosis of GD.

➔ *Refer to The American Psychiatric Association A Guide for Working With Transgender and Gender Nonconforming Patients for guidance on diagnosis of GD.*

8. GENDER-AFFIRMING MEDICAL ASSESSMENT

A MEDICAL EVALUATION should include:

- **Thorough review of all co-occurring medical conditions and whether they are reasonably controlled.**
  - *Comorbidities are not necessarily a contraindication to therapy and must be assessed for each patient. See more about drug risks in* Table 2 *(Feminizing Therapy) and* Table 3 *(Masculinizing Therapy).*
- **Review of any mental health evaluations and coordination with mental health care providers.**
- **Physical Examination:** Healthcare providers should utilize a gender-affirming approach, including using the individual's preferred name and pronouns during each clinical encounter. This also includes using non-gender specific terminology (ex. genital instead of penis/vagina or chest instead of breast) for anatomical body parts or asking if the patient has a preferred term to be used. The physical exam should only be performed on parts of the body indicated for the medical reason for the specific visit.
- **Documentation of Previous Treatment:** Hormonal therapy, surgery, etc.
- **Informed Consent:** Individuals must be counseled on the risks and long-term effects of hormonal therapy. Use of gender-affirming hormones in the management of **TG** individuals is considered an off-label use and does not currently have FDA approval but is considered a community standard. Due to the irreversibility of some of the treatment options and the side effects, the individual's informed consent is required before initiating treatment and must be documented within the medical record.
  - *See Section 9. Patient Education & Informed Consent.*
- **Contraindications and Precautions to Hormone Therapy:**
  - *See also the Summary Charts for Hormonal Therapy in Appendix 2. Feminizing Hormone Therapy and Appendix 3. Masculinizing Hormone Therapy for medication-specific contraindications.*

  FEMINIZING THERAPY

  - **CONTRAINDICATIONS:** Current diagnosis of estrogen-sensitive cancer (e.g., breast cancer); current diagnosis of thromboembolic disease (may consider after subspecialty consultation)
  - **PRECAUTIONS:** History of estrogen-sensitive cancer or history of thromboembolic disease should prompt referral to expert specialist prior to initiation of therapy. Presence of liver, kidney, or heart disease/stroke (or risk factors for heart disease such as high cholesterol, diabetes, obesity, smoking); retinal vascular thrombosis, history of macroprolactinoma, strong family history of breast cancer or thromboembolic disease; gallbladder disease.

MASCULINIZING THERAPY

- **CONTRAINDICATIONS:** Pregnancy; breast feeding; trans men with current carcinoma of the breast
- **PRECAUTIONS:** Erythrocytosis (hematocrit >50%) History of breast or uterine cancer (testosterone may have anti-proliferative effects on most, but not all cancers-referral to expert specialist recommended prior to initiation of therapy). Androgen-sensitive epilepsy; migraines; sleep apnea; depression; cardiac failure; renal failure or severe hypertension susceptible to salt retention and fluid overload; significant liver disease; coronary artery disease (**CAD**) or risk factors for CAD; bleeding disorders (for injected testosterone); significant history of violent behavior.

ASSESSMENT & DOCUMENTATION OF ACCURATE EHR CODES

Appropriately diagnosing individuals as to their gender identity is imperative for accurate individual record keeping and continuity of care ensuring all individuals are receiving appropriate preventive and gender affirming care and management both as incarcerated individuals and upon release to their community. All BOP individuals who identify as **TG or gender nonbinary** or are identified by history or current presentation as **TG or gender nonbinary**, should be referred to appropriate mental health professionals and/or health service providers. Utilization of inclusionary diagnoses in the EHR helps clinicians provide patient-centered care and medical interventions specific to organs present and transgender care (e.g., a transgender male who has residual breast tissue or an intact cervix getting a mammogram or pap smear).

For purposes of providing appropriate medical treatment and management, all individuals who identify as **TG**—whether or not they are receiving hormone treatment—need to have an accurate diagnostic code entered into the EHR health problem list, as listed in *Table 1*.

TABLE 1. ICD-10 EHR DIAGNOSTIC CODES FOR TRANSGENDER AND GENDER NONBINARY INDIVIDUALS

BOP Transgender Determination	ICD-10 EHR Codes	Corresponding Sentry CMA Codes
Transgender/Gender Identity DO/Gender Dysphoria - male to female	F64.0F[1]	TRN M2F
Transgender/Gender Identity DO/ Gender Dysphoria - female to male	F64.0M[1]	TRN F2M
Transgender/Gender Identity DO-Other-questioning/queer	F64.8Q[2]	
Personal History of Sex Reassignment	Z87890[3]	

[1] Document the degree of distress or impairment in social, occupational, or other important areas of functioning.
[2] This respective code is to be applied to patients who may not have consolidated their gender identity (questioning), or who identified as gender fluid/queer.
[3] If an individual has undergone gender-affirming surgery, use code Z87890 (Personal History of Sex Reassignment) along with the appropriate F64 code above. Document the type of surgery in detail.

9. PATIENT EDUCATION AND INFORMED CONSENT

Patient education and informed consent are crucial to the treatment process.

- Consent forms for gender affirming hormone therapy are designed to guide counseling and can be found in *Appendix 6* and *Appendix 7*. The information in these appendices is not all-inclusive and providers may add information to this document as clinically appropriate. Individuals should be provided with ample time to review this information and have all questions addressed prior to signing the document. Informed consent must be documented within the EMR.
- Securing consent for gender affirming surgery is the responsibility of the surgeon. Once the individual is approved by the Medical Director for surgical intervention for the treatment of GD, surgeons are responsible for discussing different surgical techniques, advantages and disadvantages of each, limitations of the different procedures, and a frank discussion of all the inherent risks and complications to include their own complication rates with each procedure.

10. HORMONE THERAPY: ELIGIBILITY, GOALS, OVERVIEW

Hormone therapy is an important part of gender affirming care. Studies demonstrate improved satisfaction (in the range of 70–80%) as it relates to mental health, quality of life, and sexual function for **TG** individuals who are receiving gender affirming hormone therapy (Siira et al 2023).

After a thorough and individualized evaluation, the medical provider may initiate hormone therapy after the risks and benefits have been discussed with the individual.

➔ *Refer to the Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline for more detailed information.*

ELIGIBILITY AND READINESS FOR GENDER-AFFIRMING HORMONE THERAPY

Patients do not need to meet the DSM criteria for **GD** to initiate gender-affirming hormone therapy. The eligibility for gender-affirming hormone treatment can be achieved by confirming gender incongruence, verifying transition is clinically appropriate, and patient understands the risks, and benefits of treatment through completion of the *Mental Health Assessment* and/or the *Medical Assessment*.

➔ *Gender-nonconformity is based on the individual's self-report. Therefore, the history or subjective component of the evaluation serves as the primary source for identifying a person as TG.*

➔ *An important aspect of eligibility and readiness for gender-affirming hormone therapy while incarcerated is the understanding that fertility may be affected permanently. According to BOP* ***Program Statement 6031 Patient Care****: Inmates are not authorized for fertility preservation services (sperm or egg/banking), even when infertility is an expected side effect of medically necessary treatment e.g., chemotherapy, pelvic radiation, or gender affirming treatment. Inmates are not authorized to donate sperm or eggs.*

GENERAL GOALS OF HORMONE THERAPY

The goal of hormone therapy is to reduce characteristics of the natal sex and induce those of the identified gender, allowing individuals to project their **GENDER IDENTITY**. Hormone therapy is focused on

affirming a person's gender identity, which is not always binary. Patient-centered therapy is focused on meeting the patient's needs.

11. FEMINIZING HORMONE THERAPY

The goal of feminizing hormone therapy is generally to suppress male secondary sex characteristics and the development of female secondary sex characteristics. Most clinical studies and guidelines recommend combined therapy with an anti-androgen, estrogen, and sometimes a progestin adjunct.

EXPECTATIONS OF FEMINIZING HORMONE THERAPY

Prior to beginning treatment, patients should be educated on realistic expectations of results, as well as the timeline of when to expect them. Every case is different, and slow change can lead to frustration.

➔ *It is important to discuss realistic expectations with the patient to avoid any attempts to self-increase the dosage in hopes of speeding up results.*

- Within the first six months of treatment, changes may be seen in body fat redistribution, loss of muscle mass, breast growth (usually to Tanner stage 2 or 3), testicular atrophy, decreased erections, decreased sperm production, and a slowing of body/facial hair growth.
- The maximum effect of treatment may not be seen for more than two years.
- Treatment does not provide voice alteration.
- Feminizing hormone therapy may also bring about changes in emotional and social functioning.
- Most treatment results are reversible upon cessation of treatment, but breast growth is permanent, and infertility may be irreversible.
- Refer to *Figure 1* on for a general timeline of listed effects.

FIGURE 1. FEMINIZING EFFECTS IN TRANSGENDER FEMALES

Effect	Onset	Maximum
Redistribution of body fat	3–6 mo	2–3 y
Decrease in muscle mass and strength	3–6 mo	1–2 y
Softening of skin/decreased oiliness	3–6 mo	Unknown
Decreased sexual desire	1–3 mo	3–6 mo
Decreased spontaneous erections	1–3 mo	3–6 mo
Male sexual dysfunction	Variable	Variable
Breast growth	3–6 mo	2–3 y
Decreased testicular volume	3–6 mo	2–3 y
Decreased sperm production	Unknown	>3 y
Decreased terminal hair growth	6–12 mo	>3 y[a]
Scalp hair	Variable	—[b]
Voice changes	None	—[c]

Estimates represent clinical observations: Toorians *et al.* (149), Asscheman *et al.* (156), Gooren *et al.* (157).

[a]Complete removal of male sexual hair requires electrolysis or laser treatment or both.

[b]Familial scalp hair loss may occur if estrogens are stopped.

[c]Treatment by speech pathologists for voice training is most effective.

Note: Adapted from Table 13. Feminizing Effects in Transgender Females reprinted from Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline by W.C. Hembree, P.T. Cohen-Kettenis, L Gooren, S. E. Hannema, W. J. Meyer, M. H. Muran, S. M. Rosenthal, J.D. Safer, V. Tangpricha, G. G. T'Sjoen, 2017, The Journal of Clinical Endocrinology & Metabolism 102(11):1-35.

SERUM HORMONE LEVELS FOR FEMINIZING HORMONE THERAPY

GOAL LEVELS FOR MTF: Serum Estradiol 100-200 pg/ml and Serum Total Testosterone <50 ng/dl

- While the goal of gender affirming hormone therapy is to suppress male secondary sex characteristics, serum estradiol levels should not exceed those of a premenopausal cis female (200 pg/ml); doses used to achieve an adequate level may be significantly higher than those used in hormone replacement therapy in menopausal women.
- It is important to note there are individuals who do not require estradiol as part of their hormonal therapy regimen and do well on an anti-androgen therapy alone. Bone density considerations should be fully disclosed to the patient who is considering this approach.
- There are individuals who require very little estrogen to obtain desired body characteristics and adequately treat any presenting dysphoria/incongruence (in these cases, a specific hormone level is NOT the patient's goal. Hormone levels are monitored to assure the level does not exceed 200 pg/ml).
- **Patients should be treated with the lowest effective hormone doses.**
  - ***As stated above, estradiol levels should not routinely exceed a premenopausal level of 200 pg/ml.***
  - The same holds true for total testosterone levels. While the goal is <50 ng/dl, there is a subset of individuals who do poorly with levels below 35 ng/dl. The ideal levels for these individuals may be between 35–50 ng/dl.

➔ *Titration of dose is based on the individual's goals within the context of clinical response, hormone levels, and safety monitoring (e.g., risk factors such as smoking or renal function may warrant dose adjustments).*

The Endocrine Society recommends monitoring of hormone levels every 3 months, during the first year of therapy and/or when titrating treatment regimens or altering therapy before stabilization of dosages has been achieved. After the first year of therapy, hormone levels can be monitored every 6-12 months as clinically indicated.

➔ *The laboratory monitoring guide for feminizing hormone therapy is included in Appendix 4.*

DOSE TITRATION

The science and interpretation of serum hormone levels for TG individuals is evolving. Titration of hormone therapy doses should be driven by patient goals and clinical response per individual. Monitoring for potential medication sided effects and hormone levels are critical components of adjusting treatment.

- The recommended titration approach for patients includes increasing both estrogen and antiandrogen medication dosing to achieve desired physiological changes, but not to exceed the premenopausal cis female physiologic ranges (100–200 pg/mL).
- Another approach includes maintaining current physiologic estrogen dosing, titration of antiandrogen therapy, and the addition of a progestin, if appropriate.
- Regardless of initial dosing regimen utilized, dosages may be titrated upwards over 3–6 months.

FEMINIZING MEDICATIONS

➔ *See the Summary Tables for TRANSGENDER FEMALE Hormone Therapy in Appendix 2 for information on each of the medication groups below.*

ANTI-ANDROGENS

Anti-androgens reduce testosterone levels and allow estrogen therapy to be used in lower doses while still reaching a maximum effect. Medications with anti-androgen effects include spironolactone, finasteride, GnRH agonists, and progestins.

- **SPIRONOLACTONE** is a potassium-sparing diuretic that directly inhibits testosterone secretion and androgen binding to the androgen receptor. It is the most commonly prescribed anti-androgen for gender nonconforming individuals in the United States.
  - Spironolactone can suppress facial and body hair growth, male pattern baldness, libido, and sexually stimulated erections. It decreases symptoms of benign prostate hypertrophy (BPH) and can lead to modest breast growth.
  - Due to its diuretic effects, patients may also experience self-limited polyuria, polydipsia, or orthostatic hypotension.
  - ➔ *The use of spironolactone must be carefully monitored in renal insufficiency and is contraindicated in patients with a potassium value greater than 5.5 mEq/L. Spironolactone can cause severe hyperkalemia and hypotension. Caution should be used when prescribed in conjunction with angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs). It is important to monitor potassium levels and blood pressure of individuals taking spironolactone.*
- **5α-REDUCTASE INHIBITORS (**finasteride and dutasteride) inhibit 5-alpha reductase, the enzyme responsible for converting testosterone to its potent form, dihydrotestosterone.
  - Per WPATH SOC 8, data on the use of these medications in trans feminine populations is very limited: *It is unclear whether this class of medication could have any clinical benefit in trans feminine individuals whose testosterone and dihydrotestosterone levels have already been lowered with estrogen and an antiandrogen. We [WPATH] therefore do not recommend their routine use in trans feminine populations.* Rare use may be indicated in specific clinical circumstances such as for patients unable to tolerate spironolactone and which GnRH antagonists are not indicated or available.
- **GNRH AGONISTS** (goserelin, nafarelin, and leuprolide) suppress pituitary gonadotropin levels and gonadal steroids. They are most often used in adolescents for suppression of puberty but can be used to decrease testosterone levels and the amount of estrogen needed to achieve targeted physical effects.
  - Primary utilization in adult patients is for those who are unable to tolerate spironolactone due to hyperkalemia, increased frequency of urination, and/or a reduction in blood pressure or those who have some other contraindication to spironolactone use.
  - GnRH agonists do not carry a risk of thromboembolic disease, but use can result in osteoporosis if doses of estrogen given concurrently are insufficient.

- The high cost to the patient upon release should be considered in those with proximal release dates.
- In cases of persistent elevations of testosterone despite maximized spironolactone dosing, adherence must be thoroughly evaluated prior to consideration of a GnRH antagonist. Directly observed therapy should be considered. If complete adherence is determined to exist and levels are still elevated beyond reason, autonomous endogenous production (i.e., tumor) should be considered and appropriate evaluation should be conducted.

- **PROGESTINS** are a group of hormones that include medroxyprogesterone. Use of medroxyprogesterone is controversial and not routinely recommended. It is purported to aid in breast development at a cellular level as well as mood management, but its effect is mainly on the uterus. Evidence as an effective agent in gender-affirming hormone therapy is lacking. Per WPATH: *there is currently insufficient evidence the potential benefits of progesterone administration outweigh the potential risks.* Additionally, an association between progesterone use in transgender woman and VTE has also been identified.
  - *Medroxyprogesterone treatment comes with risk of developing mood disorders (depression/ irritability), lipid abnormalities, weight gain, and edema. There is also a concern of increased cardiovascular risk.*

ESTROGENS

Estrogens are used to provide feminization in the form of physical appearance and sexual characteristics. Effects include development of breasts, redistribution of body fat, softening of the skin, shrinkage of the testes, and testicular atrophy. Many formulations of estrogen are available, including parenteral, transdermal, sublingual, and oral. Estrogen may have positive health effects more generally, including increased high-density lipoprotein, decreased low-density lipoprotein, and preservation of bone mineral density. *Table 2* below lists conditions that can be exacerbated by gender-affirming estrogen therapy.

TABLE 2. MEDICAL CONDITIONS REQUIRING INCREASED MONITORING WITH ESTROGEN THERAPY

Contraindications	
• Current thromboembolic disease (may consider after subspecialty consultation) • Current diagnosis of estrogen-sensitive cancer	• Unstable ischemic cardiovascular disease
Precautions (Consider Subspecialist Consult)	
• History of prolactinoma • Breast cancer (non-estrogen dependent) • Severe liver dysfunction *(transaminases >3x upper limit of normal)*	• Coronary artery disease • Cerebrovascular disease • Severe migraine headaches • Retinal vascular thrombosis
Precautions (Recommend Increased Monitoring)	
• Obesity • History of cigarettes, tobacco, other nicotine use • Migraines or epilepsy • Diabetes • History of thromboembolic disease	• High cholesterol • High blood pressure • Heart, liver, kidney, or clotting disease • Hypoparathyroidism • Porpyria

- All estrogens come with a risk of thromboembolism, but lower doses and transdermal formulations are considered safer and should be used in populations at higher risk of thromboembolism (>40 years old, smoker, obese, etc.). Aspirin therapy may be considered for those at higher risk of thromboembolic disease.
- Intramuscular (IM) injections can cause greater peaks and troughs in estrogen levels, causing more mood disturbances than oral and transdermal preparations, making oral and transdermal preparations preferable for some patients. Reductions in peak and troughs can be partially mitigated by more frequent dosing of the injections.
- Use of estrogen should be individualized and adjusted regularly, based on serum estradiol levels and individual-specific goals or concerns. Estrogen should be started at low doses and titrated up as needed, based on hormone levels as well as individual tolerance and goals. If discontinuation is necessary, consider tapering therapy to alleviate mood disturbances.
- In patients scheduled for surgery or an immobilizing event, the treatment team (i.e., assigned surgeon) should be made aware of current hormone therapy. Limited evidence suggests low risk for thrombotic events whether therapy is continued or temporarily held (Totaro et al 2021). An individualized risk assessment should be performed in determining the appropriate treatment plan.
- Estrogens are partially metabolized by CYP3A4 and interactions may occur with agents that inhibit or induce CYP3A4. Refer to current drug interaction references and/or a pharmacist for additional information.

➔ *Conjugated and synthetic estrogen formulations cannot be measured through serum estradiol concentrations and are no longer recommended for gender-affirming hormone therapy.*

➔ *Synthetic estrogens, especially ethinyl estradiol, have been shown to have a higher risk of thromboembolism and should be avoided. Patients entering the BOP on synthetic estrogens should be transitioned to a more appropriate formulation.*

MONITORING

Gender-affirming hormone therapy may have risks up to and equivalent of those associated with hormone replacement therapy in biological females. Appropriate monitoring is crucial.

- Weight, blood pressure, physical exams, risk factors, medications, complete blood counts, renal and liver function, and lipid and glucose metabolism should be monitored for all TG individuals receiving gender-affirming hormone therapy.
- In addition, individuals undergoing feminizing hormone treatment should be monitored for development of feminine characteristics, target blood levels, and any adverse effects of the medication.

➔ *Refer to Appendix 4. Monitoring During Feminizing Hormone Therapy for additional guidance regarding monitoring.*

12. MASCULINIZING HORMONE THERAPY

The goal of masculinizing hormone therapy is the development of male secondary sex characteristics and suppression/minimization of female sex characteristics; this is usually done by the administration of a testosterone formulation.

EXPECTATIONS OF MASCULINIZING HORMONE THERAPY

Prior to beginning treatment, patients should receive education on realistic expectations of the treatment results, as well as the timeline of when to expect them. Every case is different, and slow change can lead to frustration.

- Effects developing within the first 6 months of treatment (onset within the first 3 months) include body fat redistribution, an increase in libido, an increase in skin oiliness and acne, clitoral enlargement, vaginal atrophy, cessation of menses, and infertility. Maximum effect usually occurs in 1–2 years but may take up to 5 years in some cases.
- Effects developing in the 6–12 month time frame include increased facial and body hair, scalp hair loss, increased muscle mass and strength, and deepening of the voice. Maximum effect often occurring in 1–2 years.
- Uterine bleeding should cease within a few months of high-dose testosterone therapy, but treatments such as GnRH agonists, medroxyprogesterone, and endometrial ablation may be used to stop menses prior to starting testosterone therapy or to decrease estrogen levels, if not responding to standard treatment.
- Most effects are reversible upon cessation of treatment, but changes in hair, voice depth, and infertility may be irreversible.
- Refer to *Figure 2* below for a general timeline of listed effects.

FIGURE 2. MASCULINIZING EFFECTS IN TRANSGENDER MALES

Effect	Onset	Maximum
Skin oiliness/acne	1–6 mo	1–2 y
Facial/body hair growth	6–12 mo	4–5 y
Scalp hair loss	6–12 mo	—[a]
Increased muscle mass/strength	6–12 mo	2–5 y
Fat redistribution	1–6 mo	2–5 y
Cessation of menses	1–6 mo	—[b]
Clitoral enlargement	1–6 mo	1–2 y
Vaginal atrophy	1–6 mo	1–2 y
Deepening of voice	6–12 mo	1–2 y

Estimates represent clinical observations: Toorians *et al.* (149), Asscheman *et al.* (156), Gooren *et al.* (157), Wierckx *et al.* (158).

[a]Prevention and treatment as recommended for biological men.

[b]Menorrhagia requires diagnosis and treatment by a gynecologist.

Note: Adapted from Table 12. Masculinizing Effects in Transgender Males reprinted from Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline by W.C. Hembree, P.T. Cohen-Kettenis, L Gooren, S. E. Hannema, W. J. Meyer, M. H. Muran, S. M. Rosenthal, J.D. Safer, V. Tangpricha, G. G. T'Sjoen, 2017, The Journal of Clinical Endocrinology & Metabolism 102(11):1-35.

Serum Hormone Levels for Masculinizing Hormone Therapy

Goal Levels for Masculinizing Hormone Therapy: Serum Estradiol <50 pg/ml and Serum Total Testosterone 320–1000 ng/dl

Goal treatment levels are serum estradiol <50 pg/ml and serum total testosterone 320–1000 ng/dl (male physiologic range; some sources quote a normal reference range of 400–800 ng/dl). If a peak total testosterone level is drawn for injectable testosterone, the level should not exceed 1,000 ng/ml. If total testosterone levels exceed this range, refer to a transgender clinical care team physician or pharmacist for guidance in adjusting therapy.

➔ *Free testosterone level monitoring is rarely required during gender affirming treatment. Dose adjustments are based on Serum Total Testosterone levels.*

Masculinizing Hormone Therapy During Pregnancy

➔ *Gender-affirming hormone therapy is contraindicated during pregnancy.*

- While therapy may lead to potentially irreversible infertility, it does not function as contraception, and pregnancy is still possible during treatment. Precautions should be taken to avoid pregnancy during treatment.
- A pregnancy test is obtained prior to starting treatment for all individuals with childbearing potential.

Titration of Masculinizing Hormone Therapy

Titration of hormone therapy doses should be driven by patient goals and clinical response per individual, including hormone level and safety monitoring.

- Clinical response is measured objectively by the presence of amenorrhea by month 6 of therapy.
- Lab references for testosterone levels vary (e.g., 320–1000 ng/dl). However, TG men with levels on the lower end of the range may express concerns about slow progress in gender affirmation or may experience low energy, libido, or mood—and thus warrant increased doses.
- Titration of testosterone should be done slowly with close monitoring for adverse events. Evidence remains unclear on whether increased doses will have positive effects once testosterone levels are greater than the midpoint of the reference range.
- Daily testosterone levels in TG men do not fluctuate as they do in natal males; however, they may vary over the laboratory monitoring intervals.

MASCULINIZING MEDICATIONS

➔ *See the Summary Charts for MASCULINIZING Hormone Therapy in Appendix 3 for a full list of the different formulations of testosterone—including summarized information on dosing, adverse effects, contraindications, and interactions.*

➔ *Monitoring is covered in Appendix 5. Monitoring During Masculinizing Hormone Therapy*

TESTOSTERONE

Androgen supplementation is used to induce male sex characteristics, including cessation of menses, voice changes, increased facial/body hair growth, increased muscle mass, hairline recession/baldness, changes in sweat and odor patterns, and clitoral enlargement. Other effects include increased libido and energy. Vaginal dryness will also likely occur. Higher doses of testosterone may be needed for TG men than for natal males who are being treated for low testosterone.

- Several formulations are available, ranging from IM injections to transdermal patches and gels. Due to the classification of all testosterone preparations as DEA-controlled substances and their associated risk of potential abuse and/or diversion, in the correctional environment, injectable formulations are the preferred method of administration.
- The IM injections release slowly from the muscle but may induce cyclical adverse effects that coincide with varying plasma concentrations. This can be mitigated by using a lower dose of IM testosterone given one to twice weekly (rather than every two or more weeks).
- While oral formulations are available, they are not used, due to extensive liver metabolism and the associated potential for hepatic complications.
- Androgen use should be individualized and adjusted based on serum total testosterone levels, tolerance, efficacy, and patient goals. Dosing should start low and be titrated up to an appropriate level while keeping the dose as low as possible to minimize adverse reactions.
- Ovulation may still be possible even when undergoing long-term testosterone therapy. Therefore, it is possible for a transgender man to become pregnant.

PROGESTINS AND GNRH AGONISTS

Medroxyprogesterone and GnRH agonists are not routinely used but may be treatment options in individuals wishing to cease menstruation and decrease estrogen levels prior to testosterone treatment. These medications may also have a use in individuals receiving high-dose testosterone therapy who still experience uterine bleeding after the first few months of treatment.

Drug Risks

Table 3 lists conditions that can be exacerbated by gender-affirming testosterone therapy.

Table 3. Medical Conditions Requiring Increased Monitoring With Testosterone Therapy

Contraindications	
• Pregnancy • Breastfeeding • Trans Men with carcinoma of the breast	
Precautions	
• Severe liver dysfunction (transaminases >3x upper limit of normal) • Breast or uterine cancer • Erythrocytosis (hematocrit >50%) • Androgen-sensitive epilepsy • Migraines • Sleep apnea • Depression or significant history of violent behavior	• Epilepsy • Renal failure • Severe hypertension susceptible to salt retention and fluid overload • Coronary artery disease (CAD) or risk factors for CAD • Bleeding disorders (for injected testosterone)

Monitoring

Masculinizing hormone therapy has the same risks associated with hormone replacement therapy in biological males. Appropriate monitoring is crucial.

The Endocrine Society recommends monitoring of hormone levels every 3 months, especially when titrating treatment regimens or altering therapy before stabilization of dosages has been achieved. Once stabilization of dosages has been achieved, hormone levels are typically done every 6-12 months or as clinically indicated.

- Weight, blood pressure, physical exams, risk factors, medications, complete blood counts, renal and liver function, and lipid and glucose metabolism should be monitored for all TG individuals receiving gender-affirming hormone therapy.
- In addition, individuals undergoing masculinizing hormone treatment should be monitored for development of masculine characteristics, target blood levels, and any adverse effects of the medication. Some of the adverse effects experienced with chronic testosterone therapy are erythrocytosis, liver dysfunction, hypertension, excessive weight gain, salt retention, lipid changes, excessive or cystic acne, and adverse psychological changes.

➔ *Refer to Appendix 5. Monitoring During Masculinizing Hormone Therapy for additional guidance.*

13. PREVENTIVE HEALTH SCREENINGS

Regardless of the patient's identified gender or gender-confirming procedures, if the patient has a particular body part or organ, they must continue to have preventative health screening of that organ per recommended guidelines. Additionally, TG patients who are currently on or have previously been on gender affirming hormone treatment are at increased risk for some medical conditions which may require more frequent preventative health screenings. It is important to obtain a thorough medication and surgical history to fully ascertain the individual's screening needs. *Table 4* provides and overview of preventive screening needs of TG patients.

TABLE 4. PREVENTATIVE HEALTH SCREENING FOR TG PATIENTS

Health Screening	Transgender Women	Transgender Men
Breast cancer	• Screen patients age >50 years based on established clinical guidance.	• Intact breasts: Routine screening as for natal females. • Postmastectomy: Yearly chest wall and axillary exams.
Cardiovascular Disease	• Recommended periodically in accordance with established guidance. Parameters should include weight, BMI, blood pressure, lipids, and blood sugar/A1C.	
Cervical cancer	• Vaginoplasty: no screening.	• Cervix intact: Routine screening as for natal females. • Absent cervix: No screening
Colon cancer	• Recommended in accordance with established guidance.	
Diabetes Mellitus	• Recommended periodically in accordance with established guidance. • If on estrogen: increased risk and frequency of screening may be increased.	• Recommended periodically in accordance with established guidance.
Hyperlipidemia	• Recommended periodically in accordance with established guidance. • If on estrogen: annual lipid screening.	• Recommended periodically in accordance with established guidance • If on testosterone: annual lipid screening
Osteoporosis	• Testes intact: Routine screening as for natal males. • Postorchiectomy: Screen all patients > 65 years. • Screen all patients age 50-65 years if off hormones for >5 years	• Screen all patients age >65 years • Screen patients age 50-65 if off hormones for >5 years
Prostate cancer	• Routine screening as for natal males.	• Not applicable
Testicular cancer	• Pre-orchiectomy with intact testes: Recommended periodically in accordance with established guidance.	• Not applicable
Refer to UpToDate *Primary Care of Transgender Individuals* and BOP *Clinical Guidance for Preventive Health Care* for additional information.		

14. MINIMALY INVASIVE AND NON-INVASIVE GENDER AFFIRMING TREATMENT MODALITIES

There are several minimally invasive and non-invasive gender-affirming treatment modalities available to TG patients such as voice and communication training, professional laser facial hair removal, and chondrolaryngoplasty (tracheal shaving). Lesser invasive or minor surgical procedures may be deemed medically necessary and considered on a case-by-case basis.

The purpose of these gender-affirming treatment modalities is to decrease or stabilize the gender dysphoria/incongruence experienced by the TG patient and improve the psychosocial functioning of the TG individual. The primary care treatment provider should use sub-specialty consultation requests in the electronic health record (EHR) to order these modalities. It is the responsibility of the medical provider to document the medical necessity, using accepted medical standards for gender-affirming treatment, for each of the requested lesser invasive and non-invasive interventions.

Requests for these treatment modalities (other than hormone treatment) such as voice and communication training, professional laser facial hair removal/electrolysis, will be reviewed in accordance with **Program Statement 6031 Patient Care**, section on Utilization Review; ***a subspecialty consult will be placed in BEMR and referred to the local Utilization Review committee for review. All procedures approved at the local URC meeting will require referral to the Regional Medical Director (RMD) for review and approval per PS 6031.***

Appendix 1. Transition Pathway for Transgender Patients lists the transition pathway for the affirmation treatment of the incarcerated TG individual from diagnosis to referral for major gender affirming surgery. These steps are not required to be fulfilled in chronological order before progressing to more invasive and non-reversible gender affirming treatment modalities but are an example of treatment modalities from least to most invasive.

VOICE AND COMMUNICATION TRAINING

Providers are encouraged to reach out to Regional Physical and Occupational Therapists, who can assist in finding appropriate resources. The American Speech-Language-Hearing Association (ASHA) has a provider directory for speech language pathologists who specialize in voice and communication therapy for transgender and gender diverse people.

FACIAL HAIR REMOVAL

Facial hair is often a source of distress and suffering for patients who identify as trans-female. Several noninvasive options are available to our incarcerated population. Patients can access the commissary to purchase extra razors, hygiene items such as hair removal creams and lotions, as well as foundation/coverage cremes/liquids to match the color of their skin; some of these products require special order purchases. Hair removal through waxing is a custody concern and is avoided in an incarcerated environment.

When commissary items fail to achieve desired results, and there is continued Gender Dysphoria, Health Services may provide over-the-counter laser hair removal devices as medically necessary. These are secured/maintained in Health Services and used by the patient under monitoring of staff.

Most laser hair removal devices marketed for at-home use are IPL (Intense Pulsed Light) devices. These devices cause a reduction in hair by emitting multiple wavelengths of light to the skin targeting melanin in the hair follicle, which then heats up the hair follicle causing it to weaken or be destroyed. IPL devices only work on hair that is in the growth phase and attached to the follicle therefore multiple treatments are often required. These devices work best on brown and black hair and typically do not provide results on white, grey, light blonde, or red hair. IPL devices work best on Fitzpatrick skin types I-IV which includes all skin tones except dark brown or black skin.

Another laser hair removal device marketed for at-home use is the diode laser. The diode laser works like the IPL devices, except instead of emitting multiple various wavelengths of light it emits a single wavelength of concentrated light. The diode devices are considered safer for all skin types as the IPL cannot be used on darker skin due to lower effectiveness and increased risk of skin burning. It is important to check what skin types the device can treat prior to obtaining the device.

Patients need to be educated on realistic expectations of these devices including: understanding that treatment often is not permanent; will require multiple treatments, often to the same areas; and different devices have varied effectiveness depending on skin and hair color, among other factors. Additionally, they are not without adverse reactions, sometimes causing skin irritation, pain, blistering or scarring. They should not be used on skin with large moles, birthmarks, or tattoos. All visible hair should be shaved in the area prior to use. Sun exposure, before and after treatments, should be avoided.

Prior to obtaining a laser hair removal device, institutions must check to see if the device is FDA cleared using the link: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.* Search by device name and look for the designation of "Substantially Equivalent (SESE)" to determine if FDA cleared. In addition, institutions will need to consider the options for cleaning between patient use with each product.

If these measures fail to remove the facial hair or are contraindicated (e.g., documented allergy or repeated infections) and patient has persistent unresolved Gender Dysphoria/incongruence, a referral consultation for professional laser facial hair removal or electrolysis may be submitted to the local Utilization Review Committee for consideration.

15. INVASIVE AND COMPLEX GENDER-CONFIRMING SURGERIES

➔ *Gender-Confirming surgery has also been referred to as sex reassignment surgery. It is important to note terminology changes often and the latter term is falling out of use.*

TG patients who have been compliant with all aspects of gender affirming care may desire further gender affirming treatment by requesting consideration for invasive and complex gender-confirmation surgery.

Gender confirming surgery may be medically necessary and is considered on a case-by-case basis. The BOP strives to provide community standard medical and surgical care within the confines its systems.

Surgical confirmation for trans individuals in BOP custody may be the final stage in their transition process. While many individuals may not require any surgery, for some it is medically necessary to complete more than a single procedure to alleviate their gender dysphoria/incongruence. See *Table 5* for different examples of surgical procedures.

TABLE 5. GENDER CONFIRMING PROCEDURES

Feminizing Surgical Procedures	
• Breast Augmentation	• Enlarging the breasts using breast implants
• Clitoroplasty	• Surgical creation of a clitoris
• Labiaplasty	• Creation or reshaping of the labia around the vagina
• Penectomy	• Removal of all or part of the penis
• Orchiectomy	• Removal of one or both testicles
Masculinizing Surgical Procedures	
• Bilateral Mastectomy	• Removal of both breasts
• Male Chest Contouring	• Contouring the chest into a masculine shape
• Hysterectomy	• Removal of the uterus
• Ovariectomy/Salpingo-oophorectomy	• Removal of ovaries/removal of ovaries and fallopian tubes
• Penile Prosthesis	• An erectile prosthetic device is placed to allow for an erection
• Phalloplasty	• Construction of a penis which may involve multiple surgeries
• Scrotoplasty	• Creation of a scrotum
• Metoidioplasty	• A surgical procedure that works with existing genital tissue to form a phallus, or new penis.
• Permanent Hair Removal	• When clinically required in preparation for bottom surgery

In accordance with ***Program Statement 5200.08 Transgender Offender Manual*****,** the TEC reviews all general administrative criteria for major gender affirming surgery and reviews additional correctional/custody considerations. The request for invasive and complex gender confirming surgery requires executive level administrative approval (by TEC), and approval from the Medical Director.

The **Clinical Director's (or designee's) role** at the referral institution is to support and treat the trans patient according to this guidance and document it accordingly. In general, clinical criteria for gender confirming consideration in the Bureau include the following:

- The patient has received ongoing gender affirming treatment by assigned medical and mental health providers, and there is persistent well-documented GD.
- There is clinical documentation of patient-centered discussions and documented ongoing follow-up regarding the specific therapeutic and surgical needs.
- The patient has been deemed capable to make fully informed decisions.
- Any significant medical and mental health conditions are reasonably well controlled.
- There have been 12 continuous months of hormone therapy as appropriate to the patient's individual goals (unless medically contraindicated).
  - ► Hormone therapy in trans-males is NOT a prerequisite for mastectomy and male chest contouring.
  - ► Hormone therapy in trans-females will maximize breast growth when continued for at least 2-3 years. Some surgeons will only perform the breast augmentation surgery after this period of time has elapsed. While this may be ideal, there will be times when Gender Dysphoria symptoms may warrant breast augmentation surgery after a minimum of one year of gender-affirming hormone treatment.
  - ► Patients should undergo masculinizing hormone therapy for at least 12-24 months prior to clitoral enlargement.

- There have been 12 continuous months of living in a gender role that is congruent with their gender identity. This experience provides ample opportunity for patients to experience and socially adjust to their desired gender role before undergoing irreversible surgery.
- Per ***Program Statement 5200.08 Transgender Offender Manual***,, the Warden submits a referral request to the TEC who will complete an administrative readiness review for gender-confirming surgery.
- When the TEC administratively approves a patient for surgical consideration, a referral is made to the Medical Director who remains the final authority in approving or disapproving a patient for gender confirming procedures. At the direction of the Medical Director, all pertinent clinical information will be reviewed by the Transgender Utilization Review Advisory Group to establish medical appropriateness for the procedure according to community standards.

TRANSGENDER UTILIZATION REVIEW ADVISORY GROUP REVIEW

The Transgender Utilization Review Advisory Group is made up of members of the Transgender Clinical Care Team. Each utilization medical review meeting will require one pharmacist, one psychiatrist, a primary care physician and one social worker from the Transgender Clinical Care Team.

All clinical information in the surgical referral packet submitted by the patient's treatment providers is reviewed. The Transgender Utilization Review Advisory Group may need to interview the patient and/or contact members of the treatment team at the referring institution for additional clinical information (EKG, Pulmonary Function Testing, etc). A targeted utilization review is conducted to assure the proposed procedure(s) are medically needed and appropriate according to community standard prior to making their recommendation to the Medical Director. The Medical Director has the final clinical authority, according to BOP Policy, for approving/disapproving patients for referral for Gender Confirming Surgery.

CLINICAL CONTENTS OF THE GENDER CONFIRMING SURGICAL REFERRAL PACKET

The **SURGICAL REFERRAL PACKET** should include the following items:

MENTAL HEALTH EVALUATION: the mental health professional (typically a Psychologist familiar with the patient) will document the patient's personal mental health and gender non-conformity history, progress, and suitability for surgery based on the stability of co-existing mental illness, and consolidation of one's identity. Recommended content of the mental health provider's referral for surgery include:

- The presenting general identifying characteristics.
- A list of all active mental health diagnoses.
- A review of history of suicidality, homicidality, history of violence, any psychiatric hospitalizations, and residential treatment for mental health or substance use.
- Any current and past substance use including nicotine.
- The duration of the mental health professional's relationship with the client, including the type of evaluation(s) and therapy or counseling to date.
- If and how long the patient has been living in the identified gender.
- An explanation that the criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery.

- Formal evaluation and documentation of capacity to give consent.
- Any issues regarding communication (e.g., English fluency, hearing impairments, an autism spectrum disorder, literacy level, learning differences, etc.)

MEDICAL EVALUATION: the objective of the medical evaluation of a pre-surgical candidate for gender-confirmation surgery is to establish medical suitability for the upcoming procedure. The medical evaluation will address both gender non-binary consolidation medical needs according to *WPATH*, as well as a general pre-surgical evaluation according to community standard. Recommended content for the medical evaluation for referral for surgery should include documentation on:

- Presence of persistent gender dysphoria/incongruence.
- Type of surgery patient is requesting.
- General statement about patient's ability to understand the irreversible aspects of the procedure.
- General patient discussion regarding risks for surgery which will be dependent on what type of surgery is being done. Some general risks to discuss with the patient include but are not limited to:
  - Significant pain.
  - Suboptimal appearance.
  - Risk related to general anesthesia to include death.
  - Excessive blood loss and need for transfusion.
  - Blood clots.
  - Damage to surrounding structures.
  - Nerve damage and loss of sensation.
  - Hematomas.
  - Infection or abscess potentially resulting in necrosis.
  - Excessive scarring.
  - Patient should also be informed that any detailed surgical technique information, risks of the procedure, and complication rates will be discussed with the surgeon, who is responsible for obtaining surgical consent.
- Documentation that the patient understands expected aftercare plan, what is to be expected during the healing process, and how the plan may change based on surgical results and recommendations from the surgeon.
- Patient History
  - History of present illness
    - Current medical and mental health status.
    - Medical and mental health conditions are reasonably well controlled.
  - Past medical history
  - Allergies

  - Medications
    - All active medications.
    - Dose and frequency.
    - Duration of hormone therapy (if applicable).
  - Review of systems
  - Family history
  - Social history
  - Surgical history
  - Sexual reproductive history and wishes
- Physical Exam (complete)
  - Including HEENT, cardiac, pulmonary, abdominal, extremities and neurologic
  - Special attention to signs of conditions that would be absolute/relative contraindications to surgery
- Laboratory Studies
  - Complete blood count with differential, comprehensive metabolic panel with liver function tests
  - Applicable hormone levels
- Pre-Surgical Work-Up- this may be at the preference of the surgeon and may include:
  - Recent EKG/Chest x-ray
  - Stress test
  - Nutritional assessment

PSYCHOSOCIAL EVALUATION: The social work psychosocial assessment for gender affirming surgery is utilized to gain a comprehensive understanding of the patient within their environment, both while incarcerated and upon release. It is completed by the social worker in the EHR. The assessment addresses the following areas:

- Family relationships, past and current
- Education, work/vocation, military history
- Religious/spiritual and/or cultural needs
- Financial resources
- Mental health, substance use, and medical history
- Sexual orientation and gender identity history
- Expectations or concerns regarding surgery
- Psychosocial functioning, support, and aftercare

16. TRANSITIONS OF CARE

Quality care and treatment includes planning for what will happen when a patient leaves the institution and BOP custody. Consultation with Transitional Care Team (TCT) should be pursued to assist with release planning efforts for transgender individuals, especially as it pertains to medical needs and gender affirming hormone therapy. The TCT can coordinate with relevant stakeholders and connect patients transitioning into the community with appropriate services and resources to ensure continuity of care. Aftercare planning for transgender individuals should include the following considerations:

NOTE: *If the institution is without a staff social worker, regional social workers are available to assist with aftercare planning.*

- A *Consent for Release of Medical Information* should be obtained from the inmate patient, in accordance with BOP policy, so that the inmate patient's treatment plan can be discussed with the community health care provider.
- An adequate supply of medications should be provided to the inmate prior to release or during community placement, in accordance with BOP policy.
- Patients transferring to Residential Re-entry Centers (RRC) or Home Confinement (HC) will be referred to BOP Health Systems Specialists (HSS) and Community Treatment Specialists (CTS) for continuity of care while in the RRC or on HC.
- If a patient is receiving gender affirming hormone therapy and is not transferring to RRC or HC, an aftercare plan should be established to ensure continuity of care.

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KEY TO ABBREVIATIONS

Below is a list of abbreviations used throughout this guidance.

➔ *See Section 2. Definitions for explanation of the terms marked with an asterisk (*).*

AEs	Adverse events
ARB	Angiotensin II receptor blocker
BMD	Bone mineral density
BMP	Basic metabolic panel, including glucose, calcium, sodium, potassium, CO2, chloride, blood urea nitrogen, and serum creatinine
CAD	Coronary artery disease
CBC	Complete blood count
CCARE	BOP Care Coordination and Reentry Team
CMA	Case Management Activity (codes)
CV	Cardiovascular
DM	Diabetes mellitus
FSH	Follicle-stimulating hormone
GD*	Gender dysphoria
GnRH	Gonadotropin-releasing hormone
hCG	Human chorionic gonadotropin
IM	Intramuscular
LFT	Liver function test
LH	Luteinizing hormone
N/V	Nausea and vomiting
PCOS	Polycystic ovarian syndrome
PREA	Prison Rape Elimination Act (see *Section 3*)
q	"Every" (example: q2wk = every 2 weeks)
SHBG	Sex hormone-binding globulin
SQ	Subcutaneous
TCCT*	BOP Transgender Clinical Care Team
TEC*	BOP Transgender Executive Council
TICC	Trauma-Informed Correctional Care in the BOP
TG*	Transgender
VTE	Venous thromboembolism

APPENDIX 1. TRANSITION PATHWAY FOR TRANSGENDER PATIENTS

1	**Patient self-identifies as TG or gender nonbinary to BOP staff member. Referral is made to a mental health professional or medical provider.**	
2	The mental health professional completes an assessment and documents gender non-conformity and/or gender dysphoria as indicated. (*Section 7*) Initiate gender-affirming live experiences within the prison system.	
3	Referral to medical provider for evaluation if patient has indicated an interest in initiating gender affirming hormone treatment (*Section 8*). Hormone treatment can be initiated prior to mental health evaluation, when/if patient presents to medical provider first and meets treatment criteria.	
4	Initiation of gender affirming hormone treatment after appropriate counseling completed on expected risks, outcomes, and complications. If needed, case can be discussed with BOP TCCT prior to initiation, though not required. Obtain informed consent (*Section 9*).	
5	***FEMINIZING THERAPY***	***MASCULINIZING THERAPY***
	Begin hormonal therapy with anti-androgen (spironolactone first, unless contraindicated) and estradiol Start low and titrate (no more than every few weeks) to appropriate level while using lowest effective dose. ➔ *See Section 11. Feminizing Hormone Therapy*	Begin hormonal therapy with testosterone Start low and titrate (no more than every few weeks) to appropriate level while using lowest effective dose. ➔ *See Section 12. Masculinizing Hormone Therapy*
	If treatment has reached maximum estradiol dose without desired effects after appropriate amount of time, consider adding another anti-androgen such as finasteride, a **GnRH** agonist, or medroxyprogesterone. Consult **BOP TCCT** if needed.	If still experiencing uterine bleeding after 6 months of high-dose testosterone therapy, consider adding medroxyprogesterone or a **GnRH** agonist to suppress menstruation. Consult **BOP TCCT** if needed.
6	After initiation and compliance with continuous gender affirming hormone treatment, a patient may request further gender affirmation by living in agender affirming institution. e.g., trans-female desires to live in a female institution/ trans-male desires to live in a male institution. The warden at the respective institution will request an administrative review by the TEC	
7	If approved by the TEC, the patient will be designated to the gender affirming institution (aka institution of the identified gender)	
8	Institutions that house transgender or gender non-conforming patients should develop a multidisciplinary team[1] who meet and discuss the patient's needs and progress	

(table continues on next page)

Transition Pathway for Transgender Patients (Cont.)	
9	After 12 months of living in the identified gender at the gender-affirming institution **or** original institution if the TG patient does not request transfer, compliance with continuous gender affirming hormone treatment and with documentation of persistent gender incongruence, the patient may benefit from lesser/non-invasive gender affirming treatment modalities or invasive/complex gender confirmation surgery[2] For all lesser/non-invasive gender affirming treatment modalities (ex. voice and communication training, professional laser facial hair removal) the individual provider will place the appropriate consult in the EHR and refer to the local Utilization Review Committee for review. Referral to the RMD will be required. For invasive/complex gender confirmation surgery- the warden at the respective institution will first request an administrative review by the TEC.
10	The TEC determines whether general administrative criteria for gender confirming surgery is met and refers the case to the Medical Director for a medical review. • The Medical Director will request review by the Transgender Utilization Review Advisory Group who will clinically review the surgical referral packet submitted by the Clinical Director. If the patient meets the clinical criteria for surgery, a memo, with all accompanying clinical supporting materials will be sent to the Medical Director, who is the final authority in approving a patient for referral to the gender confirming surgeon.
11	Gender confirming surgical evaluation will be completed by the contracted community surgeon who is responsible to meet with the patient to confirm readiness and medical suitability for complex surgery. Informed consent surrounding all aspects of the surgery to include risks, complication rates, and expected outcomes is the responsibility of the surgeon.

[1] Treatment team should consist of the Clinical Director (or designee), psychiatrist (as needed), Primary Care APP, psychologist, social worker, and pharmacist. Other representative members may include unit team, captain, chaplain (or patient representative), and associate warden. The patient may be invited to attend to clearly articulate and establish his/her clinical needs.
[2] Individuals will desire to progress to different stages of the stepwise approach. Only a subset of all gender non-conforming patients will pursue a surgical intervention.

APPENDIX 2. SUMMARY TABLES FOR FEMINIZING HORMONE THERAPY

➔ *See **Section 11** for more discussion on the medications used in Feminizing Hormone Therapy.*

➔ *These charts are not all-inclusive and are meant to summarize major considerations for medications. Refer to current drug interaction references, manufacturer information, and/or a pharmacist for additional information regarding drug dosing (to include renal and hepatic dosing), interactions, adverse effects, and contraindications.*

Table 1A: Anti-Androgen Drugs for Feminizing Hormone Therapy

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL 100-200 PG/ML AND SERUM TESTOSTERONE <50 NG/DL ★				
DRUG	**DOSE**	**MECHANISM OF ACTION**	**RISK CONSIDERATION /CONTRAINDICATIONS**	**NOTES**
SPIRONOLACTONE	• **Starting:** 25mg QD or BID • **Typical:** 100-300mg/day in 2 divided doses • **Max:** 200 mg BID	• Potassium-sparing antihypertensive that directly inhibits testosterone secretion and androgen binding to the androgen receptor	• Renal insufficiency • Potassium >5.5 mmol/L (use with caution if patient has comorbid condition or medications known to increase potassium)	
FINASTERIDE	• **Low:** 1 mg daily (generally used to treat androgenetic alopecia if needed and desired **after** individualized target level of androgen blockade is achieved) • **High:** 5 mg daily (generally used in those who cannot tolerate spironolactone or as an adjunct to spironolactone)	• 5α reductase inhibitor that blocks the conversion of testosterone to the more active 5α dihydrotestosterone (DHT)	• None pertinent	• Predicted to have little utility if the testosterone levels are suppressed and there is no substrate to generate DHT. • WPATH recommends against routine use in patients where testosterone and dihydrotestosterone levels have already been lowered with estrogen and an antiandrogen. Note, this includes for the use of androgenetic alopecia. • Use in combo with spironolactone for rare individuals not achieving desired effects. • May be used after orchiectomy if hirsutism or male pattern baldness are present. • When compared to placebo, 5-alpha-reductase inhibitors have been associated with an increase in the incidence of high-grade prostate cancers.
***APPENDIX 1, TABLE 1A, PAGE 1 OF 2** (see Key to Abbreviations in section preceding Appendices)*				

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL 100-200 PG/ML AND SERUM TESTOSTERONE <50 NG/DL ★				
DRUG	**DOSE**	**MECHANISM OF ACTION**	**RISK CONSIDERATION/ CONTRAINDICATIONS**	**NOTES**
GNRH AGONISTS: **GOSERELIN** **LEUPROLIDE**	• Goserelin: 3.6 mg SQ implant q4 weeks • Leuprolide: 3.75–7.5 mg SQ/IM monthly or 11.25mg SQ/IM q3 months ○ Lupron Depot® is administered IM ○ Eligard® is administered SQ	• Blocks the GnRH receptor, thus degreasing levels of FSH & LH resulting in highly effective gonadal blockade	• None pertinent	• Primary utilization is for patients who experience intolerable hyperkalemia, increased frequency of urination, and/or a reduction in blood pressure with spironolactone. • In cases of persistent elevations of testosterone despite maximized antiandrogen dosing, adherence must be thoroughly evaluated prior to consideration of GnRH Antagonist use. Directly observed therapy should be considered. If complete adherence is determined to exist, autonomous endogenous production (i.e., tumor) should be considered and appropriate evaluation should be conducted. • High cost should be considered in patients with proximal release dates. • Use can result in osteoporosis if doses of estrogen given concurrently are insufficient.
PROGESTIGENS: **MEDROXYPROGESTERONE**	• **Starting:** 2.5 mg daily • **Typical:** 5–10 mg daily • **Max:** 10 mg daily	• Inhibits secretions of pituitary gonadotropins	• Similar to estrogen. See ***CHART 1B*** below.	• No well-designed studies documenting efficacy. • Use in standard care generally lack formal recommendation for use. • If a patient is to be placed on a progestin, goals of use should be clearly documented and periodically evaluated. If goals are not achieved, medication should be discontinued. • Antidotal reports improved breast development, mood, and libido. However, evidence of benefit is unlikely to outweigh risk, which includes VTE
APPENDIX 1, TABLE 1A, PAGE 2 OF 2 *(see Key to Abbreviations in section preceding Appendices)*				

TABLE 1B: ESTROGEN FOR FEMINIZATION

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL <200 PG/ML AND SERUM TESTOSTERONE <50 NG/DL ★				
DRUG	**DOSE**	**MECHANISM OF ACTION**	**RISK CONSIDERATION/ CONTRAINDICATIONS**	**NOTES**
ESTRADIOL	• Typical: 2-6 mg daily • Occasionally higher doses are used as clinically indicated (literature recommends maximum does of 6-8mg depending on source) • If greater than 2 mg/day, recommend divided twice-daily dosing.	• Estrogens modulate the pituitary secretion of gonadotropins, LH, and FSH through a negative feedback system	**Absolute:** • Estrogen-dependent cancer **Precautions:** • History of thromboembolic disease (e.g., stoke, MI, DVT, PE) • Coronary artery disease • Hepatic dysfunction • Hyperlipidemia • Diabetes mellitus • Cigarette smoking • Migraine • Epilepsy • Retinal vascular thrombosis • Hypoparathyroidism • Porpyria • Diseases exacerbated by fluid retention	• Transdermal formulations are preferred for persons > 40 years old or those with risk factors for thromboembolic disease • Inform treatment team prior to surgery of hormone therapy. Individual risk assessment to determine adjustments to therapy perioperatively. • Individuals who enter the BOP on conjugated estrogen should be switched to a different form of estrogen due to inability to monitor estrogen levels with this preparation • IM injections cause greater peaks and troughs in estrogen levels making oral and transdermal preparations preferable
ESTRADIOL VALERATE IM (DELESTROGEN)	• **Typical:** 5-30 mg IM q2wk • *May divide dose into weekly injections for cyclical symptoms.*			
ESTRADIOL CYPIONATE IM (DEPO-ESTRADIOL)	• **Typical:** 2–10 mg IM q1wk			
ESTRADIOL PATCH (CLIMARA, ESTRADERM, ALORA, VIVELLE-DOT)	• **Typical:** 0.025 mg – 0.2 mg/day • *Max single patch dose available is 0.1 mg per 24 hours. More than one patch can be applied at a time* • *Frequency of patch change is brand/product dependent.*	*Same as above.*		

APPENDIX 1, TABLE 1B, PAGE 1 OF 1 *(see Key to Abbreviations in section preceding Appendices)*

APPENDIX 3. SUMMARY TABLE FOR MASCULINIZING HORMONE THERAPY

➔ ***See Section 12 for more discussion on the medications used in Masculinizing Hormone Therapy.***

➔ *These charts are not all-inclusive and are meant to summarize major considerations for medications. Refer to current drug interaction references, manufacturer information, and/or a pharmacist for additional information regarding drug dosing (to include renal and hepatic dosing), interactions, adverse effects, and contraindications.*

★ GOAL LEVELS FOR FTM: SERUM ESTRADIOL <50 PG/ML AND SERUM TESTOSTERONE 320–1000 NG/DL ★				
DRUG	**DOSE**	**MECHANISM OF ACTION**	**RISK CONSIDERATION/ CONTRAINDICATIONS**	**NOTES**
TESTOSTERONE CYPIONATE (in cottonseed oil) **TESTOSTERONE ENANTHATE (in sesame oil)**	• **Typical:** 50-100mg IM/SQ once weekly or 100-200mg IM every 2 weeks • **Max:** 200 mg q2wk or 100 mg/wk	• Maintains secondary sex characteristics in androgen-deficient patients	**Absolute:** • Pregnancy • Breast cancer (testosterone may have anti-proliferative effects on most, but not all, breast cancers) • Breastfeeding **Precautions:** • Erythrocytosis • Cardiac, hepatic, renal, or vascular disease with edema or risk of edema • Sleep apnea or high risk of sleep apnea due to obesity or chronic lung disease • Dyslipidemia • Migraines • Epilepsy • Depression, significant history of violent behavior	• Causes drop in blood glucose in DM individuals • May notice cyclic variation in mood with IM dosing Q 2–4 weeks. Use a lower, more frequent dose, or transdermal • Transdermal reaches same levels as IM, but in longer timeframe. • Menses typically stop in early months of treatment but may persist when using transdermals. • Testosterone is a DEA controlled substance. • For the first 3 to 9 months of treatment, total testosterone levels may be elevated with free testosterone levels remaining in the biological female range due to high sex hormone binding globulin levels in some biological women. • 15% of patients on testosterone will experience transient elevations in liver enzymes. If increase > 3x D/C and seek consultation. • Cypionate and enanthate formulations cannot be used interchangeably due to differences in duration of action.
TESTOSTERONE PATCH **Available strengths: 2 mg, 2.5 mg, 4 mg, 5 mg**	• **Typical:** 2.5-7.5 mg/day q PM • **Max:** 8 mg/day q PM			
TESTOSTERONE GEL (TESTIM 1%, ANDROGEL 1%)	• **Typical:**50-100mg/day			
TESTOSTERONE GEL (ANDROGEL 1.62%)	No published or anecdotal experience with these preparations			
TESTOSTERONE SOLUTION (AXIRON axillary solution)				
MEDROXYPROGESTERONE AND GNRH AGONISTS	Not routinely used. Refer to current drug references for dosing, mechanism of action, and contraindications/precautions.			• Use is recommended in patients who desire but have not yet begun testosterone therapy, or in conjunction with testosterone therapy for breakthrough bleeding
APPENDIX 2, PAGE 1 OF 1 *(see Key to Abbreviations in section preceding Appendices)*				

APPENDIX 4. MONITORING DURING FEMINIZING HORMONE THERAPY

Appropriate monitoring during gender-affirming hormone therapy is crucial to (1) ascertaining that target blood levels of hormones are being met and (2) assessing and maintaining the individual's health overall.

- **Clinical and laboratory monitoring** is appropriate every three months during the first year, and then as clinically indicated (typically once or twice yearly).
  - Monitor for development of feminine characteristics, for target blood levels, and for adverse effects of medication and other treatment.
- **Cardiovascular risk assessment** is recommended periodically for all patients treated with hormones in accordance with established guidelines and BOP guidance when available.
  - Specific parameters that should be monitored include weight and body mass index, blood pressure, lipids, and blood sugar and/or hemoglobin A1C levels, in accordance with established guidelines.
- **Serum ESTRADIOL and TESTOSTERONE levels** are obtained before starting those respective medications, and then every three months while on treatment.
  - **Target levels are <200 pg/ml for estradiol and <50 ng/dl for testosterone.** Higher levels of testosterone indicate inadequate suppression; higher levels of estradiol are associated with increased risks for thromboembolic disease, liver dysfunction, and development of hypertension.
- **Serum electrolytes, most importantly potassium, and renal function** are obtained prior to starting **SPIRONOLACTONE**, every three months during the first year of treatment, periodically thereafter, or more frequently with increases in dosage or as clinically indicated.
  - Dose adjustment or discontinuation of spironolactone is recommended for elevated potassium levels or serum creatinine >4 mg/dL.
- **Screening for colon and prostate cancer** is recommended in accordance with established guidelines and BOP guidance when available.
- **Breast cancer screening** guidelines for women are followed for transgender women treated with hormone therapy.
- **Screening for osteoporosis** with a DEXA scan may be appropriate in some cases. In addition, monitoring of hormone levels to ensure suppressed gonadotropin levels may serve as a surrogate marker to indicate adequate sex hormone levels in maintaining bone density in these patients.
  - In the absence of sufficient data to formulate evidence-based guidelines, it is considered appropriate to screen those who are at least five years post-gonadectomy, those who are 50 to 65 years old and have risk factors for osteoporosis, and all those who are 65 years or older.
  - Bone density measurements for transgender women are compared with standards for biological females.

- **Baseline and periodic monitoring of liver enzymes and prolactin levels** may be appropriate in those treated with **ESTRADIOL**, but there is insufficient data available to make a specific recommendation.

The following table below summarizes the monitoring schedule for individuals undergoing FEMINIZING hormone therapy.

➔ *See Key to Abbreviations in section preceding Appendices.*

LABORATORY MONITORING DURING FEMINIZING HORMONE THERAPY

Lab Test	Comments	Baseline	3 Mos[1]	6 Mos[1]	12 Mos[1]	Yearly	PRN
BMP	For individuals on spironolactone	X	X	X	X	X	
Lipids	As clinically indicated	X					X
A1C/Glucose	As clinically indicated	X					X
Estradiol	Range: generally, 100–200 pg/mL, but should not exceed 200 pg/ml	X	X	X	X	X	
Total Testosterone[2]	Range: < 50 ng/dL		X	X	X	X	
Prolactin	Only if symptoms of prolactinemia						X
LFTs	After baseline, optional if on estrogen, progesterone, or medroxyprogesterone	X				X	

[1] In the first year of therapy only

[2] Every 3 months in the first year then 1-2 times per year thereafter.

APPENDIX 5. MONITORING DURING MASCULINIZING HORMONE THERAPY

Appropriate monitoring during gender-affirming hormone therapy is crucial to (1) ascertaining that target blood levels of hormones are being met and (2) assessing and maintaining the individual's health overall.

➔ *A pregnancy test is obtained prior to starting treatment for all persons assigned as female at birth and have child-bearing potential.*

- **Clinical and laboratory monitoring** is appropriate every three months during the first year, and then as clinically indicated (typically once or twice yearly).
  - ➔ *Monitor for development of masculine characteristics, for target blood levels, and for adverse of effects of medication and other treatments.*
- Cardiovascular risk assessment is recommended periodically for all patients treated with hormones, in accordance with established guidelines and BOP guidance when available.
  - ▸ Specific parameters that should be monitored include weight and body mass index, blood pressure, lipids, and blood sugar and/or hemoglobin A1c levels.
- Serum testosterone levels are obtained before starting treatment with testosterone, and then every three months while on treatment.
  - ▸ Timing of the testosterone level is determined by the route of administration.
    - Testosterone enanthate/cypionate injections, testosterone levels should be obtained midway between injections. The target testosterone level is 400-700ng/dL.
    - Transdermal testosterone levels can be done any time after one week of therapy.
- Serum estradiol levels are obtained before starting hormone therapy, and then every three months while on treatment until estradiol levels are < 50 pg/ml and cessation of menses has been six months.
- A complete blood count (**CBC**) and liver panel are obtained prior to starting hormone therapy, every three months during the first year of treatment, once or twice yearly thereafter, or more frequently as clinically indicated.
  - ▸ Dose adjustment or discontinuation of testosterone is indicated if the hematocrit is > 54%.
- Screening for colon cancer is recommended in accordance with established guidelines and BOP guidance when available.
- Breast cancer screening guidelines for women are followed for **TG** individuals treated with hormone therapy and who have not had mastectomies.
- Cervical cancer screening is performed annually in those who are treated with hormone therapy and have cervical tissue (i.e., no hysterectomy).
- Screening for osteoporosis with a DEXA scan may be appropriate in some cases.
  - ▸ In the absence of sufficient data to formulate evidence-based guidelines, it is considered appropriate to assess bone mineral density prior to starting treatment in those with risk factors for osteoporosis, those who are at least five years status post-gonadectomy, and all those who are 60 to 65 years or older.

- Bone density measurements for transgender men are compared with standards for biological males.

The following table below summarizes the monitoring schedule for individuals undergoing hormone masculinizing therapy.

➜ *See Key to Abbreviations in section preceding Appendices.*

LABORATORY MONITORING OF MASCULINIZING HORMONE THERAPY

Lab Test	Comments	Baseline	3 Mos[1]	6 Mos[1]	12 Mos[1]	Yearly	PRN
CBC (Hgb & Hct)		X	X	X	X	X	
hCG (if child-bearing potential)		X					
Lipids	As clinically indicated	X					X
A1C/Glucose	As clinically indicated	X					X
LFTs		X		X	X	X	
Estradiol	Range: <50pg/mL		X				X
Total Testosterone[2]		X	X	X	X	X	X

[1] In the first year of therapy only

[2] If IM/SQ – check midway between injections (target level is 400-700ng/dL). Alternatively measure peak and trough levels to ensure levels remain in the normal male range. If patch – check after 1 week. Monitor levels every 3 months until levels are at goal.

APPENDIX 6. FEMINIZING GENDER-AFFIRMING HORMONE THERAPY – CONSENT AND COUNSELING FORM

FEMINIZING GENDER-AFFIRMING HORMONE THERAPY FOR TRANSGENDER PATIENTS

CONSENT AND COUNSELING FORM

INSTITUTION NAME: _____

PATIENT NAME: _____ **ID #:** _____

You want to take estrogen and other medications to feminize your body. Once you start these medications, some of them will need to be taken for the rest of your life to maintain their effects. Before using these medications, you need to know more about how they might affect you, including possible benefits, side effects, risks, and warning signs. We have listed them here for you. It's important that you understand all this information before you start. Please notify your health care provider should you have any questions.

WHAT ARE THE DIFFERENT MEDICATIONS THAT CAN HELP TO FEMINIZE YOU?

ESTROGEN is the female gender-affirming hormone. There are also medications—called **ANDROGEN ANTAGONISTS** (or **ANTI-ANDROGENS** or **ANDROGEN BLOCKERS**)—that stop the production of male hormones and can help you appear less like a man.

WARNING — WHO SHOULD NOT TAKE ESTROGEN?

It should NOT be used by anyone who has a current diagnosis of:

- An estrogen-dependent cancer
- Blood clots that could or did travel to the lungs

It should be used WITH CAUTION, and only after a full discussion of risks, by anyone who:

- Has a personal or strong family history of breast cancer or other cancers that grow faster when estrogens are present
- History of previous clots and currently not on blood thinners
- Has diabetes
- Has eye problems such as retinopathy
- Has heart disease, heart valve problems, or a tendency to have easily clotted blood
- Has hepatitis
- Has high cholesterol
- Has kidney or liver disease
- Has migraines or seizures
- Is obese
- Smokes cigarettes

Please review and **initial each statement** to show you understand the benefits, risks, and changes that may occur from taking these medications. At the end of the document, **indicate your preference regarding hormone therapy, then sign and date it.**

FEMINIZING EFFECTS OF ESTROGEN AND ANTI-ANDROGENS:

_____ I know that estrogen or anti-androgens—or both—may be prescribed to help me appear less like a man and more like a woman.

_____ I know that it can take several months to years for the effects to become noticeable. I know that no one can predict how fast—or how much—change will happen.

_____ I know that if I am taking estrogen, I will probably develop breasts.

- I know it can take several years for breasts to get to their full size.
- I know the breasts will remain, even if I stop taking estrogen.
- I know I should examine my breasts for irregularities as soon as they start growing. I should also have a clinician examine them every year.
- I know I might have a milky discharge from my nipples (galactorrhea). If I do, I know I should have it evaluated by my clinician because it could be caused by the estrogen or by other medications or medical conditions. I know that no one knows if taking estrogen increases the risk of breast cancer.

_____ I know that the following changes are usually not permanent—they are likely to go away if I stop taking the medicines:

- I know my body hair will become less noticeable and will grow more slowly, but it won't stop completely, even if I take the medicines for years.
- I know I will probably have less fat on my abdomen and more on my buttocks, hips, and thighs. It will be redistributed to a more female shape, changing from an "apple" shape to more of a "pear" shape.
- I know that if I already have male pattern baldness, it may slow down, but will probably not stop completely. It is also unlikely that hair that has been lost will grow back.
- I know I may lose muscle and strength in my upper body.
- I know my skin may become softer.

_____ I know that my body will make less testosterone. Upon release, this may affect my sex life in different ways and my future ability to cause a pregnancy:

- I know this treatment may (but is not assured to) make me permanently unable to make a woman pregnant.
- I know my sperm may no longer reach maturity. This could make me less able to cause a pregnancy. I also know I might never produce mature sperm again, but I know that it's also possible that my sperm could still mature. So, I know that I might get someone pregnant if we have vaginal intercourse, and we don't use birth control.
- I know this treatment may cause permanent infertility, and I will not be able to preserve or donate my sperm while incarcerated.

- I know my testicles may shrink down to half their size. Even so, I know that I will need regular checkups for them.
- I know it is likely that my penis won't be hard in the morning as often as it has been before. It is also likely that I will have fewer spontaneous erections.
- I know I may lose the ability to obtain an erection for intercourse.
- I know I may have less sex drive.
- I know that sex between inmates, or between inmates and staff, is not permitted within the BOP.

_____ I know that some parts of my body will not change much by using these medicines.

- I know the hair of my beard and moustache may grow more slowly than before. It may become less noticeable, but it will not go away.
- I know the pitch of my voice will not rise, and my speech patterns will not become more like a woman's.
- I know my Adam's apple will not shrink.
- Although these medicines can't make these changes happen, there are other treatments that may be helpful.

RISKS OF TAKING FEMINIZING MEDICATIONS (ESTROGEN AND ANTI-ANDROGENS):

_____ I know that the side effects and safety of these medicines are not completely known. There may be long-term risks that are not yet known.

_____ I know that I should not take more medicine than I am prescribed. I know it increases health risks. I know that taking more than I am prescribed won't make changes happen more quickly or more significantly. I know my body can convert extra estrogen into testosterone which can slow down or stop my appearing more womanly.

_____ I know these medicines may damage the liver and may lead to liver disease. I know I should be checked for possible liver damage as long as I take them.

_____ I know these medicines cause changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones. I know I can reach out to psychology services to help me find support resources. I also know that the BOP does not tolerate harassment, discrimination, and violence in any circumstances. If I feel I am the recipient of any of these actions, I will notify a BOP staff member.

RISKS OF TAKING ESTROGEN:

_____ I know that taking estrogen increases the risk of blood clots that can result in:

- Chronic problems with veins in the legs
- Heart attack
- Pulmonary embolism (blood clot to the lungs), which may cause permanent lung damage or death
- Stroke, which may cause permanent brain damage or death

_____ I know that the risk of blood clots is much worse if I smoke cigarettes, especially if I am over 40. I know the danger is so high that I should stop smoking completely if I start taking estrogen and that I should not start to smoke again when I am released from a BOP institution.

_____ I know that taking estrogen can increase the deposits of fat around my internal organs. This can increase my risk for diabetes and heart disease.

_____ I know that taking estrogen can raise my blood pressure. I know that if my blood pressure goes up, my clinician can work with me to try to control it with diet, lifestyle changes, and/or medication.

_____ I know that taking estrogen increases my risk of getting gallstones. I know that I should talk with my clinician if I get severe or long-lasting pain in my abdomen.

_____ I know that estrogen can cause nausea and vomiting. I know that I should talk with my clinician if I have long-lasting nausea or vomiting.

_____ I know that estrogen can cause headaches or migraines. I know I should talk with my clinician if I have headaches or migraines often, or if the pain is unusually severe.

_____ I know that it is not yet known if taking estrogen increases the risk of prolactinomas. These are non-cancerous tumors of the pituitary gland. I know they are not usually life-threatening, but they can damage vision and cause headaches. I know this possibility needs to be checked periodically by a clinician for at least three years after I start taking estrogen.

_____ I know that I am more likely to have dangerous side effects if:

- I smoke.
- I am overweight.
- I am over 40 years old.
- I have a history of blood clots.
- I have a history of high blood pressure.
- My family has a history of breast cancer.

RISKS OF TAKING ANDROGEN ANTAGONISTS:

_____ I know that spironolactone affects the balance of water and salts in the kidneys, which may:

- Increase the amount of urine I produce, making it necessary to urinate more frequently.
- Increase thirst.
- Reduce blood pressure.
- Cause (although rarely) high levels of potassium in the blood, possibly leading to changes in heart rhythms that may be life-threatening.

_____ I know that some androgen antagonists make it more difficult to evaluate test results for cancer of the prostate. I know that if I am over 50, I should have my prostate evaluated every year with a prostate-specific antigen test, as applicable.

PREVENTION OF MEDICAL COMPLICATIONS:

_____ I agree to take feminizing medications as prescribed, and I agree to tell my clinician if I have any problems or if I am unhappy with the treatment.

_____ I know that the dose and type of medication that is prescribed for me may not be the same as for someone else.

_____ I know that I need periodic physical exams and blood tests to check for any side effects.

_____ I know that feminization medications can interact with other drugs and medicines—including alcohol, diet supplements, herbs, other hormones, and street drugs—causing complications. I know that I need to prevent complications because they can be life-threatening. That's why I need to be honest with my clinician about whatever else I take or use. I also know that this will not interfere with my getting medical care; I will continue to get medical care here no matter what information I share about what I take.

_____ I know that it can be risky for anyone with certain conditions to take feminizing medicines. I agree to be evaluated if my clinician thinks I may have such a condition. Then, we will decide if it's a good idea for me to start or continue using these medications.

_____ I know that there may be a risk for blood clots after surgery, especially if I will not be mobile for an extended period. I will need to talk with the surgeon and my doctor to decide if I need to stop taking estrogen before and/or after the surgery or immobilizing event.

_____ I know that using these medicines to appear more womanly is an "off-label" use. I know that this means that using these medicines for this purpose is not approved by the Food and Drug Administration (FDA). I know that the medicine and dose that is recommended for me is based on the judgment and experience of the clinician.

_____ I know that I can choose to stop taking these medicines at any time. I know that if I decide to do that, I should do it with the help of my clinician. This will help me make sure there are no negative reactions. I also know that my clinician may suggest that I cut the dose or stop taking it altogether if certain conditions develop. This may happen if the side effects are severe or if there are health risks that cannot be controlled.

MY SIGNATURE BELOW CONFIRMS THAT:

- My clinician has talked with me about:
  - The benefits and risks of taking feminizing medication.
  - The possible or likely consequences of hormone therapy.
  - Potential alternative treatments.

_____
_____
_____
_____
_____

- I understand the risks that may be involved.
- I know that the information in this form includes the known effects and risks. I also know that there may be unknown long-term effects or risks.
- I have had enough opportunity to discuss treatment options with my clinician.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to take, refuse, or postpone therapy with feminizing medications.
- I am 18 years old or older.

BASED ON ALL THIS INFORMATION:

_____ I understand the risks, and consent to taking estrogen.

_____ I understand the risks, and decided I do not consent to taking estrogen

_____ I understand the risks, and consent to taking androgen antagonists (e.g., spironolactone).

_____ I understand the risks, and decided I do not consent to taking androgen antagonists (e.g., spironolactone).

_____ _____
Patient's Signature *Date*

_____ _____
Prescribing Physician's Signature *Date*

Your health is important to us. If you have any questions or concerns, please come to sick call and an appointment with your provider will be made.

APPENDIX 7. MASCULINIZING GENDER-AFFIRMING HORMONE THERAPY – CONSENT AND COUNSELING FORM

MASCULINIZING GENDER-AFFIRMING HORMONE THERAPY FOR TRANSGENDER PATIENTS

CONSENT AND COUNSELING FORM

INSTITUTION NAME: _____

PATIENT NAME: _____ **ID #:** _____

You have expressed a desire to take testosterone to masculinize your body. Before beginning treatment, there are several details about treatment that you need to be familiar with, including the possible advantages, disadvantages, risks, warnings, and alternatives. These topics are covered below. It is important that you understand all this information before initiating treatment. Please notify your health care provider should you have any questions.

WHAT IS TESTOSTERONE?

Testosterone is the hormone responsible for male features. It builds muscle, causes the development of facial hair, and is responsible for the deepening of a person's voice during puberty. Testosterone also may increase sex-drive.

HOW IS TESTOSTERONE TAKEN?

Testosterone is usually injected every one to four weeks. It is not used as a pill because the body may not absorb it properly, and it can cause liver problems. Some people use skin creams and patches, but these are not used in the correctional environment.

The doses used for injections differ from product to product, and from patient to patient. Doses may range from 100 mg to 400 mg. The injections are administered into a large muscle to slow the release of the hormone. There can be unwanted swings in hormone levels. This can be controlled by changing how often the dose is given, how much of a dose is given, or by changing formulations.

WARNING — WHO SHOULD NOT TAKE TESTOSTERONE?

Testosterone should ***not*** be used by anyone who is pregnant or has uncontrolled coronary artery disease.

It should be used ***with caution and only after a full discussion of risks*** by anyone who has: acne, family history of heart disease or breast cancer, blood clot history, high levels of cholesterol, liver disease, or high red-blood-cell count. Caution should also be used in obese patients and persons who smoke.

MONITORING:

Periodic blood tests to check on the effects of the hormone will be required for treatment. Routine breast exams and pelvic exams with pap tests should be continued, when applicable.

BENEFITS AND RISKS OF TESTOSTERONE TREATMENT:

Benefits	Risks

• Appearing more like a man:
  • Larger clitoris*****
  • Coarser skin
  • Deeper voice*****
  • Increased body hair*****
  • Increased facial hair*****
  • Increased muscle mass
  • Increased strength
  • Elimination of menstrual periods
• Increased physical energy
• Protection against bone thinning (osteoporosis)
 	
*****_These are permanent changes._
	• Acne (may permanently scar)
	• Blood clots (thrombophlebitis)
	• Emotional changes
	• Headache
	• High blood pressure (hypertension)
	• Increased red-blood-cell count
	• Infertility
	• Inflamed liver
	• Interaction with drugs for diabetes and blood thinning, e.g., Coumadin and Warfarin
	• Male pattern baldness
	• Increased abdominal fat
	• Increased risk of heart disease
	• Swelling of hands, feet, and legs
	• Weight gain

Please review and **initial each statement** to show that you understand the benefits, risks, and changes that may occur from taking these medications. At the end of the document, **indicate your preference regarding hormone therapy, then sign and date it.**

MASCULINIZING EFFECTS OF TESTOSTERONE:

_____ I know that testosterone may be prescribed to make me appear less like a woman and more like a man.

_____ I know that it can take several months or longer for the effects to become noticeable.

_____ I know that no one can predict how fast or how much change will take place.

_____ ***I know that the changes may not be complete for two to five years after starting testosterone.***

_____ ***I know the following changes are likely to be permanent, even if I stop taking testosterone:***

- Bigger clitoris — typically about half an inch to a little more than an inch
- Deeper voice
- Growth of facial hair (moustache and beard)
- Hair loss at the temples and crown of the head and the possibility of becoming completely bald
- More, thicker, and coarser hairs on abdomen, arms, back, chest, and legs

_____ ***I know that the following changes are usually NOT permanent and will likely go away if I stop taking testosterone:***

- Acne (however, acne scars will be permanent)
- Elimination of menstrual periods (typically stop one to six months after starting testosterone)
- Increased abdominal fat (redistribution of fat to a more masculine shape)
- Decreased fat on buttocks, hips, and thighs
- More muscle mass and strength

- Vaginal dryness

_____ I know that the effects of testosterone on fertility are unknown and may cause permanent infertility. I have been told that I may or may not be able to get pregnant even if I stop taking testosterone. I know I might still get pregnant even after testosterone stops my menstrual periods. I know I cannot take testosterone if I am pregnant. By continuing treatment, I accept that I may never be able to biologically parent a child. I know this treatment may cause permanent infertility, and I will not be able to preserve or donate my eggs while incarcerated

_____ I know that some aspects of my body will not be changed:

- Losing some fat may make my breasts appear slightly smaller, but they will not shrink very much.
- Although my voice may deepen, other aspects of the way I speak will not change.

_____ I know that there are other treatments that may be helpful to make my breasts smaller or my speech manlier. If I have concerns, I can discuss treatment options with my clinician.

RISKS OF TESTOSTERONE:

_____ I know that the medical effects and safety of testosterone are not completely known. There may be long-term risks that are not yet known.

_____ I know not to take more testosterone than prescribed. I know this would be a risk to my health. I know that taking more testosterone than I am prescribed will not make changes happen more quickly or more significantly. I know that my body can convert extra testosterone into estrogen, which can slow down or reverse the progress of my transition.

_____ I know that testosterone can cause changes that increase my risk of heart disease. I know these changes include:

- Less good cholesterol (HDL), which is needed to protect against heart disease, and more bad cholesterol (LDL), which may increase the risk of heart disease
- Higher blood pressure
- Increased deposits of fat around my internal organs

_____ I know that my risk of heart disease is higher if people in my family have had heart disease, if I am overweight, or if I smoke.

_____ I know that I should have periodic heart-health checkups for as long as I take testosterone. I know I must watch my weight and cholesterol levels and have them checked by my clinician.

_____ I know that testosterone can damage the liver and possibly lead to liver disease. I know I should be checked periodically for possible liver damage for as long as I take testosterone.

_____ I know that testosterone can increase my red blood cell count and hemoglobin. I know the increase is usually only to the level that is normal for a man. I know normal levels would have no health risks; however, higher increases can cause problems that can be life-threatening. These problems include stroke and heart attack. As such, I know I need to have periodic blood checks for as long as I take testosterone.

_____ I know that taking testosterone can increase my risk for diabetes. It may decrease my body's response to insulin, cause weight gain, and increase deposits of fat around my internal organs. I know I should have periodic checks of my blood glucose for as long as I take testosterone.

_____ I know that my body can turn testosterone into estrogen. I know that no one knows if this could increase the risk of cancers of the breast, ovaries, or uterus.

_____ I know that taking testosterone can thin the tissue of my cervix and the walls of my vagina. This can lead to tears or abrasions during vaginal intercourse. I know it does not matter if my partner is a woman or a man. This raises my risk of getting a sexually transmitted infection, including HIV. I know I should speak frankly with my provider regarding the best ways to prevent and check for infections.

_____ I am aware that sex between inmates, or between inmates and staff, is not permitted.

_____ I know that testosterone can give me headaches or migraines. I know it is best to talk with my clinician if I get them frequently or if the pain is unusually severe.

_____ I know that testosterone can cause emotional changes. For example, I could become more irritable, frustrated, or angry. I know my provider can help me find resources to explore and cope with these changes.

_____ I know that testosterone causes changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones. I know I can reach out to psychology services to help me find support resources. I also know that in the BOP, harassment, discrimination, and violence are not tolerated under any circumstances. If I feel I am the recipient of any of these actions, I will notify a BOP staff member.

PREVENTION OF MEDICAL COMPLICATIONS:

_____ I agree to take testosterone as prescribed, and I agree to tell my clinician if I have any problems or am unhappy with the treatment.

_____ I know that the dose and type of medication prescribed for me may not be the same as it is for someone else.

_____ I know that I need periodic physical exams and blood tests to check for any side effects.

_____ I know that testosterone can interact with other drugs and medicines, including alcohol, diet supplements, herbs, other hormones, and street drugs. This kind of interaction can cause complications. I know that I need to prevent complications because they can be life-threatening. I need to be honest with my clinician about other items I am taking. I also know that this will not interfere with my getting medical care; I will continue to get medical care here no matter what information I share about what I take.

_____ I know that it can be risky for anyone with certain conditions to take testosterone. I agree to be evaluated if my clinician thinks I may have one of these conditions. Then, we will decide if it is a good idea to start or continue using testosterone.

_____ I know that using testosterone to appear more masculine is an "off-label" use. I know this means it is not approved by the Food and Drug Administration (FDA) for this purpose. I know the medicine and dose recommended for me is based on the judgment and experience of the clinician.

_____ I know that I can choose to stop taking testosterone at any time. I know if I decide to stop, I should discontinue with the help of my clinician to ensure there are no negative reactions. I know my clinician may suggest I cut the dose or stop taking it altogether if certain medical conditions develop. This may happen if the side effects are severe or if there are health risks that cannot be controlled.

MY SIGNATURE BELOW CONFIRMS THAT:

- My clinician has talked with me about:
  - The benefits and risks of taking testosterone.
  - The possible or likely consequences of hormone therapy.
  - Potential alternative treatments.
  - _____
    _____
    _____
    _____
- I understand the risks that may be involved.
- I know that the information in this form includes the known effects and risks. I also know that there may be unknown long-term effects or risks.
- I have had enough opportunity to discuss treatment options with my clinician.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to take, refuse, or postpone testosterone therapy.
- I am 18 years old or older.

BASED ON ALL THIS INFORMATION:

_____ I understand the risks, and consent to taking testosterone.

_____ I understand the risks, and decided I do not consent to taking testosterone at this time.

_____ _____
Patient's Signature *Date*

_____ _____
Prescribing Physician's Signature *Date*

Your health is important to us. If you have any questions or concerns, please come to sick call and an appointment with your provider will be made.

Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People

Center of Excellence for Transgender Health

Department of Family & Community Medicine

University of California, San Francisco

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Editor - Madeline B. Deutsch, MD, MPH

UCSF

center OF excellence FOR TRANSGENDER health

Introduction to the guidelines

The Center of Excellence for Transgender Health (CoE) at the University of California – San Francisco is proud to present these Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People. Transgender people have a gender identity that differs from the sex which they were assigned at birth, and are estimated to represent 0.5% of the U.S. population.[1] Numerous needs assessments have demonstrated that transgender people encounter a range of barriers to accessing primary health care. A 2006 survey of more than 600 transgender people in California found that 30% postponed seeking medical care due to prior disrespect or discrimination, and that 10% were primary care outright.[2] The 2011 National Transgender Discrimination Survey of more than 6000 transgender people in all 50 U.S. states found several noteworthy disparities, including 28% who delayed care due to past discrimination and 19% who were denied care outright. Most alarmingly, 50% of respondents reported having to teach their providers about their own healthcare.[3]

These guidelines aim to address these disparities by equipping primary care providers and health systems with the tools and knowledge to meet the health care needs of their transgender and gender nonconforming patients. These guidelines expand on the original UCSF Primary Care Protocol for Transgender Care, which since its launch in 2011 has served thousands of providers and policymakers across the U.S. and around the world; the page on hormone administration alone received more than 5000 visitors in the month of November, 2015. These Guidelines complement the existing World Professional Association for Transgender Health Standards of Care and the Endocrine Society Guidelines in that they are specifically designed for implementation in every day evidence-based primary care, including settings with limited resources.[4,5]

The overall structure and list of topics for inclusion were developed in consultation with the CoE's Medical Advisory Board (MAB), a diverse group of expert clinicians from a variety of academic and community based settings. Also contributing to the overall design and structure was a review of the range of consultation requests received by the CoE since the 2011 launch of the original Protocol. The guidelines were then written using an authorship – peer review approach. Primary authors from both within and outside the MAB were invited for individual topics, after which a peer review and modified consensus process was used to arrive at the final guidelines presented here. The diverse authorship allows the development of a broadly applicable document, rather than one that solely reflects the practice at a single academic medical center, such as UCSF.

These guidelines would not be possible without the contributions of our Medical Advisory Board and other authors and reviewers, as well as the support of my CoE colleagues JoAnne Keatley, MSW and E. Michael Reyes, MD, MPH, as well as Lissa Moran who assisted immensely with literature reviews, bibliography management, version control, copy editing, formatting, and compiling peer reviewer comments. Ben Zovod also assisted with literature reviews, bibliography management, and compiling peer reviewer comments. Their dedication and hours of hard work has resulted in a final product that is relevant, broadly applicable, evidence based, and scientifically sound. I hope you find these guidelines useful and welcome any feedback or questions, which are

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helpful in framing future revisions. Thank you for caring about the health of transgender and gender nonconforming people.

Madeline B. Deutsch, MD, MPH

Editor
Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People

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1. Grading of evidence

Selected recommendations in these Guidelines have been graded using adaptation of some components of the GRADE scoring system,[1] with the addition of two additional domains to describe details of the research which underlies the recommendation, as well as the population(s) in which such research was conducted. Each graded recommendation will include mention of the population(s) in which research was conducted (transgender (T), non-transgender (NT), or both (T/NT); an indication of, among all sources informing that particular recommendation, the strongest form of underlying evidence (meta-analyses, randomized trials, observational studies, expert opinion). Lastly, an overall grading of the strength of recommendation is made (strong, moderate, weak) which is based on the above critera as well as strength of the consensus recommendation as determined by expert opinion interpretation of available data.

Key recommendations are listed in **bold**. Some recommendations are not graded as they are based on existing recommendations from other professional organizations.

Table 1-1. Grading of Evidence

Grading indicator	Description	Code
Populations in which data exists to inform a particular recommendation		
	At least some data in transgender population	**T**
	No data in transgender population, but data from other populations	**NT**
	No data (expert opinion only)	**X**
Strongest available data to inform a particular recommendation		
	Meta-analysis	**M**
	Randomized controlled studies	**R**
	Observational studies	**O**
	Consensus expert opinion	**C**
Overall strength of recommendation, taking into consideration the above as well as expert interpretation of available data in context		
	Strong	**S**
	Medium	**M**
	Weak	**W**

References

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2. Terminology and definitions

A detailed discussion of terminology in the context of the great diversity of transgender and gender nonconforming people encountered across cultures and languages is beyond the scope of these Guidelines. Below are definitions for some commonly encountered terms, which will be used throughout these Guidelines as indicated.

Gender / Gender identity: A person's internal sense of self and how they fit into the world, from the perspective of gender.

Sex: Historically has referred to the sex assigned at birth, based on assessment of external genitalia, as well as chromosomes and gonads. In everyday language is often used interchangeably with gender, however there are differences, which become important in the context of transgender people.

Gender expression: The outward manner in which an individual expresses or displays their gender. This may include choices in clothing and hairstyle, or speech and mannerisms. Gender identity and gender expression may differ; for example a woman (transgender or non-transgender) may have an androgynous appearance, or a man (transgender or non-transgender) may have a feminine form of self-expression.

Transgender: A person whose gender identity differs from the sex that was assigned at birth. May be abbreviated to **trans**. A **transgender man** is someone with a male gender identity and a female birth assigned sex; a **transgender woman** is someone with a female gender identity and a male birth assigned sex. A **non-transgender** person may be referred to as **cisgender** (cis=same side in Latin).

Gender nonconforming: A person whose gender identity differs from that which was assigned at birth, but may be more complex, fluid, multifaceted, or otherwise less clearly defined than a transgender person. **Genderqueer** is another term used by some with this range of identities.

Nonbinary: transgender or gender nonconforming person who identifies as neither male nor female.

Trans-masculine/trans-feminine: Terms to describe gender non-conforming or nonbinary persons, based on the directionality of their gender identity. A trans-masculine person has a masculine spectrum gender identity, with the sex of female listed on their original birth certificate. A trans-feminine person has a feminine spectrum gender identity, the sex of the male listed on their original birth certificate. In portions of these Guidelines, in the interest of brevity and clarity, transgender men/women are inclusive of gender non-conforming or nonbinary persons on the respective spectrae.

They/Them/Their: Neutral pronouns used by some who have a nonbinary or nonconforming gender identity.

Transsexual: A more clinical term which had historically been used to describe those transgender people who sought medical intervention (hormones, surgery) for gender affirmation. Term is less

commonly used in present day, however some individuals and communities maintain a strong and affirmative connection to this term.

Cross dresser / drag queen / drag king: These terms generally refer to those who may wear the clothing of a gender that differs from the sex which they were assigned at birth for entertainment, self-expression, or sexual pleasure. Some cross dressers and people who dress in drag may exhibit an overlap with components of a transgender identity. The term **transvestite** is no longer used in the English language and is considered pejorative.

Sexual orientation: Describes sexual attraction only, and is not directly related to gender identity. The sexual orientation of transgender people should be defined by the individual. It is often described based on the lived gender; a transgender woman attracted to other women would be a lesbian, and a transgender man attracted to other men would be a gay man.

For the purposes of clarity and simplicity, the term *transgender* will be used throughout these guidelines to refer to transgender, gender nonconforming, and genderqueer people as a set, unless otherwise indicated. *Non-transgender* people will be referred to as such.

3. Creating a safe and welcoming clinic environment

Primary author: Madeline B. Deutsch, MD, MPH

Introduction

Transgender people may avoid seeking care due to prior discrimination or disrespect in a clinic setting.[1,2] Providing a safe, welcoming and culturally appropriate clinic environment is essential to insure that transgender people not only seek care, but return for follow-up. There are several key components to creating an appropriate setting for transgender care.

Cultural humility is a concept through which individuals recognize that their own experiences or identities may not project onto the experiences or identities of others. Each patient should be approached as an individual with no preconceptions. Individual preferences of terminology, complex or novel gender identities, and differing desires for gender-affirming treatments will be encountered daily in the clinic. Meeting patients "where they are" without judgment or editorializing (including in some cases, even positive remarks about appearance) will enhance the patient-provider relationship and avoids the perception of stigma or pathologization. While some patients may be empowered by serving as a source of information for medical providers,[3] others may be uncomfortable doing so. It should not be routinely expected that patients explicitly "teach" their providers, and providers should limit historical questions to those that are relevant to the current visit or problem.

Staff training: In addition to healthcare providers, front desk staff, nursing staff, lab and x-ray staff, etc. are often on the front lines of patient care. Training on transgender health issues should be provided to all clinic staff and providers, and should be integrated into the standard hiring and on-boarding process for all employees.

Waiting areas should include transgender-themed posters, artwork, pamphlets, magazines, etc. to indicate a commitment to serving the transgender community.

Bathroom policies should either define all bathrooms as gender-neutral, or specifically state that patients may choose either the women's or men's rooms based on their own preference. In this latter case, making at least one gender-neutral bathroom available will provide a safe space for nonbinary people as well as for those in transition and who feel uncomfortable in any gendered space.

Fluency of terminology: Providers should be aware of basic terminology used by the trans community. In addition to the terminology described in these guidelines (which are based on North American English language use), other local or individual terms may exist and also may change over time. Terminology in other countries or languages may vary. Providers should familiarize themselves with local terminology, and approach individuals with cultural humility when determining which specific terms to use.

Gender identity data includes chosen name, chosen pronouns, current gender identity, and sex listed on original birth certificate. Failure to collect and use gender identity data has several important repercussions, including invisibility of gender and sexual minority populations to policy makers and researchers,[4] difficulties in tracking the organ inventories and preventive health needs of transgender people,[5] and reduced patient satisfaction due to a failure to use chosen names and pronouns.[6] Gender identity data have been added to the requirements for the U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology Meaningful Use Stage 3 guidelines.[7]

The UCSF Center of Excellence for Transgender Health, Fenway Health in Boston, University of California, Davis, the Mayo Clinic, the U.S. Centers for Disease Control and Prevention (CDC), and many other organizations and experts advocate for the use of the "two-step" method for the collection of gender identity data. This method queries both gender identity as well as the sex listed on one's original birth certificate; transgender people can be identified as those whose gender identity differs from their birth sex. This method has been found to be superior to a single question querying gender/sex with choices of "male," "female," and "transgender," since some transgender people may choose "male" or "female," resulting in effective invisibility of their transgender status.[8]

Unfortunately many EMR vendors have lagged in developing functionality for gender identity data, resulting in a patchwork of practices and locations in which these data are stored within the record.[9] In addition to gender identity and birth sex, transgender people may also have a chosen name which differs from their legal name, and may use pronouns which differ from those associated with the legal sex listed on their identity documents. As such it is also recommended that EMRs contain functionality for the recording of chosen name and pronoun. An ideal EMR will then allow chosen name and pronoun to be displayed for all users in all views. Furthermore, EMRs there should include functionality to remove indicators of transgender status from the view of casual users once legal documents have been changed to reflect gender identity and chosen name, allowing transgender people to maintain privacy. Specific details regarding one's transgender status and transition history, including an inventory of organs and information on hormone use can be stored in the medical and surgical history sections of the chart.[6]

Recommended terminology for the collection of gender identity data is listed below.[10] Clinics can integrate these questions into their intake forms or processes by including a brief description or disclaimer to avoid confusing those patients to whom these questions do not apply.

Gender identity (two-step):

1. **What is your gender identity?**
   - ☐ Male
   - ☐ Female
   - ☐ Transgender man / Transman
   - ☐ Transgender woman / Transwoman
   - ☐ Genderqueer / Gender nonconforming
   - ☐ Additional identity (fill in) _____
   - ☐ Decline to state
2. **What sex were you assigned at birth?**
   - ☐ Male
   - ☐ Female
   - ☐ Decline to state

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4. Transgender patients and the physical examination

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Introduction

Physical examination should be relevant to the anatomy that is present, regardless of gender presentation, and without assumptions as to anatomy or identity. Sensitive history taking is required to understand the myriad and individualized changes and characteristics in the context of hormone administration and surgical intervention. Consideration should be given throughout the visit to potential prior negative experiences within the health care setting, including discrimination as well as physical or emotional abuse.[1]

When conducting a physical exam, providers should use a gender-affirming approach. Gender affirmation is when an individual is affirmed in their gender identity through social interactions.[2] This includes being referred to by the correct name and pronouns during the entire visit. This may also include using general terminology for body parts, or asking patients if they have a preferred term to be used.[3] An examination should only be performed of those body parts that pertain to the reason for a specific visit. For example, examination of the genitalia is not appropriate in the context of an acute visit for an upper respiratory infection.

Secondary sex characteristics may present on a spectrum of development in patients undergoing hormone therapy, to some degree dependent on duration of hormone use and age of initiation. Transgender men may have facial and body hair growth, clitoromegaly, increased muscle mass, masculine fat redistribution, androgenic alopecia, and acne. Transender women may have breast development (often underdeveloped), feminine fat redistribution, reduced muscle mass, thinned or absent body hair, thinned or absent facial hair, softened, thinner skin, and testicles that have decreased in size or completely retract.[4] Patients who have undergone gender-affirming surgeries may have varying physical exam findings depending on the procedures performed, approaches used, and occurance of complications. Providers should maintain an organ inventory to guide screening and management of certain specific complaints.

Special considerations for a vaginal exam in transgender women

(See also guidelines for sexually transmitted infections, and for vaginoplasty)

The anatomy of a neovagina created in a transgender woman differs from a natal vagina in that it is a blind cuff, lacks a cervix or surrounding fornices, and may have a more posterior orientation. As such using an anoscope may be a more anatomically appropriate approach for a visual examination. The anoscope can be inserted, the trocar removed, and the vaginal walls visualized collapsing around the end of the anoscope as it is withdrawn.

Special considerations for conducting a pelvic examination with transgender men

(See also guidelines for *sexually transmitted infections*, and for *cervical cancer screening*)

The pelvic exam may be a traumatic and anxiety inducing procedure for transgender men and other trans-masculine persons. Transgender men are less likely to be up to date on cervical cancer screenings [5] and have a higher rate of inadequate cytologic sampling.[6] It is essential to make clear to the laboratory that the sample being provided is indeed a cervical pap smear (especially if the listed gender marker is “male”) to avoid the sample being run incorrectly as an anal pap or discarded. The use of testosterone or presence of amenorrhea should be indicated on the requisition.

Should the individual express distress or concern about the examination, it may be deferred until a later date once a trusting relationship has been developed. A website with further details on pelvic examinations and screening can be found at checkitoutguys.ca.[7] Various techniques can be used to make a pelvic examination (including bimanual and/or speculum exam) less uncomfortable:

- Discuss procedures with the patient beforehand, including the order in which steps will occur. Allow time for the patient to express any concerns prior to beginning the exam.
- Allow the patient to have a support person in the room, listen to music on headphones, or utilize any other strategies they may have to provide distraction during the exam.
- Explain each step in a clear a direct way throughout, such as saying: “I will touch with my hand now,” “you will experience some pressure next,” “you will hear the clicking noise of the speculum now,” and reminding the patient that the exam can be stopped at any time at their request.
- Avoid using medical terms for body parts, unless discussed beforehand that these are preferred terms the patient would like you to use. Some patients may prefer to refer to their vagina as their “front” or “front-hole.”
- Offer the use of a mirror to allow the patient to directly observe the exam.
- Administration of an oral benzodiazepine 20-60 minutes prior to the exam may be helpful for those with severe anxiety.
- Administration of vaginal estrogens commonly used in menopausal management for 1-2 weeks prior to the exam may decrease the vaginal atrophy often seen with testosterone therapy.
- Allowing for self-collection of some tests may preclude the need for a speculum exam in certain scenarios, such as a swab for wet prep to analyze abnormal vaginal discharge. Specimen self-collection for HPV testing is currently under investigation.
- In the case of refusal of a speculum exam, consider offering an external and/or bimanual exam as an initial step toward establishing comfort and trust. A positive experience may lead to the patient considering further examinations in the future.

Other special considerations

Binding of the chest to create a masculine appearance may lead to skin breakdown or other complications of the skin. Patients may be hesitant to remove the binder for a physical exam.[3]

Appropriate and sensitive history taking and education about safe binding is recommended for all trans male patients.[8]

Tucking of the testicles and penis may lead to hernias or other complications at the external inguinal ring or skin breakdown at the perineum. Thorough and sensitive history and education is recommended for all trans women.[8]

When appropriate and indicated, findings suggestive of intersex conditions should be further evaluated.[4]

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5. Overview of gender-affirming treatments and procedures

Primary author: Madeline B. Deutsch, MD, MPH

Supporting evidence for providing gender-affirming treatments and procedures

Transgender people may seek any one of a number of gender-affirming interventions, including hormone therapy, surgery, facial hair removal, interventions for the modification of speech and communication, and behavioral adaptations such as genital tucking or packing, or chest binding. All of these procedures have been defined as medically necessary by the World Professional Association for Transgender Health.[1] Lower quality research has found improvements in a range of psychosocial measures after gender-affirming treatments such as hormones or surgery.[2–5] Sevelius' Model of Gender Affirmation describes the ways in which denial of access to gender affirmation is associated with high risk behaviors and increased rates of HIV infection.[6] Conversely, not all transgender people seek all interventions, and some may seek none. In contrast to past practices in which a set pathway involved a requirement of psychological assessment → hormones → genital surgery, the current standard of care is to allow each transgender person to seek only those interventions which they desire to affirm their own gender identity.[7]

Medical interventions: Gender-affirming hormone therapy is the primary medical intervention sought by transgender people. Such treatment allows the acquisition of secondary sex characteristics more aligned with an individual's gender identity.

Surgical interventions: A wide range of gender-affirming surgeries are available to transgender people. These include surgeries specific to gender affirmation, as well as procedures commonly performed in non-transgender populations.

Surgeries specific to transgender populations:

- Feminizing vaginoplasty
- Masculinizing phalloplasty / scrotoplasty
- Metaoidioplasty (clitoral release/enlargement, may include urethral lengthening)
- Masculinizing chest surgery ("top surgery")
- Facial feminization procedures
- Reduction thyrochondroplasty (tracheal cartilege shave)
- Voice surgery

Surgeries not specific to transgender populations:

- Augmentation mammoplasty
- Hysterectomy / oopherectomy
- Orchiectomy
- Vaginectomy

AR-000706

Other interventions: include facial hair removal, voice modification, genital tucking and packing, and chest binding.

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6. Initiating hormone therapy

Primary author: Madeline B. Deutsch, MD, MPH

Assessing readiness and appropriateness

While historically a "referral letter" from a mental health professional was required prior to initiation of hormone therapy, many large volume and experienced providers of transgender care have for years used an "informed consent" pathway to hormone initiation. WPATH Standards of Care, 7th Version recognizes both of these pathways to the initiation of gender-affirming hormone therapy as valid. Medical providers who feel comfortable making an assessment and diagnosis of gender dysphoria, as well as assessing for capacity to provide informed consent (able to understand risks, benefits, alternatives, unknowns, limitations, risks of no treatment) are able to initiate gender-affirming hormones without a prior assessment or referral from a mental health provider.[1] A study of the practices of 12 such clinics in a diversity of settings found minimal risk of regret and no known cases of malpractice suits.[2] More detail on assessing readiness and appropriateness for various gender-affirming treatments can be found in the topic on mental health.

Qualifications of the prescribing provider

Prescribing gender-affirming hormones is well within the scope of a range of medical providers, including primary care physicians, obstetricians-gynecologists, and endocrinologists, advanced practice nurses, and physician assistants.[1] Depending on the practice setting and juris diction, other providers with prescriptive rights (naturopathic providers, nurse midwives) may also be appropriate to prescribe and manage this care. Most medications used in gender-affirming hormone therapy are commonly used substances with which most prescribers are already familiar due to their use in the management of menopause, contraception, hirsutism, male pattern baldness, prostatism, or abnormal uterine bleeding.

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7. Overview of feminizing hormone therapy

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Introduction

The goal of feminizing hormone therapy is the development of female secondary sex characteristics, and suppression/minimization of male secondary sex characteristics. General effects include breast development (usually to Tanner stage 2 or 3), a redistribution of facial and body subcutaneous fat, reduction of muscle mass, reduction of body hair (and to a lesser extent, facial hair), change in sweat and odor patterns, and arrest and possible reversal of scalp hair loss. Sexual and gonadal effects include reduction in erectile function, changes in libido, reduced or absent sperm count and ejaculatory fluid, and reduced testicular size. Feminizing hormone therapy also brings about changes in emotional and social functioning. The general approach of therapy is to combine an estrogen with an androgen blocker, and in some cases a progestagen.

Estrogens

The primary class of estrogen used for feminizing therapy is 17-beta estradiol, which is a "bioidentical" hormone in that it is chemically identical to that from a human ovary. The general approach is similar to estrogen replacement in agonadal (i.e Turner syndrome) or menopausal states, with some dosing modifications. 17-beta estradiol (or simply estradiol) is most commonly delivered to transgender women via a transdermal patch, oral or sublingual tablet, or injection of a conjugated ester (estradiol valerate or estradiol cypionate). No outcome studies have been conducted on injectable estradiol valerate or cypionate, presumably due to their uncommon modern use outside of transgender care settings; due to this limited use manufacturers have little incentive to produce this medicine, and shortages have been reported. Other delivery routes for estradiol such as transdermal gel or spray are formulated for the treatment of menopausal vasomotor symptoms and while convenient and effective in some transgender women, in others these routes may not be able to achieve blood levels in the physiologic female range. Compounded topical creams and gels also exist from specialty pharmacies; if these are to be used it is recommended that the prescriber consult with the compounding pharmacist to understand the specific details and dosing of the individual preparation. Compounded estradiol valerate or cypionate for injection also exists, and may be an alternative in times of shortage or more cost effective for those who must pay cash for their prescriptions.

Conjugated equine estrogens (Premarin®) have been used in the past but are not recommended for a number of reasons, including inability to accurately measure blood levels and some suggestion of increased thrombogenicity and cardiovascular risk.[1,2] Equine estrogens are obtained from the urine of pregnant, catheterized horses; no evidence exists to suggest that these estrogens are superior to bioidentical human estradiol. Ethical concerns have been raised regarding the methods of production of equine estrogens. (http://www.aspca.org/fight-animal-cruelty/equine-cruelty/premarin.aspx)

Ethinyl estradiol is a synthetic estrogen used in contraceptive preparations and is associated with an increased thrombotic risk.[3,4] In the context of contraception, ethinyl estradiol has more consistent and reliable cycle control and as such is better tolerated, balancing out the potentially increased risk of VTE.[5] **In the setting of gender affirmation there is no need for cycle or bleeding regulation, and thus the use of ethinyl estradiol and its inherent risks are not warranted (Grading: T O S).**

Side effects of estrogens may include migraines, mood swings, hot flashes, and weight gain.

Antiandrogens – common approaches

Suppression of testosterone production and blocking of its effects contributes to the suppression / minimization of male secondary sexual characteristics. Unfortunately many of these characteristics are permanent upon completion of natal puberty and are irreversible. Androgen blockers allow the use of lower estradiol dosing, in contrast to the supraphysiologic estrogen levels (and associated risks) previously used to affect pituitary gonadotropin suppression.[6]

Spironolactone is the most commonly used androgen blocker in the U.S. Spironolactone is a potassium sparing diuretic, which in higher doses also has direct anti-androgen receptor activity as well as a suppressive effect on testosterone synthesis.[6] Doses of 200mg daily in non-transgender women being treated for hair loss have been described as safe, though doses of up to 400mg/day have been reported without negative effect.[7] Hyperkalemia is the most serious risk but is very uncommon when precaution is taken to avoid use in individuals with renal insufficiency, and use with caution and frequent monitoring in those on ACE inhibitor or ARB type medications. Due to its diuretic effect, patients may experience self-limited polyuria, polydipsia, or orthostasis.

5-alpha reductase inhibitors include finasteride and dutasteride. Finasteride blocks 5-alpha reductase type 2 and 3 mediated conversion of testosterone to the potent androgen dihydrotestosterone.[8] Finasteride 1mg daily is FDA-approved for male pattern baldness, while the 5mg dose is approved for management of prostatic hypertrophy.[9] Dutasteride 0.5mg more effectively blocks the type 1 isozyme, which is present in the pilosebaceous unit and therefore may have more dramatic feminizing effects. Since these medications block neither the production nor action of testosterone, their antiandrogen effect is less than that encountered with full blockade. 5-alpha reductase inhibitors may be a good choice for those unable to tolerate, or with contraindications to the use of spironolactone. 5-alpha reductase inhibitors may also be an option for use as a single agent in patients seeking partial feminization, or for those who continue to exhibit virilized features or hair loss after complete androgen blockade or orchiectomy.

Antiandrogens – other approaches

Antiandrogens can also be used alone to bring reduced masculinization and minimal breast development, or in those patients who wish to first explore reduced testosterone levels alone, or in those with contraindications to estrogen therapy. In the absence of estrogen replacement, some patients may have unpleasant symptoms of hot flashes and low mood or energy. Long term full androgen blockade without hormone replacement in men who have undergone treatment for prostate cancer results in bone loss, and this effect would also be expected to occur in transgender individuals.[10] **In addition to titrating dosing to both clinical effect and testosterone levels as**

guided by patient goals, monitoring hormone levels to insure suppressed gonadotropins (leutinizing hormone [LH] and follicle stimulating hormone [FSH]) levels may serve as a surrogate marker to indicate adequate sex hormone levels for maintaining bone density in such patients (Grading: T O W).[11]

In many countries, cyproterone acetate, a synthetic progestagen with strong anti-androgen activity is commonly used. Cyproterone has been associated with uncommon episodes of fulminant hepatitis.[12] Bicalutamide, a direct anti-androgen used for the treatment of prostate cancer, also has a small but not fully quantified risk of liver function abnormalities (including several cases of fulminant hepatitis); while such risks are acceptable when considering the benefits of bicalutamide in the management of prostate cancer, such risks are less justified in the context of gender-affirming treatment.[13] No evidence at present exists to inform such an analysis.

In some patients, complete androgen blockade may be difficult or even impossible using standard regimens. In cases of persistent elevations of testosterone in the setting of maximal antiandrogen dosing with good medication adherance, autonomous endogenous production (i.e. tumor) as well as undisclosed exogenous testosterone (i.e. to maintain erectile function) should be considered. An evaluation for testicular neoplasms should be performed with a scrotal exam as well as testing for elevated serum human chorianogonadotropin (hCG), lactate dehydrogenase (LDH), alpha-fetoprotein (AFP) levels, and possibly scrotal imaging.[14] Once these causes have been ruled out, additional options can include gonadotropin releasing hormone analogues (GnRH) or orchiectomy. GnRH analogs are used routinely in the care of peripubertal transgender youth who require pubertal delay,[15] and have been described in the care of transgender adults as well.[16] Drawbacks to the use of GnRH analogs is primarily related to cost and difficulties in obtaining insurance coverage, as well as the need for either repeated injections, multiple daily nasal sprays, or surgical implantation. Orchiectomy may represent an ideal option in transgender women who do not desire to retain their gonads; this brief, inexpensive, outpatient procedure requires only several days for recovery and does not preclude future vaginoplasty.

Progestagens: There have been no well-designed studies of the role of progestagens in feminizing hormone regimens. Many transgender women and providers alike report an anecdotal improved breast and/or areolar development, mood, or libido with the use of progestagens.[17,18] There is no evidence to suggest that using progestagens in the setting of transgender care are harmful. In reality some patients may respond favorably to progestagens while others may find negative effects on mood. While progestagens have some anti-androgen effect through central blockade of gonadotropins, there is also a theoretical risk of a direct androgenizing effect of progestagens. This class includes micronized bioidentical progesterone (Prometrium) as well as a number of synthetic progestins. The most commonly used synthetic progestin in the context of transgender care is the oral medroxyprogesterone acetate (Provera).

While concerns exist from the Women's Health Initiative (WHI) regarding risks of cardiovascular disease and breast cancer in the setting of medroxyprogesterone use, these concerns likely do not apply in the context of transgender care for several reasons. First, the transgender women may be at lower risk of breast cancer than non-transgender women. Second, this arm of the WHI involved the use of conjugated equine estrogens in combination with medroxyprogesterone in a sample of menopausal women, some of whom were as long as 10 years post-menopausal at the time of hormone initiation. Third, while statistically significant, the clinical significance of the findings in the

WHI was subtle at best. The study aimed to evaluate the role of menopausal hormone therapy in the prevention of chronic disease. The actual findings in the conjugated equine estrogen plus medroxyprogesterone group were an excess absolute risk per 10 000 person-years of 7 more cardiac events events, 8 more strokes, 8 more pulmonary emboli, and 8 more invasive breast cancers, with no change in overall mortality.[19] As such this arm of the WHI was stopped early, and it was concluded that combined menopausal hormone therapy is not indicated for prevention of chronic disease.

In the setting of gender-affirming care, there are numerous differences to the findings of the WHI: populations tend to be younger, equine estrogens are not used, and the emphasis is on gender-affirming interventions which have numerous benefits on mental health and quality of life, rather than prevention. **Considering these differences in demographics and goals of therapy, extremely modest increase in overall risk, and lack of difference in mortality, as well as more recent reassuring data with other forms of estrogen, the risks of using progestagens in transgender women are likely minimal or even absent (Grading: NT O M).** Injected depo-medroxyprogesterone acetate (Depo-Provera®) is less commonly used in transgender women. Other synthetic progestins may be used as necessitated by formulary limitations; some evidence suggests that norpregnane derived progestins (norethindrone, norgestrel) may have an increased risk of venous thromboembolism.[20]

Table 7-1. Hormone preparations and dosing (Grading: T O M)

Hormone	Initial–low[b]	Initial	Maximum[c]	Comments
Estrogen				
Estradiol oral/sublingual	1mg/day	2-4mg/day	8mg/day	if > 2mg recommend divided bid dosing
Estradiol transdermal	50mcg	100mcg	100-400 mcg	Max single patch dose available is 100mcg. Frequency of change is brand/product dependent. More than 2 patches at a time may be cumbersome for patients
Estradiol valerate IM[a]	<20mg IM q 2 wk	20mg IM q 2 wk	40mg IM q 2wk	May divide dose into weekly injections for cyclical symptoms
Estradiol cypionate IM	<2mg q 2wk	2mg IM q 2 wk	5mg IM q 2 wk	May divide dose into weekly injections for cyclical symptoms
Progestagen				
Medroxyprogesterone acetate (Provera)	2.5mg qhs		5-10mg qhs	
Micronized progesterone			100-200mg qhs	
Androgen blocker				

Hormone	Initial–low[b]	Initial	Maximum[c]	Comments
Spironolactone	25mg qd	50mg bid	200mg bid	
Finasteride	1mg qd		5mg qd	
Dutasteride			0.5mg qd	

a. Available as standard U.S. Pharmacopia (USP) as well as compounded products
b. Initial-low dosing for those who desire (or require due to medical history) a low dose or slow upward titration.
c. Maximal effect does not necessarily require maximal dosing; as such maximal doses do not necessarily represent a target or ideal dose. Dose increases should be based on patient response and monitored hormone levels.

Many patients are eager to begin maximal feminizing hormone therapy and are opposed to the idea of a slow upward titration. Weak evidence suggests that initiation of estrogen therapy at lower doses and titrating up over time may result in enhanced breast development in transgender women. **The estrogen receptor agonist activity of spironolactone may play a role in reduced breast development due to premature breast bud fusion. As such an escalating regimen beginning with low dose estrogen only, and titrating up over several months, and then adding spironolactone may be an alternative approach,[17] consistent with management practices in children with delayed pubertal onset (Grading: T O W).** Upward titration of spironolactone can also help minimize side effects such as orthostasis or polyuria. It is recommended that providers discuss these considerations with patients before initiation of hormones in order to make an informed decision.

Table 7-2. Laboratory monitoring for feminizing hormone therapy

Test	Comments	Baseline	3 months*	6 months*	12 months*	Yearly	PRN
BUN/Cr/K+	Only if spiro used	X	X	X	X	X	X
Lipids	No evidence to support monitoring at any time; use clinician discretion	Based on USPSTF guidelines					X
A1c or glucose	No evidence to support monitoring at any time; use clinician discretion	Based on USPSTF guidelines					
Estradiol			X	X			X
Total Testosterone			X	X	X		X

Test	Comments	Baseline	3 months*	6 months*	12 months*	Yearly	PRN
Sex Hormone Binding Globulin (SHBG)**			X	X	X		X
Albumin**			X	X	X		X
Prolactin	Only if symptoms of prolactinoma						X

* In first year of therapy only

** Used to calculate bioavailable testosterone; monitoring bioavailable testosterone is optional and may be helpful in complex cases (see text) (http://www.issam.ch/freetesto.htm)

Overview of titration and monitoring

The interpretation of hormone levels for transgender individuals is not yet evidence based; physiologic hormone levels in non-transgender people are used as reference ranges. However, estrogen levels in non-transgender women may not be associated with specific secondary sex characteristics (i.e. higher estrogen levels in non-transgender women are not necessarily associated with larger breasts), and specific phenotypical end points are likely multifactorial and particularly dependent on genetics and the age at which gender-affirming hormone therapy is begun. Titration upwards of dose should be driven by patient goals, in the context of clinical response, hormone level monitoring, and safety monitoring (e.g. presence of risk factors such as smoking, renal function and K+ in patients using spironolactone). A general approach for titration would include increasing of both estrogen and antiandrogen dosing until the estrogen dose is in the female physiologic range. Once this has been achieved, titration efforts can focus on increasing androgen blockade. There can be several approaches to titration of androgens. One approach is to continue increasing estrogen until it reaches the upper limit of the female physiologic range. The drawback for this approach is that patients may begin to experience estrogenic side effects as described below. Another approach is to maintain current physiologic estrogen dosing and titrate upward on antiandrogens and/or addition of a progestagen.

Some providers choose to omit the use of hormone level testing and only monitor for clinical progress or changes. The risk of this approach is that if hormone levels (particularly testosterone) have not reached the target range, but progress is judged as appropriate based on clinical exam, a suboptimal degree of feminization is possible, and the presence of supraphysiologic levels would also be obscured. Conversely, Endocrine Society guidelines recommend monitoring of hormone levels every 3 months.[21] In practice this is not realistic and not likely to add value once a stable dosing has been achieved. A prospective study of transgender women taking 4mg/day divided dose oral estradiol or 100mcg transdermal estradiol, plus 100-200mg/day divided dose spironolactone found that all women achieved physiologic estradiol levels, though only 2/3 of the women achieved female range testosterone levels.[22] Some gender-nonconforming/nonbinary patients may prefer to maintain estradiol or testosterone levels in an intermediate range. Regardless of initial dosing scheme chosen, dosing may be titrated upwards over 3-6 months. Check estradiol and

testosterone levels at 3 and 6 months and titrate dose accordingly. For those patients using spironolactone, check renal function and K+ at 3 months and 6 months, then q 6-12 months. While laboratory monitoring of hormone levels may seem complex, it is of similar difficulty to the monitoring of other similarly complex lab-monitored conditions managed by primary care providers, such as thyroid disorders, anticoagulation, or diabetes.

Once hormone levels have reached the target range for a specific patient, it is reasonable to monitor levels yearly, or only as needed as described below. As with other situations involving maintenance of hormone therapy (menopause, contraception), annual visits are sufficient for transgender women on a stable hormone regimen. Other reasons for measuring hormone levels in the maintenance phase include significant metabolic shifts such as the onset of diabetes or a thyroid disorder, substantial weight changes, subjective or objective evidence of virilization, or new symptoms potentially precipitated or exacerbated by hormone imbalances such as hot flashes or migraines. Such patients may also require more frequent office visits to manage coexisting conditions. Increased frequency of office visits may also be useful for patients with complex psychosocial situations to allow for the provision of ancillary or wraparound services.

Current Endocrine Society recommendations include the measurement of only total testosterone and estradiol. This is consistent with Endocrine Society recommendations that only total testosterone be monitored in non-transgender men being managed for testosterone deficiency, except in cases of borderline testosterone levels. However, since testosterone is of particular concern is insuring maximal feminization, the calculation of bioavailable testosterone in transgender women may still be of value. Specifically, exogenous estrogens (especially oral) may be associated with elevated levels of sex hormone binding globulin (SHBG); such elevations can vary from person to person and across regimens. As such in cases of patient concern or persistent virilized features in the presence of a female-range total testosterone, calculation of the bioavailable testosterone may help fine tune hormone regimens for optimal effect.

Interpretation of laboratory results requires special attention in the context of transgender care. Numerous sources publish target ranges for serum estradiol, total estrogens, free, total and bioidentical testosterone, and sex hormone binding globulin. However, these specific ranges may vary between different laboratories and techniques. Furthermore, the interpretation of reference ranges supplied with lab result reports may not be applicable if the patient is registered under a gender that differs from their intended hormonal sex. For example, a transgender woman who is still registered as male will result in lab reference ranges reported for a male; clearly these ranges are not applicable for a transgender woman using feminizing hormone therapy. Hormone levels for genderqueer or gender nonconforming/nonbinary patients may intentionally lie in the mid-range between male and female norms. Providers are encouraged to consult with their local lab(s) to obtain hormone level reference ranges for both “male” and “female” norms, and then apply the correct range when interpreting results based on the current hormonal sex, rather than the sex of registration.

Monitoring estradiol levels

Historically estrogen levels have been monitored using the total serum estradiol. The 2009 Endocrine Society Guidelines recommend monitoring serum estradiol and maintaining levels at the

mid-cycle range for non-transgender women.[21] This recommendation is based on expert opinion only and may be overly conservative, and hormone levels are often not easy to tightly control.[23] Providers are encouraged to review the specific estradiol reference ranges for their local lab estradiol assays, as these can vary. There is no evidence that higher estradiol levels in patients with adequate androgen suppression results in additional feminization or breast development. Maintaining estrogen levels in the physiologic range for menstruating non-transgender women minimizes risks and side effects, and makes sense clinically. Note that the use of conjugated estrogens (Premarin®) or ethinyl estradiol (found in most combined oral contraceptives) are not accurately measured by estradiol assays and will typically result in low measured levels.

In patients who have been using self-administered conjugated estrogens, or ethinyl estradiol, it is reasonable to check a total estrogens level, which may provide a more accurate estimate in these cases. This assay also measures minor estrogens such as estriol and estrone. There is some evidence that the use of oral estradiol results in higher serum levels of estrone due to first pass hepatic metabolism, as compared to parenteral forms.[24,25] This may explain dose independent reasons why some patients “feel different” on different forms of estrogen.

Monitoring testosterone levels

Testosterone levels can be difficult to measure in non-transgender men due to rapid fluctuations in levels, relating to pulsatile release of gonadotropins, with higher levels in the morning hours. Free testosterone represents the portion of testosterone unbound to serum proteins and depends on levels of sex hormone binding globulin (SHBG). While free testosterone can be measured, assays are unreliable.[26] Consensus is lacking on the role of free vs. total testosterone levels; total testosterone levels are reliable and readily available, however they do not describe the actual bioavailable testosterone level. Bioavailable testosterone is free testosterone plus testosterone weakly bound to albumin.[27] SHBG is elevated in the presence of estrogen, and in particular with exogenous estrogen supplementation, more so with oral estrogen than with parenteral routes due to first pass hepatic activity.[28] **For transgender care, The Endocrine Society recommends monitoring of the total testosterone level, with a target range of <55ng/dl** .[21] Calculation of the bioavailable testosterone may help guide dosing, and can be calculated from the total testosterone, albumin, and SHBG levels (http://www.issam.ch/freetesto.htm).[29] A general reference range for bioavailable testosterone is > 72ng/dl (2.5nmol/L).[30–32]

Monitoring gonadotropin levels

When indicated, measuring of gonadotropins (leutenizing hormone: LH and follicle stimulating hormone: FSH) can be done using the local lab ranges for eugonadal state as a reference.

Monitoring hormone levels in patients using injected estrogen

Pharmacokinetic studies of injected estrogen have been limited. Two earlier studies only examined single-dose pharmacokinetics and are therefore unable to be applied to steady-state dosing.[33] Studies of estradiol levels in the context of a monthly combined injectible contraceptive of 5mg estradiol cypionate and 25mg medroxyprogesterone acetate found peak levels 2-4 days after injection, maximum estradiol levels of approximately 250 pg/ml, and trough levels of approximately

50pg/ml.[34,35] These findings suggest that injected estradiol in the middle of the dosing ranges recommended here will result in physiologic estradiol levels, and that use of more frequent dosing will reduce peak-trough effect. When measuring hormone levels in patients using injected forms of estradiol, a mid-cycle level is often sufficient, however if the patient is experiencing cyclic symptoms such as migraines or mood swings, peak (1-2 days post injection) and trough levels of both estradiol and testosterone may reveal wide fluctuations in hormone levels over the dosing cycle; in these cases, consider changing to an oral or transdermal preparation, or reducing the injection interval (with concomitant reduction in dose, to maintain the same total dose administered over time). A single study suggests similar pharmacokinetics when estradiol is injected subcutaneously, rather than intramuscular.[34]

Interpreting sex-specific, non-hormone labs

Alkaline phosphatase, hemoglobin and hematocrit (H&H), and creatinine may vary depending on the patient's current sex hormone configuration. Several factors contribute to these differences, bone mass, muscle mass, number of myocytes, presence or lack of menstruation, and the erythropoetic effect of testosterone. While transgender women do not menstruate, those with female-range hormone levels will lack the erythropoetic effects of male-range testosterone, and it may be reasonable to use the female-range lower limit of normal when interpreting H&H. Conversely, the lack of menstruation, and potential for pulsatile undetected androgen activity in those with retained gonads make it reasonable to use the male-range upper limit of normal for H&H. Using the male-range upper limit of normal for alkaline phosphatase and creatinine may also be appropriate for transgender women due to retained bone and muscle mass or myocyte counts, respectively. This is of particular importance in transgender women using spironolactone who are registered as female, and may have a lab result flag showing an abnormal elevated creatinine. In these cases the provider should reference the male normal ranges for their lab.[19]

Table 7-3. Lower and upper limits of normal to use when interpreting selected lab tests in transgender women using feminizing hormone therapy

Lab measure	Lower Limit of normal	Upper Limit of normal
Creatinine	Not defined	Male value
Hemoglobin/Hematocrit	Female value	Male value
Alkaline Phosphatase	Not defined	Male value

Individualized dosing based on patient centered goals

Some patients may desire limited hormone effects or a mix of masculine and feminine sex characteristics. Examples include retention of erectile function with otherwise maximum feminization, or minimal feminizing effects with the exception of body or facial hair elimination or breast growth. While manipulation of dosing regimens and choice of medication can allow patients

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to achieve this goal, it is important to have a clear discussion with patients regarding expectations and unknowns. Specifically, it is not possible to select in advance an exact hormone regimen that will predictably allow patients to arrive at a specified configuration of sex characteristics. Furthermore, individual genetic and physiologic variation can result in wide variations in both blood levels and response to therapy between different individuals using the same route and dose. The best approach in these cases is to start with low doses and advance slowly, titrating to effect. At the same time, response to hormone therapy is also individualized and measures such as breast growth are variable in both degree and time course. Likely predictive factors of speed and degree of feminization include genetics, age at initiation of therapy, and body habitus.[17] Patients should be counseled on typical timeframes for changes and advised to avoid making comparisons to the experiences of others. Anecdotal sources suggest that maximal feminization may occur within 2-5 years.[36]

Specific considerations and conditions

Tobacco use:

Tobacco use in combination with estrogen therapy is associated with an increased risk of venous thromboembolism. All transgender women who smoke should be counselled on tobacco risks and cessation options at every visit. Many transgender women may be unable or unwilling to quit smoking; this should not represent an absolute contraindication to estrogen therapy. After an in depth and careful informed consent discussion, it is reasonable to prescribe estrogen using a harm reduction approach, with a preferred route of transdermal estrogen. **Aspirin 81mg/day can be considered as an additional preventive measure in smokers, though no evidence exists to allow and informed assessment of the risk/benefit ratio between VTE prevention and gastrointestinal hemorrhage (Grading: X C W). Transdermal estrogens are preferred to minimize risk (Grading: T O S).**

Loss of erectile function:

Sildenafil (Viagra) and tadalafil (Cialis) can be used for preservation of erectile function at any stage or with any feminizing hormone regimen, in consideration of the typical contraindications and precautions when using this class of medication. Individual results may vary. It is reasonable check both total and bioavailable testosterone levels, and consider reduction of androgen blockade to allow an increase in testosterone, depending on patient goals.

Low libido:

A study of sexual desire in transgender women found that 83% never or rarely experience spontaneous sexual desire, 76% never or rarely experience responsive sexual desire, and 22% meet the criteria for Hypoactive Sexual Desire Disorder (HSDD) by experiencing both of these in a way which results in personal or relational distress. This study also found decreases in sexual desire after genital surgery.[37] Another study found a rate of HSDD in transgender women of 34%, compared to 23% in non-transgender women. This study found no correlation between sexual desire and testosterone levels in the transgender women, though a significant correlation was found between hormones and desire in non-transgender women.[38] An unpublished study found positive correlations between libido and testosterone levels in transgender women treated with

testosterone, but no effect when treated with dihidroepiandrosterone sulfate (DHEA-S).[39] As such it remains unclear if HSDD relates to androgen blockade or post-gonadectomy hormonal changes, or due to anatomical, functional and psychological changes associated with hormone therapy or genital surgery.

Post-gonadectomy:

Since estrogen dosing should be based on physiologic female levels, no reduction in estrogen dosing is required after gonadectomy. Some patients may choose to use a lower dose, which is appropriate as long as dosing is adequate to maintain bone density. **Adequacy of dosing in those on low estrogen replacement post gonadectomy may be assessed by following LH and FSH levels (Grading: T O W).[11]**

Older transgender women:

Older transgender women initiating therapy may have less rapid and a lesser degree of changes. Due to higher levels of co-occurring conditions in older individuals, there may also be higher risk of adverse effects. Nevertheless a large number of women have started hormones at advanced ages and safety and satisfaction have been reported as acceptable.[40] There is no evidence to support continuation or cessation of hormones for older transgender women.

Since the mean age of menopause in the U.S. is 49,[41] it is reasonable in transgender women who have undergone gonadectomy to consider stopping hormone therapy around age 50. Expected effects of this may be similar to non-transgender women experiencing menopause. Transgender women who retain their gonads but withdraw hormone therapy may experience return of virilization. A discussion of the pros and cons of this approach, with individualized and shared decision making is recommended.

Pituitary adenoma (prolactinoma) and galactorrhea:

Prolactin elevations and growth of pituitary prolactinomas are theoretical risks associated with estrogen therapy; several cases have been reported.[42] However, with the administration of physiologic doses of estrogen, there is no clear basis for an increased risk of prolactinomas in comparison to the population background rate in non-transgender women. Furthermore, **Endocrine Society guidelines for the management of incidental prolactinomas are expectant management only, in the absence of suggestive visual or other symptoms (significant galactorrhea, headaches).[43] Routine screening with serum prolactin levels in asymptomatic transgender women would not have an impact on management, and could result in costs or harm if further workup if pursued. As such it is recommended that prolactin be checked only in cases of visual disturbances, excessive galactorrhea, and be considered in cases of new onset headaches.** It is noted that some transgender women experience a minimal amount of galactorrhea early in their hormone therapy course. The presence of non-bloody minimal galactorrhea from more than one duct and/or bilateral is almost certainly physiologic and would not warrant further evaluation.

Venous thromboembolism:

Data from studies of menopausal women suggest no increased risk of venous thromboembolism with the use of transdermal estradiol.[44] There are some data suggestive of increased

thrombogenicity and cardiovascular risk when conjugated equine estrogens (Premarin) are used.[1,2] Data on the risk associated with oral 17-beta estradiol are mixed, with some suggesting no increased risk and others suggesting a 2.5 - 4 fold increased risk.[20,44] Even in the case of a 2.5 fold increase, the background rate for VTE in the general population is very low (1 in 1000 to 1 in 10,000), so the absolute risk increase is minimal.[3] There is weak evidence that sublingual administration of oral estradiol tablets might reduce thromboembolic risk due to a bypass of hepatic first pass, with one study showing 13 fold increase in peak estradiol blood levels but similar 24 hour area-under-the-curve.[45] A study of sublingual estradiol for the management of post-partum depression found that it was well tolerated, and the increased pulsatile nature of this route may more closely mimics natural ovarian estrogen secretion.[46] Sublingual administration requires insuring that the estradiol tablets are micronized; while most commonly available estradiol tablets are micronized, specifying as such on the written prescription (or consultating with the dispensing pharmacist) is recommended.

There is also some limited evidence to suggest that the risk of VTE in menopausal women may be driven more by the choice of progestagen, and that pregnane derived progestagens such as medroxyprogesterone in combination with oral estradiol does not confer an increased risk, while norpregnane derived progestagens such as norethindrone may increase risk by 80% when used with oral estradiol.[20] Prior studies reporting a 20 to 40 fold increased risk of VTE in transgender women involved the use of high doses (100-200mcg/day) of thrombogenic ethinyl estradiol in a mix of smokers and non-smokers.[47,48] A retrospective cohort of Dutch transgender women found no increased risk in VTE once ethinyl estradiol was replaced by bioidentical estradiol as the standard regimen.[49]

Insufficient evidence exists to definitively guide estrogen therapy in transgender women with risk factors or with a personal history of prior VTE, either on or off estrogen. A report of 11 transgender women with a history of activated protein C resistance (the mechanism of action implicated in the hypercoaguable state associated with the Factor-V Lieden mutation) using transdermal estradiol without anticoagulation found no clotting events after a mean of 64 months of therapy.[50]

Figures 1-5 describe the approach to various scenarios of VTE history or risk factors and estrogen use. The decision to initiate episodic (i.e. before long airplane flights) or long term anticoagulation or antiplatelet therapy should be considered in the context of risks associated with major gastrointestinal or intracranial hemorrhage. ***Routine*** **VTE prophylaxis with aspirin in unselected transgender populations is not recommended.** Routine screening for prothrombotic mutations is not recommended in the absence of risk factors.[50] Regardless of the circumstances, estrogen therapy should not be administered in patients with significant risk factors for or history of VTE who continue to smoke tobacco.

Figure 7-1. Approach to management of estrogen in patients with a personal history of VTE

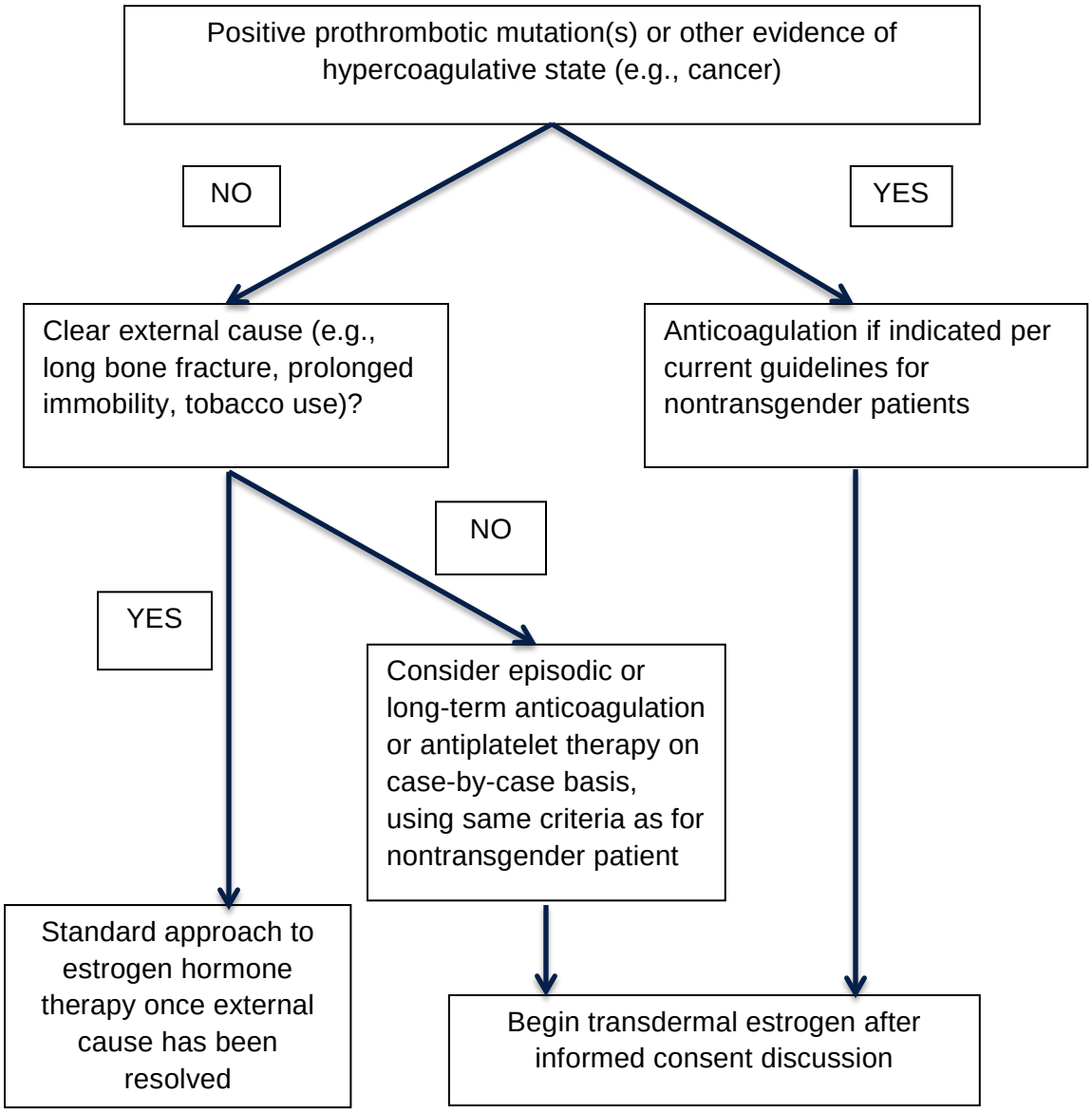

Figure 7-2. Approach to management of estrogen in patients with a family history of VTE but no personal history of VTE

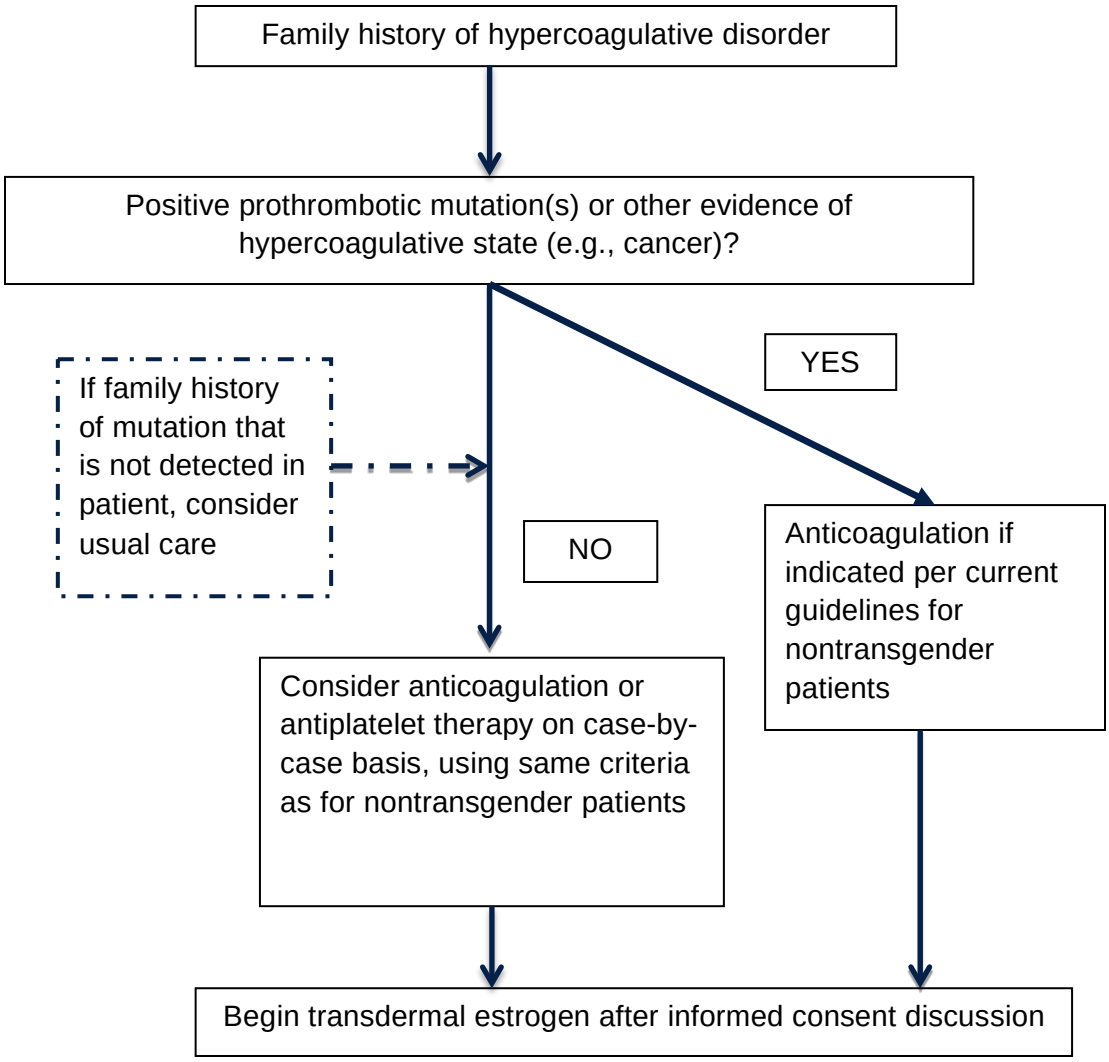

Figure 7-3. Approach to patient using oral or injected estrogen at time of first diagnosis of VTE

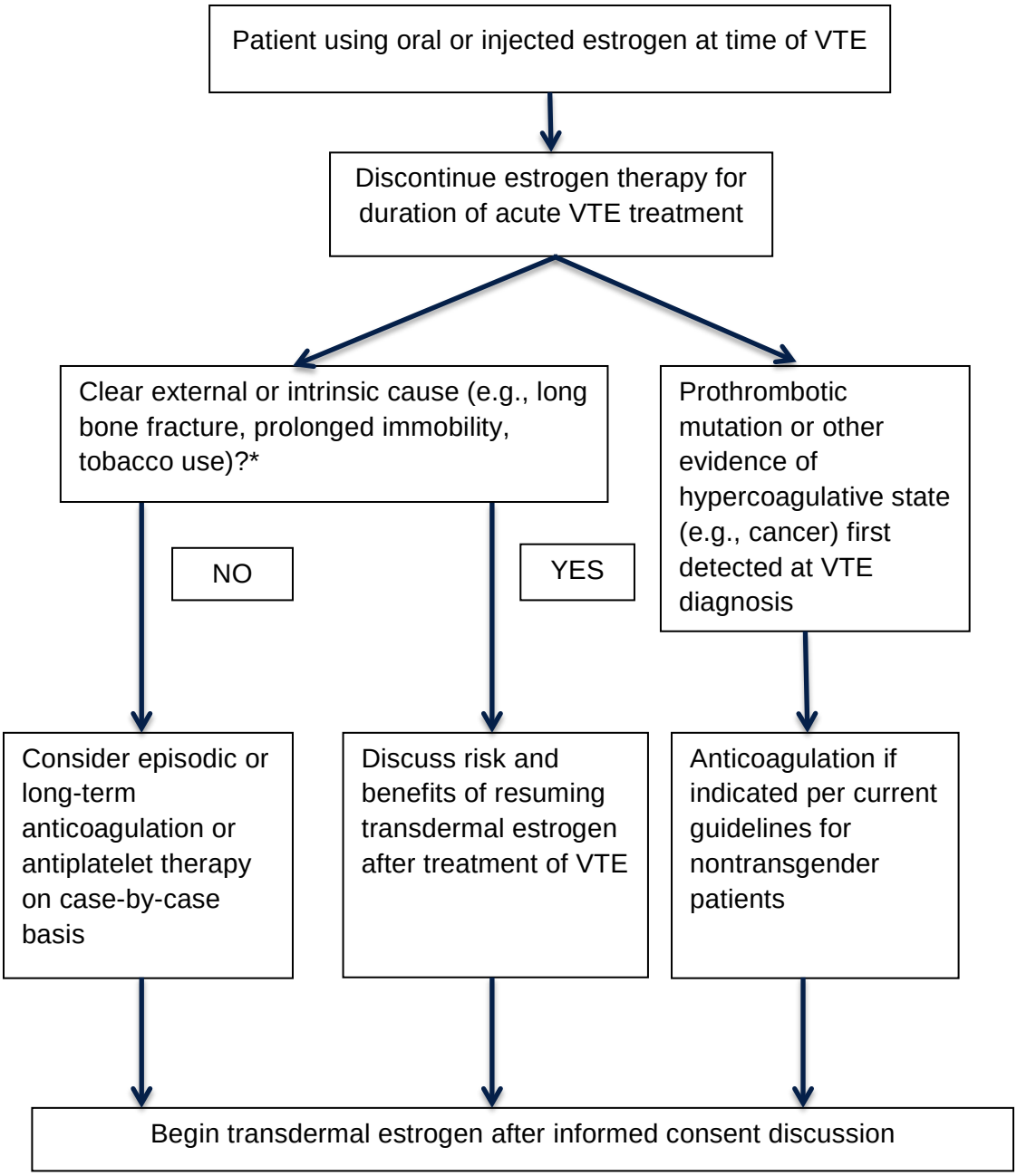

Figure 7-4. Approach to patient using transdermal estradiol at time of first diagnosis of VTE

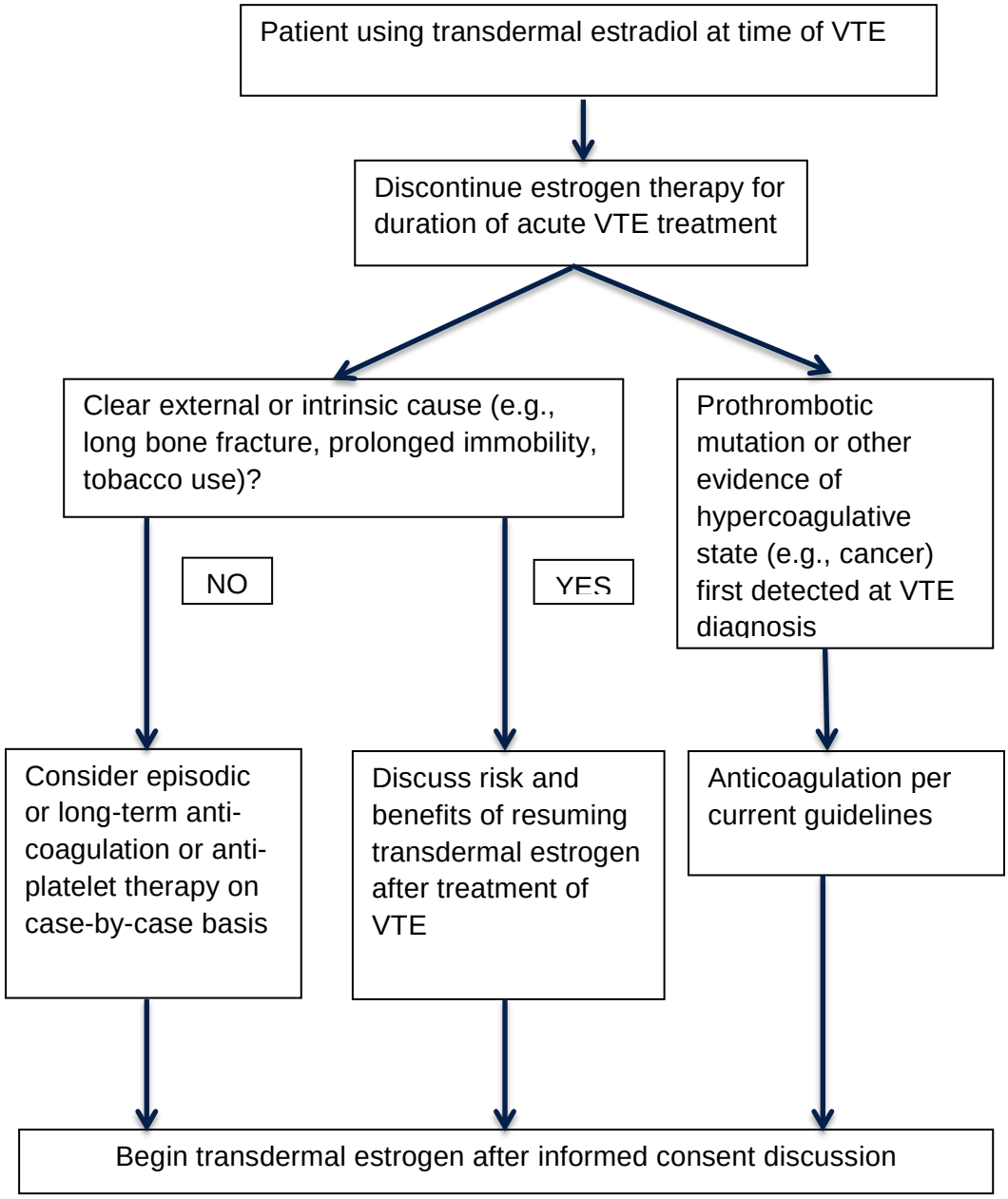

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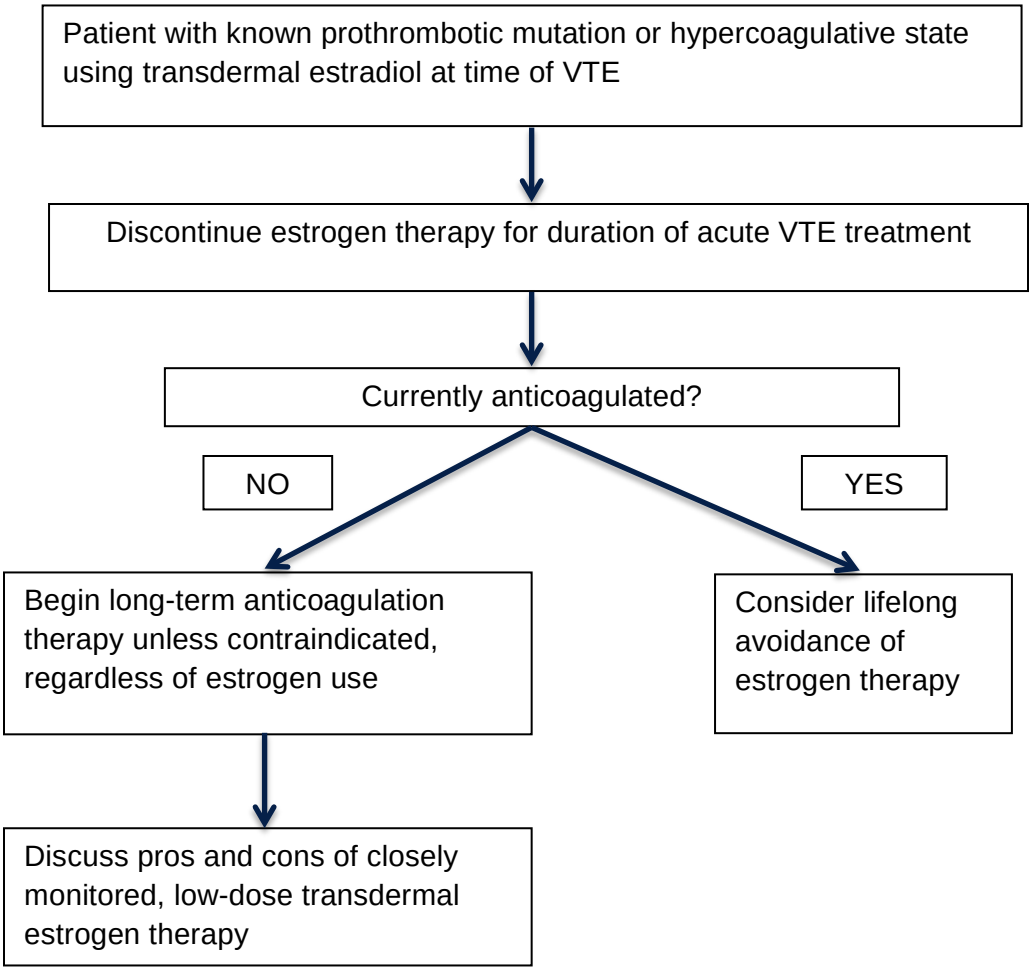
Figure 7-5. Approach to patients with known hypercoagulative state who use transdermal estradiol and present with acute VTE



Autoimmunity:

There is a certain but incompletely defined linkage between sex hormones and autoimmune conditions. Testosterone has been associated with overall immune suppression, and autoimmune conditions are more common in non-transgender women than men.[51] Testosterone deprivation results in an increased Th1:Th2 ratio.[52] However the relationship is more complex, as demonstrated by the paradoxical improvements seen in multiple sclerosis during pregnancy.[51] In transgender women who have undergone orchiectomy or have full androgen blockade, some evidence suggests that supplementation with dihydroepiandrosterone (DHEA) may counteract some of the shift toward autoimmunity.[53] Patients with autoimmune conditions should be informed that their condition could potentially worsen (or improve) once feminizing therapy has begun. Hormone dosing should begin low and advance slowly, monitoring for worsening symptoms, and in collaboration with any specialists who may be managing the autoimmune condition.

Migraine:

Migraines have a clear hormonal component and may be exacerbated by estrogen therapy. Patients with a history of migraines should consider starting with a low dose and titrating upward as tolerated. Oral or transdermal estrogen may be preferred to the potentially cyclic levels associated with injected estrogen.[54] While migraine with aura is associated with an increased risk of stroke in women using oral contraceptives,[55] it is not clear if this risk translates to the use of bioidentical estradiol.

Mental health conditions:

While hormones may contribute to mood disorders (such as in premenstrual dysphoric disorder or postpartum depression), there is no clear evidence that estrogen therapy is directly associated with the onset of or worsening of mental health conditions. In fact one study found that transgender women experience improvements in social functioning and reduced anxiety and depression once estrogen therapy is begun.[56] Mental health conditions in transgender women should be approached with a broad differential diagnosis as in any other patient. It may be advisable to avoid injected estrogen due to the potentially cyclic levels, which could bring about or worsen existing mood symptoms.

Estrogen therapy in patients with a prior history of cancer:

An active estrogen-sensitive cancer is a contraindication to estrogen therapy. For patients with a prior history of estrogen sensitive cancer (breast, pituitary), consultation with an oncologist is recommended. While androgen deprivation is a mainstay of treatment for advanced prostate cancer, it is unclear if estrogen therapy may confer an independent protection or increased risk of prostate cancer.[57] PSA should be considered unreliable in those using antiandrogen or estrogen therapy due to the high risk of false negative tests.

Perioperative use of feminizing hormones:

No direct study of the risk of perioperative venous thromboembolism in users of bioidentical estrogens has been conducted. Guidelines from two British professional organizations make a weak recommendation to discontinue menopausal hormone therapy in the perioperative period, however both acknowledge that this may not be needed in the setting of proper prophylaxis (i.e.

heparin or compression devices).[58] Studies of perioperative ethinyl estradiol in users of hormonal contraception have mixed findings and are wrought with confounding and methodological limitations.[59] Many surgeons insist that transgender women discontinue estrogen for several weeks before and after any gender-affirming procedure.[60,61] These recommendations may appear as benign to the surgeon; however to the transgender woman undergoing a life and body-altering procedure simultaneous with gonadectomy, sudden and prolonged complete withdrawal of estrogens can have a profound impact. Postoperative depression is a nontrivial concern and may have some basis in the drastic hormone shifts, including cessation of estrogens, experienced in the perioperative period. **There is no evidence to suggest that transgender women who lack specific risk factors (smoking, personal or family history, excessive doses or use of synthetic estrogens) must cease estrogen therapy before and after surgical procedures, in particular with appropriate use of prophylaxis and an informed consent discussion of the pros and cons of discontinuing hormone therapy during this time. Possible alternatives include using a lower dose of estrogen, and/or changing to a transdermal route if not already in use**.[62]

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8. Overview of masculinizing hormone therapy

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Introduction

The goal of masculinizing hormone therapy is the development of male secondary sex characteristics, and suppression/minimization of female secondary sex characteristics. General effects include the development of facial hair, virilizing changes in voice, a redistribution of facial and body subcutaneous fat, increased muscle mass, increased body hair, change in sweat and odor patterns, frontal and temporal hairline recession, and possibly male pattern baldness. Sexual and gonadal effects include an increase in libido, clitoral growth, vaginal dryness, and cessation of menses. An ovulatory state is common, though not absolute and long-term fertility may be affected, though some transgender men are able to discontinue testosterone and achieve successful pregnancy.[1] Masculinizing hormone therapy may bring about changes in emotional and social functioning, though these can vary from person to person and stereotypes should be avoided. The general approach involves the use of one of several forms of parenteral testosterone.

All testosterone preparations currently used in the U.S. are "bioidentical", meaning they are chemically equivalent to the testosterone secreted from the human testicle. Prior use of oral methyltestosterone and other synthetics commonly encountered in bodybuilding communities has resulted in unsubstantiated concerns about negative hepatic effects of testosterone use in transgender men. Testosterone is available in a number of injected and topical preparations, which have been designed for use in non-transgender men with low androgen levels (see table). Since the label dosing (not included in table) for these medications are based on the treatment of men with low, but not no, testosterone, higher dosing may be needed in transgender men (see table) than are commonly used in non-transgender men.

Table 8-1. Hormone preparations and dosing (Grading: T O M)

Androgen	Initial – low dose[b]	Initial - typical	Maximum - typical[c]	Comment
Testosterone Cypionate[a]	20 mg/week IM/SQ	50mg/week IM/SQ	100mg/week IM/SQ	For q 2 wk dosing, double each dose
Testosterone Enthanate[a]	20mg/week IM/SQ	50mg/week IM/SQ	100mg/week IM/SQ	"
Testosterone topical gel 1%	12.5-25 mg Q AM	50mg Q AM	100mg Q AM	May come in pump or packet form
Testosterone topical gel 1.62%[d]	20.25mg Q AM	40.5 – 60.75mg Q AM	103.25mg Q AM	"
Testosterone patch	1-2mg Q PM	4mg Q PM	8mg Q PM	Patches come in 2mg and 4mg size. For lower doses, may cut patch

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Androgen	Initial – low dose[b]	Initial - typical	Maximum - typical[c]	Comment
Testosterone cream[e]	10mg	50mg	100mg	
Testosterone axillary gel 2%	30mg Q AM	60mg Q AM	90-120mg Q AM	Comes in pump only, one pump = 30mg
Testosterone Undecanoate[f]	N/A	750mg IM, repeat in 4 weeks, then q 10 weeks ongoing	N/A	Requires participation in manufacturer monitored program[f]

a. Available as standard U.S. Pharmacopia (USP) as well as compounded products.
b. Initial – low dose recommended for genderqueer and nonbinary dosing.
c. Maximum dosing does not mean maximal effect. Furthermore, these dosage ranges do not necessarily represent a target or ideal dose. Dose increases should be based on patient response and/or monitored hormone levels. Some patients may require less than this amount, and some may require more.
d. Doses of less than 20.25mg with 1.62% gel, or less than 30mg with 2% axillary gel may be difficult, since measuring one-half of a pump or packet can present a challenge. Patients requiring doses lower than 20.25mg and whose insurance does not cover 1% gel may require prior authorization or an appeal.
e. Testosterone creams are prepared by individual compounding pharmacies. Specific absorption and activity varies and consultation with the individual compounding pharmacist is recommended.
f. Testosterone undecanoate has been used extensively for transgender care outside of the U.S. for many years.[2,3] It has recently become available in the U.S. Testosterone undecanoate has been associated with rare cases of pulmonary oil microembolism and anaphylaxis. As such in the United States, the drug is available only through a restricted program called the AVEED Risk Evaluation and Mitigation Strategy (REMS) Program (https://www.aveedrems.com/AveedUI/rems/preHome.action). All injections must be administered in an office or hospital setting by a trained and registered health care provider and monitored for 30 minutes afterwards for adverse reactions.

Route of injection (intramuscular vs. subcutaneous): While testosterone for injection is labeled for the intramuscular route, many providers have administered testosterone using the subcutaneous route with good efficacy and patient satisfaction, and without complications. Benefits of subcutaneous administration include a smaller and less painful needle, and may avoid scarring or fibrosis from long term (possibly > 50 years) intramuscular therapy (Grading: T O M).[4,5]

Proper use of transdermal testosterone gel: These gels involve an evaporable vehicle which contains the testosterone medication. Manufacturer labeling recommends applying in the morning. After application, the testosterone moves into the dermis, where it slowly releases over the course of the day. Care should be taken to avoid any contact of the gel with others, especially women and

children. This includes gel, which remains on clothing or other fomites. Gel should be applied only to upper arms or shoulders, and not to other sites. Site of application should remain dry for at least 2 hours. It is also recommended that the application site be washed at a later time if close skin-skin contact with another person is expected.

Table 8-2. Titration and monitoring of masculinizing hormone therapy

Therapy	Comments	Baseline	3 months*	6 months*	12 months*	Yearly	PRN
Lipids	No evidence to support lipid monitoring at any time; use clinician discretion	Based on USPSTF guidelines					X
A1c or fasting glucose	No evidence to support lipid monitoring at any time; use clinician discretion	Based on USPSTF guidelines					X
Estradiol							X
Total Testosterone			X	X	X		X
Sex Hormone Binding Globulin (SHBG) **			X	X	X		X
Albumin **			X	X	X		X
Hemoglobin & Hematocrit		X	X	X	X	X	X

* In first year of therapy only;

** Used to calculate bioavailable testosterone; monitoring bioavailable testosterone is optional and may be helpful in complex cases (see text) (http://www.issam.ch/freetesto.htm)

Titration upwards of dose should be driven by patient goals, in the context of clinical response, hormone level monitoring, and safety monitoring (i.e. hemoglobin and hematocrit [H&H]). Clinical response can be measured objectively by the presence of amenorrhea by 6 months.[4] Once within the normal male physiologic range, there is no evidence that higher doses/levels of testosterone result in a greater degree of virilization. Lab reference ranges for total testosterone levels are generally very wide (roughly 350-1100ng/dl); if men have testosterone levels at the lower end of the normal male range and are either concerned about slow progress or are having symptoms of low

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energy, libido, or mood, it is reasonable to slowly increase the dose while monitoring for side effects. Once total testosterone is greater than the midpoint value in the lab reported reference range, it is unclear if an increase in dose will have any positive effect on perceived slow progress, or on mood symptoms or other side effects.

While some providers choose to omit hormone level monitoring, and only monitor for clinical progress or changes, this approach runs the risk of a suboptimal degree of virilization if testosterone levels have not reached the target range. A prospective study of 31 transgender men newly started on either subcutaneous 50-60mg/week testosterone cypionate, 5g/day 1% testosterone gel, or 4mg/day testosterone patch found that after 6 months only 21 (68%) achieved male range testosterone levels and 5 (16%) had persistent menses, with only 9 (29%) achieving physiologic male-range estradiol levels.[5] Some genderqueer and gender-nonconforming/nonbinary patients may prefer to maintain testosterone levels in an intermediate range. Regardless of initial dosing scheme chosen, titrate upwards based on testosterone levels measured at 3 and 6 months. Once hormone levels have reached the target range for a specific patient, it is reasonable to monitor levels yearly. As with testosterone replacement in non-transgender men, annual visits and lab monitoring are sufficient for transgender men on a stable hormone regimen. Endocrine Society guidelines recommend monitoring of hormone levels every 3 months.[6] In practice this is not realistic and not likely to add value once a stable dosing has been achieved.[7] Other reasons for measuring hormone levels in the maintenance phase include significant metabolic shifts such as the onset of diabetes or a thyroid disorder, substantial weight changes, subjective or objective evidence of regression of virilization, or new symptoms potentially precipitated or exacerbated by hormone imbalances such as hot flashes, pelvic cramping or bleeding, or migraines. Such patients may also require more frequent office visits to manage coexisting conditions. Increased frequency of office visits may also be useful for patients with complex psychosocial situations to allow for the provision of ancillary or wraparound services.

General comments on hormone level interpretation

Interpretation of laboratory results requires special attention in the context of transgender care. Numerous sources publish target ranges for serum estradiol, total estrogens, free, total and bioidentical testosterone, and sex hormone binding globulin. However, these specific ranges may vary between different laboratories and techniques. Furthermore, the interpretation of reference ranges supplied with lab result reports may not be applicable if the patient is registered under a gender that differs from their intended hormonal sex. For example, a transgender man who is still registered as female will result in lab reference ranges reported for a female; clearly these ranges are not applicable for a transgender man using virilizing hormone therapy. Hormone levels for genderqueer or gender nonconforming/nonbinary patients may intentionally lie in the mid-range between male and female norms. Providers are encouraged to consult with their local lab to obtain hormone level reference ranges for both “male” and “female” norms, and then apply the correct range when interpreting results based on the current hormonal sex, rather than the sex of registration. Testosterone levels must also be interpreted in the context of knowing whether the specimen was drawn at the peak, trough or mid-cycle of the dosing interval, as values can vary widely (and if so may cause symptoms, see below and pelvic pain and bleeding guidelines)

Monitoring testosterone levels

Testosterone levels can be difficult to measure in non-transgender men due to rapid fluctuations in levels, relating to pulsatile release of gonadotropins. In transgender men who are receiving exogenous testosterone, levels may lack these rapid fluctuations (though they may vary over the dosing interval). Free testosterone represents the portion of testosterone unbound to serum proteins and depends on levels of sex hormone binding globulin (SHBG). Free testosterone can be measured, however assays are unreliable.[8] Consensus is lacking on the role of free vs. total testosterone levels; total testosterone levels are reliable and readily available, however they do not describe the actual bioavailable testosterone level. Bioavailable testosterone is free testosterone plus testosterone weakly bound to albumin.[9] SHBG is elevated in the presence of estrogen and thyroxine.[10] It is decreased in the presence of androgens, prolactin, and high levels of insulin and growth hormone. For transgender care, The Endocrine Society recommends monitoring of the total testosterone level.[11] Calculation of the bioavailable testosterone is also likely to help guide dosing in complicated cases, or in cases where results or side effects exist in the setting of a normal range total testosterone. Bioavailable testosterone can be calculated from the total testosterone, albumin, and SHBG levels (http://www.issam.ch/freetesto.htm). A general reference range for bioavailable testosterone is > 72ng/dl (2.5nmol/L).[12–15]

Monitoring hormone levels in patients using injected testosterone

When measuring hormone levels in patients using injected forms of testosterone, a mid-cycle level is often sufficient however if the patient is experiencing cyclic symptoms such as migraines, pelvic cramping, or mood swings. Peak (1-2 days post injection) and trough levels of testosterone may reveal wide fluctuations in hormone levels over the dosing cycle; in these cases, consider changing to a transdermal preparation, or reducing the injection interval (with concomitant reduction in dose, to maintain the same total dose administered over time).[16,17]

Monitoring estradiol levels

A six-month prospective study of 31 transgender men newly started on testosterone found that only 9 (29%) achieved physiologic male-range estradiol levels.[18] In reality, physiologic female estradiol ranges are wide and vary over the menstrual cycle; there can be significant overlap with the physiologic male range. Estradiol may play a role in pelvic pain or symptoms, persistent menses, or mood symptoms. It is unclear what role estrogen blockade with aromatase inhibitors (AI) or selective estrogen receptor modulators (SERM) might play in managing these symptoms, or in routine virilizing regimens. An in-depth discussion of pelvic pain and persistent menses is covered elsewhere in these guidelines.

Interpreting sex-specific, non-hormone labs

Alkaline phosphatase, hemoglobin and hematocrit, and creatinine may vary depending on the patient's current sex hormone configuration. Several factors contribute to these differences, bone mass, muscle mass, number of myocytes, presence or lack of menstruation, and erythropoetic effect of testosterone. Many transgender men do not menstruate, and those with male-range testosterone levels will experience an erythropoetic effect. As such an amenorrheic transgender

man taking testosterone, registered as female and with hemoglobin/hematocrit in the range between the male and female lower limits of normal, may be considered to have anemia, even though the lab report may not indicate so. Conversely, the lack of menstruation, and presence of exogenous testosterone make it reasonable to use the male-range upper limit of normal for hemoglobin/hematocrit. Using the male-range upper limit of normal for alkaline phosphatase and creatinine may also be appropriate for transgender men due to increased bone and muscle mass, respectively. In these cases the provider should reference the male normal ranges for their lab.[19]

Table 8-3. Lower and upper limits of normal to use when interpreting selected lab tests in transgender men using masculinizing hormone therapy

Lab measure	Lower Limit of normal	Upper Limit of normal
Creatinine	Not defined	Male value
Hemoglobin/Hematocrit	Male value if menorrheic*	Male value
Alkaline Phosphatase	Not defined	Male value

* If menstruating regularly, consider using female lower limit of normal.

Individualized dosing based on patient centered goals

Some patients may desire limited hormone effects or a mix of masculine and feminine sex characteristics. Examples include deepening of voice or growth of a beard (both irreversible), with retention of breasts or female body habitus. Some patients may choose to undergo testosterone therapy for a period of time to develop such irreversible changes, and then discontinue testosterone and revert to their endogenous estrogen hormonal milieu. While manipulation of dosing regimens and choice of medication can allow patients to achieve individual goals, it is important to have a clear discussion with patients regarding expectations and unknowns. Specifically, it is not possible to prospectively choose a regimen that will predictably allow patients to arrive at a specified configuration of sex characteristics. Furthermore, individual genetic and physiologic variation can result in wide variations in blood levels and response to therapy between different individuals using the same route and dose. The best approach in these cases is to start with low doses and advance slowly, titrating to effect. At the same time, response to hormone therapy is also individualized and measures such as beard growth or voice changes are variable in both degree and time course. Likely predictive factors of speed and degree of virilization include genetics and particulars of body habitus; younger age at start also likely contributes to faster progress and a greater degree of virilization once an endpoint is reached. Patients beginning hormone therapy later in life may experience more limited results. Patients should be counseled on setting reasonable expectations based on these factors, and avoid making comparisons to the experiences of others. Anecdotal sources suggest that maximal virilization may occur within 2-5 years.[20]

Specific considerations and conditions

Pelvic pain and **persistent menses** are covered elsewhere in these guidelines.

Post-gonadectomy: Since testosterone dosing should be based on physiologic male replacement levels, no reduction in testosterone dosing is required after gonadectomy. Some patients may choose to use a lower dose, which is appropriate as long as dosing is adequate to maintain bone density, however they should be informed of possible reduced muscle mass, energy and libido. Adequacy of dosing in those on low testosterone replacement post gonadectomy may be assessed by following LH and FSH levels and titration of dosing to maintain these in the premenopausal range.[21]

Erythrocytosis/polycythemia: Hemoglobin and hematocrit (H&H) values in transgender men should be interpreted in the context of the dose of testosterone used and menstruation status. Transgender men with physiologic male testosterone levels and who are amenorrheic would be expected to have H&H values in the male normal range. Note this may differ from the normal female range listed on the lab report if the patient is registered in the lab system as a female. Providers should reference their lab(s)' normal male range H&H, and disregard reported high flags if an amenorrheic transgender man on testosterone has an H&H above the female upper limit, but below the male upper limit. Similarly in this same patient, an H&H below the male lower limit but above the female lower limit may *not* be flagged as abnormal, but in reality may represent a true anemia. Patients with persistent menses or on lower doses of testosterone should have their H&H interpreted accordingly. Transgender men with true polycythemia should first have their testosterone levels checked, including a peak level, and have dose adjusted accordingly. Changing to a more frequent injection schedule (maintaining the same total amount of testosterone over time) or transdermal preparations may limit the risk of polycythemia.[16] Phlebotomy or blood donation may be an appropriate short term solution depending on the level of elevation; in all cases other pathologic causes of polycythemia should be excluded. In addition to neoplasms and cardiopulmonary disease, specific conditions of concern in transgender men include obesity-related obstructive sleep apnea, and tobacco use.

Older transgender men: No upper age limit exists for testosterone replacement in non-transgender men.[22] As such, there is no age recommendation for the termination of testosterone therapy in transgender men. It is reasonable to consider discontinuing hormome therapy at or around age 50, the age at which non-transgender women undergo menopause. Regardless of the presence of gonads at this age, withdrawl of testosterone will result in reduced muscle mass, body hair and libido.

Autoimmunity: There is a certain but incompletely defined linkage between sex hormones and autoimmune conditions. Testosterone has been associated with overall immune suppression, and autoimmune conditions are more common in non-transgender women than men.[23] Testosterone deprivation results in an increased Th1:Th2 ratio.[24] However the relationship is more complex, as demonstrated by the paradoxical improvements seen in multiple sclerosis during pregnancy.[23] Patients with autoimmune conditions should be informed that their condition could potentially worsen (or improve) once virilizing therapy has begun. Hormone dosing should begin low and advance slowly, monitoring for worsening symptoms, and in collaboration with any specialists who may be managing the autoimmune condition.

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Migraine: Migraines have a clear hormonal component and relationship to estrogen. Given the persistence and possible fluctuation of estrogen levels in many transgender men taking testosterone, migraines may be precipitated or exacerbated in the context of testosterone therapy. Patients with a history of migraines should consider starting with a low dose and titrating upward as tolerated. Transdermal testosterone may be preferred to avoid any potential cyclic effect associated with injected testosterone.[25]

Mental health conditions: While hormones may contribute to mood disorders (such as in premenstrual dysphoric disorder or postpartum depression), these is no clear evidence that testosterone therapy is directly associated with the onset of or worsening of mental health conditions. In fact it has been found that transgender men experience improvements in social functioning and reduced anxiety and depression once testosterone therapy is begun.[26,27] Mental health conditions in transgender men should be approached with a broad differential diagnosis as in any other patient, taking caution to avoid relating all symptoms directly to gender dysphoria or testosterone therapy. Consider using a non-injected medication form to avoid the potentially cyclic levels, which could bring about or worsen existing mood symptoms.

Testosterone therapy in patients with a prior history of cancer: An active sex hormone-sensitive cancer is an absolute contraindication to testosterone therapy. For patients with a prior history of hormone sensitive cancer (i.e. breast), consultation with an oncologist is recommended.

Hair loss: Hair loss may begin soon after beginning hormone therapy, and is dependent on genetic factors. There are two patterns of hair loss seen in transgender men; Frontal and temporal recession, and male-pattern baldness (receding at the forehead and thinning at the crown). Both forms may cause alarm for patients, and in some cases result in a desire to discontinue therapy. Patients should be counseled prior to initiation of therapy on the risk, unpredictable nature, extent and time course of this condition. Management is similar to that in non-transgender men. Over the counter minoxidil, 5-alpha reductase inhibitors, and surgical approaches may be used. The 5-alpha reductase inhibitor finasteride blocks conversion of testosterone to the potent androgen dihydrotestosterone.[28] Finasteride 1mg daily (Propecia) is approved for male pattern baldness, while the 5mg daily dose (Proscar) is approved for management of prostatic hypertrophy.[29] Side effects may include reduced libido or sexual dysfunction, though impact on erectile function (manifesting as genital engorgement) may be less relevant for transgender men who have not undergone metaoidioplasty. In general, the 1mg daily dose has minimal sexual side effects. The negative impact on results of 5-alpha reductase inhibition on transgender men early in their course of testosterone therapy is unknown. As with non-transgender men, use of the 5mg daily dose of finasteride, or use of the more potent 5-alpha reductase inhibitor dutasteride, may result in excessive testosterone blockade, and resultant sexual side effects and regression of some virilization.

Metabolic syndrome and related conditions (obesity, hyperlipidemia, impaired glucose tolerance, polycystic ovarian syndrome/PCOS): Cardiovascular and diabetes considerations are covered elsewhere in these guidelines. Polycystic ovarian syndrome can manifest with any combination of impaired fasting glucose, dyslipidemias, hirsutism, obesity, and oligo- or amenorrhea with anovulation. Some of these features (hirsutism, oligo- or amenorrhea) may be welcomed by transgender men and present prior to testosterone administration. Testosterone administration is not contraindicated in the presence of PCOS, but patients should be monitored for

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hyperlipidemia and diabetes. **Transgender men with amenorrhea in the presence of testosterone are not believed to be at elevated risk of endometrial hyperplasia, due to the atrophic effects of testosterone on the endometrium (Grading T O M).**[30,31] It may be prudent to pursue endometrial evaluation prior to initiation of testosterone in transgender men with a current history of amenorrhea/oligomenorrhea. Testosterone replacement in non-transgender men is associated with an increased risk of obstructive sleep apnea (OSA).[22] It is unknown whether OSA is increased in transgender men after the initiation of testosterone. However, the behavioral health improvements seen with testosterone therapy may result in positive lifestyle changes that reduce obesity, disorders of glucose metabolism, or hyperlipidemia. **In all but the most severe cases (diabetes out of control, active unstable coronary artery disease), transgender men should be informed of risks, and if testosterone therapy continues to be desired, it should be continued with concurrent conventional management of metabolic disorders and their sequelae (Grading: X C S).**

Acne: Acne of the face and body are common side effects of virilizing hormone therapy. Approach to symptom management is consistent with established practices in non-transgender people. Patients can be reassured that acne tends to peak in the first year of testosterone therapy, and then declines.[32] Maintaining physiologic testosterone levels, and avoiding excessive peaks associated with prolonged inection dosing intervals may help minimize acne.

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9. Pelvic pain and persistent menses in transgender men

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Introduction: Pelvic Pain

Pelvic pain in transgender men can be a clinical challenge and has a broad differential diagnosis. Pelvic pain less than 6 months of duration is considered acute. Chronic pelvic pain, which is continuous or episodic pain in the lower abdomen or pelvis lasting more than 6 months, has a large differential.[1] History is a critical component to assessment and diagnosis. Key to the history is a detailed description of pain including onset, precipitating and palliating features, quality, radiation, severity and timing. A pain diary can be helpful to elucidate pain pattern and features and there are many available online (See http://www.partnersagainstpain.com/printouts/Daily_Pain_Diary.pdf).

The general approach to the workup of pelvic pain in transgender men is similar to that for non-transgender women. An anatomic approach to history gathering that considers urological, gynecologic, gastrointestinal, musculoskeletal, and psychological components is critical. Specific etiologies may be multifactorial, such as post-surgical adhesions with or without gastrointestinal symptoms, or endometriosis and/or pelvic floor muscle dysfunction. It is also critical to assess quality of life impact and determine what the patient would consider a favorable outcome. Most evaluation and treatment guidelines stress that chronic pelvic pain can be a diagnostic and therapeutic challenge, and success will depend on comprehensive and customized evaluation and multidisciplinary care.[2,3]

Etiologies

Specific medical etiologies to consider in transgender men include: atrophic or infectious vaginitis, cervicitis, cystitis, STIs, adhesions, post-surgical sequelae, musculoskeletal disorders, and neurogenic. Specific behavioral etiologies to consider include: depression, history of emotional trauma (including sexual assault or abuse, adverse childhood events),[4] and post-traumatic stress disorder. The use of testosterone has a dose dependent effect on vaginal tissue by inducing a hypoestroenic state which promotes atrophy, increases vaginal pH and thus increases increases the risk of vaginitis and cervicitis. Additionally, transgender men may have decreased access to or utilization of screening and therefore treatment for cervicitis and sexually transmitted infections.[5–7] Prior surgery may cause adhesions, scar tissue, bladder dysfunction, or nerve injury, which may lead to a lack of visceral mobility and contribute to pain.[8] It is unclear to what extent post-surgical adhesions cause pain independently, or via secondary mechanisms such as constriction or incarceration of other organs. Transgender men who have pelvic pain after hysterectomy but have retained one or both ovaries/gonads should be screened for a gonadal pathology. The interaction between a genotypic female skeleton and increased muscle mass as a result of testosterone therapy may result in changes in postural carriage. Additionally, recent and/or history of sexual trauma may be exacerbated among those with gender minority status. Engaging with medical

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professionals can be re-traumatizing in this setting; in all cases a trauma informed approach should be taken.[9]

Taking a pelvic pain history

The initial history should include a menstrual history including age of onset, frequency of menses or cyclical menstrual-like symptoms even if amenorrheic, duration of menses, last menstrual period, and if amenorrheic, for how long. Also assess for use of pain medication, and any association with testosterone dosing cycles. A comprehensive sexual history, including assessing for specific behaviors with other individuals such as (vaginal-vaginal), vaginal or anal or receptive penile sex, recognizing that many transgender men may engage in receptive vaginal sex.[10] Assess for potential risk of pregnancy and ectopic pregnancy; transgender men who have receptive vaginal sex with a partner with sperm are at risk for unintended pregnancy, including ovulation and conception without preceding menstrual bleeding. Also note any history of pelvic inflammatory disease. A surgical history should note for history of an open, laparoscopic or vaginal approach to inform suspicions of scar tissue and adhesions and subsequent symptomatology. Note any specific risks such as a ruptured appendix or history of pelvic inflammatory disease (PID). Other history should include screens for adverse childhood events, current domestic violence, and for substance use and overuse, including tobacco.

Physical exam

On exam assess for involvement of various abdominopelvic organs, including a check for costo-vertebral angle tenderness, palpation of the abdominal wall, noting any particular tenderness along prior surgical scars or point tenderness along scars or the abdominal wall in general. Palpate the bladder for localized sensitivity, and palpate the abdomen for visceral organ involvement. Consider a speculum exam only if clearly indicated, noting vaginal discharge or any evidence of vaginitis, and assess the general condition of vaginal tissues and the cervix. If a pelvic exam is necessary, consider starting with a pediatric speculum. If a bimanual exam is performed, note any cervical, adnexal or ovarian tenderness to palpation.[5] Also assess sensation in the vulvar area with cotton tipped nerve testing as well as sharp/dull differentiation, and examine of the pelvic floor via palpation of the obturator internus (two-digit exam with palpation of muscles at 4 to 5 o'clock and 7 to 8 o'clock; pain on flexion of the two fingers at these locations suggests pelvic floor dysfunction). Also if indicated consider a rectal exam, noting masses, tenderness, or hardened stool. Laboratory testing includes a urinalysis and culture, testing for Chlamydia and gonorrhea, vaginal pH, vaginal wet mount and KOH prep, and possibly a vaginal culture. A pregnancy test should be considered, however some patients who are not sexually active with someone capable of insemination may be offended by the suggestion of this test. It is best to explain to patients in advance that this test is part of a standard protocol, and if it is certain that pregnancy is not possible based on sexual behaviors, a pregnancy test may be omitted. Imaging should be performed using transabdominal or transvaginal ultrasound; in those men who have had a vaginectomy, a transrectal ultrasound may be an option. Some transgender men may decline vaginal ultrasound and/or bimanual exams due to potential exacerbation of gender dysphoria. These patients should not be forced to undergo a pelvic examination. In these cases proceed with an abdominal exam as well as laboratory and transabdominal ultrasound for the initial workup.

Specifically for transgender men, critical components of the assessment include timing of pain and associated symptoms in relation to initiation of testosterone therapy, moliminal timing (symptoms in relation to an expected menstrual cycle) even in the presence of amenorrhea, and a detailed history of prior surgeries and related organ inventory.

Testosterone-induced dyspareunia, vaginitis, and cervicitis

The use of testosterone often results in estrogen deficient, atrophic vaginal tissues akin to a post-menopausal state in cisgender women.[11–13] These atrophic vaginal tissues represent a decline in tissue resilience, skin barrier function, and increased susceptibility to altered microbial environment and resistance which may result in bacterial vaginosis, cystitis, or cervicitis.[14] Additionally, thin atrophic vaginal tissues are more susceptible to traumatic irritation from friction and sexual contact,[13] which may result in atrophic dyspareunia or vaginitis. Symptoms are often described as “rough” “sand-paper” and “burning” or “dry” vaginal irritation. Visual inspection consistent with atrophy will demonstrate thin pale tissues, a loss of rugae, loss of elasticity, friability, and dryness. It is also possible to find hyperemic, deep red vaginal tissue. Bacterial vaginosis is more common in the estrogen-deprived state. Wet mount, vaginal culture, vaginal pH and STI testing can aid in directing treatment. Interstitial cystitis should be considered when infectious causes have been rules out and symptoms localize to the urinary bladder. Vaginal estrogen to treat underlying atrophy may be warranted and a short course may be successful in restoring comfort. Patients may be reassured that vaginal estrogen is associated with mnimal systemic absorption and should not interfere with the desired effects of Testosterone. Other therapeutic approaches may include vaginal lubricants or vaginal moisturizers.[15]

Cyclic symptoms relating to testosterone dosing

Transgender men on testosterone may complain of pain that is associated with cyclical testosterone dosing, pelvic, and/or vaginal pain with penetration (with penis, fingers, dildo, etc), or orgasmic pain. The etiology of post-testosterone administration cramping is unclear. In one cross-sectional study 20% of respondents had a hysterectomy to decrease post-testosterone cramping and another 22% to stop “extreme bleeding and cramping.”[16] Trauma informed care can be effective, as are other treatments used for chronic pelvic pain such as pelvic floor therapy, vaginal lubrication with unscented products, or the use of tricyclic antidepressants.

Co-occurring mental health conditions

As with any pain syndrome, patients with chronic pelvic pain should be evaluated for depression and post-traumatic stress disorder (PTSD). These conditions may be simultaneously present in up to 35% of non-transgender female patients with chronic pelvic pain.[1] Multiple studies link adverse childhood events with increased incidence of chronic pain and depression. Pre-existing depression may exacerbate pelvic pain. Conversely, pelvic pain and living with a chronic pain condition may result in depression. A high percentage of those who have undergone sexual assault develop PTSD, and many of those who have PTSD may develop pelvic floor muscle dysfunction and pain.[17,18] The presence of pelvic pain as well as the related workup and evaluation may trigger PTSD, especially if such trauma relates to a prior sexual assault or otherwise involves the lower abdomen and pelvis. These symptoms may be even greater in transgender men for whom examination of genital and reproductive organs may be particularly challenging and triggering of

gender dysphoria, and result in avoidance of pelvic exams.[19] Collaboration with a specialist in mental health can be an important adjunct to pathophysiological evaluation and treatment.

Pharmacologic management

The initial approach to management should include NSAIDS, with other pain management medications used as indicated and appropriate. Changing to a more even testosterone transdermal testosterone regimen, or adding a progestagen such as the levonorgesterel IUD may address underlying hormonal causes.

Role of hysterectomy

In addition to non-surgical approaches, in some cases hysterectomy may have a role in the management of pelvic pain. **Depending on the preferences and reproductive goals of an individual patient, gynecologists may revise their therapeutic approach to consider hysterectomy earlier than they might in non-transgender women (Grading: X C S).** At the same time hysterectomy should not be viewed as a cure-all, and in some cases is not effective in improving pain. For this reason, transgender men with pelvic pain must be evaluated on a case-by-case basis due to the lack of evidence-based guidance at this time. Decision to perform oophorectomy should be based on the etiology of pelvic pain, presence of comorbidities, future fertility desires, and any future plans to stop taking testosterone.

Management of specific symptoms and syndromes

If pain is vulvar and there are no identifiable lesions or infections, Consider the use of topical 2-5% topical lidocaine placed on soaked cotton-ball and left in the vestibule overnight for general pain relief, or for 30 minutes prior to sexual activity as desired.

If pain is vulvar and exam is consistent with vaginal atrophy in the setting of testosterone administration, consider a short course of vaginal estrogen in doses and administration similar to that used for post-menopausal non-transgender women. Patients who are uncomfortable with intravaginal use may be instructed to place treatment cream on their external genitalia. Choice between tablets, creams, and rings depends on patient preference and formulary considerations.[20]

If pain is triggered by pelvic floor muscle palpation, consider referral to pelvic floor physical therapy, pelvic floor relaxation exercises, and even guided instruction on massage using self or partner's fingers or a massage tool.

If pain is abdominal, present in the abdominal wall or associated with abdominal scar tissue, consider treatment with 1% lidocaine instilled at trigger points in repeated administration.

If transvaginal ultrasound is required, consider a low-dose benzodiazepine such as lorazepam 0.5mg orally, 30 minutes prior to the procedure, in coordination with administration of 2-5% lidocaine ointment applied to the vulva and vagina 10 minutes prior to the procedure. Some patients may feel safer and more comfortable placing the ultrasound probe intra-vaginally themselves. These approaches may also be used in advance of a pelvic examination.

Introduction: Persistent menses & unexpected vaginal bleeding

Many transgender men chose not to undergo hysterectomy, oopherectomy and/or gender-affirming genital procedures.[19,21,22] For transgender men of reproductive age undergoing transition without hormones, or those whom have used testosterone and later discontinued it due to unwanted side effects such as balding, menses would be expected to be within standard reference ranges from 21-35 days between cycles with no inter-menstrual bleeding and lasting on average 2-6 days and ceasing on average at age 49.[23] Variation from these ranges warrants further gynecological investigation.

For those transgender men using physiologic doses of testosterone, cessation of menses is expected, typically within 6 months. Cessation of menses is driven by a combination of testosterone induced ovulation suppression, which may be incomplete, and endometrial atrophy.[12] However, the time to cessation of menses may vary. Factors that affect time to cessation of menses likely include: dose of testosterone, route of administration, frequency of testosterone administration, presence and functioning of ovaries, body habitus, and the presence of other structural or non-structural medical conditions of the uterus or ovaries. Transgender men with a history of abnormal cycles prior to initiating testosterone (*e.g.* frequent cycles, heavy irregular bleeding) may have underlying pathology, which could result in a prolonged or complicated path to cessation of menses once on testosterone. Therefore in patients with risk factors for endometrial hyperplasia and a degree of clinical suspicion, evaluation for and elimination of known causes of irregular bleeding should be considered concurrent with testosterone administration; those with pre-existing amenorrhea or oligomenorrhea may require evaluation for endometrial abnormalities prior to initiating testosterone. This includes ruling out pregnancy in transmen who are sexually active with partners who produce sperm.

Etiologies

Abnormal uterine bleeding (AUB) may be considered present in those who have continued bleeding after 6-12 months of male-range testosterone levels and suppressed LH and FSH. AUB may be related to a variety of structural and non-structural causes. These causes can be summarized by the internationally recognized Federation of Gynecology and Obstetrics (FIGO) PALM-COEIN classification system.[24] Structural causes of AUB include: endometrial polyps, adenomyosis, leiomyomata, endometrial hyperplasia, or malignancy. As a group these are best evaluated with imaging and endometrial biopsy. Despite prior suggestions that endometrial cancer risk may be increased in transgender men on testosterone,[25] longer-term data do not support this risk.[26] Non-structural causes of AUB include: pregnancy, coagulopathy, ovulatory dysfunction, endometrial, or iatrogenic causes. While the gold standard for pelvic imaging is transvaginal ultrasound, other approaches such as a sono-hystogram, transabdominal ultrasound, CT Scan, or MRI may be warranted. Both structural and non-structural causes should be investigated in consultation with a gynecologist. The decision to pursue transvaginal ultrasonography or endometrial biopsy should not be taken lightly in transgender men who may find these procedures invasive. Noninvasive diagnostic approaches such as watchful waiting for induction of amenorrhea 6 months after initiation of testosterone, observing for a withdrawal bleed after a progestin challenge, or use of a transabdominal approach to ultrasonography should all be considered. Persistent menses despite testosterone may also be related to body habitus; those with higher

levels of body adipose tissue have higher endogenous estrogen levels and increased conversion of testosterone to estradiol through the peripheral aromatization process.

Therapeutic approaches based on etiology

Increasing the dosage and frequency of dosing (1 and 2 weeks) of intramuscular testosterone has been found to be positively correlated with rapidity of amenorrhea induction.[27] The time to cessation of menses has been reported as ranging from 1-13 months [27–31] and in addition to individual genetic and physiologic factors may very well depend on the formulation or route of testosterone administration.[28]

Physiologically, amenorrhea induction rates should correlate to increased testosterone levels (to physiologic male range) as well as possible decreased estrogen levels seen with androgen therapy, however many will achieve amenorrhea despite elevated estrogen levels and sub-physiologic male testosterone levels. For example, one study of transgender men presenting for initiation of cross-sex hormones found that 84% of those completing the study were amenorrheic at 6 months. This was despite many only 58% achieving physiologic male total testosterone levels and 68% achieving physiologic male free testosterone levels.[30] However in the setting of persistent menses, adjustment of hormone regimen and dosing may be appropriate. The addition of an oral, injected, implanted, or intrauterine (IUD) progestagen may serve as an adjunct to induction of amenorrhea. Endometrial ablation can be considered [31] for those transgender men who do not desire future fertility and who also either decline hysterectomy or have surgical complications. The levonorgestrel intrauterine system (IUS/IUD), which in non-transgender women can either significantly decrease menstrual flow or fully induce amenorrhea, has the added contraceptive benefit for those at risk since some may still ovulate despite male physiologic testosterone levels.[32]

Aromatase inhibitors (AIs) such as anastrazole or letrazole may be considered as short-term adjunctive therapy in achieving amenorrhea for those with persistent menses on testosterone. Aromatase is expressed throughout the body including the ovaries, endometrium, skin, bone, breast, brain and adipose tissue. AIs have been used for the treatment of estrogen receptor positive breast cancer, endometriosis, and ovulation induction. AIs have also been shown to reduce vaginal bleeding and pelvic pain in combination with other hormone therapies such as progestins or combined oral contraceptives.[33–35] In non-transgender women, treatment with AIs without add-back estrogen therapy has led to symptoms of medical menopause: hot-flashes, arthralgias, mood disturbances, fatigue, vaginal dryness, decreased bone mineral density, and fractures.[36] In transgender men concurrently using testosterone, these symptoms may be attenuated or even absent.

What remains unclear is the AI dose necessary in the setting of male-range testosterone levels in comparison with the roughly 10 fold lower physiological female estrogen levels released by the ovaries. Since AIs have been used for ovulation induction, contraception should be considered in transgender men who may be at risk for pregnancy. Weight loss plays a critical role in all cases for health promotion as well as resulting in amenorrhea through reduction of adipose containing aromatase.

Helpful resources

- International Pelvic Pain society: http://www.pelvicpain.org

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- American Physical Therapy Association: http://moveforwardpt.com/Default.aspx

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10. Approach to genderqueer, gender non-conforming, and gender nonbinary people

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Introduction

Genderqueer, gender non-conforming, and gender nonbinary (GNB) people do not live within the binary gender narrative. A brief discussion of terminology and pronouns will be followed by an overview of the unique considerations for nonbinary hormonal and surgical transition.

Terminology

With a broad spectrum of gender identities and expressions, GNB people may identify as both male and female; neither male nor female; in between genders; on or outside the gender spectrum; or beyond the gender binary system, not having a gender at all—identifying as agender or genderless. Some may simply identify as "queer," which has been reclaimed as a respectful umbrella term encompassing a broad range of gender identities, expressions, and sexual orientations. GNB people are as authentic in their gender status as transgender people who present with more binary gender identities or expressions. Nonbinary gender terms evolve and change rapidly; spelling and hyphenation vary widely. Some additional examples of terms used by GNB people include [1]:

- gender fluid
- gender ambiguous
- pangender
- neutrois
- gender bender
- gender blender
- gender smoothie
- gender expansive
- masculine of center
- feminine of center
- androgyne

Pronouns: People who are gender nonbinary may choose to use gender neutral pronouns such as "they," "them," and "their," or other gender neutral pronouns such as "zie(ze)/hir," instead of she/her, he/his.

As with all transgender people, identifying and using the chosen name and pronoun are central to appropriate patient care. Providers are encouraged to familiarize themselves with the diversity of pronouns which may be used by GNB people. It is not essential to memorize the chart, and if there are any questions as to how to use and conjugate pronouns for a specific person, it is recommended that you ask for clarification. Conjugation of gender neutral pronouns are described below:

Table 10-1. Pronoun Reference Sheet

3rd Person Singular Subjective	3rd Person Singular Objective	3rd Person Singular Possessive	3rd Person Singular Reflexive
She	Her	Her	Herself
He	Him	His	Himself
They	Them	Their	Themselves
Ze	Zir	Zir/Zirs	Zirself
Xe	Xem	Xyr/Xyrself	Xemself
Ze	Hir	Hir/Hirs	Hirself
Per	Per	Per/Pers	Perself

Source: Adapted from the University of Alberta Student Union

Transition

As with people who have binary transgender identities, the process of gender affirmation and transition for those who are nonbinary is for some limited to an internal or purely social process; for others the process may involve a variety of gender-affirming medical and/or surgical interventions. The WPATH Standards of Care Version 7 are now more inclusive of GNB identities and recognize the need for and appropriateness of an individualized approach. [2]

Specific approaches to gender affirmation for GNB people

The approach to hormone therapy should be guided by the person's desired configuration of secondary sex characteristics. Strategies may include using hormones at a lower dose or for a limited period of time. Nonbinary people on the feminine spectrum may choose to only use an androgen blocker, and/or use estrogen at a very low dose, or for a short time.

For those on the masculine spectrum, low dose testosterone can be acceptable, especially if menses is not a source of dysphoria, as low dose may not stop menses. If gender dysphoria worsens with menses, testosterone may be increased. If a GNB person does not want the degree of masculinization resulting from the higher doses of testosterone that could induce menstrual cessation, other approaches can be explored. These could include intramuscular medroxyprogesterone, the levonorgestrel intrauterine system or an etonogestral implant, all of which also provide contraception. On occasion, masculine spectrum clients might choose continuous combined oral contraceptives for cessation of menses as well as for contraception. Surgical options for cessation of menses may include uterine ablation or hysterectomy.

It is important to remember to address reproductive and fertility considerations as part of informed consent for medical and surgical approaches, discussed in greater detail in other sections of this protocol.

Limitations on the ability to predict specific outcomes with any given regimen should be discussed with GNB patients. Some desired combinations of results (such as a deepened voice without facial or body hair growth) may not be possible.

GNB persons may also pursue a variety of gender-affirming surgeries and procedures, including chest reconstruction or breast augmentation and genital surgeries. A masculine spectrum nonbinary person may choose to keep their vagina when pursuing metoidioplasty; this is also an option for a more traditionally binary transgender man. A feminine spectrum nonbinary person may choose to have vaginoplasty but not desire breast development and not pursue hormonal transition; in these cases hormone replacement will be necessary after gonadectomy to maintain bone health, and surgery should only be pursued after an appropriate evaluation by an experienced and qualified mental health provider. Non-medical approaches such as packing, tucking, and binding may be central to a GNB person's expression. Some GNB people may express sharply contrasting masculine and feminine characteristics simultaneously; for example, breasts and facial hair as part of authentic expression.

Other considerations: Challenges for the gender nonbinary person include the lack of nonbinary gender markers for documentation in medical records and in legal identification, such as passports and drivers licenses. Advocacy groups are making efforts to challenge the binary system, introducing nonbinary gender concepts and terminology into legal, medical, mental health, and educational arenas.

A more substantial discussion of gender nonbinary experiences can be found in blogs and websites (e.g., Neutrois Nonsense) [3] and books such as *Trans Bodies, Trans Selves.*[4]

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11. Cardiovascular disease

Primary authors: Asa Radix, MD, MPH and Madeline B. Deutsch, MD, MPH

Introduction

Sex is an independent predictor of cardiovascular health outcomes. The role played by sex hormones in this difference between the sexes is unclear. A 2010 Cochrane analysis found no interaction between menopausal hormone therapy and all-cause mortality, cardiovascular-related mortality, non-fatal myocardial infarction or angina, or the need for bypass surgery or coronary angioplasty.[1] This same analysis found a slight increase in risk of stroke (RR 1.26, 95% CI 1.11-1.43, number needed to harm = 164); however a 2015 Cochrane update found no increased risk of stroke among the subgroup of women who began hormone therapy less than 10 years after menopause, which is more likely representative of transgender women.[2] Few studies have investigated cardiovascular disease risk and burden among transgender people on hormone therapy, adjusting for risk factors such as tobacco use. Larger studies have been retrospective and did not adjust for numerous coexisting risk factors. Prospective studies have been smaller and over shorter terms. Any analysis of the possible negative effects of hormone therapy on cardiovascular disease and stroke should take into consideration the significant benefits of hormone therapy on quality of life and psychosocial functioning.[3–5]

Evidence from several studies suggests that cardiovascular risk is unchanged among transgender men using testosterone compared with non-transgender women.[6–8] Evidence in transgender women is less clear. Some studies have found increased morbidity and mortality from myocardial infarction and stroke compared with non-transgender men, however these studies did not adjust for a number of risk factors including tobacco use, obesity, and diabetes.[6–8] The largest study published to date is a report on mortality in a retrospective cohort of more than 1000 Dutch transgender women and men which did not control for a number of risk factors, including tobacco use. All-cause as well as cardiovascular- and cerebrovascular-specific mortality among transgender men did not differ from the general Dutch population. Among transgender women, all-cause mortality was 51% higher (95% CI 47 to 55) than in the general Dutch population, with the overwhelming majority of the difference due to HIV, drug overdose and suicide; a 64% increased risk (95% CI 43 to 87) in cardiovascular mortality was seen, however no significant difference was seen for cerebrovascular mortality.[9]

Several factors may contribute to an elevation of cardiovascular disease in transgender women, such as higher rates of tobacco use, obesity, diabetes and lipid disorders, and reduced physical activity.[7] Older studies demonstrating increased morbidity and mortality among transgender women included users of high doses (>100mcg/day) of ethinyl estradiol, a known thrombogenic synthetic estrogen used in oral contraceptives at typical doses of only 20-30mcg/day.[10] A meta-analysis of lipids and blood pressure in transgender people using hormone therapy found a mean increase in triglycerides of 23mg/dl (95% CI 5 to 42) among

transgender women, and a mean increase in triglycerides of 31mg/dl (95% CI 7 to 55) and systolic blood pressure of 1.7mmHg (95% CI 0.2 to 3.3), and mean decrease in HDL of 6mg/dl (95% CI 0.7 to 11) among transgender men; all other lipid and blood pressure parameters showed no statistically significant change.[11] Such statistically significant changes have small effect sizes and are of questionable clinical significance, especially in the context of primary prevention.

Direct study of the effects of hormones on lipids and blood pressure in transgender people has been limited. A retrospective study of lipids in 169 Austrian transgender people found trends of poorer lipid profiles in both transgender women and men at 5 years however these changes were mild at most, and seemed to be mitigated to some degree by the use of transdermal estradiol.[12] A prospective 6 month study of a young and healthy cohort of 31 transgender women and 17 transgender men in the U.S. found modest overall improvement in lipids in transgender women and only a slight reduction in HDL in transgender men; while statically significant, the effect sizes were small and of questionable clinical significance.[12–14]

Calculating risk

Current American Heart Association – American College of Cardiology guidelines for prevention and lipid management involve the use of sex-specific calculators to determine risk and guide interventions.[14] Determination for the use of aspirin also uses these calculators when conducting a risk-benefit assessment for gastrointestinal bleeding. Currently there is no guidance on whether to use risk calculators based on natal sex or affirmed gender. It may be reasonable to use natal sex-based calculators in transgender people who have transitioned later in life, given their long-term exposure to the natal hormonal milieu. However with an increasing percentage of transgender people beginning hormone therapy in adolescence and young adulthood, affirmed gender-based calculators may be more appropriate in these cases. Ultimately a primary goal is to calculate a realistic risk-benefit ratio between the benefits of statin therapy or aspirin and the risks of these treatments. **Depending on the age at which hormones are begun and total length of exposure, providers may choose to use the risk calculator for the natal sex, affirmed gender, or an average of the two (Grading: X C M)**. Another goal of calculating risk is to provide adequate information during the informed consent process to allow transgender people of any age, and with or without existing cardiovascular or cerebrovascular disease, to make informed decisions about the long term implications of gender-affirming hormones.

Reducing risk

For transgender women with cardiovascular risk factors or established CVD, using the transdermal route of estrogen may be preferred due to lower rates of venous thromboembolism, and lack of associated changes in lipid profile or markers of coagulation (Grading: NT O M).[15,16] Additional modifiable interventions to reduce risk include smoking cessation, weight loss, management of diabetes, and encouraging physical activity. It is theoretically possible that the psychosocial benefits of hormone therapy may

have an independent and protective effect through reduction of stress, improved body image resulting in healthier lifestyle choices, reduced tobacco use, and increased physical activity.

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12. Diabetes mellitus

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Recommendations for diabetes screening in transgender patients (regardless of hormone status) do not differ from current national guidelines.

The effect of gender-affirming hormone therapy on diabetes risk or disease course is unclear. A Dutch case-control study noted an increased prevalence of type 2 diabetes mellitus among transgender men and women in comparison to both age matched non-transgender male and female groups, however the study did not adjust for other risk factors.[1] A study of the effects of gender-affirming hormones on insulin resistance in transgender women and men found that transgender women may experience some increase in markers of insulin resistance, while transgender men exhibited no change.[2] Some data from non-transgender men suggests that testosterone lowers insulin resistance.[3] Data are mixed on the presence of increased rates of polycystic ovarian syndrome (PCOS) in transgender men prior to hormone therapy. While non-transgender female patients with PCOS require close monitoring for development of diabetes due to marked insulin resistance,[4,5] it is unclear if this risk remains once the hormonal milieu has been modified with the addition of testosterone. While insulin resistance serves as a useful surrogate marker to inform risk, outcome studies using a diagnosis of diabetes as the end point have not been conducted.

Otherwise young and healthy transgender people will often seek medical care with the sole purpose of obtaining hormone therapy or surgery. When this care is provided within the context of comprehensive primary care, identification of risk factors such as obesity, PCOS, metabolic syndrome, impaired fasting glucose, or diabetes may occur earlier than would have happened if the person were not transgender. This can be viewed as an opportunity to improve health particularly in transgender women, who may be at increased cardiovascular risk. However, caution should be used to avoid making gender-affirming care contingent on tight control of these other conditions. Numerous anecdotes exist of poorly controlled diabetic transgender patients who had improvements in self-care and resultant decline in hemoglobin A1c after initiation of gender-affirming hormones.

Management of diabetes in transgender patients has not been specifically studied. Testosterone package inserts recommend monitoring as serum glucose may be lowered in patients with diabetes receiving testosterone. It is reasonable to maintain heightened monitoring of indicators such as fasting glucose and hemoglobin A1c when initiating or adjusting hormone therapy. While the WPATH Standards of Care recommend that conditions such as diabetes be “reasonably well controlled” prior to initiating hormone therapy, no absolute criteria have been proposed, and the potential adverse effects on blood sugar should be weighed in consideration of the benefits of hormone therapy.

Patients with diabetes seeking gender-affirming surgeries represent a special group for whom aggressive treatment to normalize glucose control is desirable. Genital surgeries and breast/chest surgeries involve microvascular techniques. Healing, avoidance of infection,

functionality and cosmesis are thought to be improved with better glycemic control. While the presence of diabetes in itself may not be a contraindication for any of these surgeries, careful coordination between the surgeon and the provider managing the diabetes is recommended.[6]

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13. Bone health and osteoporosis

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Introduction

Adaptation of recommendations for osteoporosis screening to transgender populations is complicated by existing recommendations that vary widely for non-transgender people, including lack of consensus about screening for non-transgender men, and no U.S. national level recommendations on the frequency of screening.

Osteoporosis screening is currently age- and sex- based, and also individualized on the basis of risk factors. There are a number of lifestyle, genetic, endocrinologic, hematologic, rheumatoid and autoimmune diseases, as well as medications that contribute to osteoporosis. Known risk factors for osteoporosis include Caucasian or Asian race, older age, alcohol > 10 drinks/week, low body mass index, smoking, chronic corticosteroid use, hypogonadism, rheumatoid arthritis, hyperparathyroidism, immobility, vitamin D deficiency and HIV infection.[1,2]

Osteoporosis risk in transgender women

In one study, researchers found that transgender women had factors which may contribute to an increased risk of osteoporosis, independent of and existing prior to hormone use, such as reduced levels of physical activity, lower muscle mass and grip strength, and lower levels of vitamin D.[3] Studies investigating BMD in transgender women receiving hormones have shown both lower, higher and no change in bone density after initiating hormones.[4–11] The differences in results may be due to the regimens used (some used unopposed androgen blockers for a period of time before initiating hormones) and length of follow-up. Known risk factors for osteoporosis include underutilization of hormones after gonadectomy or use of androgen blockers without or with insufficient estrogen. GnRH analogues also may result in short term decrease in bone mineral density (ie. GnRH analogues without concurrent estrogen, and when estrogen added, or blockers stopped bone density returns to normal).

Osteoporosis risk in transgender men

Most published studies to date have shown either no change, or an increase in bone mineral density in transgender men treated with testosterone. Risk factors for osteoporosis in this population include oophorectomy before age 45 without optimal hormone replacement.[4,6,9–13]

Current screening guidelines in non-transgender populations

There are no consistent guidelines on the optimal frequency of screening in non-transgender people. The WHO guidelines suggest every 10 years. A recent U.S. NIH funded study suggests intervals of approximately 15 years for normal bone density or mild osteopenia, 5

years for moderate osteopenia, and 1 year for advanced osteopenia. Screening intervals in transgender people can be based on these recommendations as well. All professional organizations recommend screening for all non-transgender women over age 65. Some recommend earlier screening in those with risk factors. Some older guidelines recommend screening in non-transgender men after age 70 or in those with risk factors, while others and more recent guidelines make no recommendations for men.

Recommended screening for transgender women and men

There is insufficient evidence to guide recommendations for bone density testing in transgender women or men. **Transgender people (regardless of birth-assigned sex) should begin bone density screening at age 65. Screening between ages 50 and 64 should be considered for those with established risk factors for osteoporosis. Transgender people (regardless of birth assigned sex) who have undergone gonadectomy and have a history of at least 5 years without hormone replacement should also be considered for bone density testing, regardless of age (Grading: X C W).**

Modality of screening

Dual-energy x-ray absorptiometry (DEXA) of the hip and lumbar spine.

Special considerations

There have been no studies to determine whether clinicians should use the natal sex or affirmed gender for assessment of osteoporosis, e.g., when using the FRAX® tool (http://www.shef.ac.uk/FRAX/). Although some researchers use the natal sex, with the assumption that bone mass has usually peaked for transgender people who initiate hormones in early adulthood, this should be assessed on a case by case basis until there is more data available. This assumption will be further complicated by the increasing prevalence of transgender people who undergo hormonal transition at a pubertal age, or soon after puberty. Sex for comparison within risk assessment tools may be based on the age at which hormones were initiated, and length of exposure to hormones. In some cases it may be reasonable to assess risk using both the male and female calculators and using an intermediate value.

Weak evidence suggests that agonadal states contribute to an increased risk of osteoporosis, however long term studies are lacking.[14] **Transgender people without gonads, and who are not using hormone replacement, should follow screening and prevention guidelines for agonadal or postmenopausal women, regardless of birth-assigned sex or gender identity (Grading: X C W).**

Advice should be given to modify risk factors for osteoporosis, including tobacco cessation, Correct low vitamin D levels, maintain calcium intake in line with current guidelines for non-transgender people, weight bearing activity, and moderation of alcohol consumption.

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14. Transgender health and HIV

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Introduction

General guidelines for HIV screening, prevention, and care do not differ for transgender people; however, **HIV services for transgender people should address the specific biological, psychological, and social needs of this population**.[1] HIV prevention and care programs adapted from practices developed for non-transgender men who have sex with men (MSM) or for non-transgender women fail to address the unique structural factors and inequities that increase HIV risk and produce barriers to care among transgender people. For example, many trans women (especially young adults, racial/ethnic minorities and undocumented individuals) experience intersecting discrimination and high rates of trauma, unstable housing, poverty, incarceration, and unemployment, which all negatively impact HIV risk, testing, and continuing care.

Antiretroviral treatment (ART) recommendations for transgender women using feminizing hormones are complicated by lack of data on forms of estrogen commonly used for gender-affirming hormone therapy; therefore there is a need to extrapolate data on drug-drug interactions from studies using combination oral contraceptives. Little data exist on HIV among transgender men, likely due to much lower HIV prevalence. However, evidence for HIV risk among transgender men who have sex with men is growing.[2–4]

In line with national guidelines from the U.S. Centers for Disease Control (CDC) and the U.S. Preventive Services Task Force (USPSTF) that recommend universal screening for HIV, all transgender persons should be screened at least once for HIV. After initial screening of all patients, repeat screening is based on HIV risk assessment. **Effective risk assessment requires the ability to obtain an accurate sexual history that includes anatomy-specific sexual behavior**. Transgender women who have a penis should be asked about insertive intercourse as well as receptive intercourse. Transgender women and men who have a vagina should be asked about vaginal as well as anal intercourse, although the risk of HIV acquisition via receptive vaginal sex in a transgender woman who has undergone vaginoplasty is unknown. Risks associated with male genital reconstructions such as phalloplasty or metaoidioplasty are unknown. Open-ended questions that do not assume the anatomy and sex or gender of partners are likely to provide the most information.

Prevention

Condoms continue to be a mainstay of HIV prevention. However, using condoms may be difficult for transgender women taking feminizing hormones due to reduced tumescence. Transgender women may also lack the agency to negotiate the use of condoms during sex, especially those who engage in sex work.[5] The role of condoms in transgender men who have undergone phalloplasty is unknown and likely depends on the specific anatomy and

surgical approach used. “Female” condoms may be an option for transgender men who engage in receptive vaginal sex.

Newer biomedical HIV prevention interventions increase the options available to reduce HIV risk. There are two categories of medications currently available that are designed to be taken by people who do NOT have HIV for the purposes of preventing HIV acquisition: 1) pre-exposure prophylaxis (PrEP) and 2) non-occupational post-exposure prophylaxis (nPEP).

Pre-exposure prophyalxis (PrEP)

Daily oral PrEP with the fixed-dose combination of tenofovir disoproxil fumarate (TDF) 300 mg and emtricitabine (FTC) 200 mg has been shown to be safe and effective in reducing the risk of sexual HIV acquisition in studies with MSM, non-transgender heterosexual adults, and people who inject drugs. CDC has published detailed clinical guidelines for the use of PrEP for individuals at high risk for HIV acquisition.[6]

A sub-analysis of data from a large multi-national randomized controlled trial of PrEP suggests that PrEP is effective in preventing HIV in transgender women when they take the medication as prescribed. However, no efficacy was found among transgender women on “intent-to-treat” analysis.[7] Importantly, all of the transgender women who seroconverted in the PrEP arm of the study had no detectable TDF in their blood, suggesting that they did not take the medication as prescribed. There are no known drug-drug interactions between TDF/FTC and gender-affirming hormones, nor are there any known contraindications to concomitant use of PrEP with gender-affirming hormone therapy. To effectively engage transgender women, PrEP programs should use trans-inclusive marketing strategies, address community concerns about drug interactions between TDF and gender-affirming hormones, and ensure services are delivered by a provider who is knowledgeable about trans health.[8]

Non-occupational post-exposure prophylaxis (nPEP)

The use of nPEP in transgender people should follow guidelines as in non-transgender people. As with PrEP, social marketing and awareness campaigns should be tailored to transgender populations.

Treatment of HIV concurrent with hormone therapy

HIV and its treatment are not contraindications to hormone therapy. In fact, providing hormone therapy in the context of HIV care may improve engagement and retention in care [9] as well as adherence and viral load.[10,11] The World Health Organization [12] as well as the U.S. Department of Health and Human Services [13] recommend antiretroviral therapy for everyone living with HIV, regardless of HIV viral load or CD4 count.[14]

Metabolism of estrogens occurs via the cytochrome P450 enzyme system; therefore there are potential drug-drug interactions with ART agents. Information about these interactions are based on studies in the context of contraception and typically include ethinyl estradiol rather than 17-beta estradiol recommended for feminization. Data are not available on drug interactions between hormones and ARTs in the setting of transgender care. However, **based on available data, most ART can be likely used safely used with estrogen with two**

exceptions: Amprenavir (Agenerase) and unboosted fosamprenavir (Lexiva) are not recommended for co-administration with estrogens due to a decrease in amprenavir serum concentrations.[13]

Limited data suggest that non-nucleoside reverse transcriptase inhibitors (NNRTIs), ritonavir (RTV)-boosted protease inhibitors (PIs), or cobicistat with integrase strand inhibitors (INSTIs) may have an effect on blood levels of some hormonal contraceptive agents. There are no known drug-drug interactions between ethinyl estradiol and nucleoside reverse transcriptase inhibitors (NRTIs), CCR5 antagonists, fusion inhibitors, or non-boosted INSTs. Interactions vary between an decrease or increase in blood levels of ethinyl estradiol, norethindrone, or norgestimate. Such interactions could potentially result in decreased hormonal efficacy or increase hormonal adverse effects.

Transgender women may prioritize hormone therapy over other care; such symptoms may result in decreased ART adherence if it is perceived that these symptoms are due to ART. Consider monitoring estradiol levels and/or making empiric dosing or regimen adjustments based on development of or changes in estrogenic symptoms when initiating or changing anti-retroviral therapy.

There are limited data on the interactions between ART and masculinizing hormones or other drugs used as anti-androgens for feminization. Currently, there are no documented interactions between ART and either androgens (e.g., testosterone) or anti-androgens (e.g., spironolactone).

Hormone therapy and management of HIV-related opportunistic infections and prophylaxis

Patients with immunosuppression due to HIV may require treatment or prophylaxis for opportunistic infections. Most commonly this involves Trimethoprim – Sulfamethoxazole (TMP-SMX) daily for prevention of PCP pneumonia. A significant interaction leading to hyperkalemia, hospitalizations and deaths has been described in non-transgender patients between spironolactone and TMP-SMX. It is advisable to maintain a high index of suspicion when these drugs are used in combination, with frequent monitoring of serum electrolytes and renal function. Avoiding this combination is especially recommended especially in older patients.[15,16]

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15. Transgender health and hepatitis C

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Introduction

While there is no evidence that being transgender is an independent risk factor for hepatitis C, some transgender sub-populations may be at increased risk. Rates of HIV and injection drug use are higher among transgender people, and transgender people may inject hormones or soft tissue fillers such as silicone.[1] Sharing or use of contaminated needles, syringes, or vials represents a possible risk factor for infection with blood borne pathogens, including hepatitis C, though the actual prevalence of needle sharing among transgender people is believed to be low.[2,3] Nevertheless, patient education for transgender people using injectable hormones should include advice to use sterile syringes only once without sharing. Providers should screen all transgender people for hepatitis C risk factors and perform an antibody screen in those determined to be at risk, as per current guidelines. All transgender people who inject soft tissue fillers should be screened for hepatitis C.

Chronic HCV and hormone therapy

Chronic Hepatitis C is not a contraindication to hormone therapy. Both estrogen and testosterone undergo hepatic metabolism, and routine monitoring of hepatic function has been recommended. However, neither hormone has been associated with hepatic injury or abnormal liver function tests. Monitoring of liver function in patients with chronic hepatitis C infection should proceed as routinely recommended by disease stage and risk factors for progression dictate. Non-oral forms of hormone therapy avoid first pass through liver metabolism and may be preferred for patients with liver disease, though there is no specific evidence to support this recommendation.[4]

Hepatic dysfunction and malignancies have been noted with oral methyltestosterone. However, methyltestosterone is no longer available in most countries and should no longer be used as part of a gender-affirming hormone regimen. Oral testosterone undeconoate gel caps available outside the United States were not associated with hepatic dysfunction in a 10-year safety study among non-transgender males.[5] No published data is available on clinical outcomes among transgender individuals with chronic viral hepatitis taking hormone therapy.

Chronic HCV treatment and hormone therapy

The American Association for the Study of Liver Diseases recommends treatment for all patients with chronic HCV infection, except those with short life expectancies owing to comorbid conditions.[6] Antiviral medications used for treatment of hepatitis C vary based on HCV genotype, stage of disease, and HCV treatment history; most are metabolized via the same cytochrome P450 pathway as oral estrogens.[7] The table below summarizes currently known drug interactions between estrogens and hepatitis C antivirals.

Table 15-1. Drug Interactions between Estrogens and HCV Antivirals

Contraceptives & Hormone Replacement	Boce-previr	Daclat-asvir	Ledipasvir/ Sofosbuvir	OBV/PTV/r	OBV/PTV/r + DSV	Sime-previr	Sofos-buvir	Tela-previr
Desogestrel	?	✓	✓	?	?	✓	✓	?
Dienogest	?	✓	✓	?	?	✓	✓	?
Drospirenone	X	✓	✓	✓	✓	?	✓	?
Estradiol	?	✓	✓	?	?	✓	✓	?
Ethinyl estradiol	?	✓	✓	X	X	✓	✓	?
Norethisterone (Norethindrone)	?	✓	✓	?	?	✓	✓	?

Legend
X = These drugs should not be coadministered
? = Potential interaction – may require close monitoring, alteration of drug dosage or timing of administration
✓ = No clinically significant interaction expected

Abbreviations
OBV/PTV/r = ombitasvir/paritaprevir/ritonavir;
OBV/PTV/r + DSV = ombitasvir/paritaprevir/ritonavir + dasabuvir.

Table drawn from HEP Drug Interactions Checker (http://www.hep-druginteractions.org/interactions.aspx)

Co-administration of estradiol with boceprevir, ombitasvirparitaprevir/ritonavir, dasabuvir, or telaprevir could potentially increase estradiol exposure; however, co-administration has not been studied. Co-administration of ethinyl estradiol with boceprevir or telaprevir was found to decrease estrogen levels.[8] Elevated liver enzymes were seen in cisgender women taking ethinyl estradiol with OBV/PTV/r and concomitant use (with or without DSV) is not recommended. In summary, ethinyl estradiol is contraindicated with ombitasvir/paritaprevir/ritonavir. There is no evidence on potential interactions between HCV anti-viral meds and 17-beta estradiol, and providers should consider avoiding OBV/PTV/r with or without DSV in patients using estradiol.[8] Transgender women on estrogen therapy should be closely monitored when starting or stopping HCV treatment.

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16. Transgender people and sexually transmitted infections (STIs)

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Introduction

National guidelines exist on how to take a sexual history and the recommended frequency for sexually transmitted infections (STIs) screening by gender and risk group.[1] The 2015 CDC guidelines 2015 STD Treatment Guidelines do include transgender men and women as special populations, and recommend risk assessment based on current anatomy and sexual behaviors, awareness of symptoms consistent with common STIs, and screening for asymptomatic STIs based on behavioral history and sexual practices.[2] However, these guidelines do not include specific screening or interval recommendations. Presented here are specific considerations when screening for STIs in transgender people. Recommendations for management of confirmed STIs does not differ from those for non-transgender people. Screening intervals should be based on risk, with screening every three months in individuals at high risk (multiple partners, condomless sex, transactional sex/sex work, sex while intoxicated).

In practice, transgender people may avoid screening procedures and physical examinations due to fear of discrimination,[3] encountering providers who are inadequately trained in transgender health,[4] or personal discomfort with the visit or exam.[5] It is important for clinicians to build a trusting and respectful rapport and to clearly explain reasons for asking sexually explicit questions and performing various components of the exam.

Sexual history and risk assessment

Clinicians should assess risk for sexually transmitted infections (STIs) based on the patient's sexual behaviors and current anatomy**.** Because transgender people differ in hormone use, history of gender-affirming surgical procedures, and patterns of sexual behavior, providers should avoid making any assumptions about presence or absence of specific anatomy; sexual orientation; or sexual practices. Anatomy and behavior may change over time; therefore, it will be important to assess for changes that may impact STI risk. To facilitate a respectful rapport, use the patient's preferred terminology to refer to anatomic parts.

The Fenway Guide provides suggested sexual risk assessment questions [6] including:

- Are you having sex? How many sex partners have you had in the past year?
- Who are you having sex with? (including anatomy and gender of partners)
- What types of sex are you having? What parts of your anatomy do you use for sex?
- How do you protect yourself from STIs? (How often do you use condoms/barriers? Any use of PrEP?)
- What STIs have you had in the past, if any? When were you last tested for STIs?

- Has your partner(s) ever been diagnosed with any STIs?
- Do you use alcohol or any drugs when you have sex?
- Do you exchange sex for money, drugs, or a place to stay?

These questions are components of a complete sexual history which would include relationship types, frequency of sexual activity, age of sexual debut, use of drugs or alcohol during sex, sex work history, history of sexual abuse, and sexual function.[7]

Physical exam and STI screening

Serologic screening recommendations for transgender people (HIV, Hepatitis B and C, Syphilis) do not differ in recommendations or technique from those for non-transgender people.

Many transgender people have experienced violence, including sexual violence.[3] Therefore, providers should take a chaperone trauma-informed approach to the exam, whenever possible.[8] This approach is grounded in providing a sense of control to the patient and includes: greeting patients while they are dressed; explaining what you plan to do and why; providing information, choices, and decision-making ability.[9] Some transgender patients may prefer to collect their own specimens to allow for greater control over the screening process. Self-collected vaginal and rectal swabs as well as urine specimens have equivalent sensitivity and specificity to provider-collected samples for nucleic acid amplification testing for gonorrhea, chlamydia, and trichomonas.[1] The physical exam should focus on organs that are present and have the potential for infection based on the sexual history.

Transgender women who have undergone vaginoplasty (either penile inversion or colo-vaginoplasty) do not have a cervix, therefore screening for cervical HPV is not appropriate. Some surgical approaches include the use of urethral tissue, which could result in mucosal infectious such as chlamydia or gonorrhea. The risk of infection of intact, inverted penile skin with these organisms is unknown, though lesions such as a syphilitic chancre, herpes or chancroid are possible. When clinically indicated due to symptoms, a physical examination and appropriate testing should be performed. The anatomy of a neovagina created in a transgender woman differs from a natal vagina in that it is a blind cuff, lacks a cervix or surrounding fornices, and may have a more posterior orientation. As such using an anoscope may be a more anatomically appropriate approach for a visual examination. The anoscope can be inserted, the trocar removed, and the vaginal walls visualized collapsing around the end of the anoscope as it is withdrawn. There is no evidence to guide a decision to perform routine pelvic exams on transgender women in order to screen for such conditions as [formerly penile skin] warts or lesions.

Transgender women who have undergone vaginoplasty retain prostate tissue, therefore infectious prostatitis should be included in the differential diagnoses for sexually active trans women with suggestive symptoms. There is no evidence to guide routine screening for Chlamydia in asymptomatic transgender women who have undergone vaginoplasty, though it is reasonable to consider urinary screening in women with risk factors. The role of vaginal gonorrhea and Chlamydia specimens, as opposed to urine testing only, is unknown in women

who have undergone penile inversion. Providers may consider vaginal testing however urine testing should be considered essential.

Pelvic inflammatory disease should be in the differential for transgender men with a uterus and fallopian tubes who have vaginal intercourse. Testosterone use is associated with vaginal atrophy; therefore, use of lubricant and a small speculum may be appropriate for pelvic and speculum exams among transgender men with vaginas. Some transgender men retain patent vaginas after metoidoplasty and may require vaginal screening based on sexual history. Screening for cervical cancer and HPV are covered elsewhere in these guidelines.

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17. Testicular and scrotal pain and related complaints

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Introduction

The prevalence of scrotal contents complaints is unknown, though anecdotally are not rare.

A common cause of scrotal contents pain in transgender women is “tucking,” which allows a female-appearing genital contour in tight fitting clothing. Tucking involves manually displacing the testes upward into the inguinal canal, and then positioning the penis and scrotal skin between the legs and rearward toward the anus. Tight underwear, tape or a special garment known as a gaff is then used to maintain this positioning. Many transgender women find this practice to be gender-affirming, and may maintain this positioning even at night when asleep. Resulting pain may be traumatic, mechanical or neuropathic. Prolonged tucking may also result in urinary reflux and symptoms of prostatism or even infection such as epididymo-orchitis, prostatitis, or cystitis. Prolonged positioning of a compressed urethral meatus in close approximation to the anus may also serve as a portal of infection. Pain related to the onset of hormone therapy is a common complaint however the etiology of this symptom is unknown.

Acute scrotal contents pain requires a workup to rule out conditions requiring emergency treatment. A physical exam to rule out tumors, hernia, hydrocele or other causes of pain is appropriate. Appropriate imaging should be performed when indicated.[1,2]

Treatment approaches

For acute scrotal contents pain investigation for torsion, infection (especially gonorrhea and chlamydia), inguinal hernia, and occult trauma should be performed when appropriate. If no condition requiring emergency treatment is found, treatment with NSAIDs can be effective.[2]

Counseling and education on safer ways of tucking may be the most effective approach to relieving pain believed to be related to this practice. This might include shorter periods of tucking or less tight tucking. Ready access to transgender surgeries when medically necessary, including orchiectomy and vaginoplasty for the treatment of gender dysphoria, may also minimize this condition.

Chronic orchialgia algorithms for non-transgender men often suggest an empirical course of antibiotics (after attempting diagnosing an etiology) and discourage orchiectomy as a last resort measure. This algorithm may not be appropriate for transgender women. Patients often have gender dysphoria and maybe relieved to be offered orchiectomy (as opposed to non-transgender men, who are typically resistant to even unilateral orchiectomy when indicated); orchiectomy may be raised much higher in the treatment algorithm in these cases. When orchiectomy is not indicated, medications used in the treatment of neuropathic pain may be

useful. Pain related to onset of hormone therapy is generally benign, improves spontaneously, and can be treated expectantly and with reassurance.[1,3]

All providers should be aware that physical examination of the genitals may be traumatizing for trans women and must be done with sensitivity and care if necessary. Providers should not discount testicular pain complaints in transgender individuals, and should avoid any perception that transgender women with this complaint are malingering in hope of obtaining an orchiectomy.

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18. Free silicone and other filler use

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Introduction

Medical grade silicone has origins in aircraft lubricants developed after World War II; U.S. Army staff noticed that drums of Dow 200 silicone lubricant were disappearing from supply rooms, and traced these drums to providers who were injecting the material. By the 1960s, Dow Chemical had introduced a purified medical silicone (Dow 360), intended for use as a syringe lubricant and as a pharmaceutical vehicle. Subsequent off-label use of Dow 360 was associated with a number of poor outcomes, and by the 1970s some laws had been passed banning the use of such injections.[1] By the 1990s, a more viscous silicone material (Silikon-1000) had been approved by the FDA for vitreal injections, with soft tissue injections considered “acceptable off-label use”.[1] Medically appropriate use of free silicone injections involves recurrent injections of <0.1cc by a trained practitioner, with the intention of causing a local fibroblasic reaction and collagen growth, ultimately resulting in changes in the subcutaneous contour.[2] Such an approach has been described in the management of HIV-related lipodystrophy.[2]

“Silicone injections” in the context of transgender health actually refer to any one of a number of soft tissue fillers, typically injected by an unlicensed or unscrupulous medical provider. The actual composition of the injected substances is often unknown and may not be of medical grade; contents may include aircraft lubricant, tire sealant, window caulk, mineral oil, methylacrylates, petroleum jelly, or other substances.[3] In cases of these unsupervised injections, the injected volume (1-3 liters or more) far exceeds what may be performed by a licensed medical provider. Additionally, attention sterility and techniques to avoid embolization may be lacking. Large events (“pumping parties”) may take place at which many transgender women receive large volume injections.[4] Estimates of the frequency of injections range from 20% to more than 50% of some populations of transgender women.[5,6] Data from outside the U.S. includes an estimate of 40% of transgender women in Lima, Peru,[3] and 68% of transgender women in several large Thai cities.[7] While most data and anecdotes on soft tissue injections are in transgender women, use among transgender men is also theoretically possible.

Motivations for seeking soft tissue injections

Motivation for receiving the injections may include a strong desire for immediate body changes to relieve gender dysphoria, especially when other modalities of treatment are, unavailable, inaccessible, or perceived as ineffective or slow. The immediate results may encourage community members to recommend the procedures to their peers before any signs of adverse effects appear. A qualitative study of silicone use in transgender women found four contributing factors to this epidemic: poor self-image, misperceptions about silicone, discomfort in public settings (rapid and extensive feminization from silicone helps transgender

women blend or “pass”), and low access to health insurance.[8] Other contributing factors include lack of a general awareness of risks in the community, peer pressure, enhanced feminine features to support survival sex work, and the ability to achieve feminization without hormones in order to retain erectile function.[9]

Complications and adverse reactions

Complications may be categorized by time of onset (immediate, early, delayed/late) and by location of effect (local, remote, systemic).[10–12]

Immediate adverse effects of silicone and other substances include silicone embolization, bleeding, pain, and focal erosions and necrosis. Localized skin papules and hypersensitivity reactions are possible. Silicone embolization involving the lungs may result in adult respiratory distress syndrome (ARDS) and death. Some patients have survived multisystem failure due to this condition with severe disability as sequelae including loss of limbs.[11,13–18]

Early adverse effects in the days or weeks following injection include inflammatory nodules with infection due to traditional skin and soft tissue pathogens as well as atypical mycobacteria, and which may be fluctuant. Non-inflammatory nodules may also develop causing pain, itching, and abnormal pigmentation.[18,19] Angioedema is also possible.

Long term adverse effects occurring weeks to years after the injection include migration of silicone with associated pain or deformity. Local or remote inflammatory and non-inflammatory nodules may develop; some may evolve into sterile abscesses or fistulas. Silicone granulomas may develop, with findings of pain, swelling, ulcerations, lymphadenopathy, and possible systemic constitutional symptoms. Biopsy of such lesions shows foreign body granulomas with white vacuoles and surrounding inflammatory cells. Pathogenesis of these lesions may include T cell activation and the presence of biofilms. Other potential complications include secondary lymphedema, telangiectasias and persistent erythema.[18]

Major systemic complications include systemic inflammatory response syndrome (SIRS)/ARDS, sepsis, embolization, hypersensitivity pneumonitis, immune reconstitution inflammatory syndrome (IRIS), or hypercalcemia,[14,18,20] Organ failure is also possible due to direct mass-effects.

Diagnosis

A detailed history can help identify any prior soft tissue injections, or risk factors for use. Patients may be hesitant to disclose prior procedures. Ultrasound, CT or MRI may be helpful adjuncts. Mammography may be ineffective in breasts that have been previously injected. In those patients with a history of extensive injections, soft tissue ultrasound may be a useful tool to guide therapeutic injections for the management of syphilis, gonorrhea, HIV (enfuvirtide), or for vaccines.[21]

Prevention: No research has been conducted on the best practices in preventing the use of medically unsupervised soft tissue fillers. Strategies likely to reduce the prevalence of unlicensed silicone injection include: educating transgender women about risks and alternatives, as well as making available more conventional gender-affirming treatment such

as hormones and surgery. Community level interventions, utilizing peer health advocates or promotoras may be more effective than provider-originated interventions.

Treatment Approaches: Successful treatment of acute emergencies related to soft tissue injections requires rapid recognition and quick application of intensive care. Delays occur both because of patient hesitation to seek care or report that they received soft tissue injections, and a failure of health care providers to recognize the emergency and to have the knowledge of the necessary treatment.

Management of most complications is supportive and symptom-driven. Minocycline shows promise as a first line antibiotic in the setting of infections due to additional anti-inflammatory properties.[12] Use of surgical excision and reconstruction flaps/grafts may be necessary.[22] Complete mastectomy with breast reconstruction may be necessary for patients with free silicone spread throughout the breasts.[23,24] Other potential approaches include intralesional corticosteroid injections, topical imiquimod, or etanercept 25mg subcutaneously twice/weekly.[19] Liposuction has been described in the past but is not likely to be of benefit.[25]

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19. Fertility options for transgender persons

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Introduction

Transgender people have the same range of reproductive desires as do non-transgender people. Although data are limited, there is no evidence that children of transgender parents are harmed in any unique way.[1] **It is recommended that prior to transition all transgender persons be counseled on the effects of transition on their fertility as well as regarding options for fertility preservation and reproduction (Grading: T O S).**[2,3]

Exogenous hormones and gonadectomy (removal of testes or ovaries) have clear impacts on fertility. Reproduction in transgender persons who have initiated transition and retain their gonads generally involves discontinuation of exogenous hormones, though ovulation and spermatogenesis may continue in the presence of hormone therapy. If an individual has not undergone gonadectomy, and if an initial evaluation demonstrates an absence of ovulation or spermatogenesis, return of fertility may be possible after discontinuing hormone therapy for a period of time. Anecdotally the time to return of fertility can range from 3-6 months, though some may experience permanent loss of fertility, or require assisted technologies as described below.

Because infertility is not absolute or universal in transgender people undergoing hormone therapy, all transgender people who have gonads and engage in sexual activity that could result in pregnancy should be counseled on the need for contraception. Gender-affirming hormone therapy alone is not a reliable form of contraception, and testosterone is a teratogen that is contraindicated in pregnancy. It is unknown how long of a testosterone washout period is appropriate in transgender men prior to pregnancy (Grading: X C S).

Fertility preservation options may include sperm, oocyte, embryo, ovarian tissue or testicular tissue cryopreservation.[4] These are similar to options available to men and women undergoing gonadotoxic cancer therapies or elective fertility preservation for social reasons.

Assisted reproduction may include the full range of fertility services. Whether long-term hormone exposure confers any unique medical risks to the patient undergoing assisted reproduction procedures or any long-term impact on gametes and to future offspring is currently unknown. Transgender patients who undergo fertility preservation or assisted reproduction should be informed of the lack of data on outcomes.

Reproductive options for transgender women

In transgender women, research suggests that prolonged estrogen exposure of the testes has been associated with testicular damage.[2] Restoration of spermatogenesis following extended estrogen treatment, however, has not been well studied.[2] The most successful option for fertility preservation for transgender women is cryopreservation of sperm prior to

initiation of hormone therapy. Clomiphene citrate or hCG injections are sometimes used to stimulate spermatogenesis. Several recently reported cases of uterine transplantation into non-transgender women represent a potential future option, however this technology is still in infancy.

Reproductive options for transgender men

The effect of prolonged treatment with exogenous testosterone on ovarian function is unclear. Testosterone therapy usually leads to anovulatory state and amenorrhea. This is usually reversible upon discontinuation of testosterone therapy, and pregnancies have been reported in transmen following prolonged testosterone treatment.

Fertility preservation options for transgender men include oocyte cryopreservation, embryo cryopreservation, and ovarian tissue cryopreservation. The frozen-thawed oocytes or embryos can then be later used for establishing a pregnancy using the patient's uterus or by transfer into a female partner or gestational carrier. While solid data are lacking, transgender men who have initiated transition have been able to discontinue testosterone treatment and undergo insemination of sperm or IVF with embryo transfer to the patient's uterus, a female partner or gestational carrier.

A recently published report surveyed transgender men who experienced pregnancy after initiation of testosterone.[5] Eighty percent resumed menses within 6 months of stopping testosterone. Seven percent used fertility medications. Obstetrical outcomes were similar in the testosterone and non-testosterone users, however it is not clear if participants reporting testosterone use were receiving testosterone at the time of conception and during pregnancy. The men in the study also expressed a desire for more supportive resources and reported a lack of provider awareness and knowledge regarding fertility in transgender patients. One third of the pregnancies were unplanned, though it is not clear how many of these unplanned pregnancies occurred in the setting of current testosterone use. Nevertheless, such findings highlight the need for contraception in some patients.

Ovarian tissue cryopreservation is currently still considered experimental. There have been several live births reported worldwide resulting after autotransplantation of cryopreserved ovarian tissue.[6,7] However, there have yet to be any live births resulting from in-vitro maturation of oocytes derived from frozen-thawed ovarian tissue fragments. Research to create gametes through stem cell techniques is also ongoing.

All patients should also be informed that these assisted reproductive options are expensive and often not covered by insurance. Mental health counseling and support should be made available for those transgender people pursuing reproductive options who request or require such services.

Fertility preservation for children & adolescents

It is recommended that transgender children and adolescents, and their guardians, also be informed and counseled regarding options for fertility preservation prior to the initiation of pubertal suppression and treatment with gender-affirming hormones. In children who have

initiated natal puberty, fertility preservation options include sperm, oocyte, and embryo cryopreservation. Currently it is not possible for children who have not undergone natal puberty (and who may have used gender-affirming hormones) to preserve gametes.

Prolonged pubertal suppression using gonadotropin releasing hormone (GnRH) analogs is usually reversible and should not impair resumption of puberty upon cessation, though most children who undergo pubertal suppression go on to begin gender-affirming hormone therapy without undergoing natal puberty.

Further discussion of pubertal suppression, and the decision to undergo gonadectomy prior to the legal age of majority, is included in the guidelines for transgender children and adolescents.

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20. General approach to cancer screening in transgender people

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Long term follow up case control studies have not identified differences in cancer rates in trans patients undergoing hormone therapy compared to birth-sex controls, however these studies had many limitations.[1,2] Insufficient evidence exists to determine if transgender people increased or decreased overall as well as organ-specific cancer risk. Primary care providers should conduct an organ based routine cancer screening for all transgender patients in accordance with current guidelines as a component of comprehensive primary care. **As a rule, if an individual has a particular body part or organ and otherwise meets criteria for screening based on risk factors or symptoms, screening should proceed regardless of hormone use (Grading: X C S).** Therefore, an ongoing and thorough medical and surgical history is crucial to determine an individual patient's screening needs.

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21. Screening for breast cancer in transgender women

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Introduction

Adaptation of recommendations for screening in transgender women are complicated by the lack of consensus on breast cancer screening in non-transgender women. Existing recommendations vary widely in each of these critical considerations, and are subject to numerous biases based on the interests of the organization and its constituency.[1–7]

Ideal breast cancer screening recommendations minimize mortality and missed diagnoses, while at the same time avoiding over-screening, with its inherent risks of unnecessary follow-up studies, emotional distress, and potentially invasive biopsies and other procedures. It is noteworthy that the positive predictive value (PPV), defined as the likelihood of a positive screening test representing a true presence of the disease (as opposed to a being a false positive) declines as the prevalence of the disease within a specific population declines.

Breast cancer risk in transgender women

In transgender women, factors that may contribute to a reduced risk of breast cancer include potentially less lifetime overall or cyclical exposure to estrogen and in some cases the absence of or minimal exposure to progesterone. However, transgender women have a high prevalence of dense breasts, an independent risk for breast cancer and also a predictor of increased rates of false negative mammograms; a Dutch study of 50 transgender women found that 60% had “dense” or “very dense” breasts on mammography.[8]

Existing retrospective data on transgender women have mixed findings. Two retrospective population based studies of breast cancer in transgender women have been reported; both reported only on cases of breast cancer which were detected as part of routine clinical care, as opposed to through a structured and broad screening program. A retrospective study of 2,307 Dutch transgender women treated at a single center found an estimated incidence of 4.1/100,000 person-years, in comparison to the incidence of 155/100,000 person-years in the general Dutch non-transgender female population.[9] A retrospective review of 3,566 transgender women receiving care in the U.S. Veterans Administration Healthcare System found 3 cases total, translating to a non-significant standardized incidence ratio (SIR) of 0.7 (95% CI 0.03 to 5.57) in comparison to non-transgender women, and a significant SIR of 33.3 (95% CI 21.9 to 45.1) in comparison to non-transgender men.[10] It is unclear how many cases of breast cancer went undetected in these two populations, and were then otherwise lost to follow-up or to mortality (known to be high in transgender women) from other causes.[11]

Data on breast cancer in transgender women has been limited to the above studies as well as several case reports, and is overall reassuring with regards to risk being not higher, and possibly lower than in the non-transgender female population.

Age to first consider screening

The only large population based study of mammography before age 50 was conducted in the UK on 160,921 women and found no difference in overall breast cancer mortality.[12] Given the equivocal value of screening before age 50 and the likely lower incidence in transgender women, it is recommended that screening mammography in transgender women not begin before age 50.

Length of exposure to feminizing hormones

Transgender women differ from non-transgender women in the length of exposure to estrogens as well as variable exposure to progestagens. As such it is recommended that screening not commence in transgender women until after a minimum of 5 years of feminizing hormone use, regardless of age. Some providers may choose to discuss the risks and unknowns with patients and delay screening until after up to 10 years of feminizing hormone use, regardless of age. Note that transgender women over age 50 do not meet screening criteria until they have at least 5-10 years of feminizing hormone use.

Frequency of screening

Existing recommendations in non-transgender women vary with respect to the frequency of screening. As with the age of onset, given the likely lower incidence in transgender women, **it is recommended that screening mammography be performed every 2 years, once the age of 50 and 5-10 years of feminizing hormone use criteria have been met. Providers and patients should engage in discussions that include the risks of overscreening and an assessment of individual risk factors (Grading: T O W).** Risk score calculators such as the GAIL method may be unreliable when used in transgender women.

Modality of screening

Screening mammography is the primary recommended modality for breast cancer screening in transgender women. Transgender women are often concerned with their breast appearance and development, and may perform frequent unguided self-examinations. Early breast development may be associated with breast pain, tenderness, and nodularity. Transgender women may request breast exams for these symptoms, or may find breast examinations to be gender-affirming. As such providers may consider periodic clinical breast exams, and/or a discussion with patients about general breast awareness and health, however as with non-transgender women,[13] formal clinician or self breast exams for the purpose of breast cancer screening are not recommended in transgender women.

Special considerations

As with non-transgender women, clinicians may choose to reduce the age of onset of screening, number of years of feminizing hormone exposure, or frequency of screening in patients with significant family risk factors. Transgender women with a family history suggestive of (or known) a BRCA mutation should be referred for genetic counseling. No data exists to guide the use of estrogens in transgender women found to have a BRCA mutation. Data on breast cancer risk in non-transgender men with BRCA mutations are limited, with data on BRCA-1 suggesting a lifetime risk of 1.2-5.8%, [14-16] and data on BRCA-2 suggesting a lifetime risk of 6.8%. The risk is much higher for non-transgender women with a BRCA mutation, at 78% lifetime risk. [14, 17] It is unclear if transgender women with the BRCA-1 mutation and using estrogen have a risk above that of non-transgender men, and what role the age at start and total length of exposure to estrogen might play. A single case report of a transgender woman with the BRCA-1 mutation involved the continued use of estrogen under informed consent.[18]

A retrospective cohort study of 1,263 transgender women receiving care at a large urban community health center patients in the United States found that transgender individuals between ages 50 and 74, and with a history of at least 5 years of hormone therapy were significantly less likely than non-transgender individuals to have a mammogram per guidelines (AOR = 0.53; 95% confidence interval = 0.31, 0.91).[19] Further research is needed to understand barriers and other factors which underlie this disparity.

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22. Prostate and testicular cancer considerations in transgender women

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Prostate cancer

Documented cases of prostate cancer in trans women with a variety of hormone use and surgical histories have been reported.[1–3] Most cases of prostate cancer in trans women have been in individuals who started hormones after age 50; such cases may actually represent occult neoplasms, which existed prior to initiation of hormone therapy.[4] In a cohort of 320 transgender women in Belgium who had undergone vaginoplasty, PSAs along with transvaginal ultrasound and digital vaginal examination of the prostate revealed lower PSA and prostate volume than what would be expected in a non-transgender men of corresponding age.[5] Some anti-androgens, such as 5-alpha reductase inhibitors have also been documented to decrease the PSA result.[6] Removal of gonads in addition to estrogen exposure likely reduces risk for prostate cancer and benign prostatic hypertrophy.[4,5]

Regardless, primary care providers should remain aware of the possibility of prostate cancer in transgender women, even those who have undergone gonadectomy. The decision to perform screening for prostate cancer in transgender women should be made based on guidelines for non-transgender men. If a prostate exam is indicated, both rectal and neovaginal approaches may be considered. Transgender women who have undergone vaginoplasty have a prostate anterior to the vaginal wall, and a digital neovaginal exam examination may be more effective.[5] It should be noted that when PSA testing is performed in transgender women with low testosterone levels, it may be appropriate to reduce the upper limit of normal to 1.0 ng/ml.[4]

Testicular cancer

There has been one case of testicular cancer reported in the literature.[7] It is likely that risk decreases with androgen suppression. Routine testicular cancer screening is not recommended in non-transgender men, and there is no evidence to perform screening in transgender women. Transgender women adherent to therapeutic doses of estrogen plus an androgen blocker, and with persistent testosterone elevations, should be evaluated for testicular tumors by physical exam, as well as human chorionic gonadotropin (hCG), alpha-fetoprotein (AFP) and lactic dehydrogenase (LDH) levels, and possibly a scrotal ultrasound.

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23. Breast cancer screening in transgender men

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Transgender men who have not undergone bilateral mastectomy, or who have only undergone breast reduction, should undergo screening according to current guidelines for non-transgender women. No reliable evidence exists to guide the screening of transgender men who have undergone mastectomy. Since most or nearly all breast tissue may have been removed, mammography for the evaluation of a palpable lesion may not be technically feasible, and alternatives such as ultrasound or MRI may be necessary. The risk of breast cancer in residual breast tissues after mastectomy is unknown. It is important to obtain a clear surgical history, as some patients may have undergone only breast reduction. Some surgeons perform routine preoperative mammography. Some guidelines recommend annual chest wall exams in transgender men after mastectomy; however this is not based on evidence, and is in conflict with the move away from clinician exams in general for non-transgender women. Diagnostic physical exams may be appropriate in the case of new complaints. **Clinicians should engage in dialogue with transgender men who have undergone bilateral mastectomy about the unknown risks associated with residual breast tissue, as well as the possible technical limitations of mammography (Grading: X C S).**

24. Screening for cervical cancer in transgender men

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Introduction

Transgender men are at risk for cervical cancer. Cervical cancer is the third most common cancer globally [1]; more than 99% of which are caused by infection with one of several high risk oncogenic strains of the human papilloma virus (hr-HPV).[2] Pelvic exams to obtain pap smears may be challenging for transgender patients. Inadequate screening for cervical cancer is linked to the barriers transgender individuals face in accessing culturally sensitive health care.[3] Transgender men are less likely to be current on cervical cancer screening than non-transgender women.[4] Individuals who have never or have rarely been screened for cervical cancer are at the highest risk for progression of chronic hr-HPV infection to malignancy, morbidity and mortality.[5]

Transgender men who have sex with non-transgender men (trans MSM) report inconsistent condom use during receptive oral, vaginal and anal sex with non-transgender male sexual partners, and are at increased risk for hr-HPV infection and undetected disease progression.[6,7] HPV vaccination between the ages of 9 to 26 has the potential to significantly reduce rates of cervical, oral and anal cancer.[8–10] Adolescent non-transgender males are receptive to HPV vaccination, and 74% of non-transgender men who self-identify as gay or bisexual are willing to get vaccinated for HPV if recommended by their health care provider.[11,12]

Screening recommendations

Cervical cancer screening should never be a requirement for testosterone therapy. Cervical cancer screening for transgender men, including interval of screening and age to begin and end screening follows recommendations for non-transgender women as endorsed by the American Cancer Society, American Society of Colposcopy and Cervical Pathology (ASCCP), American Society of Clinical Pathologists, U.S. Preventive Services Task Force (USPSTF) and the World Health Organization (Grading: X C S).[13–15] As with non-transgender women, transgender men under the age of 21 should not have pap smears regardless of their age of sexual debut.[13] Pap smears on transgender men have a ten-fold higher incidence of an unsatisfactory result compared to non-transgender women, which is positively correlated with length of time on testosterone.[16] If erythema of vaginal and/or cervical tissue is noted, evaluation for usual causes of inflammation is warranted prior to reaching a diagnosis of exclusion of testosterone-mediated atrophic cervicovaginitis. Inflammation may obscure cervical cytological evaluation and result in an unsatisfactory result. In addition, the requisition should indicate any testosterone use as well

as the presence of amenorrhea, to allow the pathologist can accurately interpret cell morphology.

Improving patient experiences

Strategies to promote a more supportive and sensitive setting include using culturally sensitive language, interviewing the patient prior to disrobing, and asking the patient to change from the waist down only. A painful pap smear experience is correlated with non-adherence to future screening and colposcopy.[17] Several anecdotal techniques may reduce pain associated with speculum exams. A pediatric speculum may allow visualization of the cervix and can reduce discomfort with the exam; however it is important to avoid using a speculum so short that it requires excessive external pressure to visualize the cervix. Moving the buttocks past the end of the exam table and encouraging pelvic relaxation may also increase comfort and improve visualization of the cervix. If the examiner notes tension or anxiety, taking time to go through a verbal relaxation exercise can be helpful. Warm water may be used to lubricate a narrow speculum prior to insertion to minimize a patient's discomfort and dysphoria without compromising pap results. Water-based lubricant can reduce discomfort; using a minimal amount of lubricant on the outer portion of a speculum may reduce patient discomfort while minimally increasing the risk of an unsatisfactory sample.[18,19] Excessive lubricant should be avoided; studies have conflicting results on the effect of excessive lubricant on pap results. Some clinicians find inserting a speculum less uncomfortable for patients by first placing a finger or two in the vagina and performing posterior pressure while asking the patient to flex and relax their pelvic floor muscles. A digital (not bimanual) exam may also help identify the location of the cervix and minimize manipulation during the speculum exam. A formal bimanual exam on an otherwise asymptomatic patient may not add clinical value and may add to the patient’s discomfort.[20] Other approaches to reduce discomfort might include allowing the patient to insert the speculum themselves or watch the procedure using a mirror, administration of oral benzodiazepines prior to the exam, or the use of vaginal estrogens for 1 week prior to the exam.

Preliminary research on self-collected vaginal samples for HPV compared to clinician obtained samples shows promise, this approach may also be more acceptable to transgender men.[21,22] Future initial HPV screening for transgender men may also utilize non-vaginal sourced specimens; studies supporting concordance of HPV in the urine with HPV in the cervix represent a potential method for a non-vaginal triage algorithm.

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25. Ovarian and endometrial cancer considerations in transgender men

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Endometrial cancer

The administration of exogenous testosterone, which then undergoes aromatization to estrogen, as well as the possible anovulatory state induced by testosterone, may create a hormonal milieu of "unopposed" estrogen. This creates a theoretical risk of endometrial hyperplasia or cancer. Despite this theoretical risk, only one case report of an endometrioid adenocarcinoma exists in the literature.[1] Two studies suggest that the risk of endometrial hyperplasia is low, and that transgender men may commonly have endometrial atrophy when on testosterone: One observational study found endometrial atrophy on histological report in almost half (45%) of trans men on testosterone when histology was performed post routine hysterectomy.[2] Another case control study performed histopathology on samples comparing trans men on androgens for at least one year to pre and post-menopausal women undergoing hysterectomy or histopathology, and found trans men had endometrial atrophy similar to that found in post-menopausal women.[3]

A number of sources have recommended endometrial surveillance with annual pelvic ultrasounds in transgender men who are amenorrheic, however this recommendation is not evidence based. This recommendation may also be unrealistic since transgender men report avoiding gynecologic care due to lack of cultural competency among providers.[4]

As such, routine screening for endometrial cancer in transgender men using testosterone is not recommended. Unexplained vaginal bleeding (in the absence of missed or changed dosing of testosterone) in a patient previously with testosterone-induced ameorrhea should be explored (Grading: X C M). Transgender men should be educated on the need to inform their provider in the event of unexplained vaginal bleeding.

Hysterectomy for primary prevention of endometrial cancer is not currently recommended (Grading: X C M); consideration of hysterectomy for the purpose of eliminating the need for cervical cancer screening may be discussed on a case-by-case basis, in recognition of the role of hysterectomy in reducing gender dysphoria, and in consideration of surgical risks and irreversible infertility.

Ovarian cancer

While there have been several case reports of ovarian cancer among transgender men,[5,6] there is no evidence to suggest that trans men on testosterone are at increased risk.

Testosterone causes the ovaries to develop cortical and thecal thickening similar to that seen in the polycystic ovarian syndrome (PCOS), however histologically there are differences in antral follicle counts.[2,7] Several studies have suggested an increased prevalence of PCOS

in transgender men prior to testosterone therapy.[8–10] While historically concerns have existed about increased risk of ovarian cancer in transgender men using testosterone, these concerns were based mostly on the inaccurate premise that testosterone causes a PCOS-like ovary. Furthermore, recent data refutes the increased risk of ovarian cancer in non-transgender women with PCOS.[11]

From a primary care perspective, no effective screening algorithm is available for ovarian cancer screening in any individuals without a greater than average risk (i.e., known genetic or personal/family risk factors). Transgender men should receive the same recommended counseling and screenings for anyone with ovaries based on history and presentation. While a unilateral or bilateral oopherectomy may be performed in transgender men as part of the management of gender dysphoria or for a pathologic process, routine oopherectomy in for primary prevention of ovarian cancer is not recommended. Transgender men who undergo vaginectomy but retain one or both ovaries/gonads, and who require pelvic imaging, may be evaluated by transrectal or transabdominal sonogram.

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26. Mental health considerations with transgender and gender nonconforming clients

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Mental health in the context of primary care

Mental health is vital to positive physical outcomes and, as for all patients, should be addressed for transgender patients in primary care. Due to pathologization and mistreatment by mental health professionals, transgender people are often reluctant to engage with mental health providers.[1,2] Primary care settings may offer a safer environment for transgender people to bring up mental health concerns and may be easier to access than mental health services. Every intake for care should include a mental health history and an assessment for active mental health concerns. Screening should include primary mental health problems, environmental and social stressors, and gender-related needs. Screening also requires provision of appropriate referrals to transgender-affirming mental health services when needs are identified.

Mental health concerns endorsed by a patient should not be automatically assumed to be related their gender identity.[1] Transgender people may be seeking mental health care for a number reasons; in addition to mental health issues relating to or resulting from one's gender identity, transgender people do experience the background rates of mood disorders and other psychiatric conditions seen in the general population. While some may be seeking specific assistance for gender-related themes, others are seeking assistance with depression, anxiety, or other clinical concerns unrelated to their gender identity.[3]

Primary care should be trauma-informed in its delivery, with an understanding that many patients present with complex trauma histories with interpersonal, social and medical systems-based trauma experiences.[4] Trauma-informed care and training for all staff and providers can enhance care engagement and health outcomes. In a recent publication, Machtinger and colleagues describe a theoretical framework for providing trauma-informed primary care.[5] The model is based on the needs of women who have a history of trauma. The model proposes the need to address the primary care environment, patient screening, provider response to the patient's needs, and a foundation of organizational values that support trauma informed care across all levels of the organization. Machtinger and colleagues address the need for confidential spaces in which to conduct a thorough screening of a patient's history with a special emphasis on trauma and a patient's response. Being able to speak with a provider in a place that ensures privacy is critical.

Primary mental health needs of transgender people

Transgender and gender nonconforming people, in general, have three types of need for mental health.

1. Exploration of gender identity. This includes determining exactly what one's gender identity is, coming to terms with this gender identity, self-acceptance and individuation, and exploring individual – level ways to actualize this identity in the world. This may also include preparation and assessment for various gender-affirming treatments and procedures.
2. Coming out and social transition. This includes coming out to family, friends, and coworkers, dating and relationships, and developing tools to cope with being transgender in a sometimes transphobic world.
3. General mental health issues, possibly unrelated to gender identity. The variety of mental health concerns experienced by transgender people include mood disorders, generalized anxiety, substance abuse, and post-traumatic stress disorder (PTSD).[6]

Transgender people may seek services from mental health providers when they come to realize that their gender identity does not match the sex they were assigned at birth, or when the distress of this incongruence becomes intolerable. The age at which this realization occurs, and the age at which treatment is initially sought, may vary greatly from one person to the next. It should not be assumed that arrival at this realization or seeking treatment late in life indicates that an individual is any "less" transgender.[1]

The coming out process for transgender people can be more challenging than it is for lesbian, gay, and bisexual (LGB) people, primarily because LGB may be able to keep their sexual orientation undisclosed. Due to the nature of social and medical transitions, a transgender person must come out to people with whom they interact unless they relocate and choose to live "in stealth" (i.e. not divulging their transgender identity). The coming out process can be time consuming and emotionally challenging. This process can be gender-affirming when transgender people are supported in doing so. Conversely, a lack of support or experiences of being mistreated, harassed, marginalized, defined by surgical status, or repeatedly asked probing personal questions may lead to significant distress.

Approaches to supporting transgender people during the coming out and exploration process include reinforcing self-identification, and exploration of and integration of individualized identity. This in turn will provide a supportive foundation for interacting with unsupporting partners, friends, relatives or coworkers, as well as provide needed tools to diffuse and deflect potential implicit and unconscious transphobic messaging and rejection in every day life.

Transgender people experience the background rates of common mood disorders, bipolar disorder, schizophrenia etc. that are seen in the general population, as well as a potentially increased rate of some conditions as a result of chronic minority stress and discrimination.[7] Hendricks and Testa have extended Meyer's Minority Stress Model [8] to transgender people.[9] This model addresses the ways that proximal and distal challenges increase the likelihood that a person will experience mental health challenges. Related to this is the work conducted by Nadal addressing microaggressions (e.g., everyday slights).[10] Similar to the

concerns for mental health disorders addressed by Hendricks and Testa, Nadal's work also points to the increased risk of mental health concerns for transgender people.

Routine primary care visits should include screening for co-occurring mental health conditions, past treatments, and history of suicide and self-injurious behaviors, symptoms of posttraumatic stress, and substance use. Primary care providers should be equipped to handle basic mental health needs of transgender patients (e.g., depression and anxiety) just as any other patient. Any primary mental health concerns beyond the scope of the provider's routine practice should be referred to transgender-affirming mental health providers. Referrals should be made when appropriate to substance abuse treatment programs, including dual diagnosis programs for those with co-occurring mental illness. All primary care offices should have a clear suicide response plan for any patient endorsing thoughts of suicide. Trans Lifeline is a crisis hotline staffed by and for transgender people and can be included in safety planning with patients.[11]

Transgender people seeking care for mental health concerns require culturally competent providers.[1] This includes basic knowledge gender identity. Transgender patients should not be placed in the position of training their providers about their mental or physical health care needs.

Environmental and social considerations

Environmental and social stressors greatly impact mental health. Transgender people are more likely to live in poverty, be discriminated against in employment, and be victims of violence than non-transgender people.[12] Transgender people also face higher rates of family loss, and homelessness. Transgender people with intersecting identities such as race, ethnicity, or socioeconomic status face increased likelihood of adverse life events. Transgender women of color face extraordinarily high rates of social and health disparities.[13–16] Routine primary care visits should always assess for housing, food, financial, and safety concerns in living and/or work environments. Case management services should be provided within the primary care setting if available. Due to environmental stressors, transgender people may have secondary adjustment difficulties including depression, anxiety, and trauma reactions. Offering referrals for individual and group therapy and support can bolster protective factors in lieu of the extreme hardships many endure.[17,18]

Diagnosis of gender dysphoria

According the *Diagnostic and Statistical Manual for Mental Disorders* (5th ed.) a person may be diagnosed with a mental health disorder ("Gender Dysphoria") if their gender identity does not match the sex they were assigned at birth, and they are suffering clinically significant distress or social/occupational impairment.[6] A diagnosis may provide an explanation for their gender concerns. However, receiving a Gender Dysphoria diagnosis may be perceived as pathologizing.[19] The issue of diagnosis is further complicated by a lack of a diagnostic code for the care of those with a history of gender transition of some kind who no longer experience significant distress or social/occupational impairment. In some cases patients will have a

carve-out of mental health services from their medical plan. It is possible that in these cases medical benefits may be denied under the medical plan for transition related care, since the only current ICD10 Gender Dysphoria codes are in the mental health section. A process is in place to create an expanded and more relevant set of codes for ICD11. Insurance plans in some states exclude coverage even if the care has been deemed to be medically necessary.[20] In states that ban health insurance exclusions, or if the individual's insurance includes transgender care, a diagnosis of Gender Dysphoria may be required for insurance to pay for necessary medical and surgical treatment.

Gender identity – specific considerations

Different gender identities and differences of gender expression are not pathologies.[21] However, some transgender people seek mental health services related to their gender. Often, distress is present over the extreme social and environmental difficulties transgender people encounter and they are seeking care to assist with these stressors. Transgender people may also seek mental health services with distress that gender does not match the sex they were assigned at birth or to discuss social and medical avenues available to live as a different gender.

Transgender patients frequently access primary care providers to discuss initiation of cross-sex hormones**. Primary care providers who are experienced in working with transgender patients may feel comfortable initiating hormone therapies without an initial mental health assessment using an informed consent model (Grading: T O S)**.[22] The informed consent process includes addressing the medical *and* social risks and benefit of hormone treatment. Setting up a separate appointment for this process can be helpful to ensure the patient is given adequate time to review the information and address any questions the patient may have. Informed consent should be reviewed in person to best meet all patients' health literacy needs.

The World Professional Association for Transgender Health (WPATH) publishes the Standards of Care (SOC).[23] The SOC outlines a process for the initiation of cross-sex hormones. Per the SOC, an assessment by an experienced clinician—a primary care provider or mental health professional-- is required for initiation of cross-sex hormones. This assessment establishes the presence of persistent gender dysphoria and the ability to give informed consent. Exploration of risks and benefits of treatment to give informed consent should include not only the medical risks and benefits of treatments, but also possible social risks and benefits (such as the risks to employment, relationships, and housing), and ways to navigate and mitigate these risks. Therapy is not required to initiate a medical transition, but is encouraged to address any concerns that might arise during the process.[23] The SOC are intended to be flexible and taken on a case-by-case basis.[23] Removal of the gatekeeper role from mental health providers allows a more open and therapeutic relationship to be formed with mental health providers.

If mental illness impairs a patient's capacity for informed consent, referrals for further mental health assessment and treatment should be made prior to initiation of treatment. SOC recommends stabilizing co-occurring mental illness prior to initiation of hormones, but in some

cases the medical treatment of gender dysphoria is best done simultaneously with treatment of mental illness and substance use disorders.[24]

Some patients presenting for initial primary care services may already be on hormones. When a physician has previously prescribed these hormones no new mental health assessment is required for continued hormone treatment. Hormones and standard maintenance of physical and laboratory assessments should be continued after a discussion with the patient about their continued goals of care.

Providers are encouraged to review the tasks of the mental health provider as outlined in the SOC.[23] This document outlines the various activities of mental health providers. This might include assessment, counseling, and medication management. The SOC requires one or two evaluations by mental health professionals prior to certain surgeries for transgender people, including chest and genital surgeries. The requirements for each surgery and evaluation letter are listed in the SOC, and mental health providers can access further training online in performing these assessments.[25] See Table 1 for an explanation of the required evaluations and related referral letters. Providers are encouraged to be cautious with psychological assessment tools that were not designed for use with transgender people.

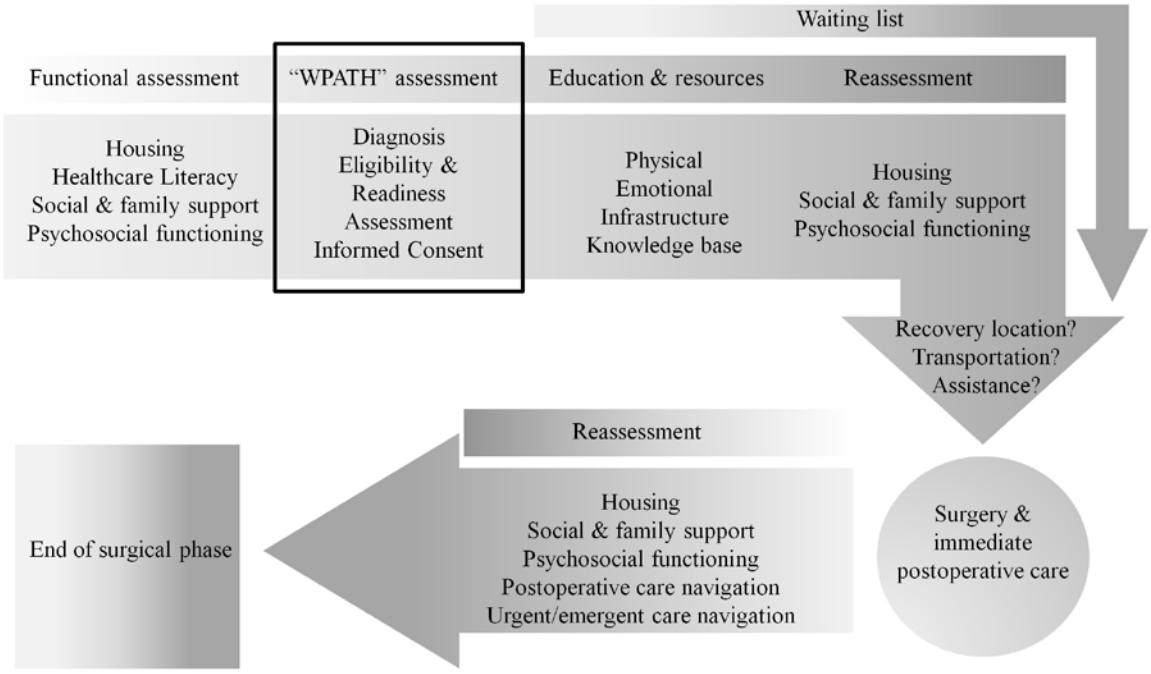
The preoperative assessment process has historically been focused on making a diagnosis of gender dysphoria, determining capacity to provide informed consent, and assessing for certain specific criteria (i.e. length of time taking hormone therapy). However, recovery from gender-affirming surgeries can be complex and involved processes, and there is an additional need for assessment of overall psychosocial functioning and support, health literacy, capacity for self-care, and social support structure in place. There is also a need to provide basic education about the surgical procedure, and provide support to fill in gaps identified during the assessment process. This need has increased with the advent of expanded access to surgery among a broad range of persons, including those who are medically indigent. A framework has been proposed in which this entire process, including the WPATH assessment, should occur (Fig 1).[26] This framework includes an evaluation of psychosocial functioning, housing status, social support system, transportation, health literacy and access to emergency care in the postop period.

Table 26-1. Assessments ("Letters") required for Gender-Affirming Medical Treatment

Procedures other than those listed below do not require a formal assessment process, though in some cases an assessment and preparation may be indicated, as with any surgery. In some cases, an assessment and letter from a medical provider who has initiated hormone therapy using an informed consent approach may be appropriate.

Type of care	One assessment	Two assessments	Time criteria
Breast augmentation	X		12 months of hormones recommended but not required
Mastectomy ("top surgery")	X		
Gonadectomy/hysterectomy		X	12 months of hormones unless contraindicated
Vaginoplasty/phalloplasty		X	12 months of hormones unless contraindicated and 12 months of living in a gender role congruent with one's gender identity, unless contraindicated

Figure 26-1. Framework for perioperative assessment, preparation, and care navigation



Adapted from: Deutsch MB. Gender- affirming Surgeries in the Era of Insurance Coverage: Developing a Framework for Psychosocial Support and Care Navigation in the Perioperative Period. J Health Care Poor Underserved; May 2016.

Counseling can be an important aspect of care for transgender people. For those patients seeking a mental health consultation or psychotherapy prior to the initiation of gender-affirming hormone therapy, there is **no minimum** requirement for number of sessions or period of time in therapy.[23] As stated above, providers must use caution about the reason for clinical services and not assume that care is related only to immediate gender dysphoria. It is important to normalize for patients any experiences related to grief and loss. Any transition a person makes in their life may include experiences of loss, regardless of the reason for the loss.

Finally, some mental health providers are trained and licensed to manage psychotropic medications for transgender people. Similar to counseling, this can be an important part of care when a patient has a co-occurring mental health concern for which medication is indicated. In some states psychologists have prescriptions privileges. In most states though, these services will be offered by psychiatrists, primary care physicians, nurse practitioners, or physician assistants.

Harm reduction

Other transgender patients may have obtained hormones by other means, such as the internet or street sources, without initial or ongoing medical assessment or supervision. The SOC has provisions for physicians to continue the medical treatment of patients who have independently initiated cross-sex hormone therapy, regardless of the patient's ability or desire to receive gender-related psychiatric/psychological evaluation.[23] Physicians may provide treatment based upon the principle of harm reduction. When patients have demonstrated their determination to continue using medication(s) without physician oversight, then it is advisable to assume their medical care and prescribe appropriate hormones. Denial of care will likely result in continued independent treatment and possible harm.

Finding a mental health provider

Making a referral to a provider who is culturally competent can be challenging. This is due, in part, to the lack of training.[27,28] Although this has been changing in recent years, it can still be a challenge. Large cities with LGBT Health Centers and providers known to offer competent care to transgender people have become a reliable source of care. Often there is a network of mental health providers in these cities. For transgender people who live in rural settings or in conservative areas of the country, finding a provider for referral can be more challenging.[16] Some providers will offer tele-mental health services. However, it is important to assure that the provider is licensed in the jurisdiction where the client is receiving services.

Patients should be encouraged to reach out to possible providers and be prepared to ask questions to assure that the provider will be able to meet their needs. Some providers will offer an initial consultation at no cost. This allows an opportunity to determine if the provider will be a good fit. A list of providers by U.S. state can be found through the WPATH website.[29]

Collaborative care

Mental health providers are encouraged to create interdisciplinary relationships.[30] Transgender people, especially those who pursue gender-affirming treatments and procedures, will require care from a variety of providers. This might include primary care physicians, endocrinologists, and surgeons. Providers are encouraged to seek out the names of providers in their area who are known to provide affirmative care with transgender clients and patients.

Summary

Transgender people deserve to receive mental health services from providers who are culturally competent. Trans-affirmative care assumes that the clients understand their own experience and identity. Providers should approach each individual with cultural humility, and avoid making assumptions or projections based on prior patients, experiences, or preconceptions. Providers are reminded to treat all clients with dignity and respect.

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27. Postoperative care and common issues after masculinizing chest surgery

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Introduction

The most common techniques applied to transgender men for masculinizing chest surgery include subcutaneous mastectomy via a periareolar incision and inframammary mastectomy with free nipple grafting. Regardless of approach chosen, the goals of masculinizing chest surgery are to sculpt a natural appearing masculine chest matched to the patient's body habitus with pectoral definition. Unfortunately, there is no consensus approach to surgical planning.[1–5] Surgical technique is dependent not only on the plastic surgeon's individual experience and patient-specific preferences, but also on evaluation of the patient's preoperative body habitus, breast size and shape, and skin quality.

The preoperative chest may be simplified into four components: the breast and subcutaneous tissue, the skin envelope, the nipple and finally the resulting incision.[5] To achieve a masculine chest shape, removal of the breast glandular tissue is required. This is distinctly different in regard to anatomy, goals, and execution from mastectomy performed for breast cancer as well as subcutaneous mastectomy performed for gynecomastia. Depending on breast tissue volume, preoperative ptosis, and skin elasticity, the skin envelope may require significant reduction for a taut, aesthetic male chest. The nipple-areola complex (NAC) likewise requires resizing, reshaping, and repositioning to match masculine proportions within the constraints of its blood supply. Finally, incisions and skin reduction should create scars with the least conspicuous size, position, and orientation.

With the number of considerations and constraints possible, a myriad of technique refinements and algorithms have been proposed; all can fit into two general categories of techniques. In smaller, less ptotic breasts, a single incision per breast designed around or through the NAC can be used to perform a subcutaneous mastectomy with a crescentic or donut-shaped skin excision. However, this approach is more difficult to apply larger ptotic breasts, as it is difficult to anatomically reposition the nipple and also achieve the necessary skin envelope reduction. In these cases, two incisions are necessary per breast. The glandular tissue and subcutaneous fat is removed and recontoured through a primary inframammary incision, and the nipple is brought through a separate oval incision. If it is not possible to transfer the NAC based on a vascular pedicle, free nipple grafting is also an option.

The procedure itself generally takes 2-4 hours, depending on technique used. Most patients require an overnight or short hospital stay.[1] General anesthetic is used. Surgical drains, left in place until a postoperative clinic visit, are the norm. The authors' preference is to use drains and compressive dressing or garment for the duration of 1-2 weeks.

In general, complications are rare for transgender men undergoing masculinizing chest surgery. Early reoperation is required in 4-9% of patients, usually for hematoma evacuation and infection, with a 12% overall complication rate.[1,2] Postsurgical complications are divided into those presenting early (within 2 weeks postoperatively) and late (after two to four weeks). Limited data specific to transgender masculinizing chest surgery are not as robust as data published for reduction mammoplasty and male gynecomastia surgery, so data on surgical complications are supplemented with data abstracted from the more extensive literature available in these fields.

Postoperative care in the primary and urgent care setting

Most early complications, although rarely life-threatening, should be expeditiously directed to the attention and experience of the operative plastic surgeon. Certain early complications (specifically hematoma, seroma, and nipple complications) can cause lasting aesthetic deformities that would be avoidable with timely intervention.

Delayed complications and specific areas of aesthetic dissatisfaction also merit referral to a surgeon. The most common complaints are related to postoperative scarring, contour deformities, and nipple appearance or discoloration. The process of healing and remodeling over the course of a year should be reinforced with patients. Prior to consideration for elective revision, patients should be medically, psychologically, and socially stable, and have realistic expectations.

Skin flap and incisional complications and scarring

Masculinizing chest surgery requires resection of redundant skin and soft tissue through surgical elevation of thin skin flaps. As a result, the blood supply to these skin flaps is tenuous.[6] This results in early complications, presenting as some degree of wound separation, delayed wound healing, or skin flap necrosis, with an estimated incidence of about 5 percent in the breast reduction population.[7]

Risk factors for early incisional and skin flap complications include high BMI (>30), hypertension, prior breast incisions, and amount of breast tissue resected. Perhaps the most important factor and one that is also modifiable for non-emergent surgery is preoperative smoking.[7,8] Patients should be counseled to stop completely for 4 weeks prior to surgery, and given the difficult nature of cessation of smoking, should consider quitting before even being referred for this type of surgery.

Unacceptable scarring, as a delayed complication, is also of concern to transgender men. A goal of surgery is to minimize the appearance of scars and optimizing their placement. Delayed wound healing results in a wide, abnormally pigmented scar that is more noticeable than the ideal fine line scar. In general, scarring from surgical incisions can be improved with some basic tenets of postsurgical wound care. Firstly, reduction of mechanical stress and tension across the wound by following postsurgical activity restrictions is paramount to reducing scar width. Tension across the incision can result in minute wound disruptions, causing excessive or widened scar formation. Patients should be counseled that incisions predictably look the worst in the early stage of healing, up to 10 weeks postoperatively, before

they begin to remodel over the next several months up to one year. Hyper- or hypopigmentation can also result in a more noticeable scar during this time of remodeling. We therefore recommend sun avoidance, or strong sunblock applied over a healed incision for the first year postoperatively. Scar compression has also been found to reduce hypertrophic scarring, although the mechanism is not known. This can take the form of gentle scar massage (beginning no earlier than 2 weeks postoperatively), taping, or silicone gels and sheets.[9] Surgical scar excision and revision is sometimes necessary if scar care fails to improve the appearance to an acceptable level.

Hematoma / seroma

Hematomas occur in approximately 1-2% of all breast reduction patients postoperatively, and usually present early after surgery.[8] The incidence has been reported as high as 5-11% among certain subgroups of transgender patients.[1–3] Hematomas can be prevented with meticulous surgical hemostasis and optimization of medical comorbidities (coagulopathies, hypertension, and stopping ongoing anticoagulation and certain herbal medications). A hematoma presents as asymmetric swelling and pain, sometimes accompanied by ecchymoses. In general, most hematomas need to be evacuated because of the physical pressure they can exert on the taut skin envelope, which can compromise skin flap viability and can also cause postoperative chest deformities. Other complications can include calcification or infection of the hematoma. Usually upon surgical re-exploration and evacuation, no discrete bleeding vessel is ever identified. Small liquefied hematomas can be aspirated or drained percutaneously.

Seromas and oil cysts are fluid collections that occur at the surgical site that are usually preemptively drained by placement of closed suction drains during the operation, combined with adherence to a postsurgical pressure garment. Occasionally, these collections can persist or recur after surgical drains are removed, and need to be drained to prevent skin flap or incisional compromise. Timing of surgical drain removal is dependent on drain output, and should be a decision made in conjunction with the surgeon.

Large oil cysts result from fat necrosis, which can cause contour irregularities and calcifications over time. These are addressed by aspiration and/or surgical revision.

Infection

Infection is a rare early complication after masculinizing chest surgery.[1,8] Usually this will present as localized cellulitis, and can usually be treated with a short course of oral antibiotics. An underlying fluid collection may need to be drained if it is associated with a persistent postsurgical infection.

Nipple-areola-complex and nipple graft complications

Whether the Nipple-Areola-Complex is preserved on a dermal pedicle, as in subcutaneous mastectomy, or it is taken as a free graft, there are associated early and late complications related to nipple healing. Decreased nipple sensitivity, numbness, or parasthesias are expected outcomes for both methods. Patients report varying degrees of sensory recovery

over time with both techniques. Both techniques result in some degree of hypopigmentation, reduction in nipple projection, and the rare complication of nipple loss; with these risks being more pronounced with free grafting. Careful adherence to postoperative instructions and nipple dressings can help assure good results with either technique,[1,2] with described overall nipple loss rates at 1% or less. It is important to distinguish between full thickness nipple necrosis and expected superficial skin slough in these postoperative patients.[6]

Nipple reconstruction and revision procedures may be required to restore the appearance of the nipple. Nipple position and size can also be adjusted during a secondary procedure. Usually these are minor procedures than can be accommodated once the initial healing phase is complete.

Contour irregularities

Minor chest wall contour deformities or asymmetry, including redundant tissue found at the end of incisions (dog ears), represented the most common reasons for patients seeking secondary chest wall surgery in multiple published series.[3,6] These can be excised as an outpatient procedure. Additionally, other contour deformities or asymmetries can be addressed with liposuction or fat grafting.

Overall operative revision rate for aesthetic improvement was reported as high as 32% in large published series of masculinizing chest surgery.[2]

Breast cancer risk

Transgender men should be counseled that androgenic hormonal therapy and chest wall contouring procedures (including subcutaneous mastectomy) do not obviate the risk of breast cancer development, particularly among those patients who are at greater risk for breast cancer due to family history. Chest wall contouring, with inherently different goals and techniques, as well as abundant intersurgeon variability in regard to technique, should not be considered a risk-reducing procedure. The presence of residual breast tissue has been acknowledged independently by various surgical authors describing various techniques.[1,3,6] Since the approaches to cosmetic mastectomy differs from those used in the management of breast cancer, all patients undergoing chest surgery should have baseline mammography to prevent an unexpected intraoperative or surgical pathology finding. Ongoing screening for breast cancer after subcutaneous mastectomy is discussed elsewhere in these guidelines.

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28. Perioperative and postoperative care for feminizing augmentation mammaplasty

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Introduction

As with non-transgender women, breast augmentation in transgender women involves implant-based augmentation mammoplasty. A prosthetic implant comprised of a silicone shell, with saline or cohesive silicone filler, is placed underneath the breast tissue (subglandular implant) or under the pectoralis muscle (subpectoral implant).

Initiation of estrogenic and antiandrogenic therapy stimulates the development of breast tissue in transgender women. In the absence of solid evidence for an optimal length of time on feminizing hormone therapy prior to augmentation, some sources recommend a minimum of 6 months of hormone therapy prior to surgery, to allow hormone-related breast development to progress.[1,2] Realistically, a minimum of 2-3 years is more likely to maximize hormonal breast development.

The choice of implant, type, and position is governed by the woman's preoperative body habitus and wishes, in consultation with a board-certified breast or plastic surgeon. Subglandular implant placement may be preferred when there is adequate breast and subcutaneous tissue to cover the implant, and prevent visible implant seams and rippling. Subpectoral implant placement may be preferred when saline implants are used, or in the absence ofadequate soft tissue to disguise the shape of the implant.[3] There are no objective outcomes data to support the use of saline vs. silicone filler, other than aesthetic considerations and preference on the part of the surgeon and patient.[4] Since many transgender women have inadequate breast development, subpectoral silicone implant placement is the typical approach used.

Breast augmentation procedures are often performed as a "same-day," ambulatory procedure under general anesthesia; operative time is approximately 2 hours. Recovery is fairly rapid over the course of several weeks, though some patients may experience prolonged soreness, swelling, and mild bruising. A small incision is made along the new inframmary crease and a space for the implant is created in the subglandular or subpectoral planes described above. The incisions are closed with several layers of sutures and the patient generally feels well enough to go home the same evening.

In general, results are durable and complications are rare for feminizing augmentation mammoplasty.[2] Complications are typically divided into early (less than two to four weeks) or late complications (more than four weeks). Surgical data on augmentation mammoplasty specific to transgender women [2,5] are limited; some data are extrapolated from data published on non-transgender women undergoing this procedure. In one study, 75% of transgender women reported satisfaction in long-term follow-up with implant-based

augmentation, with the majority of dissatisfaction related to subjective aesthetic outcome (primarily inadequate breast size) rather than technical surgical complications.[5]

Postoperative complications in the primary and urgent care setting

Any concern for an early postoperative complication (as detailed in sections below) should be expeditiously referred to the operative surgeon.

A plastic surgery referral is also appropriate for a patient presenting late after augmentation mammoplasty with new symptomatic or objective breast complaints related to prior breast augmentation (e.g. swelling, pain, erythema, significant deformity/asymmetry, and implant deflation). Benign and malignant breast tumors are always in the differential diagnosis and should be worked up appropriately. Breast cancer screening should be up-to-date prior to referral. If a fluid collection or implant rupture is suspected based on history or exam, it is helpful to confirm this with an ultrasound or MRI prior to seeing the plastic surgeon.

Women who present with subjective dissatisfaction after previous breast augmentation may require a second surgical consultation or referral to another plastic surgeon. Elective secondary revision of augmented breasts is not uncommon. Prior to any referral for breast surgery, patients should be medically, psychologically, and socially stable, up-to-date in regard to breast cancer screening if indicated), and have reasonable postsurgical expectations.

Anesthetic complications particular to gender-affirming feminizing mammoplasty

In addition to standard anesthetic complications, patients undergoing feminizing mammoplasty should be assessed for risk factors for venous thromboembolism,and appropriate mechanical and chemoprophylaxis measures applied based on individual risk factors. Management of perioperative estrogen therapy and estrogenic risks of venous thromboembolism are discussed elsewhere in this protocol.

Hematoma

A hematoma typically presents early (within 1-2 weeks) after augmentation mammoplasty, typically as a localized or unilateral swelling accompanied by pain and bruising at the surgical site. In the absence of breast trauma, delayed hematomas are rare.[6]

Close adherence to postoperative care protocols is necessary to prevent early postoperative hematomas. Specifically, the patient should be counseled to avoid strenuous activity and situations where the chest could be exposed to external trauma. Additionally, strict medical adherence (especially in regard to withholding anticoagulant, antiplatelet, and certain herbal medications and compliance with antihypertensive medications) can decrease incidence of postoperative hematoma.

Hematomas are typically treated with surgical re-exploration, evacuation with identification of the bleeding source, and reclosure, with or without exchange of the prosthetic implant. Small hematomas can occasionally be managed expectantly. An untreated large hematoma can result in secondary complications, such as infection, capsular contracture, or implant malposition.[7]

Seroma

A sterile postsurgical fluid collection is expected to form periprosthetically and typically is resorbed after the early recovery period.[6] Unless there is reason to suspect that there is concomitant infection or that the fluid collection is in danger of causing incisional breakdown and implant exposure, there is no reason for concern or need for further radiographic evaluation with an early postoperative fluid collection. There is no evidence in the plastic surgery literature to support the routine use of drains in augmentation mammoplasty. A delayed seroma is generally abnormal, and should be evaluated by a plastic surgeon.[4]

Infection

Infections are uncommon and typically present as early (1-4 weeks) complications following breast augmentation. The severity of infection can range from a mild incisional cellulitis to a purulent periprosthetic infection. The most common pathogens in periprosthetic infections are skin flora, and as a result, surgeons go to extensive lengths to avoid contamination.[8]

A majority of postoperative infections will respond to medical treatment with antibiotics. However, most authors would advocate for implant removal in cases that fail to resolve, with delayed secondary augmentation performed in 6-12 months, once the patient has time to heal and fully clear the infection.[3]

Incisional complications

Incisional scarring is a late complication of augmentation mammoplasty. Patients should be cautioned on appropriate scar care, including sun avoidance in the early postoperative period. Patients with darker or oily skin types or a prior history of hypertrophic scar or keloid formation should also be aware of their increased risk for these complications.

In general, scarring from surgical incisions can be improved by following some basic tenets of postsurgical wound care. Firstly, reduction of mechanical stress and tension across the wound by following postsurgical activity restrictions is paramount to reducing scar width. Tension across the incision can result in minute wound disruptions, causing excessive or widened scar formation. Patients should be counseled that incisions predictably look the worst in the early stage of healing, up to 10 weeks postoperatively, before they begin to remodel over the next several months to up to one year. Hyper- or Hypopigmentation can also result in a more noticeable scar during this time of remodeling. We therefore recommend sun avoidance, or strong sunblock applied over a healed incision for the first year postoperatively. Scar compression has also been found to reduce hypertrophic scarring, although the mechanism is not known. This can take the form of gentle scar massage (beginning no earlier than 2 weeks postoperatively and after the wound is fully healed), taping, or silicone gels and sheets.[9]

Implant rupture

A break in the silastic shell of a saline [10] implant will be recognized immediately as deflation and loss of breast volume. Implants placed prior to the late 2000s contained a liquid silicone gel which was prone to leakage, both due to shell rupture and leaching. Potential complications include deformity, inflammation, and pain. Currently available silicone breast implants (4th or 5th generation implants, also termed cohesive gel implants), even a break in the outer shell of the implant will not allow free silicone gel to escape the implant. As a result, silicone implant rupture often goes undetected. Suspected rupture can be confirmed by MRI imaging. A long-term MRI study of implant integrity found that more than 90% of the current generation of silicone implants were intact at 10 years.[11]

A 2011 report by the FDA recommended routine MRI screening for asymptomatic silicone implant rupture, initially three years after implantation and biannually thereafter,[12] although there is no evidence base to support such a recommendation and an MRI may not be covered by insurance.[13] Patients should receive preoperative counseling regarding this recommendation, as well the lack of objective evidence to support it.

Implant malposition and capsular contracture

Implant malposition can occur over time as the breast adapts to breast implant placement and aging. Nonpathologic capsule formation over the surface of the implant is expected. Pathologic fibrotic capsule formation, known as capsular contracture, can cause the implant to be hard and palpable, or cause implant displacement, breast deformation, or even breast pain related to the implant. Once symptomatic or disfiguring, implant removal and surgical excision of the capsule is indicated. Capsular contracture rates in modern implants are felt to be less than 10%, although long-term followup is needed.[3] There has not been any link between breast implants or periprosthetic capsule formation and connective tissue diseases.[3] While the U.S. Food and Drug Administration recommends screening for silicone implant rupture with MRI every 3 years, there is no evidence to support this practice in the absence of symptoms (pain, deformity), since the recommended approach to an incidental and assymptomatic implant rupture is non-operative observation.

Inadequate size and aesthetic deformities

A long-term study of transgender women who underwent augmentation mammoplasty found that 16% of the patients underwent a second augmentation procedure for breasts that were too small.[5] These patients accounted for the majority of dissatisfaction related to augmentation.

A number of aesthetically unappealing complications can occur and result in dissatisfaction requiring revisional surgery and secondary augmentation. These complications are generally a result of a combination of technique and patient anatomy. Some of these complications can include a visible implant and implant folding or rippling, which occurs in saline implants or when the patient has inadequate soft tissue covering the implant. Other patients can develop asymmetry related to scar formation or displacement over time by the action of the pectoralis

muscle (in the case of submuscular implants). These deformities will need to be addressed with secondary revision breast augmentation procedures.

Breast masses

Breast cancer epidemiology and screening in transgender women is covered elsewhere in this protocol. For those transgender women requiring screening or diagnostic mammography or breast ultrasound, both are possible with breast implants. However, mammography cannot detect implant-related complications, such as ruptures.[14]

Breast soft tissue injections

Although autologous fat grafting is gaining acceptance in plastic surgery,[15] its use in transgender women has not been widespread or well-described. Injection of silicone and other non-medical substances by unlicensed providers is covered in detail elsewhere in this protocol.

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29. Vaginoplasty procedures, complications and aftercare

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Introduction

The most common vaginoplasty technique is some variation of the penile inversion procedure. In this technique, a vaginal vault is created between the rectum and the urethra, in the same location as a non-transgender female between the pelvic floor (Kegel) muscles, and the vaginal lining is created from penile skin. An orchiectomy is performed, the labia majora are created using scrotal skin, and the clitoris is created from a portion of the glans penis. The prostate is left in place to avoid complications such as incontinence and urethral strictures. Furthermore, the prostate has erogenous sensation and is the anatomic equivalent to the "g-spot." Great care is taken to limit the external scars from a vaginoplasty by locating the incisions appropriately and with meticulous closure. Typical depth is 15 cm (6 inches), with a range of 12-16cm (5-6.5 inches); in comparsion, typical vaginal depth in non-transgender females is between 9-12cm (3.5 to 5 inches). In the case of prior circumcision a skin graft, typically scrotal in origin, may be required. If there is insufficient skin between the penis and the scrotum to achieve 12cm (5 inches) of depth, a skin graft from the hip, lower abdomen or inner thigh may be used. Resultant scarring at the donor site may be minimized or hidden using standard techniques. Because the penile inversion approach does not create a vaginal mucosa, the vagina does not self-lubricate and requires the use of an external lubricant for dilation or penetrative sex.

Scrotal skin has abundant hair follicles and it is possible to transfer skin with sparse hair growth into the vagina unless hair is removed in advance. Some surgeons rely on treating all the visible hair with aggressive thinning of the skin and cauterization of visible hair follicles at the time of surgery. However, since hair grows in stages this approach might not adequately address dormant follicles. The most reliable method of preventing hair growth in the vagina is to perform scrotal electrolysis, at least three full clearings 8-12 weeks apart, depending on electrolysist preference and hair type and distribution. Surgeons should provide a diagram of the specific area for clearance.

A common outcome of penile inversion vaginoplasty performed in a single stage (a "one-stage" vaginoplasty), with penile skin positioned between scrotal skin, is labia majora that are spaced too far apart. There may also be minimal if any clitoral hooding (except in heavier patients) and the labia minora may be insufficient after one operation. Although there are different variations of the one-step procedure, it has been the author's experience that these previously mentioned deficiencies are common. This constraint is due to factors inherent to the penile inversion approach and the limitations of the blood supply. From the standing position and with the legs together, most results appear acceptable; however, upon direct examination or intimate view, the deficiencies discussed above will be apparent. In order to

adequately address these deficiencies, the author believes that a second operation is required. A secondary labiaplasty provides an opportunity to bring the labia majora closer to the midline in a more anatomically correct location, provide adequate clitoral hooding, and define the labia minora. In addition, there are many variables that can affect healing and the final result. Specifically, this secondary procedure also allows the surgeon to deal with differences in healing, such as revision of the urethra, correction of any vaginal webbing or persistent asymmetries, or revise scars that are unsatisfactory. These revisions will improve functionality and the final outcome for the patient and might not otherwise be addressed.

Immediate postoperative considerations

Gauze packing or a stenting device is placed in the vagina intraoperatively and remains in place for 5-7 days. Once removed, the patient is instructed in vaginal dilation, with dilators generally provided by the surgeon; dilation schedules vary between surgeons. Table 1 shows sample postoperative instructions, and Table 2 shows dilation instructions and a sample dilation schedule.

Table 29-1. Vaginoplasty Postoperative Instructions

Focus area	Instructions
Activity	Avoid strenuous activity for 6 weeks. Avoid swimming or bike riding for 3 months.
Sitting	For the first month post-op, sitting may be uncomfortable, but not unsafe. Recommendation to use donut ring to relieve pressure at surgical site.
Bathing	Resume showering following first postoperative visit, patting incisional areas dry. Do not take baths or submerge in water for 8 weeks post-op.
Swelling	Labial swelling is normal and will gradually resolve 6-8 weeks postoperatively. Swelling may be aggravated with long-term sitting or standing. For the first week post-op, applying ice on the perineum for 20 minutes every hour can assist in relieving some swelling.
Sexual intercourse	You may resume sexual intercourse 3 months after surgery, unless you have been instructed otherwise.
Hygiene	Wash hands before and after any contact with the genital area. Shower or wash daily. When washing, wipe from front to back to avoid contamination by bacteria from the anal region. Avoid tight clothing; friction may facilitate bacteria transfer.
Vaginal	Vaginal discharge that is brownish yellow should be expected in the first 4-6 weeks postoperatively. Bleeding and spotting should be

Focus area	Instructions
discharge	expected in the first 8 weeks postoperatively. Soap and water douche should help reduce this. Chamomile or lavender liquid soap can help cleanse the neo vagina as well.
Tobacco/ smoking	Avoid tobacco use or smoking 1 month postoperatively, as this can interfere with the healing process.
Diet/nausea/ constipation	Begin with a liquid diet and increase to your usual diet as tolerated. Anti-nausea medication may be prescribed. Narcotic pain medication may cause constipation; a stool softener such as Colace can help prevent constipation.
Pain medication	Postoperative pain is normal, and pain medication may be prescribed. Pain medication is to be taken as prescribed, and can be switched for Extra Strength Tylenol at any time.
Dilation	Dilation is an important part of recovery. Dilators may be provided to patient with instructions regarding dilation in the post-op period.

Source: Brownstein & Crane Surgical Services

Dilation Instructions

Source: Brownstein & Crane Surgical Services

Please be aware that each person's dilation schedule may vary.

- Prior to insertion into the vagina, ensure the dilator is clean.
- Clean the dilator with warm water and antibacterial soap. Rinse well and dry with a clean paper towel or cloth.
- Apply Surgilube or KY Jelly to the dilator prior to insertion. Only use water based lubrication.
- Avoid silicone-based lubricants.
- Gently insert dilator into the vagina at an angle of 45 degrees until under the pubic bone, and then continue inserting straight inward.
- Expect to feel a small amount of resistance and tenderness. Stop immediately if there is too much resistance or severe pain.
- Insert the dilator into the full depth of the vagina (until you feel moderate pressure or resistance) and leave in place for 10 minutes. You should be inserting until only one or two white dots remain outside of the vagina.
- Start dilating three times daily for three months on the day the vaginal packing is removed.
- You may start using the next size dilator after three months of dilating. You should use the next size for three months.

- Dilation frequency: 0-3 months after surgery 3 times/day for 10 minutes each time, 3-6 months after surgery 1/day for 10 minutes each time, more than 6 months after surgery 2-3/week for 10 minutes each time, more than 9 months 1-2x/week.
- If the vagina begins to feel tight, increase the frequency of the dilation schedule.
- You should use soap and water to cleanse the vaginal canal after each dilation.

Table 29-2. Dilation Sample Schedule

Months Since Surgery	Color of Dilator	Diameter of Dilator	Frequency
0-3	**VIOLET**	1-1/8”	3X per day
3-6	**BLUE**	1-1/4”	Once daily
6-9	**GREEN**	1-3/8”	Every other day
9-12	**ORANGE**	1-1/2”	1-2x per week

Source: Brownstein & Crane Surgical Services

Immediate risks include bleeding, infection, skin or clitoral necrosis, suture line dehiscence, urinary retention or vaginal prolapse. Fistulas from the rectum, urethra or bladder usually present early on.

Acute bleeding usually originates from the urethra and most often can be controlled with local pressure. If local pressure is unable to achieve hemostasis, then placing a larger catheter (20F) in the urethra alone may stop the bleeding. If necessary, placing a suture around the bleeding site (with the catheter in place) will stop the bleeding in almost all cases. It is not unusual for localized hematomas to spontaneously drain through the vagina or suture line. This usually occurs a week or greater after surgery as the hematomas liquefy. The blood characteristically appears dark and old, and is not accompanied by clots. Although frightening to the patient, no treatment is indicated.

The genitalia and perineum have an excellent blood supply, so infections should be rare and seldom require more than a broad-spectrum antibiotic. Skin slough or loss is also rare, and should be treated conservatively. Separation of the suture line can occur, most often at the posterior perineum due to the pressure and stretching that occurs with dilation. Separations should be treated conservatively with antibiotic ointment, most will heal without consequence. Dilation should not be discontinued, and is critical at this stage. Failure to adequately dilate in the immediate postoperative period will likely result in severe vaginal stenosis. No attempt at immediate secondary closure of the dehiscence is indicated since it is a contaminated wound and would likely fail. In some cases, dehiscence may result in the development of a posterior web, which can be easily revised at a later stage.

Partial or complete clitoral necrosis may occur and should be treated conservatively with antibacterial ointments. In the majority of cases, the neurovascular bundle and a portion of the clitoris is still present and will usually maintain good sensitivity.

Urinary retention due to swelling and/or temporary peripheral nerve injury (neuropraxia) should be treated with replacement of a catheter for 5-7 days. Flomax is helpful, and this is almost always temporary. Early strictures are very rare.

A patient may lose a portion of the added skin graft and pass it out through the vagina. This usually occurs at least 2 weeks from surgery, and typically due to excessive skin grafting into the vagina. It is not accompanied with bleeding and the sloughed skin appears nonviable. Recovery is uneventful and patients should continue to dilate. A more severe scenario is expulsion of the entire vaginal skin lining, which occurs earlier (usually within the first postoperative week) and is frequently accompanied with at least some bleeding. While uncommon, in most cases it is a disastrous complication and the patient will require surgical intervention, typically one year later to re-line the vagina.

Delayed / long-term postoperative maintenance and considerations

Adherence to the dilation regimen is critical to healing and maintaining vaginal depth and girth. After the initial healing period, dilation must continue regularly for at least one year postoperatively. The depth and the width of the vagina should be checked regularly as one tapers down the dilation schedule. If it is noticed that vaginal depth or width are diminishing either by patient report or in-office examination, the dilation schedule should be increased. If the patient experiences difficulty with dilation due to discomfort, instillation of lubricant ahead of the dilator with either a 3cc syringe, or the applicator device supplied with vaginal antifungals may be helpful. Patients may develop a sensitivity to the preservative in the water based lubricant; simply changing the brand of lubricant is often an effective solution.

Loss of vaginal girth due to inadequate dilation can often be remedied by increasing dilation frequency; loss of vaginal depth is more difficult to address by dilation alone. Persistent pain or otherwise problematic dilation should be discussed with the surgeon. Other possible causes of painful or inadequate dilation include a small pelvic inlet or muscle spasm and vaginismus. Approaches may include but are not limited to botulinum toxin injections, removal of webbing at the entry of the vagina, and/or a referral to a physical therapist that specializes in pelvic pain and pelvic floor issues.

The vagina is skin-lined and under normal conditions is colonized with a combination of skin flora as well as some vaginal species; a study of vaginal flora in a mix of transgender women with and without symptoms of odor and discharge found Staphylococcus, Streptococcus, Enterococcus, Corynebacterium, Mobiluncus, and Bacteroides species to be most common. Lactobacilli were found in only 1 of 30 women, and candida was not found. There was no correlation between the presence of vaginal symptoms and any one particular species.[1] These findings suggest that vaginal discharge and odor in transgender women is unlikely to due to common causes in non-transgender women such as bacterial dysbiosis or candida; indeed the lack of a mucosa or low pH are consistent with this study's findings of rare lactobacilli and no candida. In most cases discharge is most likely due to sebum, dead skin or keratin debris, or retained semen or lubricant.

Since the vagina does not contain a mucosa, routine cleaning or douching with soapy water should be adequate to maintain hygiene. Initially the patient should douche daily during frequent dilation. Douching can be reduced to 2-3 times a week when dilation is less frequent. If odor or discharge persists, an examination for lesions or granulation tissue should be performed. Use of a solution of vinegar or 25% povidine iodine in water for 2-3 days may help in cases of flora overgrowth or imbalance, after which the patient can return to regular soap and water cleaning. If the drainage and odor persist, an empiric 5-day course of vaginal metronidazole is reasonable.

It is reasonable to consider a yearly visual pelvic exam to screen for lesions, granulation tissue, or undesired loss of depth and girth, though no evidence exists to support this recommendation. Since the vagina is skin lined, there is a risk of developing the same skin cancers that occur on the penile and scrotal skin (squamous cell, basal cell, melanoma). Other skin disorders such as psoriasis can also affect the vagina and should be treated similarly. If indicated, a prostate exam may be performed endovaginally since the rectal approach may be obscured by the new presence of the vaginal walls in between the rectum and the prostate.

A far less common approach to vaginoplasty is the use of either colon or small bowel to line the vaginal vault. This technique has the advantages of diminished need for dilation, greater depth and is naturally self-lubricating. However, this approach requires abdominal surgery with a risk of serious or even life-threatening complications. The primary indication for an intestinal approach is the revision of prior penile-inversion vaginoplasties. Since the secretion is digestive there is a risk of malodor and frequent secretions, and secretions are constant rather than only with arousal. Wearing panty liners or pads may be necessary for the long term. Bacterial overgrowth (diversion colitis) is common and may present with a greenish discharge, treatment includes. The bowel lining is also not as durable as skin. Use of intestinal tissue also places the vagina at risk of diseases of the bowel including inflammatory bowel disease, arterio-venous malformations (AVM) or neoplasms; screening or diagnostic evaluations for these conditions should be performed as indicated.

Fistulas

The most common fistula is a rectovaginal fistula. These usually occur at the midline within 5 cm of the vaginal opening, and are almost universally the result of a surgical injury to the rectum. Small fistulas may only pass flatus, while larger fistulas can allow stool to drain through the vagina. A temporary diverting colostomy may be required for hygiene. Dilation should continue to avoid closure of the vagina, with the plan to repair the fistula in a minimum of 6 months.

Urethrovaginal fistulas present with urine leakage from the vagina. The majority of cases do not need or require immediate intervention, and in most cases the patient will still be continent. The patient should be counseled that they will be more susceptible to urinary tract infections--particularly after intercourse. Voiding promptly after intercourse and/or acidifying the urine with juices or cranberry pills is usually adequate preventive care. Fistulas between the bladder and vagina are the least common, but are the most difficult to manage. A foley

catheter in the bladder will divert a majority, but not all of the urine; in general surgical intervention will be required.

Granulation tissue

Granulation tissue in the vagina is the result of delayed healing and is common. The need for frequent dilation in the early post-operative period exacerbates the problem by causing repeated trauma to the area of granulation. The typical complaint is of mildly blood-streaked yellowish discharge. In most cases this will heal as the need for frequent dilations diminishes over time. If persistent, regular silver nitrate treatments and topical treatment of steroid cream (triamcinolone) or medical grade honey (Medihoney) will speed the healing. Silver nitrate can be applied to granulation areas until cautery is observed with resultant grey scabbing and coagulation. Steroid creams or honey can be applied on the tip of the dilator. Long term, the penile skin lined vagina should be very durable.

Urinary tract infections (UTIs)

Urinary tract infections are not uncommon, since the urethra is shortened during a vaginoplasty. Proper hygiene and hydration are generally adequate preventive measures. A patient who has recurrent urinary tract infections should be evaluated for a urethral stricture. A simple diagnostic test is to attempt to pass a 16F catheter into the bladder to rule out strictures, including post-bulbar or meatal stenosis. Patients with a mucosal flap causing a large meatus will require meticulous hygiene and possibly prophylaxis. Most patients will see a reduction in their ability to hold larger volumes of urine over longer times as a consequence of the involution of the prostate. Rarely some may even experience urgency incontinence. Bladder relaxants like tolterodine or darifenacin are helpful in these cases.

Sensation and orgasm

No major sensory nerves should have been divided during surgery, so sensitivity should not be adversely affected after vaginoplasty. In an outcome study published in 2002, 86% of the author's patients were orgasmic.[2] Pre-operative functionality is an important indicator, though it is possible that a previously anorgasmic patient will be orgasmic following vaginoplasty. The combination of prolonged estrogen/anti-androgen therapy and orchiectomy during surgery may result in a reported decline in libido for some patients, which is discussed elsewhere in these guidelines.

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30. Phalloplasty and metaoidioplasty – overview and postoperative considerations

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Introduction

Phalloplasty in transgender men involves the creation of a penis using any one of a number of procedures; either a free flap or pedicled flap of skin, usually taken from the arm (radial forearm free-flap, RFF) or anterior lateral thigh (anterior lateral thigh pedicled flap phalloplasty, ALT). In a free flap procedure, tissue is completely removed from the donor site along with its blood supply. The blood supply is then anastomosed to a recipient blood supply at the site of transfer. In a pedicled flap procedure, the tissue is never severed from its blood supply. Using either procedure, the donor skin is rolled into a tube like structure and grafted to the inguinal area. In order to minimize the risk of fistula, most commonly this procedure is performed after a hysterectomy and vaginectomy (or vaginal mucosal ablation) is performed. Scrotoplasty may also be performed using skin flaps. Scrotoplasty may be performed with or without testicular implants. A urethral hookup may be performed using cheek or vaginal mucosa, and an erectile implant may be placed. Often the entire phalloplasty procedure involves multiple staged surgeries, with earlier stages allowing skin grafts to develop local blood supply prior to cosmetic procedures to complete the phalloplasty. Depending on the surgical approach, the penis may or may not have intact erotic sensation.

Risks associated with phalloplasty

There are general risks associated with any surgery, including infection, bleeding, damage to surrounding tissues, and pain. Specific to phalloplasty in transgender men, there is risk of flap loss, urethral complications, wound breakdown, pelvic bleeding or pain, bladder or rectal injury, lack of sensation, prolonged need for drainage, or need for further procedures. Donor site risks include unsightly scarring, wound breakdown, granulation tissue formation, decreased mobility, hematoma, pain and decreased sensation. If patients are discharged from their surgeon's care and are not local, they should see their primary care provider every three months during the first year.

Some of the most common complications are listed below. Different techniques and approaches can have varying levels of complexity. Different surgeons may also have different complications rates; understanding what procedures different surgeons perform, their experience, frequency with which they perform these procedures, and complication rates is helpful.

Immediate/early (within one month) complications after free or pedicled flap phalloplasty

Wound infections typically occur within the first few weeks after surgery and can present as cellulitis, fungal infection or both. Antibiotics and antifungal cream are usually sufficient for treatment. In some cases intravenous antibiotics may be required.

Wound breakdown is common and typically occurs at points where multiple suture lines meet (i.e. perineal-scrotal junction and base of phallus). Most wound breakdown issues can be managed with local wound care (wet to dry dressing changes) as the wounds heal by secondary intention. Some wound breakdowns may require debridement(s), and fewer may require skin grafting or further surgical procedure(s) to close the wound.

Urinary catheter difficulties present as a clogged catheter or bladder spasms. This is managed by making sure there are no kinks or twists in the tubing, flushing the catheter, and antispasmodic medications (anticholinergics). Urinary tract infections (UTIs) in the setting of a urinary catheter can develop and present with a constellation of symptoms including cloudy urine, odorous urine, increased bladder spasms or leakage around catheter. These symptoms may or may not present with fever or other systemic symptoms. If a patient does not have a constellation of these symptoms, it is unlikely to be a true UTI even if the urinalysis (UA) and urine culture (UCx) demonstrate laboratory findings consistent with infection.

Flap loss is rare and typically occurs due to technical error (misplaced microsurgical suture or vascular pedicle kinking/compression). Flap loss typically presents within the first 72 hours, and if recognized early (within hours) can be salvaged by emergent return to the operating room. On return to the OR, drainage of a hematoma compressing the vascular pedicle, revision of the arterial or venous anastomosis, or in some cases mechanical thrombectomy with balloon catheters or instilling tissue plasminogen activator (tPA) into the flap can save a flap from loss. Even with these measures, partial or complete flap loss is possible. Hypercoagulable states can predispose a patient to clotting after surgery and flap loss. Undiagnosed clotting disorder such as Factor V Leiden, antiphospholipid syndrome, prothrombin gene mutation G20210A, antithrombin III deficiency, Protein C and S deficiency, and hyperhomocysteinemia should be considered in the case of flap thrombosis.

Pelvic or groin hematomas can occur, and may be managed by drains, or may require surgical drainage. While medical deep vein thrombosis prophylaxis with unfractionated heparin or lovenox may place the patient at higher risk of hematoma formation, this risk must be weighed against the risk of deep vein thrombosis and pulmonary emboli. Risk assessment models exist to help determine individualized perioperative anticoagulation modalities.[1] While these risk assessments will generally be performed by surgeons, primary care providers with knowledge of an individual patient's increased risk for thromboembolism or perioperative bleeding should notify surgeons pre-operatively.

Rectal injury is a rare but serious complication. The vaginectomy portion of the procedure involves developing a plane between the posterior wall of the vagina and the anterior wall of the rectum. Laceration with scissors or cautery can cause this injury. Inadvertent injury to the rectal wall can present acutely (immediately known and repaired) or subacutely (days to

weeks later). Recognition of a rectal injury in the subacute period can be based on constitutional symptoms of fever, chills, malaise, or more overt symptoms of sepsis. The portion of the rectum in the surgical field is extraperitoneal, so abdominal pain or peritoneal signs would be unusual. Drainage of stool from the perineal incisions, scrotum or base of the phallus indicates formation of a fistula between the rectal wall and the skin. Such wounds require hospitalization and general surgical involvement in the care plan. A short-term colostomy may be required to divert the fecal stream and allow the fistula to close. Washout of a pelvic abscess and closure of the rectal fistula, with secondary wound healing may be required.

Long-term complications after free or pedicled flap phalloplasty

Urethral strictures typically present 6-12 months after surgery with symptoms of a weak stream, straining with urination, and sometimes concomitant fistulas secondary to distal obstruction from the stricture. This will require surgical intervention with either dilation or urethroplasty.

Wound contraction and scarring are complications that occur any time the skin is cut, but the degree to which they occur is highly variable between patients. Some patients form scar more robustly than others. All scars contract with time as myofibroblasts within the wound become active in the first 2-9 days.[2] Wound contracture is a natural mechanism to decrease the defect size, decreasing the effective surface area that must be healed. However, wound contracture can lead to distortion of surrounding tissues and contour defects. Wounds that close by secondary intent show more contracture than primary closure.

Scars can be thin lines, or can widen or become “proud” (hypertrophic), or even pass beyond the borders of the scar (keloid). Hypertrophic scars can successfully be revised by excision and reclosure with skin tension reducing measures to decrease recurrence. Keloids occur infrequently, often in people predisposed to keloid formation. The recurrence of keloids after simple excision and closure is very high (at least 70%). Steroid injections, silicone and compressive dressings, and radiation therapy have been offered as treatment modalities, with limited improvements in recurrence rates.

Granulation tissue is common at the donor site around and within the skin graft. Its appearance represents an over exuberant proliferation of fibroblasts and small blood vessels. Most granulation tissue can be treated with topical application of silver nitrate applied periodically over several office visits, as needed. Silver nitrate can lead to dark discoloration of the treated tissues, which can persist for weeks to months. However, granulation tissue rarely requires more involved treatment.

Corona flattening can occur on occasion and may require revision surgery done at the same time of the 2nd stage surgery (typically penile and testicular implantation)

Erectile implants

Roughly nine months after the penis is created, the patient can have a penile implant placed to allow rigidity for penetration. Currently there are no FDA approved implants specifically

created for transgender patients. As such, implants created for non-transgender males with erectile dysfunction are rigidly fixed to the pubic bone. Complications can include infection and erosion.

Infection is the most common complication of the penile implant. Pre and post op antibiotics reduce the risk, as well as intraoperative sterile technique. If an implant becomes infected, it typically has to be removed. A new implant may be replaced six months later.

Erosion is when the implant protrudes through the skin of the phallus or the urethra. The presence of sensation in the phallus, and avoiding an excessively large implant reduce the risk of erosion. As with infection, erosion of an implant necessitates surgical removal.

Dysuria

Should a recently postop phalloplasty patient have dysuria, the best approach is to obtain a urine culture. Urinalysis is of little value as white and red cells can be detectable in normal post op patients for months after reconstruction. If a urine culture is positive, the infection should be treated with culture specific antibiotics. If it is negative, the most likely culprit is a urethral stricture, which should be evaluated by the surgeon who performed the phalloplasty, or if unavailable, a local urologist.

Metoidioplasty

Metoidioplasty (metaoidioplasty) is a Greek word that means “towards male genitalia.” Testosterone causes growth of the clitoris; metoidioplasty uses only local tissue (no grafting) to create a smaller, 1 to 3 inch phallus with girth approximately the size of someone’s thumb. Patients may opt to have a urethra placed in the phallus, but not all patients choose to do this. A scrotum can also be created from the labia majora and a vaginectomy may be performed. Because metoidioplasty is a shorter procedure, occasionally hysterectomy is performed at the same time as metoidioplasty. Some surgeons may use tissue expanders to create the scrotum, while others do not find this necessary. Testicular implants are typically placed at a second stage approximately 4 months later. While the phallus is not large enough to accept a penile implant, erections are possible since the procedure involves the use of natal clitorial and other genital tissues.

Complications associated with metoidioplasty are very similar to free flap phalloplsaty, except for flap loss since no flap is used. Wound breakdown, infection, urethral stricture and fistula are all seen in similar anatomic sites to that of free flap phalloplasty, although the incidence is lower in metoidioplasty. Risks such as coronal flattening do not occur in metoidioplasty, as the corona does not require sculpting in metoidioplasty. Management of complications similar to as is detailed in the phalloplasty section.

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31. Hysterectomy

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Introduction

Hysterectomy with and without salpingectomy/oophorectomy is considered by WPATH to be a medically necessary component of gender-affirming surgical therapy for those transgender men who choose to seek this procedure.[1] It is unknown how many transgender men desire and obtain hysterectomy for the purposes of gender affirmation or in the context of gender dysphoria. In the National Transgender Discrimination Survey, 21% of trans men surveyed had undergone hysterectomy.[2] 58% desired a hysterectomy at some time in the future, and 21% had no desire for a hysterectomy, It is unclear what differentiated individuals who had already undergone hysterectomy from those who desired the procedure in the future, though access to care and financial considerations are likely contributors. Also unclear is how reproductive desires may play into decisions about hysterectomy and or oophorectomy. Furthermore, it is unclear from this study what proportion of these hysterectomies were due to a medically pathologic condition rather than gender dysphoria, since hysterectomy is one of the most common non-obstetrical surgical procedures.

A study of 134 transgender men reported a diversity of indications for hysterectomy, though most procedures were performed for gender affirmation. In that study, 58% underwent hysterectomy because organs were incongruent with current gender identity, 47% for further physical masculinization, 43% to facilitate a change in legal documents, and 37% to avoid future gynecological appointments. However, this same study also noted that for many this procedure was seen as “preventive” in 59%, was performed because of pre-existing medical problems in 26%, specifically for “tumors, cysts, fibroids or endometriosis” in 22% or to stop extreme bleeding and cramping in 22%.[3] Since widespread explicit insurance coverage for hysterectomy for purposes of gender affirmation is both recent and evolving, it is possible that some of the decisions to perform hysterectomy in the setting of pathologic conditions may have been hastened by coexisting gender dysphoria.

Surgical approaches

Best practice for the surgical approach to hysterectomy in transgender men has not been studied. Hysterectomy may be performed abdominally, laparoscopically, or vaginally. Based on existing evidence, the American Congress of Obstetricians and Gynecologists has stated that for patients in whom the approach is appropriate, a vaginal approach has the fewest complications and blood loss, quickest recovery, and is the most cost-effective.[4] For transgender men, vaginal hysterectomy has the added benefit of leaving no abdominal scars. Initial data [5,6] support the notion that vaginal hysterectomy is appropriate for transgender men. Many other studies have noted that laparoscopic hysterectomy, the second least invasive form of hysterectomy, is also possible and can successfully be accomplished without additional complications.[7–11]

Hysterectomy has been successfully combined with other gender-affirming surgeries performed on the same day in the same operating suite including vaginectomy, mastectomy, and genital reconstruction including metoidioplasty and phalloplasty.[10,12] Hysterectomy itself does not largely differ, however some modifications in concurrent surgeries and extent of dissection may differ depending on the goals of the transgender patient. For example if a transgender man undergoing hysterectomy has no plans for penetrative vaginal intercourse in the future, the vaginal cuff closure could be much more exterior, such that less of a vaginal orifice remains. Similarly, vaginectomy (removal of vaginal mucosal tissue) and colpocleisis (closure of the vaginal canal) could be performed if no vaginal orifice is desired, as long as there is no desire for future genital reconstructive surgery that would make use of the vaginal mucosa (for urethral lengthening etc). Finally, consideration of whether to retain or remove the ovaries and fallopian tubes at the time of surgery is also a personal decision and will be based on considerations of patient desire, future fertility, plans for exogenous (steroid) hormone administration, and other pathology that may be aided or exacerbated by ovarian removal (e.g., endometriosis).

While the WPATH Standards of Care require two mental health assessments prior to hysterectomy, this has been challenged academically [13] and in practice [7] given that non-transgender women may undergo a hysterectomy for equally or less compelling complaints without similar restrictions.

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32. Binding, packing, and tucking

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Tucking allows a visibly smooth crotch contour. In this practice, the testicles (if present) are moved into the inguinal canal, and moving the penis and scrotum posteriorly in the perineal region. Tight fitting underwear, or a special undergarment known as a *gaffe* is then worn to maintain this alignment. In some cases, adhesive or even duct tape may be used. In addition to local skin effects, this practice could result in urinary trauma or infections, as well as testicular complaints, which are covered elsewhere.

Packing is the placing of a penile prosthesis in one's underwear, giving both an outward appearance as well as reducing gender dysphoria.

Binding involves the use of tight fitting sports bras, shirts, ace bandages, or a specially made *binder* to provide a flat chest contour. In some people with larger breasts, multiple garments may be used, and breathing may be restricted. Prolonged binding may result in breast pain, local skin irritation, or fungal infections.

33. Hair removal

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Introduction

The management of unwanted hair is often a challenge for transgender people, for many reasons. Barriers include access to trans-experienced aesthetic providers, transportation, affordability, and confusion regarding the options, risks and benefits.[1,2] While insurance coverage for hair removal in transgender persons is expanding, it remains inconsistent and can be a significant source of frustration and anxiety for both patient and provider.[3,4]

Transgender men, transgender women, and other gender nonconforming individuals may seek services; a care plan for each patient is best individualized according to their personal needs and transition goals. Transgender woman typically seek hair removal on the face, neck, as well as in the genital area in the case of pre-operative preparation for vaginoplasty.[5,6] Transgender men typically seek hair reduction on forearm or thigh future graft sites in preparation for phaloplasty.[5,7] While epilation (plucking, waxing, or Epi-Lady type devices) and the use of depilatories (chemicals) offer temporary measures, many seek one of several modalities that offer permanent hair reduction/removal: light amplification by stimulated emission of radiation (laser) hair removal (LHR) and electrolysis hair removal (EHR).[8,9] As with any referral for care, it is ideal to establish relationships with experienced, accessible practitioners with a positive reputation in the transgender community.

Methods: pros and cons of each

The hair growth cycle consists of three successive stages that include the anagen (growth) phase, the catagen (transitional) phase, and the telogen (resting) phase. Each strand is at its own stage of development. Time in each phase can vary by location, from an anagen phase of one to two months on the body, to two to six years on the scalp. Patterns of hair growth may also vary based on gender and ethnicity.[10] The effectiveness of both methods rely to some extent on the timing of the hair growth cycle, with the ideal response being when hairs are in the active (anagen) growth phase. Both require multiple sessions, and since effectiveness is approximately 85-90%, combined LHR and EHR may offer the best result for many. Lifelong treatment is often required for sustained effect.[10–12]

Laser Hair Removal: The use of lasers is considered a 'medical procedure' and offers the use of light to selectively target dark, coarse hairs.[13] The pigment in dark hairs absorbs the light to create heat that is transmitted down the shaft to destroy the follicle. It treats larger surface areas and is less time consuming than EHR. Treatments are typically every 4-8 weeks, depending on the treatment location, as the hair growth cycles vary by area. Safety and effectiveness may vary depending on the platform used (diode, ruby, neodymium-doped yttrium aluminum garnet; [Nd: YAG], etc.), patient skin type and hair characteristics. LHR is generally ineffective on thin, light, red, blonde or gray hairs. A wavelength of 1064 (Nd: YAG)

is the only wavelength considered safe for dark-skinned individuals (Fitzpatrick skin types 5 or 6).[9,11]

LHR is FDA approved for permanent hair *reduction.* Patients are required to be evaluated by a medical provider (NP/PA/MD, etc.) prior to being treated; regulations on the qualifications and licensure of the laser operator vary by U.S. state, with some states requiring registered nurses.[10]

As with any light-based treatment that uses selective photothermolysis, overheating can result in redness, blisters, burns, and subsequent hyper or hypo-pigmentation.[14–16] The majority of these are infrequent and temporary; however care should be taken with any patient with a history of keloids (test spot on low visibility area) and LHR is contraindicated in conditions that might flare in reaction to light exposure, such as lupus erythematous [17] It is suggested that patients with a history of herpes simplex outbreaks be aware of the potential for a light-stimulated outbreak (in treatment area) and have antivirals available for self-treatment. Treatments should be avoided when photosensitizing medications are being used (see table [18]). Do not treat areas of active infection. Flashing lights have been known to induce seizures in susceptible patients, so patients should be screened for this risk.[19] Treatments on the face require occlusion of both eyes to protect from retinal exposure and damage. Protective, wavelength specific, eye-ware is used during non-facial body treatments.[20]

Relative CONTRAINDICATIONS to laser hair removal:

- History of melanoma, raised moles, suspicious lesions, keloid scar formation, healing problems, active infections, open lesions, hives, herpetic lesions, cold sores, tattoos or permanent make-up in area of treatment, recent use of isoretinoin, tetracycline, or St. John's wort in the last year, autoimmune diseases such as lupus, scleroderma, vitiligo.[17,18]
- While not a contraindication to treatment, the following drugs may cause increased hair growth: penicillin, cyclosporins, corticosteroids, haldol, phenytoin, thyroid medications.[18]

Electrolysis involves use of an electric current with a very fine needle–shaped probe to destroy the root of individual hair follicles. There are three types of electrolysis; galvanic (direct electrical current produces a chemical reaction), thermolysis (diathermy: short-wave which produces heat) and blend (combination of galvanic and thermolysis).[21] Since electrolysis involves direct mechanical destruction of the root, it can be used on all hair colors and skin types. Treatments are typically weekly and lasting up to 1 hour, based on patient pain tolerance. Targeting individual hairs may be time consuming and costly, however is very effective when used to treat hairs that have not or will not respond to LHR. Newer technologies/epilators (27MHz frequency) offer a more comfortable treatment and may be safer than older model machines (14MHz frequency). As the frequency is increased, so is the heat produced, resulting in improved effectiveness.[22] Electrolysis is FDA approved for permanent hair *removal*. In the U.S., electrologists are licensed in their state of practice and practice independently.

Some of the same risks associated with LHR also apply: redness, pigment changes, and avoiding areas of active dermatitis or infection.[23] Patients with pacemakers are most safely

treated with thermolysis, but should discuss with their cardiologist prior to treatment. Home laser or electrolysis devices have not demonstrated effectiveness and may cause harm.[24]

Managing pain during the procedure

At least some discomfort can be expected during either procedure.[25] Each patient is best assessed individually to determine the optimal approach for pain control. The response to each treatment can vary based on the location of treatment, level of hydration, anxiety and stress. Creating a soothing environment, the use of reassurance, deep-breathing, thoughtful orientation to the device, use of a 'test-spot,' pre-treatment with a cold compress and over-the-counter pain medication (acetaminophen) may all be helpful. It is best to avoid NSAIDS immediately prior and after treatments to minimize the risk of bruising. The use of narcotics is typically not needed, but may be appropriate in some cases.

Topical anesthetics

Lidocaine-containing products (alone or in compounded form) should be provided to the patient initially and then as requested. Topical anesthetics reduce procedure-related pain with minimal side effects. Careful attention must be paid to the particular anatomic location, the total surface area covered, and the duration of anesthetic skin contact. Topical anesthetics can be applied 15-45 minutes prior to treatment and are typically removed during or after the procedure(s).[26–30] The use of EMLA (lidocaine 2.5% and procaine 2.5%) may have limited effect, primarily due to the prolonged onset of action and need for an occlusive barrier during the pre-treatment phase. The combination of benzocaine 20%, lidocaine 8% and tetracaine 4% (BLT) is a common and effective combination. This preparation should only be applied by a licensed medical provider or nurse, as application of excessive amounts can result in toxicity.

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34. Transgender voice and communication - vocal health and considerations

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Introduction

Voice and communication are crucial aspects of daily life for all humans. Within the transgender community voice and communication are often brought to the forefront when the incongruence between gender identity and voice/communication style are greatest. Aspects of voice and communication are highly related to gender [1] and culture.[2] These include pitch, intonation, loudness and stress patterns, voice quality, resonance, articulation, speech rate, language, and nonverbal communication.[3,4] Altering the aspects of voice and communication related to gender have been reported to reduce gender dysphoria while improving mental health and quality of life.[1]

There are many resources to help trans people identify communication characteristics that may be targeted to develop more gender specific communication style. These may include vocal coaches, theater professionals, singing teachers, and movement experts.[3] **Specialty trained speech language pathologists (SLPs) are best equipped to facilitate overall vocal health and efficiency,** in addition to behavioral changes related to voice and communication for transgender people.[1–3,5] Otolaryngologists with subspecialty training in laryngology are skilled in vocal fold surgery techniques (phonosurgery) which may act as an adjunct to voice therapy.

Approach to voice complaints

Transgender people may present with voice complaints related to quality change or fatigue that are unrelated to gender transition.[2] This could be non-organic, organic, iatrogenic, or idiopathic in nature (Table 1). It is important that a comprehensive voice evaluation is completed, including voice and communication needs related to gender transition, by a laryngologist and voice trained speech pathologist prior to initiating voice treatment. Evaluation should include a thorough laryngeal examination including videostroboscopy to assess the anatomy and physiology of structures related to voice production.

Table 34-1. Common Voice Complaints and Diagnosis

Origin	Diagnosis	Voice Complaints
Organic	Nodules, Polyp(s), Cyst(s) Granuloma Scar	Roughness, breathiness, pitch breaks Voice fatigue Increased vocal effort
Non-Organic	Muscle Tension Dysphonia	Roughness Voice fatigue Increased vocal effort
Iatrogenic	Vocal Fold Motion Impairment Scar	Breathiness, roughness, increased pitch Voice Fatigue Increased effort
Idiopathic	Vocal Fold Paralysis/Paresis	Breathiness Voice Fatigue Increased effort

The overarching treatment goal for transgender people who present with voice and communication complaints is to aid in achieving a gender congruent voice in an efficient and safe manner. Treatment should be patient specific and can be accomplished through behavioral and medical/surgical intervention.

Voice feminization

In a study of self-perceptions of trans females, it was found that the strongest contributor to communication satisfaction was voice.[6] The components of voice production include pitch, resonance, intonation and intensity.

Pitch

Pitch may be perceived as the most important factor for voice and subsequently gender identification.[2,7,8] A strong marker for the perception of female voice is an average speaking pitch of 180 Hz in a range of approximately 140 to 300 Hz.[9,10] The average non-transgender female pitch is approximately 225Hz while the average non-transgender male pitch is approximately 125Hz. A pitch range that is considered gender neutral generally falls between 155-185Hz.[11] It has been demonstrated that increasing speaking pitch impacts the degree of voice feminization.[9,12,13] However, increasing pitch into the female range does not necessarily result in listener perception of the speaker as female.[7,14] Research indicates that other voice characteristics such as speaking pitch range, intonation, resonance, and voice quality play varying roles in the perception of femininity.[5] Similarly, pitch floor (the bottom of the pitch range) and the proximity of the usual speaking pitch to this floor is thought to influence the perceived maleness of voice, rather than the speaking pitch alone.[14]

Resonance

There is some discrepancy in the literature on the role of resonance, as studied through formant (harmonic) frequencies. Harmonic frequencies are multiples of the root speaking pitch; the combination and configuration of formant frequencies for any given sound determine its "tone." Contributors to vocal resonance include the length of the pharynx and size of the sinuses, which in transgender women who have undergone a male puberty are fixed in a larger size than with non-transgender women. One report suggests a primary role of resonance in perceptual identification of the speaker's gender.[10] However, another study reports that a combination of both pitch and resonance are found to contribute to perceived femininity and should be addressed.[4,15]

Intonation

Intonation, or variability in pitch during speaking, is a recommended component of behavioral intervention for voice feminization. In one study, there were no significant differences in overall intonation patterns observed between genders. Transgender participants who were identified as female had a larger number of upward intonation patterns and larger semi-tone range within utterances than other groups. Transgender women who were misidentified as male had fewer upward and more downward intonation patterns than females and transgender females who were correctly identified.[16]

Intensity and other voice characteristics contributing to perception of gender

Increasing breathiness [9,17] using lower vocal intensity [13,17] and avoiding vocal fry [13] can contribute to voice feminization.

Behavioral Intervention

The components of voice production are primarily addressed through behavioral voice therapy. It is thought that the total number of voice therapy sessions, in addition to living full time as female might be predictive of response to behavioral intervention.[18]

Two common voice therapy techniques include flow phonation and resonant voice therapy. Flow phonation targets balanced exhalation of airflow during voice production to achieve vocal efficiency and may aid in altering breathiness and intensity. Resonant voice therapy focuses on achieving easy phonation while experiencing the energy or vibration of sound in the oral cavity therefore altering resonance.[19] When used with transgender women, oral resonance therapy is reported to increase femininity by altering resonance to more closely approximate female resonance with a spontaneous increase in pitch.[4] Vocal function exercises, a systematic program of physiologic voice exercises that are designed to strengthen and balance the laryngeal musculature and to achieve balance between airflow and muscular effort,[20] do not seem to improve therapy outcomes in trans women.[18]

Long-term gains have been reported related to listeners' perception of gender following voice therapy that targeted primarily pitch and resonance.[15] Voice therapy has also been shown to generate changes that significantly impact listener's perception of femininity; however femininity is perceived as higher immediately following therapy than 15 months later.[21] Trans women having varying voice goals and may choose to use feminine communication

patterns all of the time or situationally.[1,17] The decreased perception of femininity over time, mentioned above, and the variable application of feminine voice may indicate the place for a maintenance program following voice therapy. While research is required in this area, intermittent 'checking-in' and recalibration of voice components may be warranted.

Studies indicate that trans women attain improvement in voice following voice therapy and most are satisfied with the outcome.[17,21] If, after a course of behavioral therapy the desired outcome is not achieved, surgical intervention may be considered.[22] At this time, surgical intervention primarily targets alteration in pitch. Pitch change alone has been shown to be insufficient for listeners to accurately identify gender [7,14] and should not be considered the initial or only treatment for voice feminization.

Effects of hormone therapy on voice

Hormone therapy in trans women, while resulting in reduction of testosterone levels and increases in levels of progesterone and estrogen, has not been perceived to have a significant effect on voice or the perception of feminine voice.[23] Vocal pitch is a function of the overall size and mass of the vocal folds, and there are few if any formal studies in the English literature that support that hormonal manipulation in post pubescent males will significantly alter vocal pitch. During male puberty, exposure to testosterone results in hypertrophy of the laryngeal muscles, cartilage and mucosa. This results in the characteristic voice changes that occur in pubescent males.

While withdrawing testosterone result in a modest degree of mucosal and muscle thinning, this effect takes years and cannot reverse the significant hypertrophy caused by the previous exposure. Thus pitch, which is related to vocal fold mass and size remains lowered, and the overall effect on voice from withdrawal of androgens is minimal once these changes have occurred. This is consistent with what is seen in females who have been exposed to androgens for the treatment of medical conditions. Once the exposure has occurred and the vocal pitch is lowered, the withdrawal of androgens is not generally associated with a significant re-elevation of pitch. Therefore, if behavioral interventions do not result in a sustained improvement in patient satisfaction with the characteristics of voice, then surgery may be considered.

Surgical considerations

As previously stated, pitch of voice is related to overall vocal fold mass and the tension of the vocal fold while the patient is producing voice. We can all voluntarily increase the tension in our vocal folds to elevate pitch. This, however, requires continuous muscular effort. With attention, training and time, this increased effort may become habitual. However, even successful patients often complain of a sensation of vocal effort and/or fatigue at the end of the day. Therefore, surgeries have been designed to elevate pitch by either altering vocal fold tension, mass, or both. The tendency of biological structures to relax when artificially stretched or tensed represents a significant challenge to surgical approaches to voice modification. Furthermore, procedures which attempt to alter the tension by scarring the vibratory portion of the vocal fold, or reducing the overall vocal fold mass, risk inducing

negative alteration in the delicate tissue of the vocal folds, which must vibrate at high frequencies to produce normal vocal quality.

Surgical attempts to elongate the vocal folds

One of the earliest procedures reported for elevation of vocal pitch is a criothyroid approximation, or type 4 thyroplasty, initially developed in the 1970s. In this surgery, the vocal folds are placed under permanent increased tension, using sutures that approximate the front aspect of the thyroid cartilage to the cricoid ring. A year-long longitudinal report of 11 patients (only 1 of whom was transgender) who underwent this procedure showed initial promise immediately postop.[24] However, while pitch did remain elevated at one year, it was lower in comparison to the postop pitch, and it was theorized that the vocal chronic vocal tension resulted in stretching of the tissue with relaxation or that the sutures pulled through the cartilage. This has led to proposed modifications to the originally described procedure, either by altering the method of suture placement,[25] or by scarifying the thyroid to the cricoid.[26] Other case series have found similar results of initial improvement with benefits that wane over time.

Other attempts to permanently elongate the vocal folds to increase tension have resulted in similar outcomes.[27,28] These modifications have proposed pulling the anterior aspect of the vocal folds forward without fixing the cricoid to the thyroid. The theorized advantage is that the patient would be able to further modulate pitch. However, this has not been the outcome and the results are variable when the patients are followed long-term.

Surgeries to reduce vocal fold mass and length

In 1982, Donald et al [29] proposed surgery to reduce the size of the vocal folds, and create a web between the anterior portion of the vocal folds, by opening the larynx, removing the front third of the vocal folds and suturing the larynx closed. This surgery has the advantage of being able to be combined with procedures to reduce the prominence of the larynx in the neck.[30] Though the length of follow-up is not noted, Donald reported on successful pitch elevation and patient satisfaction in 3 patients. The procedure has been modified by other surgeons, and combined with shortening of the pharynx by bringing the larynx and the hyoid bone closure together. In a series of 94 patients (74 of whom were followed for approximately 1 year or more), these authors reported an average elevation of pitch from 139 Hz preoperatively to 196 Hz postoperatively. Complications were relatively rare and transient.[31] While promising, the results were somewhat unpredictable in terms of overall vocal quality and vocal range. In addition, while the surgery is generally well tolerated, it does place the airway at risk and require an external incision in the anterior neck skin.

Surgeries to increase tension by producing scar on the vocal folds

As previously mentioned, vocal fold vibration rate, which determines the pitch of the voice, is affected by vocal fold mass (as the mass decreases, the vibration rate or pitch increases) and tension (as the tension increases the vibration and pitch increases). This has led surgeons to attempt to elevate pitch by increasing tension through scarring the surface of the vocal folds or scarring the front portion of the vocal folds together to shorten the portion available for vibration. The main advantage of these types of procedures is that they can be done through

the mouth without an incision in the neck, are well tolerated, and do no place the patient's breathing at significant risk. The main disadvantage is that healing and scar production can be unpredictable and results variable.

The initial reports of this type of surgery were present by Wendler in 1989.[32] The procedure, which has come to be known as the Wendler glottopasty, is relatively easy to perform. The mucosa or skin from the front aspect of the vocal folds is removed. This can be done with either a CO2 laser, or with traditional non-powered instruments; the front aspect of the vocal folds is then sutured together. Variations on this procedure have replicated results in multiple small patient series from other centers.[12,22,33,34] In general, the vocal fold pitch is significantly elevated, but the overall pitch range and vocal loudness levels are reduced. In all patients, there is a modest increase in degree of vocal roughness postoperatively, and this is more noticeable when the procedure is performed in patients over 50 years of age. The procedure can also be repeated if healing does not result in as much scar as desired, and can be performed in patients who have failed other types of surgery.[35]

Finally, some surgeons have attempted to create scar on the top/superior surface of the vocal folds, either as a separate procedure [36] or as an adjunct to Wendler Glottoplasty.[37] These attempts have not been shown to produce reliable results or benefits over glottoplasty alone, and are likely best avoided.

Voice masculinization

Far fewer transgender males present for voice evaluation and treatment than transgender females. This may be related to the reduction in pitch that transgender males experience as a result of hormone therapy.[38,39] As a result, the need for voice therapy for transgender men may be underestimated.[40] The hormone induced pitch change is not always without problems and it remains unclear if it is in all cases sufficient for the speaker to be identified as male.[38,39] Research supports that voice and communication should be targeted in voice therapy.[2,5,40–42]

Pitch

With hormone therapy, final lowered pitch is achieved sometime after 1 year. Following response to this treatment, it is reported that about 75% of trans men are identified as male by telephone.[42] This leaves 1 in 4 transgender men who may not be perceived vocally as male. The perceived masculinity of voice is related not only to pitch but also to the proximity of the habitual speaking pitch to the pitch floor, or lowest pitch.[5] Following behavioral intervention with a speech pathologist, it was demonstrated that speaking pitch decreased by an additional 35Hz and pitch instability and voice fatigue resolved.[40]

Resonance

Increased 'chest resonance' is suggested as a goal in voice therapy.[2] Achieving balanced resonance during voice production contributes to overall vocal efficiency and may play a role in the reported improvement in voice complaints for trans men following voice therapy. These changes in resonance are further supported by data showing a change in formant frequencies

(the acoustic correlate of resonance) during the first year of hormone treatment in conjunction with behavioral intervention.[5]

Intonation

In one study, there were no significant differences in overall intonation patterns observed between 4 gender groups (12 non-transgender males, 12 non-transgender females, 6 transgender men, 14 transgender women). However, transgender women who were misidentified as male had fewer upward and more downward intonation patterns than females and transgender females who were correctly identified.[16] Decreasing pitch variation, while avoiding monotonicity is suggested for trans men.[2]

Intensity

Vocal intensity in trans males is not well documented in the research literature. However, if increasing breathiness [9,17] and using lower vocal intensity [13,17] contributes to voice feminization, it may be considered that reducing breathiness and avoiding a soft voice may be perceived as more masculine.

Behavioral intervention

While pitch is primarily addressed through hormone therapy and secondarily by voice therapy, the other components of voice production are primarily addressed through behavioral voice therapy.

Flow phonation and resonant voice therapy are two common voice therapy techniques. Flow phonation targets the balanced exhalation of airflow during voice production using respiration as the power source to achieve vocal efficiency. Resonant voice therapy focuses on achieving easy phonation while experiencing the energy or vibration of sound in the oral cavity.[19] The combination of these techniques can work to maximize voice production targeting pitch, resonance, intonation and intensity for trans men; efficacy data is needed to support this.

Some transmasculine spectrum people seek only some voice masculinization, and desire flexibility with their voice and communication.[5] While the literature supports the role of voice therapy for voice masculinization,[40,41] this is an area that needs further attention. With this in mind, voice therapy should be patient specific and physiologically based to achieve patient and therapy goals in a vocally efficient and safe manner.

Effects of testosterone hormone therapy on voice

90% of trans men will achieve acceptable voice results, lowering of pitch into a gender neutral or male range, after 4 to 5 months of taking exogenous androgens.[38] In multiple reports of small series, the average speaking pitch dropped for a female range of 190- 200 Hz to an acceptable male range of 100 to 140Hz.[5,43] However, while lowered pitch occurs as a consequence of thickening of the tissues due to the effects of androgens, in some cases male speaking patterns must be learned through behavioral therapy. 10% of patients or more will have some difficulty during transition either due to inability to produce efficient vocalizations with the altered laryngeal apparatus, or an inability to naturally adopt male speaking

patterns.[44] These patients usually respond to counseling with a certified speech-language pathologist who has experience in managing individuals with transgender voice issues.

Surgical consideration

As hormonal therapies and behavioral therapies are effective in helping 90% of transgender men achieve acceptable voice, surgical intervention is rarely indicated in this group. If needed, however, relaxation thyroplasty, designed to reduce the tension of the vocal folds can be performed. This same surgery is used in male patients with inappropriately elevated pitch and results in a reduction of pitch if performed in the original method [45] and an even greater reduction if modified as described by other authors. Typical pitch reduction is in the range of 100 Hz and usually results in the patient attaining an acceptable male vocal pitch. However, as the vocal cord tension is less controllable after the intervention, the voice is often perceived as more rough and with less volume.[46]

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35. Health insurance coverage issues for transgender people in the United States

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Introduction

Insurance plans issued in the United States since the 1980s routinely contained broadly written exclusions prohibiting payment for care related to "transsexualism," "sex change treatments," "gender identity disorders," or "transgender care." In some cases providers or clinic administrators, as well as claims administrators within insurance companies, would interpret these exclusionary statements in the broadest possible terms, assuming that transgender people could not receive medical care. The burden of fighting against this level of adversity when people are physically ill or injured represents a significant barrier to care. This adversity has contributed to the high incidence of transgender people avoiding seeking needed health care.[1]

Complexities of insurance and health benefits plans

Insurance policies are regulated by each of the 50 U.S. states; therefore, for example, an Anthem Blue Cross policy issued in one state may be very different in content from a policy issued by the same carrier in another state, though the plans may appear at first to be equivalent. Further, many people with private insurance in the U.S. receive coverage through their employer, and many large employers are able to negotiate their coverage to include or exclude specific care. These are "health benefits plans" and are not "insurance plans" strictly speaking, although they may appear the same to the enrolled member. Often referred to as "ERISA plans," (in some cases referred to as "self-insured" plans) such health benefits plans are usually regulated under the federal Employee Retirement Income Security Act of 1974), These ERISA plans are issued and administered by the same insurance companies that offer individual or small group plans, but the employer pays the direct costs of all care. As such ERISA plans have greater flexibility in what is covered, depending on the mission and intentions of the employer. In non-ERISA plans (in some cases referred to as a "fully funded" plan), the insurance company assumes the risk that the individual or group will not cost them more than the premium and co-pays will bring in. Being further removed from an incentive (i.e. covered employee recruitment and retention), non-ERISA plans may be less nimble in adding coverages or responding to case-by-case scenarios.

Although plans insured by or administered by a given carrier (e.g., Aetna, United Health, Anthem BCBS, et cetera) are often very different from each other, there are also often similarities in approach as carriers strive to standardize internal processes. Most carriers have now issued their own internal guidelines specific to transgender-related healthcare, especially surgical interventions. These guidelines (called by various names such as medical policies or coverage positions) spell out what services will be covered for a specific medical condition

and usually apply to all insurance products issued by a carrier. However, they may not apply to some ERISA-regulated health benefits plans since large employers have the ability to negotiate medical guidelines specific to their own employee health plans.

Thus, what is covered by a given health plan will vary not only by state but also by employer. Some large companies choose to offer transgender health benefits under their ERISA plan in order, for example, to maximize their talent recruitment, to provide a just and equitable workplace, or to control healthcare costs by providing the services people need. These large employers have chosen to implement medical guidelines that offer increased access, such as coverage of a greater range of medically necessary services. Smaller businesses, which depend on the insurance company to assume the risk (and whose risk is combined with other small employers), may not have the leverage to negotiate inclusion of transgender health benefits. However, smaller employers can inquire with their carrier representative as to feasibility and per-member, per-month costs of doing so, since coverage is becoming increasingly common across the country.

Gaining coverage: changing the paradigm

From the 1960s through the 1990s, some very persistent Individuals, often with support from their health care providers, were able to secure benefits payments, in certain instances. However, systemic reform did not begin until the 2000s, after advocates were able to convince the City & County of San Francisco to eliminate exclusions in at least one of the five plans City & County employees could select from for their health care coverage. Utilization data from the first five years showed that there was little or no increase in plan cost when medically necessary gender-affirming care was included in a large group plan. These results were used to inform the inclusion of transgender health benefits in the Human Rights Campaign's Corporate Equality Index, an instrument devised to grade companies on their approach to LGBT employee and customer relations.[2]

Private and public insurance reform

As of 2015, an increasing number of employers are offering transgender-inclusive health benefits plans, and insurance Commissioners in numerous states and the District of Columbia have issued regulations prohibiting the sale of insurance plans that discriminate against transgender people.[3] Further, on May 30, 2014, the U.S. Department of Health and Human Services issued a ruling that Medicare's longstanding exclusion of "transsexual surgical procedures" was no longer valid, leaving the provision of services up to local coverage determinations.[4] Following suit, some states have begun to revise their Medicaid plans to offer transgender-inclusive health care.[5] Specific Medicaid policies can be obtained from individual state Medicaid regulatory agencies. Currently (as of 2015) the Center for Medicare and Medicaid Services (CMS) is in the process of developing a new National Coverage Determination with regards to inclusion of gender-affirming care in the Medicare program. Private health insurance products are often regulated by the State Department of Insurance or Department of Managed Care (department nomenclature may differ by state); specific policies and coverage details can be obtained from individual state agencies

Claim denials for sex-specific procedures

In some automated systems, if for example the patient is designated as "female" in the electronic record (EMR), and a treatment or procedure code is entered for care that is exclusively covered for bodies designated male [e.g., prostatic ultrasound]), that claim may be automatically rejected. The reverse would be true for someone designated as "male" in the EMR but who requires care that is exclusively covered for bodies designated "female." If the patient's plan document or individual state regulations provide that transgender care is covered (or that care may not be restricted on the basis of sex), then the patient may need support from the physician's office to inform the carrier or administrator that the patient is transgender, and that this claim cannot be rejected. If there is no provision for transgender care in this instance, it will be necessary for the provider to appeal to the carrier for coverage of the specific treatment or diagnosis.

Overriding a "sex mismatch": condition code 45

All federally-funded health institutions (e.g., most hospitals) have received instruction on the use of Code 45 (and the KX modifier) in their coding practices and all Medicare Administrative Contractors are required to process this code,[6] which is an override for a sex mismatch. However, the code may not have been implemented by all hospitals or carriers' systems; in these cases using Code 45 may result in a returned claim for correction, or outright denial of the claim.

Discrimination claims

The Office for Civil Rights of the U.S. Department of Health and Human Services (HHS) has already issued guidance that preventive services may not be denied simply on the basis of sex, resulting for example in CDC coverage of mammograms for transgender women. In May 2015, CMS issued sub-regulatory guidance clarifying that preventive services are available under the Affordable Care Act (ACA) regardless of an individual's gender identity, sex assigned at birth, or recorded gender. Section 2713 of the Public Health Service Act, as amended by the ACA, requires most health plans to cover certain preventive services, regardless of gender.[7,8] Over time resolution of other sex-gender "mismatch" problems is expected to evolve as a result of new regulations guiding the implementation of non-discrimination provisions based on sex, contained in Section 1557 of the Affordable Care Act (forthcoming from the U.S. Department of Health and Human Services, HHS).[7] In the meantime, those who experience denials on the basis of sex-gender mismatches for sex-specific services are encouraged to file complaints with HHS Office for Civil Rights.[8]

Claims denials and discrimination

Many transgender people experience denials of their claims for transgender transition-specific services. Many more never receive a formal denial because their plan contains transgender-specific exclusions and the physician never files paperwork for prior authorization for such services. Many call their insurance carrier and are told services will not be covered, and on that basis never attempt to file a claim. Transgender individuals and their health providers

should be aware that unless a denial is in writing, it is not a denial and cannot be appealed. More importantly, transgender individuals with well-documented claims are increasingly achieving success in their appeals. Individuals are encouraged to work proactively with their medical providers to ensure that appeals documents include individualized, extensive documentation of the necessity and appropriateness of services. Such appeals should also include a comprehensive and detailed overview of the process of gender transition, including the role of and evidence in support of the specific services requested. In addition to providing a background to uninformed reviewers, such comprehensive documentation conveys the individual's intent to pursue the appeals to the final stages, which can be quite persuasive.

Over time resolution of these problems is expected to evolve as a result of new regulations guiding the implementation of non-discrimination provisions based on sex, which will be issued by HHS in the coming months.[9] In the meantime, individuals whose health plans contain provisions which discriminate on the basis of sex, including transgender-specific exclusions, are encouraged to file complaints with the HHS Office for Civil Rights.[8] While not every health plan in the U.S. is currently regulated under Section 1557 of the ACA, the ACA does specify that the Essential Health Benefits they are required to provide must also not discriminate on the basis of sex.

Table 35-1. Available health coverage in the U.S.

Coverage Type	General Characteristics and Caveats
ACA/Exchange Plans	Affordable Care Act coverage for individuals and families who are not eligible for Medicaid or Medicare, and who do not have insurance coverage through their employer, or may be self-employed. Until HHS implements Section 1557, only states with laws forbidding discrimination against transgender people in insurance products are likely to have transgender-inclusive plans available. To see if your state is one of these, check for the latest information on health coverage at www.transequality.org [10] or www.transgenderlawcenter.org.[11] However, even in several states currently prohibiting transgender exclusions in insurance plans, some or all marketplace plans may still retain exclusions.
Employer Plans, Fully-Funded (ERISA)	These are group plans available to small businesses, and sometimes may include plans offered to qualified individuals. Fully-funded means that purchaser of the plan pays a premium to fund the cost of services provided by medical providers and by the insurance company. Insurance companies often aggregate these plans to reduce their risk by pooling similar customers; if a small employer could find out who else was in their "pool," they might be able to convince the other companies to also ask for a policy change to make their plan transgender-inclusive. However, aggregate group composition is not public information, allowing insurers to control variables to maintain

Coverage Type	General Characteristics and Caveats
	profit margins. These plans are subject to state regulation, so their terms may vary by state. To see if your state is one of these, check for the latest information on health coverage at www.transequality.org or www.transgenderlawcenter.org.
Employer Plans, Self-Insured (non-ERISA)	These are group plans that are administered by insurance companies, using the same kind of provider networks and claim processing mechanisms as their other plans, but the employer pays ALL the costs themselves, and thus the employer bears all the risk. These plans are exempt from state regulation by the federal ERISA regulations, which give the employer/customers of the plans much more leeway to request the features and coverage levels that they want, including transgender-specific care. Some of these plans have their own internal medical guidelines that provide for coverage of all services medically necessary for transition.
Health Maintenance Organizations (HMO)	These state-regulated organizations provide both the insurance coverage and the medical services that they cover. In some cases, available services may not include transgender-specific care, but many HMOs are working hard to provide competent trans-sensitive care. As of December 2015, thirteen states including the District of Columbia have prohibitions on transgender exclusions (note a prohibition on exclusions is not the same as mandated inclusion) in these health plans, with implementation varying by state. Individual state information is available at www.transequality.org or www.transgenderlawcenter.org.
Medicaid	These are state-run (partially funded by federal money) safety net programs that provides payment to providers who will accept the amount the program is willing to pay (usually much less than private insurance will pay). Medicaid provides coverage for qualified low-income people, families and children, pregnant women, the elderly, and people with disabilities. Some states are starting to remove exclusions for trans-specific care from their Medicaid plans. To see if your state is one of these, check for the latest information on health coverage at www.transequality.org or www.transgenderlawcenter.org.
Medicare	This is the federal program that covers people over 65 years old, and disabled people under age 65. HHS ruled in May 2014 that blanket exclusions for “transsexual surgery” are no longer appropriate because the medical evidence exists to show that such care, when delivered appropriately, is effective, and it is no longer experimental surgery, nor is it “simply cosmetic.” Currently coverage is available through Local Coverage Determination on a case-by-case basis.
Railroad Medicare	Under this program, people who worked for railroads for at least 10

Coverage Type	General Characteristics and Caveats
	years may access Medicare Part B services at favorable rates through the railroad-specified administrator. Transgender-specific services may be available according to Local Coverage Determinations (LCDs) through the Center for Medicare and Medicaid Serves (CMS).
TRICARE	This is the health benefit administration program for U.S. active duty military service members and their dependents and retirees who are not eligible for Medicare. Transgender-specific services are not available while transgender people are not permitted to serve openly in the military. This policy may change in mid-2016.
Union Plans	Some labor unions, in some states, may have transgender-inclusive policies available; check with the union's benefits office/department. Several labor unions have resolutions at the national level calling for the elimination of transgender exclusions. Although not binding on member unions, these may help union members fight for benefits equity.
Veteran's Administration	Transgender Veterans may obtain regular medical care, including hormone therapy. Transgender-specific surgical procedures are currently restricted or prohibited, although this may change as the U.S. military considers the role of transgender service members.

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36. Legal and identity documents

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The concept of a "legal sex" is complex, though for simplicity the term will be used in this discussion. The World Professional Association for Transgender Health advocates a simple administrative procedure to change legal identity documents to match experienced gender.[1] While self-determination of legal gender is the law in a small (but growing) number of countries, including Argentina, Denmark, Malta, and Ireland, most countries require the involvement of health professionals, if legal "change of sex" is possible at all.[2]

Under United States federal law, and in some states, surgery is not required to change legal sex, but a health professional must certify that their patient has undergone "necessary" medical or psychological treatment for transition.[3] In completing this paperwork, the health professional should be aware that there is no particular clinical treatment (such as hormones or surgery) that is "necessary" for all trans people, and that legal documents reflecting a sex congruent with one's gender identity contribute to a patient's health, by supporting employment, safe travel, and other necessities of daily living, as well as facilitating access to medical care.

In some jurisdictions, there is a surgical requirement to change legal sex. The health provider may have leeway, depending on the law, as there is no particular surgery that is "necessary" for all trans people. Some trans people are unable to change their birth certificate in their home state or country, but may still change their gender markers on their U.S. passport, Social Security card, and driver's license.[4]

Transgender people may encounter a conflict between their legal sex and sex-specific medical care, such as screening for cervical cancer or prostatic disease. While state laws may vary, in some cases it may be necessary for the provider to contact the insurance company and explain the specific circumstances in the case of a sex-specific denial. Once legal documents have been changed, patients should be sure to update their legal name and sex with their insurance company and medical provider to prevent a denial based on a mismatch of information.

Legal change of name is not a gendered process in many, but not all jurisdictions; in most jurisdictions the name change process for transgender people is identical to that for non-transgender people.

U.S. Department of State guidelines for passports [5]:

http://travel.state.gov/content/passports/en/passports/information/gender.html

U.S. Social Security Administration guidelines [6]:

https://secure.ssa.gov/apps10/poms.nsf/lnx/0110212200

The National Center for Transgender Equality maintains a resource center with links to guidelines for changing identification documents in each U.S. state [3]: http://www.transequality.org/documents

Information on changing gender identity documents in Europe can be found at tgeu.org.[7]

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37. Sex-segregated systems

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A guiding principle in sex-segregated systems is to give people the autonomy to use the facilities and programs most aligned with their gender identity. This includes using restroom facilities, inpatient and residential beds, and locker rooms concordant with experienced gender (Grading: X C S). When available and preferred by the individual, non-gendered facilities can be utilized, but services should not be dependent on their availability.

The legal right to access to programs according to gender identity has expanded with recent state and federal regulation. Schools are required to allow students to use facilities and programs concordant with their gender identity, under the laws of some states, including California.[1] Under California law, students should be able to choose facilities according to their gender identity, or to use a private facility. Students should be able to participate in athletic programs and facilities according to gender identity. Students should be referred to according to preferred name and pronoun, and be listed according to gender identity in data systems. The Department of Education, under Title IX, has ruled that the students must be able to use programs and facilities according to their identity.[2]

The U.S. Department of Health and Human Services now requires shelters and other housing programs to provide housing and other accommodations and services to trans people according to their gender identity.[3]

WPATH SOC 7 addresses the care of people in institutional environments, stating that all aspects of transition care should be available to people living in institutions, and states that sex segregation by external genitalia may be inappropriate and place trans people at risk for victimization.[4]

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38. Homeless transgender individuals

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Introduction

One fifth of transgender people surveyed in the National Transgender Discrimination Survey reported experiencing homelessness. Homelessness frequently resulted from fleeing intolerant family, being forced out by family, by losing a job due to discrimination, or not being able to be employed due to discrimination and disability. In the same survey, of those who experienced homelessness, the majority of those trying to access a homeless shelter were harassed by shelter staff or residents (55%), 29% were turned away altogether, and 22% were sexually assaulted by residents or staff.[1] Many transgender individuals have found health care and social service providers to be ignorant about transgender issues and needs. It is essential that homeless service providers are well educated in this area as they are likely to encounter trans individuals.[2] The National Healthcare for the Homeless Clinicians Network has offered high quality trainings in this area.[2–4]

Assault and discrimination in public settings, especially homeless shelters, are frequently reported by homeless trans people.[5] While federal and other policies forbid discrimination,[6] many individuals are still unable to express their felt gender due to this discrimination, and best practices start with the collection of gender identity data in a confidential non-discriminatory manner, followed by an inquiry of housing preference if the shelter is sex segregated. Most individuals will prefer to be housed according to the gender in which they live or identify, however in some instances individuals may prefer to be housed based on their birth sex due to safety or other concerns. Best practice guidelines for shelters are now available.[7,8]

Functional disability is very common in homeless transgender individuals. Many homeless transgender individuals are unable to work due to disabilities. Gender dysphoria itself may lead to severe depression, anxiety, and suicidality.[9] Adverse childhood experiences, losses, and traumas may result in PTSD and other persistent problems. Physical assaults, alcohol and drug use may result in chronic physical conditions. Loss of educational opportunities and lack of job opportunities may result in poor capacity to learn and acquire new skills. These problems often cause long-term loss of capacity to work. Individuals may be eligible for social security disability, which may be their only way out of homelessness. Careful documentation of disability will be helpful for these individuals.[10]

Homelessness and gender-affirming care

Hormone therapy and transgender surgeries are considered medically necessary (when desired) for the treatment of gender dysphoria. Homelessness has in some cases been used as a blanket exclusion for these medical services. In most cases individuals who need hormone therapy are highly motivated, and despite the stresses of homelessness are able to adhere to treatment and monitoring. Healthcare for the Homeless providers have successfully

treated many patients with hormone therapy.[3] Homelessness is also not a contraindication for planning surgery for those patients who seek chest, breast, genital or other gender confirming procedures. The degree of housing stability required for successful outcomes for each of these surgeries will vary with the procedure and individual. Medical respite programs may have the capacity to allow some patients to recuperate from some surgeries. Since there is often a year or more waiting period from referral to surgery, this period is a time to intensively work on stabilization of housing status. The hope and promise of surgery is often a very strong motivator for individuals who were previously hopeless. Some patients may have unrealistic ideas about the rigor of surgery, recovery and aftercare or the possibility of their being stably housed. These individuals require intensive work with primary care providers, mental health providers, care navigators, and others to develop the stability needed for successful surgery outcomes. Care should be taken during the education and preparation process prior to surgery to avoid creating the perception of caregivers' concerns about housing instability as discriminatory or as arbitrary "hoops to jump through."[11]

Prevention

Prevention of homelessness is dependent upon decreasing discrimination in family, work, and other social settings, and providing transgender individuals with equal opportunities. Assisting people who are unable to work to obtain disability entitlements is an important way out of homelessness. Prevention of the harms of homelessness can be accomplished by implementing best practices and educating homeless service providers. While substantial research has been initiated in this area [12,13] more research is needed to inform the development of best practices for implementing these changes.

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39. Health considerations for gender non-conforming children and transgender adolescents

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Introduction

Care for transgender and gender non-conforming (TGNC) youth is a rapidly expanding field of medicine, and lends itself to controversy among professionals. It stands to reason that transgender adults started as transgender youth, and if identified in childhood or adolescence may benefit from early access to hormone blockers and/or gender-affirming hormones. While sparse data exist regarding the impact of puberty suppression and gender-affirming hormones administered during adolescence, there have been promising results from the Netherlands indicating that this approach in adolescents results in improved quality of life and diminished gender dysphoria.[1] The principle challenge in determining best practice for transgender youth lies in the fact that development is different for each individual. While there are standard ranges of pubertal initiation in children,[2] the age at which children begin to articulate their experience of gender dysphoria or assert a gender identity that is distinct from their assigned sex at birth is highly variable. Providers of transgender youth care should be skilled at meeting the needs of young people presenting for care at any stage in their process. The care of transgender youth does not need to be limited to pediatric endocrinologists. General pediatricians, specialists in adolescent medicine, family medicine, medicine/pediatrics, as well as nurse practitioners, physician assistants and others are all potentially qualified to provide high quality care for transgender youth.

Creating affirming spaces for youth

Cultural sensitivity and awareness begins with front office staff, and other staff that are initial points of contact for parents and patients. Staff and provider inquiry about, and consistent use of appropriate pronouns and name is the first, and potentially most important step toward creating a culturally sensitive and welcoming environment. Professionals can model appropriate use of names and pronouns in the presence of parents and caregivers.

Increasing numbers of young people are presenting with nonbinary or gender queer identities, preferring gender-neutral pronouns as a more accurate way to be described. It is not uncommon for providers, parents, friends and family members to struggle with gender-neutral pronouns, and inadvertently invalidate nonbinary identities. Regardless of whether nonbinary identities are a stepping stone to a more binary identity, or are landing spots, they are valid and need to be honored.

Mental health support

Mental health professionals have a critical role in the care of TGNC youth. Even prior to disclosure of an authentic gender identity that differs from assigned sex at birth, transgender youth commonly experience symptoms of depression, anxiety, social isolation, behavioral problems, school struggles, and suicidal ideation.[3] Often young people are engaged in mental health services long before presenting for care related to phenotypic gender transition. Unfortunately, because so few mental health providers are experienced in the care of TGNC youth, inaccurate recommendations are not uncommon. Mental health support should not be sought in order to convince TGNC youth into accepting a gender identity that aligns with their assigned sex at birth, but rather, to provide a safe and welcoming space for young people to discuss and explore their gender, and any mental health challenges that may exist. While historically mental health professionals have been charged with authenticating the gender of their TGNC clients, this approach is rapidly falling out of favor, and is being replaced by a support model, rather than a gatekeeper model of accessing care.[4] Mental health professionals play an important role in helping youth learn to articulate their gender experience, and identify their needs around a gender that is not aligned with their sex assigned at birth. Therapists should spend time with young people gathering historic information from youth about their experience of their gender, and how that has been handled by the young person's support system. Additionally, therapists can help youth develop strategies around disclosure, self-acceptance, integration of transgender identity, intimate partnerships, and social transition if that is desirable. Therapists can help youth clarify what they are hoping to gain from pubertal suppression, gender-affirming hormones, and/or surgery.

Mental health providers also play a major role in educating parents, family members, schools and others about the needs of TGNC youth, as well as advocating for the young person across multiple domains. Therapists also can work closely with parents to help them understand what their child is experiencing, and will likely need from their parents and/or caregivers. Many TGNC adolescents, like most people of any age undergoing a significant life change, will benefit from ongoing therapy during both pubertal suppression, and the first few years of gender-affirming hormone administration, and perhaps, beyond. Despite increasing visibility and acceptance, TGNC youth are likely to experience transphobia and its negative consequences, and may benefit from ongoing support. Requiring participation in therapy in order to access medical care related to physical gender transition is neither successful, nor does it promote honest communication between young people and therapists. Therapy should be strongly recommended, and discussed routinely with youth, though due to an ongoing lack of skilled gender mental health professionals it is not always feasible, financially or geographically, for TGNC youth or families to access this resource. Increasingly, therapists skilled in supporting TGNC youth are offering online or telephonic therapy to assist in these difficult situations. Additionally, youth are often accessing mental health care for reasons not related to gender, such as social anxiety, depression, self-harm, and others. While these symptoms overlap with gender dysphoria, there are plenty of mental health professionals who are familiar with these particular challenges. Issues addressed by mental health providers can also be addressed by medical providers who are experienced, comfortable and have the time

to have such discussions with youth. This is often necessary in geographic locations without available or accessible mental health professionals.

Pre-pubertal gender non-conforming (GNC) children

Over the past five years, it has become increasingly common for families with young children to request advice about the best way to approach their gender non-conforming child. Children as young as 18 months old have articulated information about their gender identity and gender expression preferences. Most parents are at a loss as to how to best help their child, and may seek the advice of a professional; commonly a psychiatrist or pediatrician. At this stage of development, no medical intervention is warranted or necessary. For young children, decisions must be made to create safe environments that promote healthy growth and development. For some children this may include a social transition – changing of external appearance (clothing, hairstyle) and possibly name and pronouns to match one's internal gender.

While there still exists uncertainty as to which GNC children will continue into adolescence and adulthood with transgender identities and/or gender dysphoria and which will not, it is been noted in prior studies that increased intensity of gender dysphoria is a predictor of a future transgender identity. This finding is subject to confounding, as youth who repress gender dysphoria due to safety or lack of basic language to express ones feelings may be no less likely to persist into adulthood, yet not present at an early age. Clinical experience has shown that it is those children who are the most dysphoric who seek social transition – the opportunity to live and be seen as a gender other than their assigned sex. Social transition has become more common, and a recent research endeavor reported good mental health among transgender children supported in their asserted gender.[5] Social transition for children can be logistically complicated and is best facilitated by a support team that includes the family, medical providers, mental health therapists and even lawyers. This team can work together to advocate for the child in school, sports, and other places so that GNC children can participate safely in these activities. Mental health therapists can play a significant role in the education of parents and other family members about GNC children, and their need for support and love.

Medical care for transgender youth

The approach to care may be simplified by defining two distinct cohorts of youth: those in the peri-pubertal, or early pubertal stages of development (Tanner 2-3), and those who are well along, in the final stages of, or completed with pubertal development (Tanner 4-5). These two cohorts often require different medical interventions; suppression of endogenous puberty, and/or the use of gender-affirming hormones for the development of masculinizing or feminizing features.

Suppression of endogenous puberty in early pubertal youth

Youth with gender dysphoria often experience significant trauma at the onset of their endogenous pubertal process.[6] Not uncommonly, gender dysphoria first emerges with the

onset of puberty. The development of secondary sexual characteristics can be the solidification of an undesired physical developmental process for those with a gender identity that is incongruent with their assigned sex at birth. With the high frequency among transgender youth of mental health challenges including anxiety, depression, social isolation, self-harm, drug and alcohol misuse, many providers view early treatment as life-saving.

For those youth on a transmasculine spectrum, puberty begins with the development of breast buds at approximately age 10, though a large cross-sectional study demonstrated that 10% of caucasians, 23% of black non-Hispanics, and nearly 15% of hispanics had Tanner 2 breast development by 7 years of age.[7] For those youth who identify on the transfeminine spectrum, the first sign of puberty is enlargement of the testicles to beyond 4 mL in volume, with an approximate average age of onset of 11 years. Development of undesired secondary sex characteristics related to natal puberty can have profound negative psychosocial effects and for many, are a source of great distress.

A team of experts in the Netherlands at the Gender Identity Clinic at the VU University Medical Center in Amsterdam was the first to develop a protocol that presented the possibility of delaying, or avoiding altogether, the development of undesired secondary sex characteristics resulting from an unwanted endogenous pubertal process.[8] This model of care includes the use of gonadotropin releasing hormone (GnRH) analogues, most commonly in the United States, leuprolide acetate or histrelin, medications that have been used for decades to delay pubertal development in children with central precocious puberty.[9] GnRH analogues offer a reversible intervention that allows youth temporary relief from an undesired, and potentially traumatic endogenous puberty. While data are sparse, preliminary results from the Netherlands indicate that behavioral problems and general psychological functioning improve while youth (age 12 and older) are undergoing puberty suppression.[10]

In order to avoid the development of undesired secondary sexual characteristics, GnRH analogues ideally are initiated at the earliest stages of puberty (Tanner 2-3).[11] There is a role for using GnRH analogues in youth who are in the later stages of pubertal development, either for induction of amenorrhea, or to halt ongoing development of undesired secondary sex characteristics. In addition, GnRH analogues are an effective complement to estrogen treatment in transfeminine youth, given that estrogen alone, at physiologic doses, is typically insufficient to adequately suppress testosterone production (see below). Youth cannot remain on GnRH analogues alone indefinitely, as bone mineralization relies on the presence of sex steroids. While clinically becoming increasingly common, the impact of GnRH analogues administered to transgender youth in early puberty and < 12 years of age has not been published. While rare, reported side effects from the use GnRH analogues may include diminished bone mineral density acquisition, weight gain, abscesses at the site of injection (if injectable form is used), irregular vaginal bleeding, and emotional lability.

Obtaining consent for treatment

Additional challenges arise when parents have discordant opinions about their TGNC child, or if a youth is in the custody of the courts. If both parents maintain medical decision-making for the youth then it becomes the task of the medical and mental health providers to help both

parents understand the necessity of medical interventions. This process is not always straightforward, can take a lot of time, and sometimes necessitates involvement of legal assistance. For youth in the child welfare system, judges can order that medical intervention, including the administration of gender-affirming hormones, be undertaken.

Dosing of GnRH analogs

Leuprolide acetate can be delivered via injection anywhere from daily, to every 3 to 4 months.[12] Histrelin is delivered via a time-release implant that is surgically inserted in the underside of the upper arm. The implant lasts between 12 and 36 months.

The physical exam for children beginning an unwanted puberty can be extremely stressful. Providers should work on developing clinical rapport with children in order to foster trust prior to carrying out to a genital exam. Providers should discuss the importance of genital exams (for those with testicles) and chest exams (for those with ovaries) in assessing pubertal progress. Using techniques to distract children during these exams with phones, devices, books and other things can make the exam tolerable. Significant genital and chest dysphoria are common among youth, and aversion to an examination of secondary sex characteristics should not be a barrier to moving forward with suppression of puberty. In fact, the provider should consider deferring a genital or chest exam until a follow-up visit, after a positive rapport has hopefully been established. In extreme cases, providers should consider creative approaches such as obtaining labs first to confirm initiation of puberty, and following up with the genital and/or chest exam after the relationship is better established.

Monitoring youth on GnRH analogues

Blood tests to determine if the hypothalamic-pituitary-gonadal axis is suppressed with GnRH analogues should occur 6-8 weeks after starting monthly doses, or 8 weeks after starting the 3-month dosing. For those with implants, blood levels assessing efficacy should be obtained 8 weeks after the implant is placed. Blood tests include ultrasensitive LH/FSH/total testosterone (in those with testes) or estradiol (in those with ovaries). There is some evidence that LH/FSH levels are not necessarily reliable indicators of suppression in those with GnRH analogue implants, therefore more accurate assessment of adequate suppression might require gonadotropin response to a subcutaneous leuprolide acetate stimulation test.[13]] While current guidelines recommend laboratory tests every three months to assess adequate suppression of the hypothalamic-pituitary-gonadal (HPG) axis,[11] repeated blood draws can be expensive and traumatizing for TGNC children. Suppression of the hypothalamic-pituitary-gonadal (HPG) axis should be assessed with clinical evaluation including height and weight, every three to four months, with blood serum ultrasensitive LH, FSH, estradiol/testosterone levels, renal and liver function, lipids, glucose, insulin, glycosylated hemoglobin considered annually, as clinically deemed appropriate while patients are on GnRH analogues. If there are clinical concerns regarding the efficacy of the puberty blocker, ultrasensitive pediatric FSH/LH, and sex steroid levels may be considered more frequently. More comprehensive and frequent laboratory tests will occur if the child is involved in a clinical or research trial.

There are potential benefits of baseline information about bone density, although no consensus about the necessity of obtaining bone densitometry prior to, and during GnRH analogue administration exists. If there is a family history of non-traumatic bone fractures, or osteoporosis, baseline screening is recommended. To optimize bone health, providers should ensure adequate dietary intake of calcium and should monitor vitamin D levels (25-OH) and supplement if indicated. Weight-bearing activity should also be encouraged. Physical changes of puberty should be assessed at follow up visits.

Follow-up conversation with youth who are undergoing pubertal suppression should include an assessment of an ongoing desire for endogenous puberty suppression. While extraordinarily rare, some youth may want to discontinue GnRH analogues and experience their endogenous puberty. For young people who remain gender dysphoric, and are interested in moving forward with masculinization or feminization, gender-affirming hormones can be added to GnRH analogues.

Gender-affirming hormones

Gender-affirming hormones may be added to GnRH analogues to assist in the development of feminizing or masculinizing features in transgender youth. **While the current Endocrine Society guidelines recommend starting gender-affirming hormones at about age 16,**[11] **some specialty clinics and experts now recommend the decision to initiate gender-affirming hormones be individually determined, based more on state of development rather than a specific chronological age. (Grading: X C S)**.[12] Factors which support consideration of hormone initiation prior to age 16 include:

1. Length of time on GnRH analogues – for those youth whose endogenous puberty is suppressed in the earliest stages of puberty, waiting until age 16 to add hormones means a potential 5-7 year gap, during which bone mineral density is only accruing at a pre-pubertal rate. This could potentially impact peak bone mineral density, and place youth at risk for relative osteopenia/osteoporosis.
2. Experiencing puberty in the last years of high school or early college years presents multiple potential challenges. The emotional upheaval that occurs for youth undergoing puberty happens normally at 11 or 12 years of age. For those youth who struggle with emotional lability at that age, they do so in a relatively protected environment, regulated by parents/caregivers, and without access to potential dangers such as motor vehicles, drugs, alcohol and adult (or almost adult) peers and sexual partners. Having the physical appearance of a sexually immature 11 year old in high school can present emotional and social challenges that are amplified by gender dysphoria.
3. Available data from the Netherlands indicates that those youth who reach adolescence with gender dysphoria are unlikely to revert to a gender identity that is congruent with their assigned sex at birth.[10]

Awareness of one's gender identity **does not** require cognitive capacity acquired in adolescence or early adulthood, nor does it require a fully myelinated frontal lobe. Gender studies in non-transgender participants have found that children are aware of their gender by the age of five or six, and often earlier.[14]

Induction of amenorrhea in post-pubertal youth

Commonly, trans-masculine youth are either not yet ready for, or are not yet at an appropriate age to begin testosterone therapy, but are interested in induction of amenorrhea. GnRH analogues may be used in this situation, however access is often difficult for financial and other reasons, and these medications cannot be used without hormone replacement indefinitely. Other mechanisms for inducing amenorrhea include continuous administration of oral contraceptive pills, and progestagen-only long acting reversible contraceptives (LARC) such as depo-medroxyprogesterone acetate injections, a levonorgestrel intrauterine device (IUD), or etonorgestrel rod implants (Grading: NT R M). Progesterone releasing intrauterine devices may result in amenorrhea in approximately half of all users.[15] Note that some trans-masculine youth are uncomfortable using “female” hormones, even for induction of amenorrhea. Youth can be informed that the administration of progestagens alone have little if any feminizing effect. Careful consideration of the individual’s needs is critical in this decision making process.

Preparing for gender-affirming hormone use in transgender youth

Prior to the initiation of gender-affirming hormones, providers should review the expectations that patients have about the use of hormones in their phenotypic gender transition. It is important for young people to have realistic expectations about gender-affirming hormones, and have an understanding about what hormones can and cannot achieve. Both GnRH analogue and gender-affirming hormone administration require parental/legal guardian consent if a youth is under the age of 18. Side effects, risks, and benefits should be reviewed during the consent process, as well as addressing the possibility of unknown long-term risks. The consent process for hormones should include a conversation about fertility. While options are being explored to preserve future fertility for transgender youth, the current reality is that cryopreservation is very expensive, in many cases prohibitively so for those with ovaries. For youth whose pubertal process has been suspended in the earliest stages, followed by administration of gender-affirming hormones, development of mature sperm or eggs is unlikely at the present time, although it is noteworthy that there is active research developing gametes in vitro from the field of juvenile oncology. The issue of future infertility is often far more problematic for parents and family members than for youth, especially at the beginning stages of discussing moving forward with gender-affirming hormones. Youth who determine that future genetic contribution to offspring is more important than avoiding the development of unmatched secondary sex characteristics can choose to stop GnRH analogues, and progress through endogenous puberty in order to cryopreserve sperm, or harvest eggs.

Administration of gender-affirming hormones in youth undergoing concurrent GnRH analogue puberty suppression

For those youth who are on GnRH analogues for puberty suppression, providers have the opportunity to create a more natural puberty with exogenous hormones. Because there is no need to use exogenous sex hormones to suppress endogenous secretion of sex hormones,

an escalating dose of either testosterone (for transmasculine youth) or estradiol (for transfeminine youth) can be used.

Transmasculine youth – hormone therapy with GnRH analogs

For those youth assigned female at birth who identify on the transmasculine spectrum, testosterone is used for the development of masculine secondary sexual characteristics. Testosterone can be delivered by injection, or topically via gel, compounded cream or a patch. Most adolescents are not enthusiastic about using gels or patches for a variety of reasons including necessity of daily application, potential of absorption for others in close proximity, and high incidence of local skin irritation in when a patch is used. Although injectable testosterone has historically been given intramuscularly, many practices have moved toward the less painful, and equally effective subcutaneous delivery mechanism.[16] Some patients note a surge of hormone with subcutaneous dosing, as serum testosterone levels may rise rapidly. Subcutaneous dosing must be weekly as the testosterone level decreases significantly by a weeks' time, whereas intramuscular testosterone lasts longer and may be dosed either weekly or every other week.

Subcutaneous dosing of testosterone with concurrent GnRH analogue use:

Dosing schedules may start with 12.5 mg SC weekly for 8-12 weeks, increase to 25 mg SC weekly. Check levels after three months and adjust in 12.5 mg intervals accordingly. Practitioners may decide to mimic total testosterone levels that correspond to Tanner stages, and increase at 6-month intervals. Most patients achieve a normal male range of total testosterone and good clinical results at 50-75mg of testosterone delivered subcutaneously each week. Providing or prescribing 1 mL syringes for achieving these small doses is helpful. Providers should also prescribe 18 gauge 1-inch needles for drawing up medication, and 25 gauge 5/8-inch needles for injecting subcutaneously. Youth can learn to self-inject into the subcutaneous space in the flank or thigh, switching sides each week. A common side effect is induration in the area of injection that can be minimized if the area is massaged liberally after injection.

Intramuscular dosing of testosterone with concurrent GnRH analogue use:

Intramuscular dosing of testosterone weekly or bi-weekly with an escalating schedule that is similar; 25 mg IM every week for 8 weeks, then increase to 50 mg IM every week. If dosing is every two weeks, the dose is doubled, but it is not uncommon for patients to experience fatigue, irritability and overall lack of energy toward the end of the second week of the cycle; weekly injections helps minimize these issues. Dosing is adjusted in 25 mg increments as guided by hormone level monitoring. Most patients do well on a final dose 50-100mg IM every week, or 100-200 mg every two weeks. Practitioners should provide or prescribe 1 mL syringes, 18 g 1-inch needles for drawing medication, and 21, 22, 23 or 25 g 1-inch needles (most commonly 23 or 25 gauge) for injecting intramuscularly. Youth can be taught to self-inject into the thigh, switching sides each time.

Injectable testosterone is suspended in oil, commercially in cottonseed oil, but often compounded for a less expensive form in sesame oil. Clinicians should be aware that some

youth may have an allergic reaction to either of these oils, and usually switching to another oil is successful in alleviating the problem.

Topical dosing of testosterone with concurrent GnRH analog use:

Occasionally there are youth who prefer testosterone delivery be topical, rather than injectable. Testosterone is available as a patch, gel or cream. Testosterone patches and gel are commercially available, cream can be compounded by specialty pharmacies. Testosterone patches come in 2mg and 4mg strengths, testosterone gel is available in 1% and 1.62% concentrations. There are no consensus dosing schedules for testosterone patches or testosterone gel in the induction of male puberty, only cited case examples of hypogonadal cisgender boys who's puberty was induced by topical testosterone.[17] Testosterone patches only come in two strengths and are difficult to titrate because of this, but testosterone pumps make titration a more feasible option.[18]

Monitoring

Monitoring for safety of testosterone is outlined elsewhere in these guidelines (link to testosterone administration), and the Endocrine Society have also published guidelines for testosterone administration.[11] Dosing adjustments should be made according to clinical response, and testosterone levels. Depending on the patient's age, providers may want to aim for testosterone levels that correspond to Tanner stages as doses are escalated.

Transfeminine youth – hormone therapy with GnRH analogs

For those youth assigned male at birth who identify on the transfeminine spectrum, 17 β estradiol is used for induction of feminizing secondary sex characteristics: breast development, fat distribution in the hip and chest area, and softening of the facial features. Estradiol will also help suppress the production of testosterone, which is unnecessary if youth are on GnRH analogues. Estrogen alone is not typically sufficient to fully inhibit testosterone production, and a second agent—either a GnRH analog or an antiandrogen such as spironolactone should be used (see below). As outlined in a recent review by Rosenthal [12] escalation of estrogen can be achieved in the following manner:

a. Transdermal: twice weekly patches (6.25 μg [achieved by cutting a 25-μg patch] with gradual increase to full adult dose of 400μg);
b. Oral/sublingual: daily (0.25 mg with gradual increase to full adult dose of 6 – 8 mg/d);
c. Parenteral IM (synthetic esters of 17β-estradiol): estradiol valerate (5–20 mg up to 30 – 40 mg/2 wk) or estradiol cypionate (2–10 mg/wk).

Monitoring for safety of estradiol is outlined elsewhere in these guidelines (link to testosterone administration), and the Endocrine Society have also published guidelines for estrogen administration.[11] Dosing adjustments should be made according to clinical response, and safety.

Timing for discontinuation of GnRH analogues

No consensus exists on the length of time GnRH analogues should continue after youth begin gender-affirming hormones. The Dutch Model follows a protocol in which simultaneous GnRH analogues and gender-affirming hormones continues until transgender individuals have their gonads removed. This model is appropriate in the Netherlands, where gonadectomy is easier to access at the age of 18 years old, and both gonadectomy as well as GnRH analogs are paid for by health insurance. In the United States, genital surgeries related to phenotypic gender transition are often not covered by insurance, and pose significant access issues. Additionally, gonadectomy is not necessarily desirable for all transgender persons, especially if future fertility is desired. Continuation of GnRH analogs in tandem with gender-affirming hormones into late adolescence or even early adulthood may be beneficial. Continued suppression of the HPG axis will permit use of lower doses of estradiol, and antiandrogens may not be necessary.

Administration of gender-affirming hormones without concurrent GnRH analogue administration

Many transgender youth accessing services are well beyond the early stages of puberty, and many are not able to get GnRH analogues covered by insurance. Because the cost of GnRH analogues is prohibitive for most families, gender-affirming hormones (in combination with other agents such as hormone blockers) are used to both suppress endogenous hormone production and masculinize or feminize bodies.

Hormone dosing in youth will vary based on the age, health, and other factors specific to the young person. In order to achieve amenorrhea with testosterone alone, masculinization will likely occur, which may or may not be desirable. In these cases, there may be a role for using other methods of suppressing menstruation such as continuous delivery of combined or progestin-only oral contraceptives, injected depo-medroxyprogesterone acetate, levonorgestrel containing-IUD, or etonorgestrel rod implants.

Transmasculine youth – hormone therapy without GnRH analogues

Similar to those transmasculine patients on GnRH analogues, testosterone is used for the induction of masculinizing features including body and facial hair growth, increased muscle mass, deepened voice, and body fat redistribution. Testosterone can be delivered via injections (subcutaneous or intramuscular), or topical (via gels, compounded creams or patches) for those youth not using GnRH analogues to suppress the HPG axis.

Subcutaneous dosing:

Dosing schedules may start with 25 mg SC weekly for 8-12 weeks, increase to 50 mg SC weekly. Check levels after three months and adjust in 25 mg intervals accordingly. Practitioners may decide to mimic total testosterone levels that correspond to Tanner stages, and increase at 3-6-month intervals. Most patients will experience normal male ranges of total

testosterone and good clinical response at 50-75 mg delivered subcutaneously each week. Providing or prescribing 1 mL syringes for achieving these small doses is helpful. Providers should also prescribe 18 gauge 1-inch needles for drawing up medication, and 25 gauge 5/8-inch needles for injecting. Youth can learn to self-inject into the subcutaneous space in the flank or thigh, switching sides each week. A common side effect is induration in the area of injection that can be minimized if the area is massaged liberally after injection.

Intramuscular dosing:

If intramuscular dosing is preferential, some experts recommend doubling the above doses for IM administration. Intramuscular dosing can be done every one or two weeks with an escalating schedule that is similar; 25 mg IM every week, or 50 mg IM every two weeks for 8-12 weeks, then increase to 50 mg every week or 100 mg IM every two weeks. Check levels, and adjust in 25 mg increments accordingly. Most patients do well on a final dose 50-100mg IM every week, or 100-200 mg every two weeks. It is not uncommon for patients to experience fatigue, irritability and overall lack of energy toward the end of the second week of the cycle. Some patients prefer to dose at other intervals such as every 10 days with adjusting of the dose. Practitioners should provide or prescribe 1 mL syringes, 18 g 1-inch needles for drawing medication, and 21, 22, 23 or 25 g 1-inch needles for injecting intramuscularly. Youth can be taught to self-inject into the thigh, switching sides each time.

It is noted that for older youth who are well past endogenous puberty, the value of a very slow escalation is unclear, and may cause undue distress if masculinization takes years to achieve.

Regardless of technique used, injectable testosterone cypionate is suspended in oil, commercially in cottonseed oil. Clinicians should be aware that some youth may have an allergic reaction to either of these oils, and usually switching to another oil is successful in alleviating the problem. For those youth that are allergic to cottonseed oil, testosterone enanthate is suspended commercially in sesame oil. Additionally, some compounding pharmacies suspend testosterone cypionate in sesame oil for a less expensive option.

Transfeminine youth - hormone therapy without GnRH analogues

17 β estradiol is used for induction of feminizing secondary sex characteristics: breast development, fat distribution in the hip and chest area, and softening of the facial features. Estradiol will also help suppress the production of testosterone, but usually is administered in conjunction with an antiandrogen such as spironolactone. Estradiol is available in oral, injectable and topical delivery via patch and compounded creams.

Approaches for estrogen delivery vary based on the age of the young person. Slower escalation of estradiol may be beneficial for breast development, although is often unbearably slow for patients. For younger patients, smaller starting doses may be more advisable. As outlined in a recent review by Rosenthal [12] escalation of estrogen can be achieved in the following manner:

a. Transdermal: twice weekly patches (6.25 μg [achieved by cutting a 25-μg patch] with gradual increase to full adult dose of 400μg);
b. Oral/sublingual: daily (0.25 mg with gradual increase to full adult dose of 6 – 8 mg/d);
c. Parenteral IM (synthetic esters of 17β-estradiol): estradiol valerate (5–20 mg up to 30 – 40 mg/2 wk) or estradiol cypionate (2–10 mg/wk).

Because there is no concomitant use of GnRH analogues, dosing may need to be started higher than the schedule outlined above. Initial doses and escalation of dosing quantity should be individually tailored to each young person. For example, a youth who has experienced endogenous male puberty and enters care at age 16 or 17 may follow a dosing schedule such as:

Oral 17β–estradiol: start at 2 mg/day for 4-8 weeks, and increase by 1 mg increments depending on clinical response.

Parenteral IM (synthetic esters of 17β-estradiol): estradiol valerate 10-15 mg IM Q 14 days for 8-12 weeks, then increase by 5 mg as needed based on clinical and monitoring results.

It is noted that for older youth who are well past endogenous puberty, the value of a very slow escalation is unclear, and may cause undue distress if feminization takes years to achieve.

The utility of escalating doses of spironolactone (to decrease side effects including blood pressure instability or dizziness) is unclear, but because of the diuretic effect, it may be useful to start at 25 mg bid and taper up each week to a final dose of 200 mg BID.

The use of progesterone in transfeminine individuals does not have consensus among providers. It may be advisable when using progesterone to choose bio-identical micronized progesterone, as some experts have concerns of side effects with synthetic progesterone such as exacerbation of underlying depression or weight gain. A detailed discussion on the role and dosing of progestagens are included in the adult guidelines.

Surgical interventions for transgender youth

Transmasculine youth who have undergone endogenous puberty commonly experience significant chest dysphoria, and may engage in inappropriate methods of chest binding. Binding with duct tape, ace bandages and plastic wrap can all lead to serious medical complications. Even well fitted chest binders are hot, uncomfortable and make exercising difficult. Male chest reconstruction is a medically necessary part of phenotypic gender transition for many trans-masculine individuals. While increasing numbers of insurance companies are covering the cost of male chest reconstruction, there are often arbitrary barriers to surgery citing that youth need to be at least 18 years of age prior to undergoing this procedure. Providers should participate in appeal processes so that patients can undergo chest surgery. There are currently no available data that report the positive impact of male chest reconstruction in minors, although a study is underway now.

Despite advances in youth care that include the use of puberty blockers and hormones in adolescence, many transgender youth (particularly transfeminine youth) often experience genital dysphoria that results in significant anxiety and depression, and has been reported by

many youth as a barrier to quality of life. The ability to develop skills and experience in social relationships is negatively impacted in those youth with genitals that do not correspond to their gender. High school is a time when young people begin to explore intimacy, as well as experience their own, and each other's physical bodies. For transgender adolescents, the very idea of sharing intimate space with a potential partner is often overwhelmingly terrifying, since their transgender status can be disclosed in an instant if their bodies are inadvertently exposed. For many transgender women, this disclosure has resulted in physical assault and all too often, death, at the hands of an angry partner. For many youth, social situations and dating are foregone, and the opportunity to learn necessary social skills during this stage of development is lost. Both the Endocrine Society Guidelines and the World Professional Association of Transgender Health (WPATH) Standards of Care version 7.0 recommend deferring genital surgery for both transmasculine and transfeminine youth until the age of 18 years. As youth are transitioning at increasingly younger ages, genital surgery is being performed on a case-by-case basis more frequently in minors, in order to address the issues mentioned above.

Editor's note: Gender-affirming care for transgender youth is a young and rapidly evolving field. In the absence of solid evidence, providers often must rely on the expert opinions of innovators and thought leaders in the field; many of these expert opinions are expressed in this youth guideline. The four primary authors for this youth protocol represent many years of expertise in clinical care and research, in both academic and community practice settings, and within the disciplines of adolescent medicine, pediatric endocrinology, family medicine, and advanced practice nursing.

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Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline

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*Cosponsoring Associations: American Association of Clinical Endocrinologists, American Society of Andrology, European Society for Pediatric Endocrinology, European Society of Endocrinology, Pediatric Endocrine Society, and World Professional Association for Transgender Health.

Objective: To update the "Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline," published by the Endocrine Society in 2009.

Participants: The participants include an Endocrine Society–appointed task force of nine experts, a methodologist, and a medical writer.

Evidence: This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation approach to describe the strength of recommendations and the quality of evidence. The task force commissioned two systematic reviews and used the best available evidence from other published systematic reviews and individual studies.

Consensus Process: Group meetings, conference calls, and e-mail communications enabled consensus. Endocrine Society committees, members and cosponsoring organizations reviewed and commented on preliminary drafts of the guidelines.

Conclusion: Gender affirmation is multidisciplinary treatment in which endocrinologists play an important role. Gender-dysphoric/gender-incongruent persons seek and/or are referred to endocrinologists to develop the physical characteristics of the affirmed gender. They require a safe and effective hormone regimen that will (1) suppress endogenous sex hormone secretion determined by the person's genetic/gonadal sex and (2) maintain sex hormone levels within the normal range for the person's affirmed gender. Hormone treatment is not recommended for prepubertal gender-dysphoric/gender-incongruent persons. Those clinicians who recommend gender-affirming endocrine treatments—appropriately trained diagnosing clinicians (required), a mental health provider for adolescents (required) and mental health

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Abbreviations: BMD, bone mineral density; DSD, disorder/difference of sex development; DSM, Diagnostic and Statistical Manual of Mental Disorders; GD, gender dysphoria; GnRH, gonadotropin-releasing hormone; ICD, International Statistical Classification of Diseases and Related Health Problems; MHP, mental health professional; VTE, venous thromboembolism.

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professional for adults (recommended)—should be knowledgeable about the diagnostic criteria and criteria for gender-affirming treatment, have sufficient training and experience in assessing psychopathology, and be willing to participate in the ongoing care throughout the endocrine transition. We recommend treating gender-dysphoric/gender-incongruent adolescents who have entered puberty at Tanner Stage G2/B2 by suppression with gonadotropin-releasing hormone agonists. Clinicians may add gender-affirming hormones after a multidisciplinary team has confirmed the persistence of gender dysphoria/gender incongruence and sufficient mental capacity to give informed consent to this partially irreversible treatment. Most adolescents have this capacity by age 16 years old. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to age 16 years, although there is minimal published experience treating prior to 13.5 to 14 years of age. For the care of peripubertal youths and older adolescents, we recommend that an expert multidisciplinary team comprised of medical professionals and mental health professionals manage this treatment. The treating physician must confirm the criteria for treatment used by the referring mental health practitioner and collaborate with them in decisions about gender-affirming surgery in older adolescents. For adult gender-dysphoric/gender-incongruent persons, the treating clinicians (collectively) should have expertise in transgender-specific diagnostic criteria, mental health, primary care, hormone treatment, and surgery, as needed by the patient. We suggest maintaining physiologic levels of gender-appropriate hormones and monitoring for known risks and complications. When high doses of sex steroids are required to suppress endogenous sex steroids and/or in advanced age, clinicians may consider surgically removing natal gonads along with reducing sex steroid treatment. Clinicians should monitor both transgender males (female to male) and transgender females (male to female) for reproductive organ cancer risk when surgical removal is incomplete. Additionally, clinicians should persistently monitor adverse effects of sex steroids. For gender-affirming surgeries in adults, the treating physician must collaborate with and confirm the criteria for treatment used by the referring physician. Clinicians should avoid harming individuals (via hormone treatment) who have conditions other than gender dysphoria/gender incongruence and who may not benefit from the physical changes associated with this treatment. (***J Clin Endocrinol Metab*** **102: 3869–3903, 2017)**

Summary of Recommendations

1.0 Evaluation of youth and adults

1.1. We advise that only trained mental health professionals (MHPs) who meet the following criteria should diagnose gender dysphoria (GD)/gender incongruence in adults: (1) competence in using the Diagnostic and Statistical Manual of Mental Disorders (DSM) and/or the International Statistical Classification of Diseases and Related Health Problems (ICD) for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)

1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or the ICD for diagnostic purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)

1.3. We advise that decisions regarding the social transition of prepubertal youths with GD/gender incongruence are made with the assistance of an MHP or another experienced professional. (Ungraded Good Practice Statement).

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1.4. We recommend against puberty blocking and gender-affirming hormone treatment in prepubertal children with GD/gender incongruence. (1 |⊕⊕◯◯)

1.5. We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (1 |⊕⊕⊕◯)

2.0 Treatment of adolescents

2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment, and are requesting treatment should initially undergo treatment to suppress pubertal development. (2 |⊕⊕◯◯)

2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty. (2 |⊕⊕◯◯)

2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. (1 |⊕⊕◯◯)

2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years. (1 |⊕⊕◯◯).

2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 |⊕◯◯◯)

2.6. We suggest monitoring clinical pubertal development every 3 to 6 months and laboratory parameters every 6 to 12 months during sex hormone treatment. (2 |⊕⊕◯◯)

3.0 Hormonal therapy for transgender adults

3.1. We recommend that clinicians confirm the diagnostic criteria of GD/gender incongruence and the criteria for the endocrine phase of gender transition before beginning treatment. (1 |⊕⊕⊕◯)

3.2. We recommend that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment. (1 |⊕⊕⊕◯)

3.3. We suggest that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. (2 |⊕⊕◯◯)

3.4. We suggest that endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment. (2 |⊕◯◯◯)

4.0 Adverse outcome prevention and long-term care

4.1. We suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex steroid hormone levels every 3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly. (2 |⊕⊕◯◯)

4.2. We suggest periodically monitoring prolactin levels in transgender females treated with estrogens. (2 |⊕⊕◯◯)

4.3. We suggest that clinicians evaluate transgender persons treated with hormones for cardiovascular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. (2 |⊕⊕◯◯)

4.4. We recommend that clinicians obtain bone mineral density (BMD) measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. (1 |⊕⊕◯◯)

4.5. We suggest that transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for non-transgender females. (2 |⊕⊕◯◯)

4.6. We suggest that transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. (2 |⊕◯◯◯)

4.7. We advise that clinicians determine the medical necessity of including a total hysterectomy and oophorectomy as part of gender-affirming surgery. (Ungraded Good Practice Statement)

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5.0 Surgery for sex reassignment and gender confirmation

5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being. (1 |⊕⊕◯◯)

5.2. We advise that clinicians approve genital gender-affirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)

5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)

5.4. We recommend that clinicians refer hormone-treated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 |⊕◯◯◯)

5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 |⊕⊕◯◯).

5.6. We suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement. (2 |⊕◯◯◯)

Changes Since the Previous Guideline

Both the current guideline and the one published in 2009 contain similar sections. Listed here are the sections contained in the current guideline and the corresponding number of recommendations: Introduction, Evaluation of Youth and Adults (5), Treatment of Adolescents (6), Hormonal Therapy for Transgender Adults (4), Adverse Outcomes Prevention and Long-term Care (7), and Surgery for Sex Reassignment and Gender Confirmation (6). The current introduction updates the diagnostic classification of "gender dysphoria/gender incongruence." It also reviews the development of "gender identity" and summarizes its natural development. The section on clinical evaluation of both youth and adults, defines in detail the professional qualifications required of those who diagnose and treat both adolescents and adults. We advise that decisions regarding the social transition of prepubertal youth are made with the assistance of a mental health professional or similarly experienced professional. We recommend against puberty blocking followed by gender-affirming hormone treatment of prepubertal children. Clinicians should inform pubertal children, adolescents, and adults seeking gender-confirming treatment of their options for fertility preservation. Prior to treatment, clinicians should evaluate the presence of medical conditions that may be worsened by hormone depletion and/or treatment. A multidisciplinary team, preferably composed of medical and mental health professionals, should monitor treatments. Clinicians evaluating transgender adults for endocrine treatment should confirm the diagnosis of persistent gender dysphoria/gender incongruence. Physicians should educate transgender persons regarding the time course of steroid-induced physical changes. Treatment should include periodic monitoring of hormone levels and metabolic parameters, as well as assessments of bone density and the impact upon prostate, gonads, and uterus. We also make recommendations for transgender persons who plan genital gender-affirming surgery.

Method of Development of Evidence-Based Clinical Practice Guidelines

The Clinical Guidelines Subcommittee (CGS) of the Endocrine Society deemed the diagnosis and treatment of individuals with GD/gender incongruence a priority area for revision and appointed a task force to formulate evidence-based recommendations. The task force followed the approach recommended by the Grading of Recommendations, Assessment, Development, and Evaluation group, an international group with expertise in the development and implementation of evidence-based guidelines (1). A detailed description of the grading scheme has been published elsewhere (2). The task force used the best available research evidence to develop the recommendations. The task force also used consistent language and graphical descriptions of both the strength of a recommendation and the quality of evidence. In terms of the strength of the recommendation, strong recommendations use the phrase "we recommend" and the number 1, and weak recommendations use the phrase "we suggest" and the number 2. Cross-filled circles indicate the quality of the evidence, such that ⊕◯◯◯ denotes very low–quality evidence; ⊕⊕◯◯, low quality; ⊕⊕⊕◯, moderate quality; and ⊕⊕⊕⊕, high quality. The task force has confidence that persons who receive care according to the strong recommendations will derive, on average, more benefit than harm. Weak recommendations require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action. Linked to each recommendation is a description of the evidence and the

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values that the task force considered in making the recommendation. In some instances, there are remarks in which the task force offers technical suggestions for testing conditions, dosing, and monitoring. These technical comments reflect the best available evidence applied to a typical person being treated. Often this evidence comes from the unsystematic observations of the task force and their preferences; therefore, one should consider these remarks as suggestions.

In this guideline, the task force made several statements to emphasize the importance of shared decision-making, general preventive care measures, and basic principles of the treatment of transgender persons. They labeled these "Ungraded Good Practice Statement." Direct evidence for these statements was either unavailable or not systematically appraised and considered out of the scope of this guideline. The intention of these statements is to draw attention to these principles.

The Endocrine Society maintains a rigorous conflict-of-interest review process for developing clinical practice guidelines. All task force members must declare any potential conflicts of interest by completing a conflict-of-interest form. The CGS reviews all conflicts of interest before the Society's Council approves the members to participate on the task force and periodically during the development of the guideline. All others participating in the guideline's development must also disclose any conflicts of interest in the matter under study, and most of these participants must be without any conflicts of interest. The CGS and the task force have reviewed all disclosures for this guideline and resolved or managed all identified conflicts of interest.

Conflicts of interest are defined as remuneration in any amount from commercial interests; grants; research support; consulting fees; salary; ownership interests [*e.g.*, stocks and stock options (excluding diversified mutual funds)]; honoraria and other payments for participation in speakers' bureaus, advisory boards, or boards of directors; and all other financial benefits. Completed forms are available through the Endocrine Society office.

The Endocrine Society provided the funding for this guideline; the task force received no funding or remuneration from commercial or other entities.

Commissioned Systematic Review

The task force commissioned two systematic reviews to support this guideline. The first one aimed to summarize the available evidence on the effect of sex steroid use in transgender individuals on lipids and cardiovascular outcomes. The review identified 29 eligible studies at moderate risk of bias. In transgender males (female to male), sex steroid therapy was associated with a statistically significant increase in serum triglycerides and low-density lipoprotein cholesterol levels. High-density lipoprotein cholesterol levels decreased significantly across all follow-up time periods. In transgender females (male to female), serum triglycerides were significantly higher without any changes in other parameters. Few myocardial infarction, stroke, venous thromboembolism (VTE), and death events were reported. These events were more frequent in transgender females. However, the quality of the evidence was low. The second review summarized the available evidence regarding the effect of sex steroids on bone health in transgender individuals and identified 13 studies. In transgender males, there was no statistically significant difference in the lumbar spine, femoral neck, or total hip BMD at 12 and 24 months compared with baseline values before initiating masculinizing hormone therapy. In transgender females, there was a statistically significant increase in lumbar spine BMD at 12 months and 24 months compared with baseline values before initiation of feminizing hormone therapy. There was minimal information on fracture rates. The quality of evidence was also low.

Introduction

Throughout recorded history (in the absence of an endocrine disorder) some men and women have experienced confusion and anguish resulting from rigid, forced conformity to sexual dimorphism. In modern history, there have been numerous ongoing biological, psychological, cultural, political, and sociological debates over various aspects of gender variance. The 20th century marked the emergence of a social awakening for men and women with the belief that they are "trapped" in the wrong body (3). Magnus Hirschfeld and Harry Benjamin, among others, pioneered the medical responses to those who sought relief from and a resolution to their profound discomfort. Although the term transsexual became widely known after Benjamin wrote "The Transsexual Phenomenon" (4), it was Hirschfeld who coined the term "transsexual" in 1923 to describe people who want to live a life that corresponds with their experienced gender vs their designated gender (5). Magnus Hirschfeld (6) and others (4, 7) have described other types of trans phenomena besides transsexualism. These early researchers proposed that the gender identity of these people was located somewhere along a unidimensional continuum. This continuum ranged from all male through "something in between" to all female. Yet such a classification does not take into account that people may have gender identities outside this continuum. For instance, some experience themselves as having both a male and female gender identity, whereas others completely renounce any gender classification (8, 9). There are also reports of individuals experiencing a continuous and rapid involuntary alternation between a male and female identity (10) or men who do not experience themselves as men but do not want to live as women (11, 12). In some countries, (*e.g.*, Nepal, Bangladesh, and Australia), these nonmale or nonfemale genders are officially recognized (13). Specific treatment protocols, however, have not yet been developed for these groups.

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Instead of the term transsexualism, the current classification system of the American Psychiatric Association uses the term gender dysphoria in its diagnosis of persons who are not satisfied with their designated gender (14). The current version of the World Health Organization's ICD-10 still uses the term transsexualism when diagnosing adolescents and adults. However, for the ICD-11, the World Health Organization has proposed using the term "gender incongruence" (15).

Treating persons with GD/gender incongruence (15) was previously limited to relatively ineffective elixirs or creams. However, more effective endocrinology-based treatments became possible with the availability of testosterone in 1935 and diethylstilbestrol in 1938. Reports of individuals with GD/gender incongruence who were treated with hormones and gender-affirming surgery appeared in the press during the second half of the 20th century. The Harry Benjamin International Gender Dysphoria Association was founded in September 1979 and is now called the World Professional Association for Transgender Health (WPATH). WPATH published its first Standards of Care in 1979. These standards have since been regularly updated, providing guidance for treating persons with GD/gender incongruence (16).

Prior to 1975, few peer-reviewed articles were published concerning endocrine treatment of transgender persons. Since then, more than two thousand articles about various aspects of transgender care have appeared.

It is the purpose of this guideline to make detailed recommendations and suggestions, based on existing medical literature and clinical experience, that will enable treating physicians to maximize benefit and minimize risk when caring for individuals diagnosed with GD/gender incongruence.

In the future, we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols. Specifically, endocrine treatment protocols for GD/gender incongruence should include the careful assessment of the following: (1) the effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain (including effects on cognitive, emotional, social, and sexual development); (2) the effects of treatment in adults on sex hormone levels; (3) the requirement for and the effects of progestins and other agents used to suppress endogenous sex steroids during treatment; and (4) the risks and benefits of gender-affirming hormone treatment in older transgender people.

To successfully establish and enact these protocols, a commitment of mental health and endocrine investigators is required to collaborate in long-term, large-scale studies across countries that use the same diagnostic and inclusion criteria, medications, assay methods, and response assessment tools (*e.g.*, the European Network for the Investigation of Gender Incongruence) (17, 18).

Terminology and its use vary and continue to evolve. Table 1 contains the definitions of terms as they are used throughout this guideline.

Biological Determinants of Gender Identity Development

One's self-awareness as male or female changes gradually during infant life and childhood. This process of cognitive and affective learning evolves with interactions with parents, peers, and environment. A fairly accurate timetable exists outlining the steps in this process (19). Normative psychological literature, however, does not address if and when gender identity becomes crystallized and what factors contribute to the development of a gender identity that is not congruent with the gender of rearing. Results of studies from a variety of biomedical disciplines—genetic, endocrine, and neuroanatomic—support the concept that gender identity and/or gender expression (20) likely reflect a complex interplay of biological, environmental, and cultural factors (21, 22).

With respect to endocrine considerations, studies have failed to find differences in circulating levels of sex steroids between transgender and nontransgender individuals (23). However, studies in individuals with a disorder/difference of sex development (DSD) have informed our understanding of the role that hormones may play in gender identity outcome, even though most persons with GD/gender incongruence do not have a DSD. For example, although most 46,XX adult individuals with virilizing congenital adrenal hyperplasia caused by mutations in *CYP21A2* reported a female gender identity, the prevalence of GD/gender incongruence was much greater in this group than in the general population without a DSD. This supports the concept that there is a role for prenatal/postnatal androgens in gender development (24–26), although some studies indicate that prenatal androgens are more likely to affect gender behavior and sexual orientation rather than gender identity *per se* (27, 28).

Researchers have made similar observations regarding the potential role of androgens in the development of gender identity in other individuals with DSD. For example, a review of two groups of 46,XY persons, each with androgen synthesis deficiencies and female raised, reported transgender male (female-to-male) gender role changes in 56% to 63% and 39% to 64% of patients, respectively (29). Also, in 46,XY female-raised individuals with cloacal

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Table 1. Definitions of Terms Used in This Guideline

Biological sex, biological male or female: These terms refer to physical aspects of maleness and femaleness. As these may not be in line with each other (*e.g.*, a person with XY chromosomes may have female-appearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided.

Cisgender: This means not transgender. An alternative way to describe individuals who are not transgender is "non-transgender people."

Gender-affirming (hormone) treatment: See "gender reassignment"

Gender dysphoria: This is the distress and unease experienced if gender identity and designated gender are not completely congruent (see Table 2). In 2013, the American Psychiatric Association released the fifth edition of the DSM-5, which replaced "gender identity disorder" with "gender dysphoria" and changed the criteria for diagnosis.

Gender expression: This refers to external manifestations of gender, expressed through one's name, pronouns, clothing, haircut, behavior, voice, or body characteristics. Typically, transgender people seek to make their gender expression align with their gender identity, rather than their designated gender.

Gender identity/experienced gender: This refers to one's internal, deeply held sense of gender. For transgender people, their gender identity does not match their sex designated at birth. Most people have a gender identity of man or woman (or boy or girl). For some people, their gender identity does not fit neatly into one of those two choices. Unlike gender expression (see below), gender identity is not visible to others.

Gender identity disorder: This is the term used for GD/gender incongruence in previous versions of DSM (see "gender dysphoria"). The ICD-10 still uses the term for diagnosing child diagnoses, but the upcoming ICD-11 has proposed using "gender incongruence of childhood."

Gender incongruence: This is an umbrella term used when the gender identity and/or gender expression differs from what is typically associated with the designated gender. Gender incongruence is also the proposed name of the gender identity–related diagnoses in ICD-11. Not all individuals with gender incongruence have gender dysphoria or seek treatment.

Gender variance: See "gender incongruence"

Gender reassignment: This refers to the treatment procedure for those who want to adapt their bodies to the experienced gender by means of hormones and/or surgery. This is also called gender-confirming or gender-affirming treatment.

Gender-reassignment surgery (gender-confirming/gender-affirming surgery): These terms refer only to the surgical part of gender-confirming/gender-affirming treatment.

Gender role: This refers to behaviors, attitudes, and personality traits that a society (in a given culture and historical period) designates as masculine or feminine and/or that society associates with or considers typical of the social role of men or women.

Sex designated at birth: This refers to sex assigned at birth, usually based on genital anatomy.

Sex: This refers to attributes that characterize biological maleness or femaleness. The best known attributes include the sex-determining genes, the sex chromosomes, the H-Y antigen, the gonads, sex hormones, internal and external genitalia, and secondary sex characteristics.

Sexual orientation: This term describes an individual's enduring physical and emotional attraction to another person. Gender identity and sexual orientation are not the same. Irrespective of their gender identity, transgender people may be attracted to women (gynephilic), attracted to men (androphilic), bisexual, asexual, or queer.

Transgender: This is an umbrella term for people whose gender identity and/or gender expression differs from what is typically associated with their sex designated at birth. Not all transgender individuals seek treatment.

Transgender male (also: trans man, female-to-male, transgender male): This refers to individuals assigned female at birth but who identify and live as men.

Transgender woman (also: trans woman, male-to female, transgender female): This refers to individuals assigned male at birth but who identify and live as women.

Transition: This refers to the process during which transgender persons change their physical, social, and/or legal characteristics consistent with the affirmed gender identity. Prepubertal children may choose to transition socially.

Transsexual: This is an older term that originated in the medical and psychological communities to refer to individuals who have permanently transitioned through medical interventions or desired to do so.

exstrophy and penile agenesis, the occurrence of transgender male changes was significantly more prevalent than in the general population (30, 31). However, the fact that a high percentage of individuals with the same conditions did not change gender suggests that cultural factors may play a role as well.

With respect to genetics and gender identity, several studies have suggested heritability of GD/gender incongruence (32, 33). In particular, a study by Heylens *et al.* (33) demonstrated a 39.1% concordance rate for gender identity disorder (based on the DSM-IV criteria) in 23 monozygotic twin pairs but no concordance in 21 same-sex dizygotic or seven opposite-sex twin pairs. Although numerous investigators have sought to identify specific genes associated with GD/gender incongruence, such studies have been inconsistent and without strong statistical significance (34–38).

Studies focusing on brain structure suggest that the brain phenotypes of people with GD/gender incongruence differ in various ways from control males and females, but that there is not a complete sex reversal in brain structures (39).

In summary, although there is much that is still unknown with respect to gender identity and its expression, compelling studies support the concept that biologic factors, in addition to environmental factors, contribute to this fundamental aspect of human development.

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Natural History of Children With GD/Gender Incongruence

With current knowledge, we cannot predict the psychosexual outcome for any specific child. Prospective follow-up studies show that childhood GD/gender incongruence does not invariably persist into adolescence and adulthood (so-called "desisters"). Combining all outcome studies to date, the GD/gender incongruence of a minority of prepubertal children appears to persist in adolescence (20, 40). In adolescence, a significant number of these desisters identify as homosexual or bisexual. It may be that children who only showed some gender nonconforming characteristics have been included in the follow-up studies, because the DSM-IV text revision criteria for a diagnosis were rather broad. However, the persistence of GD/gender incongruence into adolescence is more likely if it had been extreme in childhood (41, 42). With the newer, stricter criteria of the DSM-5 (Table 2), persistence rates may well be different in future studies.

1.0 Evaluation of Youth and Adults

Gender-affirming treatment is a multidisciplinary effort. After evaluation, education, and diagnosis, treatment may include mental health care, hormone therapy, and/or surgical therapy. Together with an MHP, hormone-prescribing clinicians should examine the psychosocial impact of the potential changes on people's lives, including mental health, friends, family, jobs, and their role in society. Transgender individuals should be encouraged to experience living in the new gender role and assess whether this improves their quality of life. Although the focus of this guideline is gender-affirming hormone therapy, collaboration with appropriate professionals responsible for each aspect of treatment maximizes a successful outcome.

Diagnostic assessment and mental health care

GD/gender incongruence may be accompanied with psychological or psychiatric problems (43–51). It is therefore necessary that clinicians who prescribe hormones and are involved in diagnosis and psychosocial assessment meet the following criteria: (1) are competent in using the DSM and/or the ICD for diagnostic purposes, (2) are able to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (3) are trained in diagnosing psychiatric conditions, (4) undertake or refer for appropriate treatment, (5) are able to do a psychosocial assessment of the patient's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) regularly attend relevant professional meetings.

Because of the psychological vulnerability of many individuals with GD/gender incongruence, it is important that mental health care is available before, during, and sometimes also after transitioning. For children and adolescents, an MHP who has training/experience in child and adolescent gender development (as well as child and adolescent psychopathology) should make the diagnosis, because assessing GD/gender incongruence in children and adolescents is often extremely complex.

During assessment, the clinician obtains information from the individual seeking gender-affirming treatment. In the case

Table 2. DSM-5 Criteria for Gender Dysphoria in Adolescents and Adults

A. A marked incongruence between one's experienced/expressed gender and natal gender of at least 6 mo in duration, as manifested by at least two of the following:
   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
   3. A strong desire for the primary and/or secondary sex characteristics of the other gender
   4. A strong desire to be of the other gender (or some alternative gender different from one's designated gender)
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's designated gender)
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's designated gender)

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Specify if:
   1. The condition exists with a disorder of sex development.
   2. The condition is posttransitional, in that the individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one sex-related medical procedure or treatment regimen—namely, regular sex hormone treatment or gender reassignment surgery confirming the desired gender (*e.g.*, penectomy, vaginoplasty in natal males; mastectomy or phalloplasty in natal females).

Reference: American Psychiatric Association (14).

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of adolescents, the clinician also obtains information from the parents or guardians regarding various aspects of the child's general and psychosexual development and current functioning. On the basis of this information, the clinician:

- decides whether the individual fulfills criteria for treatment (see Tables 2 and 3) for GD/gender incongruence (DSM-5) or transsexualism (DSM-5 and/or ICD-10);
- informs the individual about the possibilities and limitations of various kinds of treatment (hormonal/surgical and nonhormonal), and if medical treatment is desired, provides correct information to prevent unrealistically high expectations;
- assesses whether medical interventions may result in unfavorable psychological and social outcomes.

In cases in which severe psychopathology, circumstances, or both seriously interfere with the diagnostic work or make satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues. Literature on postoperative regret suggests that besides poor quality of surgery, severe psychiatric comorbidity and lack of support may interfere with positive outcomes (52–56).

For adolescents, the diagnostic procedure usually includes a complete psychodiagnostic assessment (57) and an assessment of the decision-making capability of the youth. An evaluation to assess the family's ability to endure stress, give support, and deal with the complexities of the adolescent's situation should be part of the diagnostic phase (58).

Social transitioning

A change in gender expression and role (which may involve living part time or full time in another gender role that is consistent with one's gender identity) may test the person's resolve, the capacity to function in the affirmed gender, and the adequacy of social, economic, and psychological supports. It assists both the individual and the clinician in their judgments about how to proceed (16). During social transitioning, the person's feelings about the social transformation (including coping with the responses of others) is a major focus of the counseling. The optimal timing for social transitioning may differ between individuals. Sometimes people wait until they start gender-affirming hormone treatment to make social transitioning easier, but individuals increasingly start social transitioning long before they receive medically supervised, gender-affirming hormone treatment.

Criteria

Adolescents and adults seeking gender-affirming hormone treatment and surgery should satisfy certain criteria before proceeding (16). Criteria for gender-affirming hormone therapy for adults are in Table 4, and criteria for gender-affirming hormone therapy for adolescents are in Table 5. Follow-up studies in adults meeting these criteria indicate a high satisfaction rate with treatment (59). However, the quality of evidence is usually low. A few follow-up studies on adolescents who fulfilled these criteria also indicated good treatment results (60–63).

Recommendations for Those Involved in the Gender-Affirming Hormone Treatment of Individuals With GD/Gender Incongruence

1.1. We advise that only trained MHPs who meet the following criteria should diagnose GD/gender incongruence in adults: (1) competence in using the DSM and/or the ICD for diagnostic purposes, (2) the ability to diagnose GD/gender incongruence and make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (3) training in diagnosing psychiatric conditions, (4) the ability to undertake or refer for appropriate treatment, (5) the ability to psychosocially assess the person's understanding, mental health, and social conditions that can impact gender-affirming hormone therapy, and (6) a practice of regularly attending relevant professional meetings. (Ungraded Good Practice Statement)

1.2. We advise that only MHPs who meet the following criteria should diagnose GD/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or ICD for diagnostic

Table 3. ICD-10 Criteria for Transsexualism

Transsexualism (F64.0) has three criteria:
1. The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatments.
2. The transsexual identity has been present persistently for at least 2 y.
3. The disorder is not a symptom of another mental disorder or a genetic, DSD, or chromosomal abnormality.

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Table 4. Criteria for Gender-Affirming Hormone Therapy for Adults

1. Persistent, well-documented gender dysphoria/gender incongruence
2. The capacity to make a fully informed decision and to consent for treatment
3. The age of majority in a given country (if younger, follow the criteria for adolescents)
4. Mental health concerns, if present, must be reasonably well controlled

Reproduced from World Professional Association for Transgender Health (16).

purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (*e.g.*, body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents. (Ungraded Good Practice Statement)

Evidence

Individuals with gender identity issues may have psychological or psychiatric problems (43–48, 50, 51, 64, 65). It is therefore necessary that clinicians making the diagnosis are able to make a distinction between GD/gender incongruence and conditions that have similar features. Examples of conditions with similar features are body dysmorphic disorder, body identity integrity disorder (a condition in which individuals have a sense that their anatomical configuration as an able-bodied person is somehow wrong or inappropriate) (66), or certain forms of eunuchism (in which a person is preoccupied with or engages in castration and/or penectomy for

Table 5. Criteria for Gender-Affirming Hormone Therapy for Adolescents

Adolescents are eligible for GnRH agonist treatment if:

1. A qualified MHP has confirmed that:
- the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed),
- gender dysphoria worsened with the onset of puberty,
- any coexisting psychological, medical, or social problems that could interfere with treatment (*e.g.*, that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment,
- the adolescent has sufficient mental capacity to give informed consent to this (reversible) treatment,

2. And the adolescent:
- has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,
- has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,

3. And a pediatric endocrinologist or other clinician experienced in pubertal assessment
- agrees with the indication for GnRH agonist treatment,
- has confirmed that puberty has started in the adolescent (Tanner stage $\geq$G2/B2),
- has confirmed that there are no medical contraindications to GnRH agonist treatment.

Adolescents are eligible for subsequent sex hormone treatment if:

1. A qualified MHP has confirmed:
- the persistence of gender dysphoria,
- any coexisting psychological, medical, or social problems that could interfere with treatment (*e.g.*, that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start sex hormone treatment,
- the adolescent has sufficient mental capacity (which most adolescents have by age 16 years) to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent to this (partly) irreversible treatment,

2. And the adolescent:
- has been informed of the (irreversible) effects and side effects of treatment (including potential loss of fertility and options to preserve fertility),
- has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process,

3. And a pediatric endocrinologist or other clinician experienced in pubertal induction:
- agrees with the indication for sex hormone treatment,
- has confirmed that there are no medical contraindications to sex hormone treatment.

Reproduced from World Professional Association for Transgender Health (16).

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reasons that are not gender identity related) (11). Clinicians should also be able to diagnose psychiatric conditions accurately and ensure that these conditions are treated appropriately, particularly when the conditions may complicate treatment, affect the outcome of gender-affirming treatment, or be affected by hormone use.

Values and preferences

The task force placed a very high value on avoiding harm from hormone treatment in individuals who have conditions other than GD/gender incongruence and who may not benefit from the physical changes associated with this treatment and placed a low value on any potential benefit these persons believe they may derive from hormone treatment. This justifies the good practice statement.

1.3. We advise that decisions regarding the social transition of prepubertal youths with GD/gender incongruence are made with the assistance of an MHP or another experienced professional. (Ungraded Good Practice Statement).

1.4. We recommend against puberty blocking and gender-affirming hormone treatment in prepubertal children with GD/gender incongruence. (1 |⊕⊕◯◯)

Evidence

In most children diagnosed with GD/gender incongruence, it did not persist into adolescence. The percentages differed among studies, probably dependent on which version of the DSM clinicians used, the patient's age, the recruitment criteria, and perhaps cultural factors. However, the large majority (about 85%) of prepubertal children with a childhood diagnosis did not remain GD/gender incongruent in adolescence (20). If children have completely socially transitioned, they may have great difficulty in returning to the original gender role upon entering puberty (40). Social transition is associated with the persistence of GD/gender incongruence as a child progresses into adolescence. It may be that the presence of GD/gender incongruence in prepubertal children is the earliest sign that a child is destined to be transgender as an adolescent/adult (20). However, social transition (in addition to GD/gender incongruence) has been found to contribute to the likelihood of persistence.

This recommendation, however, does not imply that children should be discouraged from showing gender-variant behaviors or should be punished for exhibiting such behaviors. In individual cases, an early complete social transition may result in a more favorable outcome, but there are currently no criteria to identify the GD/gender-incongruent children to whom this applies. At the present time, clinical experience suggests that persistence of GD/gender incongruence can only be reliably assessed after the first signs of puberty.

Values and preferences

The task force placed a high value on avoiding harm with gender-affirming hormone therapy in prepubertal children with GD/gender incongruence. This justifies the strong recommendation in the face of low-quality evidence.

1.5. We recommend that clinicians inform and counsel all individuals seeking gender-affirming medical treatment regarding options for fertility preservation prior to initiating puberty suppression in adolescents and prior to treating with hormonal therapy of the affirmed gender in both adolescents and adults. (1 |⊕⊕⊕◯)

Remarks

Persons considering hormone use for gender affirmation need adequate information about this treatment in general and about fertility effects of hormone treatment in particular to make an informed and balanced decision (67, 68). Because young adolescents may not feel qualified to make decisions about fertility and may not fully understand the potential effects of hormonal interventions, consent and protocol education should include parents, the referring MHP(s), and other members of the adolescent's support group. To our knowledge, there are no formally evaluated decision aids available to assist in the discussion and decision regarding the future fertility of adolescents or adults beginning gender-affirming treatment.

Treating early pubertal youth with GnRH analogs will temporarily impair spermatogenesis and oocyte maturation. Given that an increasing number of transgender youth want to preserve fertility potential, delaying or temporarily discontinuing GnRH analogs to promote gamete maturation is an option. This option is often not preferred, because mature sperm production is associated with later stages of puberty and with the significant development of secondary sex characteristics.

For those designated male at birth with GD/gender incongruence and who are in early puberty, sperm production and the development of the reproductive tract are insufficient for the cryopreservation of sperm. However, prolonged pubertal suppression using GnRH analogs is reversible and clinicians should inform these individuals that sperm production can be initiated following prolonged gonadotropin suppression. This can be accomplished by spontaneous gonadotropin recovery after

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cessation of GnRH analogs or by gonadotropin treatment and will probably be associated with physical manifestations of testosterone production, as stated above. Note that there are no data in this population concerning the time required for sufficient spermatogenesis to collect enough sperm for later fertility. In males treated for precocious puberty, spermarche was reported 0.7 to 3 years after cessation of GnRH analogs (69). In adult men with gonadotropin deficiency, sperm are noted in seminal fluid by 6 to 12 months of gonadotropin treatment. However, sperm numbers when partners of these patients conceive are far below the "normal range" (70, 71).

In girls, no studies have reported long-term, adverse effects of pubertal suppression on ovarian function after treatment cessation (72, 73). Clinicians should inform adolescents that no data are available regarding either time to spontaneous ovulation after cessation of GnRH analogs or the response to ovulation induction following prolonged gonadotropin suppression.

In males with GD/gender incongruence, when medical treatment is started in a later phase of puberty or in adulthood, spermatogenesis is sufficient for cryopreservation and storage of sperm. *In vitro* spermatogenesis is currently under investigation. Restoration of spermatogenesis after prolonged estrogen treatment has not been studied.

In females with GD/gender incongruence, the effect of prolonged treatment with exogenous testosterone on ovarian function is uncertain. There have been reports of an increased incidence of polycystic ovaries in transgender males, both prior to and as a result of androgen treatment (74–77), although these reports were not confirmed by others (78). Pregnancy has been reported in transgender males who have had prolonged androgen treatment and have discontinued testosterone but have not had genital surgery (79, 80). A reproductive endocrine gynecologist can counsel patients before gender-affirming hormone treatment or surgery regarding potential fertility options (81). Techniques for cryopreservation of oocytes, embryos, and ovarian tissue continue to improve, and oocyte maturation of immature tissue is being studied (82).

2.0 Treatment of Adolescents

During the past decade, clinicians have progressively acknowledged the suffering of young adolescents with GD/gender incongruence. In some forms of GD/gender incongruence, psychological interventions may be useful and sufficient. However, for many adolescents with GD/gender incongruence, the pubertal physical changes are unbearable. As early medical intervention may prevent psychological harm, various clinics have decided to start treating young adolescents with GD/gender incongruence with puberty-suppressing medication (a GnRH analog). As compared with starting gender-affirming treatment long after the first phases of puberty, a benefit of pubertal suppression at early puberty may be a better psychological and physical outcome.

In girls, the first physical sign of puberty is the budding of the breasts followed by an increase in breast and fat tissue. Breast development is also associated with the pubertal growth spurt, and menarche occurs ~2 years later. In boys, the first physical change is testicular growth. A testicular volume ≥4 mL is seen as consistent with the initiation of physical puberty. At the beginning of puberty, estradiol and testosterone levels are still low and are best measured in the early morning with an ultrasensitive assay. From a testicular volume of 10 mL, daytime testosterone levels increase, leading to virilization (83). Note that pubic hair and/or axillary hair/odor may not reflect the onset of gonadarche; instead, it may reflect adrenarche alone.

2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment (Table 5), and are requesting treatment should initially undergo treatment to suppress pubertal development. (2 |⊕⊕◯◯)

2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty (Tanner stages G2/B2). (2 |⊕⊕◯◯)

Evidence

Pubertal suppression can expand the diagnostic phase by a long period, giving the subject more time to explore options and to live in the experienced gender before making a decision to proceed with gender-affirming sex hormone treatments and/or surgery, some of which is irreversible (84, 85). Pubertal suppression is fully reversible, enabling full pubertal development in the natal gender, after cessation of treatment, if appropriate. The experience of full endogenous puberty is an undesirable condition for the GD/gender-incongruent individual and may seriously interfere with healthy psychological functioning and well-being. Treating GD/gender-incongruent adolescents entering puberty with GnRH analogs has been shown to improve psychological functioning in several domains (86).

Another reason to start blocking pubertal hormones early in puberty is that the physical outcome is improved compared with initiating physical transition after puberty has been completed (60, 62). Looking like a man or woman when living as the opposite sex creates difficult

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barriers with enormous life-long disadvantages. We therefore advise starting suppression in early puberty to prevent the irreversible development of undesirable secondary sex characteristics. However, adolescents with GD/gender incongruence should experience the first changes of their endogenous spontaneous puberty, because their emotional reaction to these first physical changes has diagnostic value in establishing the persistence of GD/gender incongruence (85). Thus, Tanner stage 2 is the optimal time to start pubertal suppression. However, pubertal suppression treatment in early puberty will limit the growth of the penis and scrotum, which will have a potential effect on future surgical treatments (87).

Clinicians can also use pubertal suppression in adolescents in later pubertal stages to stop menses in transgender males and prevent facial hair growth in transgender females. However, in contrast to the effects in early pubertal adolescents, physical sex characteristics (such as more advanced breast development in transgender boys and lowering of the voice and outgrowth of the jaw and brow in transgender girls) are not reversible.

Values and preferences

These recommendations place a high value on avoiding an unsatisfactory physical outcome when secondary sex characteristics have become manifest and irreversible, a higher value on psychological well-being, and a lower value on avoiding potential harm from early pubertal suppression.

Remarks

Table 6 lists the Tanner stages of breast and male genital development. Careful documentation of hallmarks of pubertal development will ensure precise timing when initiating pubertal suppression once puberty has started. Clinicians can use pubertal LH and sex steroid levels to confirm that puberty has progressed sufficiently before starting pubertal suppression (88). Reference ranges for sex steroids by Tanner stage may vary depending on the assay used. Ultrasensitive sex steroid and gonadotropin assays will help clinicians document early pubertal changes.

Irreversible and, for GD/gender-incongruent adolescents, undesirable sex characteristics in female puberty are breasts, female body habitus, and, in some cases, relative short stature. In male puberty, they are a prominent Adam's apple; low voice; male bone configuration, such as a large jaw, big feet and hands, and tall stature; and male hair pattern on the face and extremities.

2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. (1 |⊕⊕◯◯)

Evidence

Clinicians can suppress pubertal development and gonadal function most effectively via gonadotropin suppression using GnRH analogs. GnRH analogs are long-acting agonists that suppress gonadotropins by GnRH receptor desensitization after an initial increase of gonadotropins during ~10 days after the first and (to a lesser degree) the second injection (89). Antagonists immediately suppress pituitary gonadotropin secretion (90, 91). Long-acting GnRH analogs are the currently preferred treatment option. Clinicians may consider long-acting GnRH antagonists when evidence on their safety and efficacy in adolescents becomes available.

During GnRH analog treatment, slight development of secondary sex characteristics may regress, and in a later phase of pubertal development, it will stop. In girls, breast tissue will become atrophic, and menses will stop. In boys, virilization will stop, and testicular volume may decrease (92).

An advantage of using GnRH analogs is the reversibility of the intervention. If, after extensive exploration of his/her transition wish, the individual no longer desires transition, they can discontinue pubertal suppression. In subjects with

Table 6. Tanner Stages of Breast Development and Male External Genitalia

The description of Tanner stages for breast development:
1. Prepubertal
2. Breast and papilla elevated as small mound; areolar diameter increased
3. Breast and areola enlarged, no contour separation
4. Areola and papilla form secondary mound
5. Mature; nipple projects, areola part of general breast contour

For penis and testes:
1. Prepubertal, testicular volume <4 mL
2. Slight enlargement of penis; enlarged scrotum, pink, texture altered, testes 4–6 mL
3. Penis longer, testes larger (8–12 mL)
4. Penis and glans larger, including increase in breadth; testes larger (12–15 mL), scrotum dark
5. Penis adult size; testicular volume > 15 ml

Adapted from Lawrence (56).

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precocious puberty, spontaneous pubertal development has been shown to resume after patients discontinue taking GnRH analogs (93).

Recommendations 2.1 to 2.3 are supported by a prospective follow-up study from The Netherlands. This report assessed mental health outcomes in 55 transgender adolescents/young adults (22 transgender females and 33 transgender males) at three time points: (1) before the start of GnRH agonist (average age of 14.8 years at start of treatment), (2) at initiation of gender-affirming hormones (average age of 16.7 years at start of treatment), and (3) 1 year after "gender-reassignment surgery" (average age of 20.7 years) (63). Despite a decrease in depression and an improvement in general mental health functioning, GD/gender incongruence persisted through pubertal suppression, as previously reported (86). However, following sex hormone treatment and gender-reassignment surgery, GD/gender incongruence was resolved and psychological functioning steadily improved (63). Furthermore, well-being was similar to or better than that reported by age-matched young adults from the general population, and none of the study participants regretted treatment. This study represents the first long-term follow-up of individuals managed according to currently existing clinical practice guidelines for transgender youth, and it underscores the benefit of the multidisciplinary approach pioneered in The Netherlands; however, further studies are needed.

Side effects

The primary risks of pubertal suppression in GD/gender-incongruent adolescents may include adverse effects on bone mineralization (which can theoretically be reversed with sex hormone treatment), compromised fertility if the person subsequently is treated with sex hormones, and unknown effects on brain development. Few data are available on the effect of GnRH analogs on BMD in adolescents with GD/gender incongruence. Initial data in GD/gender-incongruent subjects demonstrated no change of absolute areal BMD during 2 years of GnRH analog therapy but a decrease in BMD *z* scores (85). A recent study also suggested suboptimal bone mineral accrual during GnRH analog treatment. The study reported a decrease in areal BMD *z* scores and of bone mineral apparent density *z* scores (which takes the size of the bone into account) in 19 transgender males treated with GnRH analogs from a mean age of 15.0 years (standard deviation = 2.0 years) for a median duration of 1.5 years (0.3 to 5.2 years) and in 15 transgender females treated from 14.9 (±1.9) years for 1.3 years (0.5 to 3.8 years), although not all changes were statistically significant (94). There was incomplete catch-up at age 22 years after sex hormone treatment from age 16.6 (±1.4) years for a median duration of 5.8 years (3.0 to 8.0 years) in transgender females and from age 16.4 (±2.3) years for 5.4 years (2.8 to 7.8 years) in transgender males. Little is known about more prolonged use of GnRH analogs. Researchers reported normal BMD *z* scores at age 35 years in one individual who used GnRH analogs from age 13.7 years until age 18.6 years before initiating sex hormone treatment (65).

Additional data are available from individuals with late puberty or GnRH analog treatment of other indications. Some studies reported that men with constitutionally delayed puberty have decreased BMD in adulthood (95). However, other studies reported that these men have normal BMD (96, 97). Treating adults with GnRH analogs results in a decrease of BMD (98). In children with central precocious puberty, treatment with GnRH analogs has been found to result in a decrease of BMD during treatment by some (99) but not others (100). Studies have reported normal BMD after discontinuing therapy (69, 72, 73, 101, 102). In adolescents treated with growth hormone who are small for gestational age and have normal pubertal timing, 2-year GnRH analog treatments did not adversely affect BMD (103). Calcium supplementation may be beneficial in optimizing bone health in GnRH analog–treated individuals (104). There are no studies of vitamin D supplementation in this context, but clinicians should offer supplements to vitamin D–deficient adolescents. Physical activity, especially during growth, is important for bone mass in healthy individuals (103) and is therefore likely to be beneficial for bone health in GnRH analog–treated subjects.

GnRH analogs did not induce a change in body mass index standard deviation score in GD/gender-incongruent adolescents (94) but caused an increase in fat mass and decrease in lean body mass percentage (92). Studies in girls treated for precocious puberty also reported a stable body mass index standard deviation score during treatment (72) and body mass index and body composition comparable to controls after treatment (73).

Arterial hypertension has been reported as an adverse effect in a few girls treated with GnRH analogs for precocious/early puberty (105, 106). Blood pressure monitoring before and during treatment is recommended.

Individuals may also experience hot flashes, fatigue, and mood alterations as a consequence of pubertal suppression. There is no consensus on treatment of these side effects in this context.

It is recommended that any use of pubertal blockers (and subsequent use of sex hormones, as detailed below) include a discussion about implications for fertility (see recommendation 1.3). Transgender adolescents may

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want to preserve fertility, which may be otherwise compromised if puberty is suppressed at an early stage and the individual completes phenotypic transition with the use of sex hormones.

Limited data are available regarding the effects of GnRH analogs on brain development. A single cross-sectional study demonstrated no compromise of executive function (107), but animal data suggest there may be an effect of GnRH analogs on cognitive function (108).

Values and preferences

Our recommendation of GnRH analogs places a higher value on the superior efficacy, safety, and reversibility of the pubertal hormone suppression achieved (as compared with the alternatives) and a relatively lower value on limiting the cost of therapy. Of the available alternatives, depot and oral progestin preparations are effective. Experience with this treatment dates back prior to the emergence of GnRH analogs for treating precocious puberty in papers from the 1960s and early 1970s (109–112). These compounds are usually safe, but some side effects have been reported (113–115). Only two recent studies involved transgender youth (116, 117). One of these studies described the use of oral lynestrenol monotherapy followed by the addition of testosterone treatment in transgender boys who were at Tanner stage B4 or further at the start of treatment (117). They found lynestrenol safe, but gonadotropins were not fully suppressed. The study reported metrorrhagia in approximately half of the individuals, mainly in the first 6 months. Acne, headache, hot flashes, and fatigue were other frequent side effects. Another progestin that has been studied in the United States is medroxyprogesterone. This agent is not as effective as GnRH analogs in lowering endogenous sex hormones either and may be associated with other side effects (116). Progestin preparations may be an acceptable treatment for persons without access to GnRH analogs or with a needle phobia. If GnRH analog treatment is not available (insurance denial, prohibitive cost, or other reasons), postpubertal, transgender female adolescents may be treated with an antiandrogen that directly suppresses androgen synthesis or action (see adult section).

Remarks

Measurements of gonadotropin and sex steroid levels give precise information about gonadal axis suppression, although there is insufficient evidence for any specific short-term monitoring scheme in children treated with GnRH analogs (88). If the gonadal axis is not completely suppressed—as evidenced by (for example) menses, erections, or progressive hair growth—the interval of GnRH analog treatment can be shortened or the dose increased. During treatment, adolescents should be monitored for negative effects of delaying puberty, including a halted growth spurt and impaired bone mineral accretion. Table 7 illustrates a suggested clinical protocol.

Anthropometric measurements and X-rays of the left hand to monitor bone age are informative for evaluating growth. To assess BMD, clinicians can perform dual-energy X-ray absorptiometry scans.

2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule (see Table 8) after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years (Table 5). (1 |⊕⊕◯◯)

2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 |⊕◯◯◯)

2.6. We suggest monitoring clinical pubertal development every 3 to 6 months and laboratory parameters every 6 to 12 months during sex hormone treatment (Table 9). (2 |⊕⊕◯◯)

Table 7. Baseline and Follow-Up Protocol During Suppression of Puberty

Every 3–6 mo
Anthropometry: height, weight, sitting height, blood pressure, Tanner stages
Every 6–12 mo
Laboratory: LH, FSH, E2/T, 25OH vitamin D
Every 1–2 y
Bone density using DXA
Bone age on X-ray of the left hand (if clinically indicated)

Adapted from Hembree *et al.* (118).

Abbreviations: DXA, dual-energy X-ray absorptiometry; E2, estradiol; FSH, follicle stimulating hormone; LH, luteinizing hormone; T, testosterone;

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Table 8. Protocol Induction of Puberty

Induction of female puberty with oral 17β-estradiol, increasing the dose every 6 mo:
- 5 μg/kg/d
- 10 μg/kg/d
- 15 μg/kg/d
- 20 μg/kg/d
- Adult dose = 2–6 mg/d
- *In postpubertal transgender female adolescents, the dose of 17β-estradiol can be increased more rapidly:*
  - 1 mg/d for 6 mo
  - 2 mg/d

Induction of female puberty with transdermal 17β-estradiol, increasing the dose every 6 mo (new patch is placed every 3.5 d):
- 6.25–12.5 μg/24 h (cut 25-μg patch into quarters, then halves)
- 25 μg/24 h
- 37.5 μg/24 h
- Adult dose = 50–200 μg/24 h
- *For alternatives once at adult dose, see Table 11.*
- *Adjust maintenance dose to mimic physiological estradiol levels (see Table 15).*

Induction of male puberty with testosterone esters increasing the dose every 6 mo (IM or SC):
- 25 mg/m^2/2 wk (or alternatively, half this dose weekly, or double the dose every 4 wk)
- 50 mg/m^2/2 wk
- 75 mg/m^2/2 wk
- 100 mg/m^2/2 wk
- Adult dose = 100–200 mg every 2 wk
- *In postpubertal transgender male adolescents the dose of testosterone esters can be increased more rapidly:*
  - 75 mg/2 wk for 6 mo
  - 125 mg/2 wk
- *For alternatives once at adult dose, see Table 11.*
- *Adjust maintenance dose to mimic physiological testosterone levels (see Table 14).*

Adapted from Hembree *et al.* (118).

Abbreviations: IM, intramuscularly; SC, subcutaneously.

Evidence

Adolescents develop competence in decision making at their own pace. Ideally, the supervising medical professionals should individually assess this competence, although no objective tools to make such an assessment are currently available.

Many adolescents have achieved a reasonable level of competence by age 15 to 16 years (119), and in many countries 16-year-olds are legally competent with regard to medical decision making (120). However, others believe that although some capacities are generally achieved before age 16 years, other abilities (such as good risk assessment) do not develop until well after 18 years (121). They suggest that health care procedures should be divided along a matrix of relative risk, so that younger adolescents can be allowed to decide about low-risk procedures, such as most diagnostic tests and common therapies, but not about high-risk procedures, such as most surgical procedures (121).

Currently available data from transgender adolescents support treatment with sex hormones starting at age 16 years (63, 122). However, some patients may incur potential risks by waiting until age 16 years. These include the potential risk to bone health if puberty is suppressed

Table 9. Baseline and Follow-up Protocol During Induction of Puberty

Every 3–6 mo
- •Anthropometry: height, weight, sitting height, blood pressure, Tanner stages

Every 6–12 mo
- •In transgender males: hemoglobin/hematocrit, lipids, testosterone, 25OH vitamin D
- •In transgender females: prolactin, estradiol, 25OH vitamin D

Every 1–2 y
- •BMD using DXA
- •Bone age on X-ray of the left hand (if clinically indicated)

BMD should be monitored into adulthood (until the age of 25–30 y or until peak bone mass has been reached).
For recommendations on monitoring once pubertal induction has been completed, see Tables 14 and 15.

Adapted from Hembree *et al.* (118).

Abbreviation: DXA, dual-energy X-ray absorptiometry.

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for 6 to 7 years before initiating sex hormones (*e.g.*, if someone reached Tanner stage 2 at age 9-10 years old). Additionally, there may be concerns about inappropriate height and potential harm to mental health (emotional and social isolation) if initiation of secondary sex characteristics must wait until the person has reached 16 years of age. However, only minimal data supporting earlier use of gender-affirming hormones in transgender adolescents currently exist (63). Clearly, long-term studies are needed to determine the optimal age of sex hormone treatment in GD/gender-incongruent adolescents.

The MHP who has followed the adolescent during GnRH analog treatment plays an essential role in assessing whether the adolescent is eligible to start sex hormone therapy and capable of consenting to this treatment (Table 5). Support of the family/environment is essential. Prior to the start of sex hormones, clinicians should discuss the implications for fertility (see recommendation 1.5). Throughout pubertal induction, an MHP and a pediatric endocrinologist (or other clinician competent in the evaluation and induction of pubertal development) should monitor the adolescent. In addition to monitoring therapy, it is also important to pay attention to general adolescent health issues, including healthy life style choices, such as not smoking, contraception, and appropriate vaccinations (*e.g.*, human papillomavirus).

For the induction of puberty, clinicians can use a similar dose scheme for hypogonadal adolescents with GD/gender incongruence as they use in other individuals with hypogonadism, carefully monitoring for desired and undesired effects (Table 8). In transgender female adolescents, transdermal 17β-estradiol may be an alternative for oral 17β-estradiol. It is increasingly used for pubertal induction in hypogonadal females. However, the absence of low-dose estrogen patches may be a problem. As a result, individuals may need to cut patches to size themselves to achieve appropriate dosing (123). In transgender male adolescents, clinicians can give testosterone injections intramuscularly or subcutaneously (124, 125).

When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion. Gonadotropin secretion and endogenous production of testosterone may resume and interfere with the effectiveness of estrogen treatment, in transgender female adolescents (126, 127). Therefore, continuation of GnRH analog treatment is advised until gonadectomy. Given that GD/gender-incongruent adolescents may opt not to have gonadectomy, long-term studies are necessary to examine the potential risks of prolonged GnRH analog treatment. Alternatively, in transgender male adolescents, GnRH analog treatment can be discontinued once an adult dose of testosterone has been reached and the individual is well virilized. If uterine bleeding occurs, a progestin can be added. However, the combined use of a GnRH analog (for ovarian suppression) and testosterone may enable phenotypic transition with a lower dose of testosterone in comparison with testosterone alone. If there is a wish or need to discontinue GnRH analog treatment in transgender female adolescents, they may be treated with an antiandrogen that directly suppresses androgen synthesis or action (see section 3.0 "Hormonal Therapy for Transgender Adults").

Values and preferences

The recommendation to initiate pubertal induction only when the individual has sufficient mental capacity (roughly age 16 years) to give informed consent for this partly irreversible treatment places a higher value on the ability of the adolescent to fully understand and oversee the partially irreversible consequences of sex hormone treatment and to give informed consent. It places a lower value on the possible negative effects of delayed puberty. We may not currently have the means to weigh adequately the potential benefits of waiting until around age 16 years to initiate sex hormones vs the potential risks/harm to BMD and the sense of social isolation from having the timing of puberty be so out of sync with peers (128).

Remarks

Before starting sex hormone treatment, effects on fertility and options for fertility preservation should be discussed. Adult height may be a concern in transgender adolescents. In a transgender female adolescent, clinicians may consider higher doses of estrogen or a more rapid tempo of dose escalation during pubertal induction. There are no established treatments yet to augment adult height in a transgender male adolescent with open epiphyses during pubertal induction. It is not uncommon for transgender adolescents to present for clinical services after having completed or nearly completed puberty. In such cases, induction of puberty with sex hormones can be done more rapidly (see Table 8). Additionally, an adult dose of testosterone in transgender male adolescents may suffice to suppress the gonadal axis without the need to use a separate agent. At the appropriate time, the multidisciplinary team should adequately prepare the adolescent for transition to adult care.

3.0 Hormonal Therapy for Transgender Adults

The two major goals of hormonal therapy are (1) to reduce endogenous sex hormone levels, and thus reduce

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the secondary sex characteristics of the individual's designated gender, and (2) to replace endogenous sex hormone levels consistent with the individual's gender identity by using the principles of hormone replacement treatment of hypogonadal patients. The timing of these two goals and the age at which to begin treatment with the sex hormones of the chosen gender is codetermined in collaboration with both the person pursuing transition and the health care providers. The treatment team should include a medical provider knowledgeable in transgender hormone therapy, an MHP knowledgeable in GD/gender incongruence and the mental health concerns of transition, and a primary care provider able to provide care appropriate for transgender individuals. The physical changes induced by this sex hormone transition are usually accompanied by an improvement in mental well-being (129, 130).

3.1. We recommend that clinicians confirm the diagnostic criteria of GD/gender incongruence and the criteria for the endocrine phase of gender transition before beginning treatment. (1 |⊕⊕⊕◯)

3.2. We recommend that clinicians evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment (Table 10). (1 |⊕⊕⊕◯)

3.3. We suggest that clinicians measure hormone levels during treatment to ensure that endogenous sex steroids are suppressed and administered sex steroids are maintained in the normal physiologic range for the affirmed gender. (2 |⊕⊕◯◯)

Evidence

It is the responsibility of the treating clinician to confirm that the person fulfills criteria for treatment. The treating clinician should become familiar with the terms and criteria presented in Tables 1–5 and take a thorough history from the patient in collaboration with the other members of the treatment team. The treating clinician must ensure that the desire for transition is appropriate; the consequences, risks, and benefits of treatment are well understood; and the desire for transition persists. They also need to discuss fertility preservation options (see recommendation 1.3) (67, 68).

Transgender males

Clinical studies have demonstrated the efficacy of several different androgen preparations to induce masculinization in transgender males (Appendix A) (113, 114, 131–134). Regimens to change secondary sex characteristics follow the general principle of hormone replacement treatment of male hypogonadism (135). Clinicians can use either parenteral or transdermal preparations to achieve testosterone values in the normal male range (this is dependent on the specific assay, but is typically 320 to 1000 ng/dL) (Table 11) (136). Sustained supraphysiologic levels of testosterone increase the risk of adverse reactions (see section 4.0 "Adverse Outcome Prevention and Long-Term Care") and should be avoided.

Similar to androgen therapy in hypogonadal men, testosterone treatment in transgender males results in increased muscle mass and decreased fat mass, increased facial hair and acne, male pattern baldness in those genetically predisposed, and increased sexual desire (137).

Table 10. Medical Risks Associated With Sex Hormone Therapy

Transgender female: estrogen
- Very high risk of adverse outcomes:
  - •Thromboembolic disease
- Moderate risk of adverse outcomes:
  - •Macroprolactinoma
  - •Breast cancer
  - •Coronary artery disease
  - •Cerebrovascular disease
  - •Cholelithiasis
  - •Hypertriglyceridemia

Transgender male: testosterone
- Very high risk of adverse outcomes:
  - •Erythrocytosis (hematocrit > 50%)
- Moderate risk of adverse outcomes:
  - •Severe liver dysfunction (transaminases > threefold upper limit of normal)
  - •Coronary artery disease
  - •Cerebrovascular disease
  - •Hypertension
  - •Breast or uterine cancer

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Table 11. Hormone Regimens in Transgender Persons

Transgender females[a]	
Estrogen	
Oral	
Estradiol	2.0–6.0 mg/d
Transdermal	
Estradiol transdermal patch (New patch placed every 3–5 d)	0.025–0.2 mg/d
Parenteral	
Estradiol valerate or cypionate	5–30 mg IM every 2 wk 2–10 mg IM every week
Anti-androgens	
Spironolactone	100–300 mg/d
Cyproterone acetate[b]	25–50 mg/d
GnRH agonist	3.75 mg SQ (SC) monthly 11.25 mg SQ (SC) 3-monthly
Transgender males	
Testosterone	
Parenteral testosterone	
Testosterone enanthate or cypionate	100–200 mg SQ (IM) every 2 wk or SQ (SC) 50% per week
Testosterone undecanoate[c]	1000 mg every 12 wk
Transdermal testosterone	
Testosterone gel 1.6%[d]	50–100 mg/d
Testosterone transdermal patch	2.5–7.5 mg/d

Abbreviations: IM, intramuscularly; SQ, sequentially; SC, subcutaneously.

[a]Estrogens used with or without antiandrogens or GnRH agonist.

[b]Not available in the United States.

[c]One thousand milligrams initially followed by an injection at 6 wk then at 12-wk intervals.

[d]Avoid cutaneous transfer to other individuals.

In transgender males, testosterone will result in clitoromegaly, temporary or permanent decreased fertility, deepening of the voice, cessation of menses (usually), and a significant increase in body hair, particularly on the face, chest, and abdomen. Cessation of menses may occur within a few months with testosterone treatment alone, although high doses of testosterone may be required. If uterine bleeding continues, clinicians may consider the addition of a progestational agent or endometrial ablation (138). Clinicians may also administer GnRH analogs or depot medroxyprogesterone to stop menses prior to testosterone treatment.

Transgender females

The hormone regimen for transgender females is more complex than the transgender male regimen (Appendix B). Treatment with physiologic doses of estrogen alone is insufficient to suppress testosterone levels into the normal range for females (139). Most published clinical studies report the need for adjunctive therapy to achieve testosterone levels in the female range (21, 113, 114, 132–134, 139, 140).

Multiple adjunctive medications are available, such as progestins with antiandrogen activity and GnRH agonists (141). Spironolactone works by directly blocking androgens during their interaction with the androgen receptor (114, 133, 142). It may also have estrogenic activity (143). Cyproterone acetate, a progestational compound with antiandrogenic properties (113, 132, 144), is widely used in Europe. 5α-Reductase inhibitors do not reduce testosterone levels and have adverse effects (145).

Dittrich *et al.* (141) reported that monthly doses of the GnRH agonist goserelin acetate in combination with estrogen were effective in reducing testosterone levels with a low incidence of adverse reactions in 60 transgender females. Leuprolide and transdermal estrogen were as effective as cyproterone and transdermal estrogen in a comparative retrospective study (146).

Patients can take estrogen as oral conjugated estrogens, oral 17β-estradiol, or transdermal 17β-estradiol. Among estrogen options, the increased risk of thromboembolic events associated with estrogens in general seems most concerning with ethinyl estradiol specifically (134, 140, 141), which is why we specifically suggest that it not be used in any transgender treatment plan. Data distinguishing among other estrogen options are less well established although there is some thought that oral routes of administration are more thrombogenic due to the "first pass effect" than are transdermal and parenteral routes, and that the risk of thromboembolic events is dose-dependent. Injectable estrogen and sublingual

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estrogen may benefit from avoiding the first pass effect, but they can result in more rapid peaks with greater overall periodicity and thus are more difficult to monitor (147, 148). However, there are no data demonstrating that increased periodicity is harmful otherwise.

Clinicians can use serum estradiol levels to monitor oral, transdermal, and intramuscular estradiol. Blood tests cannot monitor conjugated estrogens or synthetic estrogen use. Clinicians should measure serum estradiol and serum testosterone and maintain them at the level for premenopausal females (100 to 200 pg/mL and <50 ng/dL, respectively). The transdermal preparations and injectable estradiol cypionate or valerate preparations may confer an advantage in older transgender females who may be at higher risk for thromboembolic disease (149).

Values

Our recommendation to maintain levels of gender-affirming hormones in the normal adult range places a high value on the avoidance of the long-term complications of pharmacologic doses. Those patients receiving endocrine treatment who have relative contraindications to hormones should have an in-depth discussion with their physician to balance the risks and benefits of therapy.

Remarks

Clinicians should inform all endocrine-treated individuals of all risks and benefits of gender-affirming hormones prior to initiating therapy. Clinicians should strongly encourage tobacco use cessation in transgender females to avoid increased risk of VTE and cardiovascular complications. We strongly discourage the unsupervised use of hormone therapy (150).

Not all individuals with GD/gender incongruence seek treatment as described (*e.g.*, male-to-eunuchs and individuals seeking partial transition). Tailoring current protocols to the individual may be done within the context of accepted safety guidelines using a multidisciplinary approach including mental health. No evidence-based protocols are available for these groups (151). We need prospective studies to better understand treatment options for these persons.

3.4. We suggest that endocrinologists provide education to transgender individuals undergoing treatment about the onset and time course of physical changes induced by sex hormone treatment. (2 |⊕○○○)

Evidence

Transgender males

Physical changes that are expected to occur during the first 1 to 6 months of testosterone therapy include cessation of menses, increased sexual desire, increased facial and body hair, increased oiliness of skin, increased muscle, and redistribution of fat mass. Changes that occur within the first year of testosterone therapy include deepening of the voice (152, 153), clitoromegaly, and male pattern hair loss (in some cases) (114, 144, 154, 155) (Table 12).

Transgender females

Physical changes that may occur in transgender females in the first 3 to 12 months of estrogen and antiandrogen therapy include decreased sexual desire, decreased spontaneous erections, decreased facial and body hair (usually mild), decreased oiliness of skin, increased breast tissue growth, and redistribution of fat mass (114, 139, 149, 154, 155, 161) (Table 13). Breast development is generally maximal at 2 years after initiating hormones (114, 139, 149, 155). Over a long period of time, the prostate gland and testicles will undergo atrophy.

Although the time course of breast development in transgender females has been studied (150), precise information about other changes induced by sex hormones is lacking (141). There is a great deal of variability among individuals, as evidenced during pubertal development. We all know that a major concern for transgender females is breast development. If we work with estrogens, the result will be often not what the transgender female expects.

Alternatively, there are transgender females who report an anecdotal improved breast development, mood, or sexual desire with the use of progestogens. However, there have been no well-designed studies of the role of progestogens in feminizing hormone regimens, so the question is still open.

Our knowledge concerning the natural history and effects of different cross-sex hormone therapies on breast

Table 12. Masculinizing Effects in Transgender Males

Effect	Onset	Maximum
Skin oiliness/acne	1–6 mo	1–2 y
Facial/body hair growth	6–12 mo	4–5 y
Scalp hair loss	6–12 mo	—[a]
Increased muscle mass/strength	6–12 mo	2–5 y
Fat redistribution	1–6 mo	2–5 y
Cessation of menses	1–6 mo	—[b]
Clitoral enlargement	1–6 mo	1–2 y
Vaginal atrophy	1–6 mo	1–2 y
Deepening of voice	6–12 mo	1–2 y

Estimates represent clinical observations: Toorians *et al.* (149), Asscheman *et al.* (156), Gooren *et al.* (157), Wierckx *et al.* (158).

[a] Prevention and treatment as recommended for biological men.

[b] Menorrhagia requires diagnosis and treatment by a gynecologist.

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Table 13. Feminizing Effects in Transgender Females

Effect	Onset	Maximum
Redistribution of body fat	3–6 mo	2–3 y
Decrease in muscle mass and strength	3–6 mo	1–2 y
Softening of skin/decreased oiliness	3–6 mo	Unknown
Decreased sexual desire	1–3 mo	3–6 mo
Decreased spontaneous erections	1–3 mo	3–6 mo
Male sexual dysfunction	Variable	Variable
Breast growth	3–6 mo	2–3 y
Decreased testicular volume	3–6 mo	2–3 y
Decreased sperm production	Unknown	>3 y
Decreased terminal hair growth	6–12 mo	>3 y[a]
Scalp hair	Variable	—[b]
Voice changes	None	—[c]

Estimates represent clinical observations: Toorians *et al.* (149), Asscheman *et al.* (156), Gooren *et al.* (157).

[a]Complete removal of male sexual hair requires electrolysis or laser treatment or both.

[b]Familial scalp hair loss may occur if estrogens are stopped.

[c]Treatment by speech pathologists for voice training is most effective.

development in transgender females is extremely sparse and based on the low quality of evidence. Current evidence does not indicate that progestogens enhance breast development in transgender females, nor does evidence prove the absence of such an effect. This prevents us from drawing any firm conclusion at this moment and demonstrates the need for further research to clarify these important clinical questions (162).

Values and preferences

Transgender persons have very high expectations regarding the physical changes of hormone treatment and are aware that body changes can be enhanced by surgical procedures (*e.g.*, breast, face, and body habitus). Clear expectations for the extent and timing of sex hormone–induced changes may prevent the potential harm and expense of unnecessary procedures.

4.0 Adverse Outcome Prevention and Long-Term Care

Hormone therapy for transgender males and females confers many of the same risks associated with sex hormone replacement therapy in nontransgender persons. The risks arise from and are worsened by inadvertent or intentional use of supraphysiologic doses of sex hormones, as well as use of inadequate doses of sex hormones to maintain normal physiology (131, 139).

4.1. We suggest regular clinical evaluation for physical changes and potential adverse changes in response to sex steroid hormones and laboratory monitoring of sex steroid hormone levels every 3 months during the first year of hormone therapy for transgender males and females and then once or twice yearly. (2 |⊕⊕○○)

Evidence

Pretreatment screening and appropriate regular medical monitoring are recommended for both transgender males and females during the endocrine transition and periodically thereafter (26, 155). Clinicians should monitor weight and blood pressure, conduct physical exams, and assess routine health questions, such as tobacco use, symptoms of depression, and risk of adverse events such as deep vein thrombosis/pulmonary embolism and other adverse effects of sex steroids.

Transgender males

Table 14 contains a standard monitoring plan for transgender males on testosterone therapy (154, 159). Key issues include maintaining testosterone levels in the physiologic normal male range and avoiding adverse events resulting from excess testosterone therapy, particularly erythrocytosis, sleep apnea, hypertension, excessive weight gain, salt retention, lipid changes, and excessive or cystic acne (135).

Because oral 17-alkylated testosterone is not recommended, serious hepatic toxicity is not anticipated with parenteral or transdermal testosterone use (163, 164). Past concerns regarding liver toxicity with testosterone have been alleviated with subsequent reports that indicate the risk of serious liver disease is minimal (144, 165, 166).

Transgender females

Table 15 contains a standard monitoring plan for transgender females on estrogens, gonadotropin suppression, or antiandrogens (160). Key issues include avoiding supraphysiologic doses or blood levels of estrogen that may lead to increased risk for thromboembolic disease, liver dysfunction, and hypertension. Clinicians should monitor serum estradiol levels using laboratories participating in external quality control, as measurements of estradiol in blood can be very challenging (167).

VTE may be a serious complication. A study reported a 20-fold increase in venous thromboembolic disease in a large cohort of Dutch transgender subjects (161). This increase may have been associated with the use of the synthetic estrogen, ethinyl estradiol (149). The incidence decreased when clinicians stopped administering ethinyl estradiol (161). Thus, the use of synthetic estrogens and conjugated estrogens is undesirable because of the inability to regulate doses by measuring serum levels and the risk of thromboembolic disease. In a German gender clinic, deep vein thrombosis occurred in 1 of 60 of transgender females treated with a GnRH analog and oral

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Table 14. Monitoring of Transgender Persons on Gender-Affirming Hormone Therapy: Transgender Male

1. Evaluate patient every 3 mo in the first year and then one to two times per year to monitor for appropriate signs of virilization and for development of adverse reactions.
2. Measure serum testosterone every 3 mo until levels are in the normal physiologic male range:[a]
   a. For testosterone enanthate/cypionate injections, the testosterone level should be measured midway between injections. The target level is 400–700 ng/dL to 400 ng/dL. Alternatively, measure peak and trough levels to ensure levels remain in the normal male range.
   b. For parenteral testosterone undecanoate, testosterone should be measured just before the following injection. If the level is <400 ng/dL, adjust dosing interval.
   c. For transdermal testosterone, the testosterone level can be measured no sooner than after 1 wk of daily application (at least 2 h after application).
3. Measure hematocrit or hemoglobin at baseline and every 3 mo for the first year and then one to two times a year. Monitor weight, blood pressure, and lipids at regular intervals.
4. Screening for osteoporosis should be conducted in those who stop testosterone treatment, are not compliant with hormone therapy, or who develop risks for bone loss.
5. If cervical tissue is present, monitoring as recommended by the American College of Obstetricians and Gynecologists.
6. Ovariectomy can be considered after completion of hormone transition.
7. Conduct sub- and periareolar annual breast examinations if mastectomy performed. If mastectomy is not performed, then consider mammograms as recommended by the American Cancer Society.

[a] Adapted from Lapauw *et al.* (154) and Ott *et al.* (159).

estradiol (141). The patient who developed a deep vein thrombosis was found to have a homozygous C677 T mutation in the methylenetetrahydrofolate reductase gene. In an Austrian gender clinic, administering gender-affirming hormones to 162 transgender females and 89 transgender males was not associated with VTE, despite an 8.0% and 5.6% incidence of thrombophilia (159). A more recent multinational study reported only 10 cases of VTE from a cohort of 1073 subjects (168). Thrombophilia screening of transgender persons initiating hormone treatment should be restricted to those with a personal or family history of VTE (159). Monitoring D-dimer levels during treatment is not recommended (169).

4.2. We suggest periodically monitoring prolactin levels in transgender females treated with estrogens. (2 l⊕⊕◯◯)

Evidence

Estrogen therapy can increase the growth of pituitary lactrotroph cells. There have been several reports of prolactinomas occurring after long-term, high-dose estrogen therapy (170–173). Up to 20% of transgender females treated with estrogens may have elevations in prolactin levels associated with enlargement of the pituitary gland (156). In most cases, the serum prolactin levels will return to the normal range with a reduction or discontinuation of the estrogen therapy or discontinuation of cyproterone acetate (157, 174, 175).

The onset and time course of hyperprolactinemia during estrogen treatment are not known. Clinicians should measure prolactin levels at baseline and then at least annually during the transition period and every 2 years thereafter. Given that only a few case studies reported prolactinomas, and prolactinomas were not reported in large cohorts of estrogen-treated persons, the risk is likely to be very low. Because the major presenting findings of microprolactinomas (hypogonadism and sometimes gynecomastia) are not apparent in transgender females, clinicians may perform radiologic examinations of the pituitary in those patients whose prolactin levels persistently increase despite stable or reduced estrogen levels. Some transgender individuals receive psychotropic medications that can increase prolactin levels (174).

Table 15. Monitoring of Transgender Persons on Gender-Affirming Hormone Therapy: Transgender Female

1. Evaluate patient every 3 mo in the first year and then one to two times per year to monitor for appropriate signs of feminization and for development of adverse reactions.
2. Measure serum testosterone and estradiol every 3 mo.
   a. Serum testosterone levels should be <50 ng/dL.
   b. Serum estradiol should not exceed the peak physiologic range: 100–200 pg/mL.
3. For individuals on spironolactone, serum electrolytes, particularly potassium, should be monitored every 3 mo in the first year and annually thereafter.
4. Routine cancer screening is recommended, as in nontransgender individuals (all tissues present).
5. Consider BMD testing at baseline (160). In individuals at low risk, screening for osteoporosis should be conducted at age 60 years or in those who are not compliant with hormone therapy.

This table presents strong recommendations and does not include lower level recommendations.

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4.3. We suggest that clinicians evaluate transgender persons treated with hormones for cardiovascular risk factors using fasting lipid profiles, diabetes screening, and/or other diagnostic tools. (2 |⊕⊕◯◯)

Evidence

Transgender males

Administering testosterone to transgender males results in a more atherogenic lipid profile with lowered high-density lipoprotein cholesterol and higher triglyceride and low-density lipoprotein cholesterol values (176–179). Studies of the effect of testosterone on insulin sensitivity have mixed results (178, 180). A randomized, open-label uncontrolled safety study of transgender males treated with testosterone undecanoate demonstrated no insulin resistance after 1 year (181, 182). Numerous studies have demonstrated the effects of sex hormone treatment on the cardiovascular system (160, 179, 183, 184). Long-term studies from The Netherlands found no increased risk for cardiovascular mortality (161). Likewise, a meta-analysis of 19 randomized trials in nontransgender males on testosterone replacement showed no increased incidence of cardiovascular events (185). A systematic review of the literature found that data were insufficient (due to very low–quality evidence) to allow a meaningful assessment of patient-important outcomes, such as death, stroke, myocardial infarction, or VTE in transgender males (176). Future research is needed to ascertain the potential harm of hormonal therapies (176). Clinicians should manage cardiovascular risk factors as they emerge according to established guidelines (186).

Transgender females

A prospective study of transgender females found favorable changes in lipid parameters with increased high-density lipoprotein and decreased low-density lipoprotein concentrations (178). However, increased weight, blood pressure, and markers of insulin resistance attenuated these favorable lipid changes. In a meta-analysis, only serum triglycerides were higher at ≥24 months without changes in other parameters (187). The largest cohort of transgender females (mean age 41 years, followed for a mean of 10 years) showed no increase in cardiovascular mortality despite a 32% rate of tobacco use (161).

Thus, there is limited evidence to determine whether estrogen is protective or detrimental on lipid and glucose metabolism in transgender females (176). With aging, there is usually an increase of body weight. Therefore, as with nontransgender individuals, clinicians should monitor and manage glucose and lipid metabolism and blood pressure regularly according to established guidelines (186).

4.4. We recommend that clinicians obtain BMD measurements when risk factors for osteoporosis exist, specifically in those who stop sex hormone therapy after gonadectomy. (1 |⊕⊕◯◯)

Evidence

Transgender males

Baseline bone mineral measurements in transgender males are generally in the expected range for their pretreatment gender (188). However, adequate dosing of testosterone is important to maintain bone mass in transgender males (189, 190). In one study (190), serum LH levels were inversely related to BMD, suggesting that low levels of sex hormones were associated with bone loss. Thus, LH levels in the normal range may serve as an indicator of the adequacy of sex steroid administration to preserve bone mass. The protective effect of testosterone may be mediated by peripheral conversion to estradiol, both systemically and locally in the bone.

Transgender females

A baseline study of BMD reported T scores less than −2.5 in 16% of transgender females (191). In aging males, studies suggest that serum estradiol more positively correlates with BMD than does testosterone (192, 193) and is more important for peak bone mass (194). Estrogen preserves BMD in transgender females who continue on estrogen and antiandrogen therapies (188, 190, 191, 195, 196).

Fracture data in transgender males and females are not available. Transgender persons who have undergone gonadectomy may choose not to continue consistent sex steroid treatment after hormonal and surgical sex reassignment, thereby becoming at risk for bone loss. There have been no studies to determine whether clinicians should use the sex assigned at birth or affirmed gender for assessing osteoporosis (*e.g.*, when using the FRAX tool). Although some researchers use the sex assigned at birth (with the assumption that bone mass has usually peaked for transgender people who initiate hormones in early adulthood), this should be assessed on a case-by-case basis until there are more data available. This assumption will be further complicated by the increasing prevalence of transgender people who undergo hormonal transition at a pubertal age or soon after puberty. Sex for comparison within risk assessment tools may be based on the age at which hormones were initiated and the length of exposure to hormones. In some cases, it may be

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reasonable to assess risk using both the male and female calculators and using an intermediate value. Because all subjects underwent normal pubertal development, with known effects on bone size, reference values for birth sex were used for all participants (154).

4.5. We suggest that transgender females with no known increased risk of breast cancer follow breast-screening guidelines recommended for those designated female at birth. (2 |⊕⊕◯◯)

4.6. We suggest that transgender females treated with estrogens follow individualized screening according to personal risk for prostatic disease and prostate cancer. (2 |⊕◯◯◯)

Evidence

Studies have reported a few cases of breast cancer in transgender females (197–200). A Dutch study of 1800 transgender females followed for a mean of 15 years (range of 1 30 years) found one case of breast cancer. The Women's Health Initiative study reported that females taking conjugated equine estrogen without progesterone for 7 years did not have an increased risk of breast cancer as compared with females taking placebo (137).

In transgender males, a large retrospective study conducted at the U.S. Veterans Affairs medical health system identified seven breast cancers (194). The authors reported that this was not above the expected rate of breast cancers in cisgender females in this cohort. Furthermore, they did report one breast cancer that developed in a transgender male patient after mastectomy, supporting the fact that breast cancer can occur even after mastectomy. Indeed, there have been case reports of breast cancer developing in subareolar tissue in transgender males, which occurred after mastectomy (201, 202).

Women with primary hypogonadism (Turner syndrome) treated with estrogen replacement exhibited a significantly decreased incidence of breast cancer as compared with national standardized incidence ratios (203, 204). These studies suggest that estrogen therapy does not increase the risk of breast cancer in the short term (<20 to 30 years). We need long-term studies to determine the actual risk, as well as the role of screening mammograms. Regular examinations and gynecologic advice should determine monitoring for breast cancer.

Prostate cancer is very rare before the age of 40, especially with androgen deprivation therapy (205). Childhood or pubertal castration results in regression of the prostate and adult castration reverses benign prostate hypertrophy (206). Although van Kesteren *et al.* (207) reported that estrogen therapy does not induce hypertrophy or premalignant changes in the prostates of transgender females, studies have reported cases of benign prostatic hyperplasia in transgender females treated with estrogens for 20 to 25 years (208, 209). Studies have also reported a few cases of prostate carcinoma in transgender females (210–214).

Transgender females may feel uncomfortable scheduling regular prostate examinations. Gynecologists are not trained to screen for prostate cancer or to monitor prostate growth. Thus, it may be reasonable for transgender females who transitioned after age 20 years to have annual screening digital rectal examinations after age 50 years and prostate-specific antigen tests consistent with U.S. Preventive Services Task Force Guidelines (215).

4.7. We advise that clinicians determine the medical necessity of including a total hysterectomy and oophorectomy as part of gender-affirming surgery. (Ungraded Good Practice Statement)

Evidence

Although aromatization of testosterone to estradiol in transgender males has been suggested as a risk factor for endometrial cancer (216), no cases have been reported. When transgender males undergo hysterectomy, the uterus is small and there is endometrial atrophy (217, 218). Studies have reported cases of ovarian cancer (219, 220). Although there is limited evidence for increased risk of reproductive tract cancers in transgender males, health care providers should determine the medical necessity of a laparoscopic total hysterectomy as part of a gender-affirming surgery to prevent reproductive tract cancer (221).

Values

Given the discomfort that transgender males experience accessing gynecologic care, our recommendation for the medical necessity of total hysterectomy and oophorectomy places a high value on eliminating the risks of female reproductive tract disease and cancer and a lower value on avoiding the risks of these surgical procedures (related to the surgery and to the potential undesirable health consequences of oophorectomy) and their associated costs.

Remarks

The sexual orientation and type of sexual practices will determine the need and types of gynecologic care required following transition. Additionally, in certain countries, the approval required to change the sex in a birth certificate for transgender males may be dependent on having a complete hysterectomy. Clinicians should help patients research nonmedical administrative criteria and

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provide counseling. If individuals decide not to undergo hysterectomy, screening for cervical cancer is the same as all other females.

5.0 Surgery for Sex Reassignment and Gender Confirmation

For many transgender adults, genital gender-affirming surgery may be the necessary step toward achieving their ultimate goal of living successfully in their desired gender role. The type of surgery falls into two main categories: (1) those that directly affect fertility and (2) those that do not. Those that change fertility (previously called sex reassignment surgery) include genital surgery to remove the penis and gonads in the male and removal of the uterus and gonads in the female. The surgeries that effect fertility are often governed by the legal system of the state or country in which they are performed. Other gender-conforming surgeries that do not directly affect fertility are not so tightly governed.

Gender-affirming surgical techniques have improved markedly during the past 10 years. Reconstructive genital surgery that preserves neurologic sensation is now the standard. The satisfaction rate with surgical reassignment of sex is now very high (187). Additionally, the mental health of the individual seems to be improved by participating in a treatment program that defines a pathway of gender-affirming treatment that includes hormones and surgery (130, 144) (Table 16).

Surgery that affects fertility is irreversible. The World Professional Association for Transgender Health Standards of Care (222) emphasizes that the "threshold of 18 should not be seen as an indication in itself for active intervention." If the social transition has not been satisfactory, if the person is not satisfied with or is ambivalent about the effects of sex hormone treatment, or if the person is ambivalent about surgery then the individual should not be referred for surgery (223, 224).

Gender-affirming genital surgeries for transgender females that affect fertility include gonadectomy, penectomy, and creation of a neovagina (225, 226). Surgeons often invert the skin of the penis to form the wall of the vagina, and several literatures reviews have reported on outcomes (227). Sometimes there is inadequate tissue to form a full neovagina, so clinicians have revisited using intestine and found it to be successful (87, 228, 229). Some newer vaginoplasty techniques may involve autologuous oral epithelial cells (230, 231).

The scrotum becomes the labia majora. Surgeons use reconstructive surgery to fashion the clitoris and its hood, preserving the neurovascular bundle at the tip of the penis as the neurosensory supply to the clitoris. Some surgeons are also creating a sensate pedicled-spot adding a G spot to the neovagina to increase sensation (232). Most recently, plastic surgeons have developed techniques to fashion labia minora. To further complete the feminization, uterine transplants have been proposed and even attempted (233).

Neovaginal prolapse, rectovaginal fistula, delayed healing, vaginal stenosis, and other complications do sometimes occur (234, 235). Clinicians should strongly remind the transgender person to use their dilators to maintain the depth and width of the vagina throughout the postoperative period. Genital sexual responsivity and other aspects of sexual function are usually preserved following genital gender-affirming surgery (236, 237).

Ancillary surgeries for more feminine or masculine appearance are not within the scope of this guideline. Voice therapy by a speech language pathologist is available to transform speech patterns to the affirmed gender (148). Spontaneous voice deepening occurs during testosterone treatment of transgender males (152, 238). No studies have compared the effectiveness of speech therapy, laryngeal surgery, or combined treatment.

Breast surgery is a good example of gender-confirming surgery that does not affect fertility. In all females, breast size exhibits a very broad spectrum. For transgender females to make the best informed decision, clinicians should delay breast augmentation surgery until the patient has completed at least 2 years of estrogen therapy, because the breasts continue to grow during that time (141, 155).

Another major procedure is the removal of facial and masculine-appearing body hair using either electrolysis or

Table 16. Criteria for Gender-Affirming Surgery, Which Affects Fertility

1. Persistent, well-documented gender dysphoria
2. Legal age of majority in the given country
3. Having continuously and responsibly used gender-affirming hormones for 12 mo (if there is no medical contraindication to receiving such therapy)
4. Successful continuous full-time living in the new gender role for 12 mo
5. If significant medical or mental health concerns are present, they must be well controlled
6. Demonstrable knowledge of all practical aspects of surgery (*e.g.*, cost, required lengths of hospitalizations, likely complications, postsurgical rehabilitation)

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laser treatments. Other feminizing surgeries, such as that to feminize the face, are now becoming more popular (239–241).

In transgender males, clinicians usually delay gender-affirming genital surgeries until after a few years of androgen therapy. Those surgeries that affect fertility in this group include oophorectomy, vaginectomy, and complete hysterectomy. Surgeons can safely perform them vaginally with laparoscopy. These are sometimes done in conjunction with the creation of a neopenis. The cosmetic appearance of a neopenis is now very good, but the surgery is multistage and very expensive (242, 243). Radial forearm flap seems to be the most satisfactory procedure (228, 244). Other flaps also exist (245). Surgeons can make neopenile erections possible by reinervation of the flap and subsequent contraction of the muscle, leading to stiffening of the neopenis (246, 247), but results are inconsistent (248). Surgeons can also stiffen the penis by imbedding some mechanical device (*e.g.*, a rod or some inflatable apparatus) (249, 250). Because of these limitations, the creation of a neopenis has often been less than satisfactory. Recently, penis transplants are being proposed (233).

In fact, most transgender males do not have any external genital surgery because of the lack of access, high cost, and significant potential complications. Some choose a metaoidioplasty that brings forward the clitoris, thereby allowing them to void in a standing position without wetting themselves (251, 252). Surgeons can create the scrotum from the labia majora with good cosmetic effect and can implant testicular prostheses (253).

The most important masculinizing surgery for the transgender male is mastectomy, and it does not affect fertility. Breast size only partially regresses with androgen therapy (155). In adults, discussions about mastectomy usually take place after androgen therapy has started. Because some transgender male adolescents present after significant breast development has occurred, they may also consider mastectomy 2 years after they begin androgen therapy and before age 18 years. Clinicians should individualize treatment based on the physical and mental health status of the individual. There are now newer approaches to mastectomy with better outcomes (254, 255). These often involve chest contouring (256). Mastectomy is often necessary for living comfortably in the new gender (256).

5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being. (1 |⊕⊕◯◯)

5.2. We advise that clinicians approve genital gender-affirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)

5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)

5.4. We recommend that clinicians refer hormone-treated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 |⊕◯◯◯)

5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 |⊕⊕◯◯).

5.6. We suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement. (2 |⊕◯◯◯)

Evidence

Owing to the lack of controlled studies, incomplete follow-up, and lack of valid assessment measures, evaluating various surgical approaches and techniques is difficult. However, one systematic review including a large numbers of studies reported satisfactory cosmetic and functional results for vaginoplasty/neovagina construction (257). For transgender males, the outcomes are less certain. However, the problems are now better understood (258). Several postoperative studies report significant long-term psychological and psychiatric pathology (259–261). One study showed satisfaction with breasts, genitals, and femininity increased significantly and showed the importance of surgical treatment as a key therapeutic option for transgender females (262). Another analysis demonstrated that, despite the young average age at death following surgery and the relatively larger number of individuals with somatic morbidity, the study does not allow for determination of

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causal relationships between, for example, specific types of hormonal or surgical treatment received and somatic morbidity and mortality (263). Reversal surgery in regretful male-to-female transsexuals after sexual reassignment surgery represents a complex, multistage procedure with satisfactory outcomes. Further insight into the characteristics of persons who regret their decision postoperatively would facilitate better future selection of applicants eligible for sexual reassignment surgery. We need more studies with appropriate controls that examine long-term quality of life, psychosocial outcomes, and psychiatric outcomes to determine the long-term benefits of surgical treatment.

When a transgender individual decides to have gender-affirming surgery, both the hormone prescribing clinician and the MHP must certify that the patient satisfies criteria for gender-affirming surgery (Table 16).

There is some concern that estrogen therapy may cause an increased risk for venous thrombosis during or following surgery (176). For this reason, the surgeon and the hormone-prescribing clinician should collaborate in making a decision about the use of hormones before and following surgery. One study suggests that preoperative factors (such as compliance) are less important for patient satisfaction than are the physical postoperative results (56). However, other studies and clinical experience dictate that individuals who do not follow medical instructions and do not work with their physicians toward a common goal do not achieve treatment goals (264) and experience higher rates of postoperative infections and other complications (265, 266). It is also important that the person requesting surgery feels comfortable with the anatomical changes that have occurred during hormone therapy. Dissatisfaction with social and physical outcomes during the hormone transition may be a contraindication to surgery (223).

An endocrinologist or experienced medical provider should monitor transgender individuals after surgery. Those who undergo gonadectomy will require hormone replacement therapy, surveillance, or both to prevent adverse effects of chronic hormone deficiency.

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MEDICAL MANAGEMENT OF TRANSGENDER INMATES

Federal Bureau of Prisons

Clinical Guidance

DECEMBER 2016

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1. PURPOSE

The Federal Bureau of Prisons (BOP) Clinical Guidance for *Medical Management of Transgender Inmates* provides recommendations for the medical management and treatment of transgender federal inmates, referred to in these guidelines as *individual(s) or person(s)*.

2. INTRODUCTION

NATURAL HISTORY

TRANSGENDER (**TG**) individuals are those whose gender identity is different from their biological sex. **GENDER DYSPHORIA** (**GD**), previously known as **GENDER IDENTITY DISORDER** (**GID**), is the *discomfort or distress* caused by a discrepancy between a person's **GENDER IDENTITY** and that person's **GENDER** assigned at birth. Not all **TG** will be diagnosed with **GD**, and a diagnosis of **GD** is not required for access to services. Data indicate significantly higher rates of mental health morbidity among **TG** individuals, compared with the general population—particularly anxiety, depression, and suicidality. Present-day treatment approaches involve supporting individuals in modifying their lifestyle—and if indicated, physically modifying their body—to better match the gender with which they psychologically identify.

DEFINITIONS

ASEXUAL: Refers to a person not attracted to either sex.

BISEXUAL: Refers to a person attracted to both sexes.

BOP TRANSGENDER CLINICAL CARE TEAM (TCCT): A multidisciplinary group of BOP personnel with **TG** subject matter expertise. The team provides assistance to institution staff and develops clinical treatment recommendations for the BOP **TG** population.

BOP TRANSGENDER EXECUTIVE COUNCIL (TEC): A group of BOP management personnel who mitigate executive level non-clinical issues. This group provides oversight to the **BOP TCCT**.

FEMALE-TO-MALE (FTM): Refers to a biological female who identifies as, or desires to be, a member of the male gender. The term *transgender male*, or *trans male* for short, is used to refer to the **GENDER IDENTITY** of a person who is **FTM**. (See the definition of **TRANSGENDER** below.)

GAY: Refers to a person who is romantically or sexually attracted to persons of the same gender. The term is mostly used to describe males. (See the definition of **LESBIAN** below.)

GENDER: A biopsychosocial construct used to classify a person as male, female, both, or neither. **GENDER** encompasses all relational aspects of social identity, psychological identity, and human behavior.

GENDER-AFFIRMING HORMONES: Hormonal therapy utilized to facilitate biological change(s) during **TRANSITION.** The term **CROSS-SEX HORMONES** is often utilized in the medical literature.

GENDER CONFORMITY: Behavior and appearance that adheres to the social expectations of a particular **GENDER**. (See the definition of **GENDER NONCONFORMITY** below.)

GENDER DYSPHORIA (GD): The condition of feeling that one's emotional and psychological identity as male or female is different from one's biological sex. By definition, **GD** implies that there is a state of distress or anxiety directly related to this conflict. In the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)*, released in May 2013, people whose assigned sex at birth is contrary to the one they identify with *and* who are experiencing a state of distress should be diagnosed with **GD**. This diagnosis is a revision of the criteria in the *DSM-IV* for **GENDER IDENTITY DISORDER**, and is intended to better characterize the experiences of affected individuals.

➔ *Individuals identifying as TG do not necessarily have GD.*

GENDER EXPRESSION: Includes mannerisms, clothing, hair style, and choice of activities that individuals use to express their **GENDER IDENTITY**.

GENDER IDENTITY: Individuals' own sense of their **GENDER**, which they may choose to communicate to others by means of **GENDER EXPRESSION**.

GENDER IDENTITY DISORDER (GID): Strong, persistent feelings of identification with the opposite gender and discomfort with one's own assigned sex.

➔ *The DSM-5 no longer uses this term. See the definition of* **GENDER DYSPHORIA** *above.*

GENDER NONCONFORMITY: Behavior or appearance that does not match the societal roles or expectations for one's assigned **GENDER**.

HETEROSEXUAL: Refers to a person attracted to the opposite gender.

HOMOSEXUAL: Refers to a person attracted to the same gender.

INTERSEX: Refers to a person whose sexual/reproductive anatomy or chromosomal pattern does not seem to fit the typical biological definition of male or female.

LESBIAN: Refers to a female who is attracted to other females.

MALE-TO-FEMALE (MTF): Refers to a biological male who identifies as, or desires to be, a member of the female gender. The term *transgender female*, or *trans female* for short, is used to refer to the **GENDER IDENTITY** of a person who is **MTF**. (See the definition of **TRANSGENDER** below.)

REAL-LIFE EXPERIENCE (RLE): When individuals live as the **GENDER** with which they identify.

SEX: A biological classification based on chromosomal composition, reproductive anatomy (primary sex characteristics), and phenotypic characteristics (secondary sex characteristics) that develop during pubertal maturation.

SEX REASSIGNMENT SURGERY: The surgical component of an individual's **TRANSITION**; also referred to as **GENDER-AFFIRMING SURGERY**.

SEXUAL ORIENTATION: The direction of one's sexual interest toward members of the same sex, the opposite sex, both, or neither.

TRANSGENDER (TG): A general term used for individuals whose **GENDER IDENTITY** does not conform to the typical expectations associated with the gender they were assigned at birth.

- While the term is often used synonymously with the term **GD**, being **TG** does not necessarily imply anxiety or distress about one's gender not matching one's assigned sex.
- The term **TRANSGENDER** also does *not* imply a particular **SEXUAL ORIENTATION.**
- A **MALE-TO-FEMALE (MTF) TRANSGENDER** person refers to a biological male who identifies as, or desires to be, a member of the female gender; a **FEMALE-TO-MALE (FTM) TRANSGENDER** person refers to a biological female who identifies as, or desires to be, a member of the male gender.

TRANSITION: The period during which **TG** individuals change their physical, social, and legal characteristics to the gender with which they identify. **TRANSITION** may also be regarded as an ongoing process of physical change and psychological adaptation.

SPECIAL CONSIDERATIONS

STIGMA

Stigma and prior negative experiences in institutions can impede transition services, and/or diagnosis and treatment of **GD**.

SUICIDALITY

Transgender adults with **GD** are at an increased risk of suicidal ideation and suicide prior to initiation of their gender transition, regardless of the clinical endpoint of their **TRANSITION—** whether that endpoint is living as the psychologically identified gender, hormone therapy, cosmetic treatments, breast augmentation/removal, and/or sex reassignment surgery. For many individuals, the risk of suicide may decrease after receiving the appropriate, individual treatment.

COMORBID CONDITIONS

- The most common comorbid conditions seen in **TG** adults with **GD** are anxiety and depression.
- Epidemiologic studies indicate a higher prevalence of HIV in the **TG** populations, specifically among **MtF** persons.

➔ *See CDC, HIV Among Transgender People, #13 in the References section.*

GENERAL INTERACTIONS WITH TRANSGENDER INDIVIDUALS

Respect and trust are essential to a clinician-client (physician-patient) relationship. Respectful language and terms should always be used when discussing or referring to all individuals regardless of gender. Once an individual has identified as **TG**, use of pronouns or salutations preferred by the **TG** individual is appropriate, especially for those inmates with a Case Management Activity (CMA) Sentry assignment of **TRANSGENDER** (either TRN M2F or TRN F2M). This practice is more likely to facilitate a cooperative relationship between the **TG** individual and others, and generally reduces the stress of gender transition.

➔ *Please note that this informal approach is distinct from a legal name change while in BOP custody; a legal name change must conform to the policy requirements in the Correctional Systems manual, currently Program Statement 5800.15 (or the most recent version).*

MULTIDISCIPLINARY TREATMENT APPROACH

A multidisciplinary approach is recommended for managing issues associated with the incarceration of **TG** individuals, including the provision of medical treatment when indicated. Institutional staff training programs should consider incorporating Continuing Medical Education on the clinical care of **TG** individuals.

The BOP offers **TRAUMA-INFORMED CORRECTIONAL CARE (TICC),** which incorporates an understanding that inmate attitudes, behaviors, and concerns are likely to be affected by prior traumatic experiences. **TICC** includes both training and treatment programs, emphasizes the recognition of trauma in all forms, and incorporates the principle that all staff may have a role in reducing its impact. Subject matter experts within the BOP are available to assist providers and other staff working with **TG** inmates.

HOUSING ASSIGNMENTS, PROGRAM ASSIGNMENTS, AND PAT SEARCHES

- *Refer to the current version of BOP Program Statement 5324.11, Sexually Abusive Behavior Prevention and Intervention Program.*
- *Refer also to the Transgender Offender Manual Program Statement.*

3. INTAKE SCREENING REGULATIONS

Prison Rape Elimination Act (PREA) regulations, incorporated into *BOP Program Statement 5324.11, Sexually Abusive Behavior Prevention and Intervention Program*, state that the intake screening shall consider, at a minimum, the following criteria to assess individuals for risk of sexual victimization—whether the individual is known or perceived to be gay, lesbian, bisexual, **TG**, intersex, or gender nonconforming.

- ***See 28 C.F.R. § 115.41 (d).***

Individuals may not be disciplined for refusing to answer, or for not disclosing complete information in response to, questions about being gay, lesbian, bisexual, **TG**, intersex, or gender nonconforming.

- ***See 28 C.F.R. § 115.41 (h).***

Staff shall not search or physically examine any inmate, to include a **TG** or intersex individual, for the sole purpose of determining the individual's genital status. If the individual's genital status is unknown, and as appropriate, it may be determined during conversations with the individual, by reviewing medical records, or, if necessary, learning that information as part of a broader medical examination conducted in private by a medical provider.

- ***See 28 C.F.R. § 115.15 (e).*** *This provision does not limit searches of individuals to ensure the safe and orderly running of the institution.*

4. TRANSGENDER-IDENTIFYING CHARACTERISTICS

Transgender status is based on an individual's self-report of identifying characteristics. When an individual self-identifies as **TG**—or requests referral or evaluation for treatment—a medical and/or mental health evaluation is conducted according to policy, and as clinically appropriate to fully evaluate the individual's treatment needs.

The following criteria may be useful in identifying a person's status as **TG**:

A persistent and marked difference between a person's preferred gender and their biologic or natal sex, which may be experienced as or accompanied by:

- ***Strong feelings about primary or secondary sex characteristics;***
- ***Strong feelings about being treated as or becoming another gender; or***
- ***Belief that one's actions, feelings, or mannerisms are more characteristic of another gender.***

ELECTRONIC MEDICAL RECORD (EMR) CODES

For purposes of providing appropriate medical treatment and management, all individuals who identify as **TG**—whether or not they are receiving hormone treatment—need to have the appropriate code for transgender individuals entered into the EMR health problem list, as listed below in *Table 1.*

TABLE 1. EMR CODES FOR TRANSGENDER INDIVIDUALS

BOP Transgender Determination	EMR Codes[1,2]	Corresponding Sentry CMA Codes
Transgender, male to female	F64.0f	TRN M2F
Transgender, female to male	F64.0m	TRN F2M

[1] *EMR Transgender codes are solely for the use of clinical providers during the course of medical intervention and treatment. The respective codes are to be applied to inmates whose transgender identity has been confirmed and for whom medical treatment is appropriate, as described in the Transgender Offender Manual Program Statement and in this BOP Clinical Guidance.*

[2] *If an individual has undergone sex reassignment surgery, use code Z87.890 (Personal History of Sex Reassignment) along with the appropriate F64 code above.*

IMPORTANCE OF CODING TG INDIVIDUALS: Coding of the **TG** determination status is imperative for accurate individual records to ensure all individuals are receiving appropriate care and management. All BOP individuals who self-identify as **TG**, or are identified by history or current presentation as **TG**, need to be assessed by the appropriate psychology and/or health service staff in a timely fashion. Treatment and management of the **TG** individual are individualized and proceed from a thoughtful assessment, consideration of the individual's presentation and preferences, and attention to safety and security needs of the individual. This is all performed within the context of ensuring the safe and orderly operation of the institution.

5. ASSESSMENT AND MANAGEMENT OF THE TG INDIVIDUAL – A MULTIDISCIPLINARY APPROACH

Healthcare for **TG** individuals requires a multidisciplinary approach. The following process is recommended for transgender individuals (especially those newly identifying as **TG**) seeking medical intervention to assist with gender transition needs:

- **FIRST STEP – MENTAL HEALTH ASSESSMENT:** The first step in the process is for the individual to be seen by psychology staff for a comprehensive mental health assessment. Psychology staff will be able to confirm an individual's **TG** identity, diagnose mental health conditions based on DSM criteria, address the inmate's mental health concerns, and provide individualized counseling support and other interventions as appropriate.

  ➔ *See Section 6, Mental Health Assessment.*

- **SECOND STEP – MEDICAL ASSESSMENT:** The second step is for psychology staff to refer the individual for an evaluation by a medical provider if the patient desires medical intervention. If appropriate, the medical provider can initiate hormone therapy after the risks and benefits have been discussed with the individual, and the **BOP TCCT** has been consulted. Pharmacists may also play a role in treatment by counseling individuals on medications and recommending appropriate medication selection and/or lab monitoring to the medical provider. Psychiatrists may be consulted in cases of significant mental health challenges requiring medical intervention.

  ➔ *See Section 7, Medical Assessment.*

- **THIRD STEP – INDIVIDUALIZED TREATMENT:** In many cases, treatment is designed to reduce characteristics of the natal sex and induce those of the identified gender, allowing individuals to project their **GENDER IDENTITY**. The treatment and management of the **TG** individual requires individualized care guided by treatment goals to allow for successful **TRANSITION** through education, counseling, real-life experience, medical evaluation, hormone treatment, and in some cases, sex reassignment surgery.

  ➔ *See Section 8, Stepwise Approach to Medical and Mental Health Treatment of TG Individuals.*

GENDER DYSPHORIA (GD) CRITERIA

Individuals identifying as transgender do not necessarily have GD. Although data are insufficient to know the prevalence rates of **GD** in the transgender population, anecdotally many clinicians report that most transgender individuals experience some degree of dysphoria in the absence of treatment. Because untreated or under-treated **GD** is associated with increased morbidity and mortality, screening for **GD** in **TG** individuals is essential. Without treatment, this population may experience higher rates of depression, anxiety, and suicidality. Treatment modalities may include psychotherapy, supportive changes in gender expression and role, hormone therapy, and surgical therapy. Where indicated, hormonal interventions may improve **GD**, mental health comorbidities, and overall quality of life.

The DSM-5 criteria may be used to make the diagnosis of GD, and include two major categories: (1) Gender incongruence, i.e. a significant difference between a person's experienced or expressed gender and their assigned gender, and **(2)** significant distress or dysfunction that results from the gender incongruence. Readers are referred to the DSM-5 or to the DSM website (subscription required for access to copyrighted material) for the specific DSM-5 criteria.

➔ *See DSM-5, #1 in the References section.*

A diagnosis of **GD** will be recorded in the EMR health problem list under the appropriate DSM code (F64.1). Referral to a mental health professional for co-management of **GD** is recommended.

6. MENTAL HEALTH ASSESSMENT

Transgender status is based on an individual's self-report. Therefore, the history or subjective component of the evaluation serves as the primary source for identifying a person as TG. When transgender individuals request mental health services or are referred to Psychology Services, or when medical intervention for **TG** transition is being considered, it is appropriate to conduct a mental health evaluation.

The mental health assessment typically includes: (1) Obtaining a history of gender identity and screening for **GD**; **(2)** screening for other mental health disorders related to autism, eating, mood, personality, psychosis, and substance use; **(3)** identifying a history of abuse or neglect and any current or past self-harm ideations or attempts; **(4)** performing an assessment of affective, cognitive, and psychosocial functioning, if indicated; **(5)** psychosocial treatment recommendations; and/or **(6)** medical referral, if indicated.

➔ *Please also refer to APA, Guidelines for psychological practice with transgender and gender nonconforming people, #12 in the References section.*

DIAGNOSTIC ASSESSMENT

Diagnostic assessments are completed in PDS-BEMR under the title Diagnostic and Care Level Formulation and include the following:

- **PRESENTING PROBLEMS/SYMPTOMS:** Outline the individual's concerns, including who made the referral and when.
- **RELEVANT HISTORICAL INFORMATION:** This psychosocial history may include a review of the individual's developmental history (including gender identity), sexual history (including sexual predation or victimization), trauma, mental health history, suicide attempts or self-harm, criminal history, educational experience and progress, family dynamics, peer relations, and social support expected upon release.
- **DIAGNOSTIC FORMULATION:** If applicable, list diagnostic impressions.
- **CARE LEVEL FORMULATION:** Provide a discussion of the individual's ongoing need for mental health services and assign a care level consistent with the individual's needs.

MENTAL HEALTH TREATMENT CONSIDERATIONS

The mental health team plays an important role in diagnosing individuals, as well as providing psychotherapy and counseling:

- **INDIVIDUAL'S UNDERSTANDING/EXPECTATIONS OF TREATMENT OPTIONS:** Prior to engaging in treatment, conversations regarding the individual's expectations of outcome are required in order to identify realistic goals.
  - ➔ *A collaborative education session for the inmate, with both psychology and medical services staff, is highly recommended.*
- **PSYCHOTHERAPY:** This is a general term for treating mental health problems by the individual discussing them with a mental health provider. Psychotherapy can be used to learn about and treat an individual's moods, thoughts, and behaviors. It can also be supportive to individuals experiencing distressing thoughts and/or feelings.
- **PSYCHIATRY SERVICES:** Individuals can also be referred to psychiatry services for mental health concerns or medication management of other mental illness in conjunction with **GD**.
  - ➔ *A psychiatry consult is not needed for a diagnosis of GD. The diagnosis may be made by another mental health provider, based on DSM-5 criteria.*

7. MEDICAL ASSESSMENT

Once Psychology Services has completed the mental health assessment and ascertained the individual's **TG** goals—or otherwise determined that the individual is in need of a medical evaluation—the psychologist will refer the individual to the appropriate Health Services staff for specific medical interventions. A medical assessment should include:

- **REVIEW OF THE MENTAL HEALTH ASSESSMENT**
- **ASSESSMENT OF OVERALL HEALTH**
- **ASSESSMENT OF PREVIOUS TREATMENT** (hormonal therapy, surgery, etc.).
- **CO-OCCURRING MEDICAL DISORDERS:** Given the increased risk for individuals with thrombotic, hepatic, and oncological conditions who undergo hormonal therapy, it is crucial that comorbid conditions be managed appropriately and carefully.
  - ➔ *Please note that comorbidities are not necessarily a contraindication to therapy and must be assessed for each individual. See more about drug risks in Table 3 (**MTF**) and Table 4 (**FTM**).*
- **INFORMED CONSENT:** Individuals must be counseled on the risks and long-term effects of hormonal therapy. Use of gender-affirming hormones in the management of **TG** individuals is considered an off-label use and does not currently have FDA approval. Due to the irreversibility of some of the treatment options and the side effects, the individual's informed consent is required before initiating treatment and must be documented within the medical record.
  - ➔ *See Section 12, Patient Education & Informed Consent.*

- **CONTRAINDICATIONS:**
  - ➔ *See the Treatment Summary Charts in Appendix 1a (**MTF**) and Appendix 1b (**FTM**) for medication-specific contraindications.*

  MTF

  - **ABSOLUTE:** History of estrogen-sensitive cancer (e.g., breast cancer); history of thromboembolic disease (unless provided with concurrent anti-coagulation therapy); history of macroprolactinoma.
  - **RELATIVE:** Liver, kidney, or heart disease/stroke (or risk factors for heart disease such as high cholesterol, diabetes, obesity, smoking); strong family history of breast cancer or thromboembolic disease; gallbladder disease.

  FTM

  - **ABSOLUTE:** Pregnancy; breast feeding; history of breast cancer (testosterone may have anti-proliferative effects on most, but not all, breast cancers).
  - **RELATIVE:** Androgen-sensitive epilepsy; migraines; sleep apnea; polycythemia (elevated red blood cell count); cardiac failure; renal failure or severe hypertension susceptible to salt retention and fluid overload; significant liver disease; coronary artery disease (CAD) or risk factors for CAD; history of uterine cancer; bleeding disorders (for injected testosterone); significant history of violent behavior.

8. STEPWISE APPROACH TO MEDICAL AND MENTAL HEALTH MANAGEMENT OF TG INDIVIDUALS

Table 2 summarizes the step-by-step approaches to medical and mental health management of **TG** individuals in the BOP. It should be noted that ongoing release preparation and BOP Social Worker referral may facilitate a successful return to the community.

➔ *See Section 9, Hormone Treatment, Section 10, Medications for MtF Individuals, and Section 11, Medications for FtM Individuals for more detailed information on medical treatment.*

TABLE 2. STEPWISE APPROACH TO MTF AND FTM MEDICAL AND MENTAL HEALTH MANAGEMENT

1	Individual identifies as **TG** and seeks medical intervention to assist with transition; mental health assessment provided (see *Section 6*); continuation of counseling by psychology services if indicated; and implementation/initiation of **REAL-LIFE EXPERIENCE (RLE)**.	
2	Referral to medical provider for medical evaluation; laboratory workup; discussion of realistic expectations of hormonal therapy; and informed consent for hormone treatment. See Section 7.	
3	Discussion with **BOP TCCT** and psychiatric clinical pharmacist consultant, followed by a non-formulary request submission.	
4	***MtF***	***FtM***
	Once non-formulary request has been approved, begin hormonal therapy with anti-androgen (spironolactone first, unless contraindicated) and estrogen (see *Appendix 1a* for choosing a preparation). Start low and titrate to appropriate level while using lowest effective dose. ➔ *See Hormone Therapy for MtF in Section 9.*	Once non-formulary request has been approved, begin hormonal therapy with testosterone (see *Appendix 1b* for choosing a preparation). Start low and titrate to appropriate level while using lowest effective dose. ➔ *See Hormone Therapy for FtM in Section 9.*
5	***MtF***	***FtM***
	If treatment has reached maximum estrogen dose without seeing desired effects, consider adding another anti-androgen such as finasteride, gonadotropin-releasing hormone (GnRH) agonist, or medroxyprogesterone. Consult **BOP TCCT**.	If still experiencing uterine bleeding after first few months of high-dose testosterone therapy, consider adding medroxyprogesterone or a GnRH agonist to suppress menstruation. Consult **BOP TCCT**.
6	Evaluation of individual by **BOP TCCT** for potential appropriateness of surgical intervention upon institution referral. ➔ *See Section 12 for general criteria for consideration of surgery.*	
7	Surgical intervention.*****	
***** For further considerations, please refer to the most recent guidelines from the World Professional Association on Transgender Health (WPATH), the Endocrine Society, and the American Association of Obstetricians and Gynecologists (Committee Opinion), available at: *http://www.wpath.org/site_page.cfm?pk_association_webpage_menu=1351*. Cases will be reviewed on a case by case basis by BOP Central Office through a referral from the **BOP TCCT**.		

9. HORMONE TREATMENT: ELIGIBILITY, GOALS, OVERVIEW

Hormone supplementation is an important part of transitional treatment for many transgender individuals. Studies demonstrate improvement (in the range of 70–80%) in gender dysphoria, mental health, quality of life, and sexual function, for transgender treatment that included hormone therapy. The goals of hormone treatment are **(1)** to suppress endogenous hormones and physical characteristics of the natal sex and **(2)** to supplement hormones and enhance characteristics of the preferred gender, utilizing the principles of hormone replacement therapy for hypogonadal individuals of the **TG** individual's identified gender.

➔ *The information in this section is in part adapted from VA Pharmacy Benefits Management Services, Transgender Cross-Sex Hormone Therapy Use, (#2 in the References section) and Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline (#3 in the References section).*

ELIGIBILITY AND READINESS FOR GENDER-AFFIRMING HORMONE THERAPY

WPATH CRITERIA: Current WPATH guidelines identify four eligibility criteria for hormone therapy, but also emphasize the need for individualized treatment plans that may include hormone therapy in selected cases that do not meet all four criteria. The WPATH criteria are as follows:

(1) Gender dysphoria that is persistent and documented.

(2) Medical and/or mental health conditions, if present, are reasonably well-controlled.

(3) Legal age of majority (currently 18 years in all states except Alabama and Nebraska, which use 19 years).

(4) Informed consent.

ENDOCRINE SOCIETY CRITERIA: As part of their eligibility criteria, the Endocrine Society also includes ICD-10 criteria for transsexualism as an alternate criterion for gender dysphoria, and requires three months of documented real life experience or psychotherapy. The Endocrine Society further describes readiness criteria to include further consolidation of the preferred gender identity and progress in the gender transition, as well as willingness and ability to take hormones as prescribed.

HORMONE THERAPY FOR MALE-TO-FEMALE (MTF)

Feminizing treatment is generally the more complex of the two gender-affirming regimens and consists of either one medication alone or a combination of an anti-androgen and an estrogen, with a potential progestin adjunct. Most clinical studies and guidelines recommend therapy with an anti-androgen and an estrogen, although androgen suppression may be used alone in individuals desiring a more androgynous appearance.

- **Individuals should have realistic expectations of the treatment results, as well as the timeline of when to expect them.** Medical staff should provide enough information on an ongoing basis to help individuals set these realistic expectations. Every case is different, and slow change can lead to frustration. It is important to discuss realistic expectations with the

individual in order to avoid any attempts to self-increase the dosage in hopes of speeding up results.

- Within the first six months of treatment, changes may be seen in body fat redistribution, loss of muscle mass, breast growth, testicular atrophy, decreased erections, decreased sperm production, and a slowing of body/facial hair growth.
- The maximum effect of treatment may not be seen for more than two years.
- Treatment does not provide voice alteration, and training to feminize the voice with a speech pathologist may be indicated, based on consultation with the **BOP TCCT**.

- Most treatment results are reversible upon cessation of treatment, but breast growth is permanent and infertility may be irreversible.
- Goal levels of treatment are serum estradiol <200 pg/ml (premenopausal level) and testosterone <55 ng/dl. Serum estradiol levels should not exceed those of a premenopausal female, but doses used to achieve an adequate level may be significantly higher than those used in hormone replacement therapy in menopausal women.
  - It is important to note that there are individuals who do not require estradiol as part of their hormonal therapy regimen and do well on an anti-androgen therapy alone. There are others who require very little estrogen to obtain desired body characteristics and adequately treat any presenting dysphoria.
  - Individuals should uniformly be treated with the lowest effective hormone doses. As previously stated, estradiol levels should not routinely exceed a premenopausal level of 200 pg/ml, but the average individual does not usually require levels near that threshold. The same holds true for testosterone levels. While the goal is <55 ng/dl, there is a subset of individuals who do poorly with levels below 35 ng/dl. The ideal levels for these individuals would be between 35–55 ng/dl.
  - ➔ *Dose adjustments, based on the individual's response, are made once hormone levels are in the target range.*

HORMONE THERAPY FOR FEMALE-TO-MALE (FTM)

Masculinizing treatment is the less complex of the two gender-affirming regimens and consists mainly of testosterone supplementation.

- **The individual's realistic expectations about treatment results and the associated timeline are essential prior to beginning treatment.**
- Within the first six months of treatment, body fat redistribution, an increase in libido, an increase in acne, clitoral enlargement, vaginal atrophy, cessation of menses, and infertility may be evident. Alterations in hair growth, voice depth, and muscle mass may take longer—reaching full effects of treatment in two to five years.
- Uterine bleeding should cease within a few months of high-dose testosterone therapy, but treatments such as gonadotropin-releasing hormone (GnRH) agonists, medroxyprogesterone, and endometrial ablation may be used to stop menses prior to starting testosterone therapy or to decrease estrogen levels.

- Most effects are reversible upon cessation of treatment, but changes in hair, voice depth, and fertility may be irreversible.
- Goal treatment levels are serum estradiol <50 pg/ml and serum total 350–700 ng/dl (male physiologic range; some sources quote a normal reference range of 400-800 ng/dl). If a peak testosterone level is drawn for injectable testosterone, the level should not exceed 1,000 ng/ml. Prior to the ninth month of treatment, total testosterone levels may read high, while free testosterone levels are within the normal range. This may be due to the possibility of high levels of sex hormone binding to globulin in some women.
  - ➔ *Dose adjustments, based on the individual's response, are made once hormone levels are in the target range.*

HORMONE THERAPY DURING PREGNANCY

Gender-affirming hormone therapy is contraindicated during pregnancy. While therapy may lead to potentially irreversible infertility, it does not function as contraception, and pregnancy is still possible during treatment.

➔ *Precautions should be taken to avoid pregnancy during treatment.*

10. MEDICATIONS FOR MTF INDIVIDUALS

MTF MEDICATIONS: DRUG CLASSES

➔ *See the **MTF Treatment Summary Chart** in Appendix 1a for summarized information on each of the medication groups below—including dosing, adverse effects, contraindications, interactions, and monitoring.*

ANTI-ANDROGENS

Anti-androgens reduce testosterone levels, allowing estrogen therapy to be used in lower doses while still reaching a maximum effect. Medications with anti-androgen effects include spironolactone, finasteride, GnRH agonists, and progestins.

- **SPIRONOLACTONE** is a potassium-sparing diuretic that directly inhibits testosterone secretion and androgen binding to the androgen receptor. Spironolactone can suppress facial and body hair growth, male pattern baldness, libido, and sexually stimulated erections. It decreases symptoms of benign prostate hypertrophy (BPH) and can lead to modest breast growth.
  - ➔ *The use of spironolactone is contraindicated in renal insufficiency and with a potassium value greater than 5.5 mEq/L. Spironolactone can cause hyperkalemia and hypotension. It is important to monitor potassium levels and blood pressure of individuals taking spironolactone, as stated in Appendix 1a.*
- **FINASTERIDE** inhibits the enzyme responsible for converting testosterone to its potent form. It can be used alone at high doses (5–10 mg/day) in individuals intolerant to spironolactone, or as an adjunct to spironolactone. Effects are similar to those of spironolactone treatment, but spironolactone treatment is considered first line due to observed responses. Finasteride can be used in low doses (1 mg/day) to treat male pattern baldness. Finasteride can reduce BPH symptoms by reducing the size of the prostate.
  - ➔ *Finasteride should not be used when prostate cancer is suspected, due to its ability to lower prostate-specific antigen levels.*

- **GnRH Agonists** include goserelin, nafarelin, and leuprolide. These medications suppress pituitary gonadotropin levels and gonadal steroids. They are most often used in adolescents for suppression of puberty, but can be used to decrease testosterone levels and the amount of estrogen needed for **MtF TG** individuals. One advantage of using GnRH agonists in adolescents is that their effects are generally fully reversible. GnRH agonists do not carry the risk of thromboembolic disease.

- **Progestins** are a group of hormones that include medroxyprogesterone. Use of medroxyprogesterone is controversial and not routinely recommended, but it can be used alone in individuals intolerant to other agents, or as an adjunct for individuals receiving maximum estrogen doses without desired effects. Medroxyprogesterone has anti-androgen effects at high doses, but is not more effective than spironolactone. It is purported to aid in breast development at a cellular level, but its effect is mainly on the uterus, and evidence as an effective agent in gender-affirming hormone therapy is lacking.
  - *Medroxyprogesterone treatment comes with risk of developing mood disorders (depression/irritability), lipid abnormalities, weight gain, and edema. There is also a concern of increased cardiovascular risk.*

- **Other anti-androgenic agents** include flutamide and cyproterone acetate, but are not commonly used in the U.S. Cyproterone acetate is widely used in Europe, but is not available in the United States. Flutamide blocks androgen binding, but comes with a risk of hepatotoxicity and has little to no efficacy in reducing testosterone levels.

Estrogens

Estrogens are used to provide feminization in the form of physical appearance and sexual characteristics. Effects include development of breasts, redistribution of body fat, softening of the skin, shrinkage of the testes, and testicular atrophy. Many formulations of estrogen are available, including parenteral, transdermal, and oral. Estrogen may have positive health effects more generally, including increased high-density lipoprotein, decreased low-density lipoprotein, and preservation of bone mineral density.

A list of adverse events and necessary lab monitoring can be found in Appendix 1a.

- All estrogens come with a risk of thromboembolism, but lower doses and transdermal formulations are considered safer and should be used in populations at higher risk of thromboembolism (>35 years old, smoker, obese). Synthetic estrogens, especially ethinyl estradiol, have been shown to have a higher risk of thromboembolism.
- Intramuscular (IM) injections can cause greater peaks and troughs in estrogen levels, causing more mood issues than oral and transdermal preparations, making oral and transdermal preparations preferable.
- Use of estrogen should be individualized and adjusted regularly, based on serum estradiol levels and individual-specific concerns. Estrogen should be started at low doses and titrated up as needed, based on hormone levels and individual tolerance. If discontinuation is necessary, consider tapering therapy to alleviate mood disturbances.
  - *Conjugated and synthetic estrogen formulations cannot be measured through serum estradiol concentrations and are no longer recommended for gender-affirming hormone therapy.*

MTF MEDICATIONS: DRUG EFFECTS TIMELINE

➔ *Refer to the Endocrine Society guideline, Table 14, page 3145 (reference 3 in the References section of this guidance) for specific expectations of feminizing effects of medication therapy.*

In general, a person may expect decreased libido and spontaneous erections to occur within one to three months of starting therapy, with a maximum effect in three to six months. Effects that usually develop in the first three to six months of treatment include redistribution of body fat, decrease in muscle mass and strength, softening and decreased oiliness of skin, breast growth, and decreased testicular volume with a maximum effect in one to three years. A decrease in terminal hair growth usually does not occur until six to 12 months into treatment, with a maximum effect not occurring for at least three years or more. The timelines for male sexual dysfunction and decreased sperm production are either variable or unknown. Voice changes do not occur with hormone treatments.

MTF MEDICATIONS: DRUG RISKS

Table 3 lists conditions that can be exacerbated by gender-affirming estrogen therapy. See *Appendix 1a* for more information on the adverse effects of estrogen therapy and androgen suppression.

TABLE 3. MEDICAL CONDITIONS EXACERBATED BY GENDER-AFFIRMING ESTROGEN THERAPY (MTF)

Very high risk of serious adverse outcomes:	
• Thromboembolic disease	
Moderate to high risk of adverse outcomes:	
• Macroprolactinoma • Breast cancer • Severe liver dysfunction *(transaminases >3x upper limit of normal)*	• Coronary artery disease • Cerebrovascular disease • Severe migraine headaches

MTF MEDICATIONS: MONITORING

Gender-affirming hormone therapy has the same risks associated with hormone replacement therapy in biological males and females. Appropriate monitoring is crucial. Weight, blood pressure, physical exams, risk factors, medications, complete blood counts, renal and liver function, and lipid and glucose metabolism should be monitored for all **TG** individuals receiving gender-affirming hormone therapy.

- Clinical and laboratory monitoring is appropriate every three months during the first year, and then once or twice yearly thereafter, except as noted.
  - ➔ *Monitor for development of feminine characteristics, for target blood levels, and for adverse effects of medication and other treatment.*

- Cardiovascular risk assessment is recommended periodically for all patients treated with hormones in accordance with established guidelines and BOP guidance when available.
  - ➔ *Specific parameters that need to be monitored include weight and body mass index, blood pressure, lipids, and blood sugar/glycohemoglobin levels, in accordance with established guidelines.*

- Serum testosterone and estradiol levels are obtained before starting those respective medications, and then every three months while on treatment.
  - ➔ *Target levels are < 55 ng/dl for testosterone and < 200 pg/ml for estradiol. Higher levels of testosterone indicate inadequate suppression; higher levels of estradiol are associated with increased risks for thromboembolic disease, liver dysfunction, and development of hypertension.*
- Serum electrolytes, most importantly potassium, and renal function are obtained prior to starting spironolactone, every three months during the first year of treatment, periodically thereafter, or more frequently with increases in dosage or as clinically indicated.
  - ➔ *Dose adjustment or discontinuation of spironolactone is recommended for elevated potassium levels or serum creatinine > 4 mg/dL.*
- Screening for colon, and prostate cancer is recommended in accordance with established guidelines and BOP guidance when available.
- Breast cancer screening guidelines for women are followed for **MTF TG** individuals treated with hormone therapy.
- Screening for osteoporosis with a DEXA scan may be appropriate in some cases.
  - ➔ *In the absence of sufficient data to formulate evidence-based guidelines, it is considered appropriate to screen those who are at least five years post-gonadectomy, those who are 50 to 65 years old and have risk factors for osteoporosis, and all those who are 65 years or older.*
  - ➔ *Bone density measurements for transgender women (**MTF**) are compared with standards for biological females.*
- Baseline and periodic monitoring of liver enzymes and prolactin levels may be appropriate in those treated with estradiol but there is insufficient data available to make a specific recommendation.

11. MEDICATIONS FOR FTM INDIVIDUALS

DRUG CLASSES AND MEDICATION INFORMATION

➔ *See the **FTMTreatment Summary Chart** in Appendix 1b for a full list of the different formulations of testosterone—including summarized information on dosing, adverse effects, contraindications, interactions, and monitoring.*

TESTOSTERONE

Androgen supplementation is used to induce male sex characteristics, including cessation of menses, voice changes, increased facial/body hair growth, increased muscle mass, and clitoral enlargement. Other effects include increased libido and energy.

- Several formulations are available, ranging from IM injections to transdermal patches and gels. The IM injections release slowly from the muscle, but may induce cyclical side effects that coincide with varying plasma concentrations. To avoid these effects, transdermal preparations can be used; alternatively, for testosterone cypionate and enanthate, a lower dose of IM testosterone can be given once-weekly (instead of every two or more weeks).
- Transdermal patches may take longer than IM doses to reach adequate levels. As a result, testosterone levels should be checked after completing at least one week of therapy with a patch. Precautions should be taken to avoid unintentional exposure.

- While oral formulations are available, they are not used, due to extensive liver metabolism and the associated potential for hepatic complications.
- Androgen use should be individualized and adjusted based on serum testosterone levels, tolerance, and efficacy. As with estrogen, dosing should start low and be titrated up to an appropriate level while keeping the dose as low as possible to minimize side effects.
- Ovulation may still be possible even when undergoing long-term testosterone therapy.
  - ➔ *Measures should be taken to avoid pregnancy in those undergoing hormonal therapy.*

Due to the classification of all testosterone preparations as DEA-controlled substances and their associated risk of potential abuse and/or diversion, transdermal patches or gels should be avoided in the correctional environment, if possible.
➔ ***INJECTABLE TESTOSTERONE is the preferred formulation in the correctional environment.***

PROGESTINS AND GNRH AGONISTS

Medroxyprogesterone and GnRH agonists are not typically used, but may be beneficial in individuals wishing to cease menstruation and decrease estrogen levels prior to testosterone treatment. These medications may also have a use in individuals receiving high-dose testosterone therapy who still experience uterine bleeding after the first few months of treatment.

➔ *See Appendix 1a and Appendix 1b for information on Medroxyprogesterone and GnRH agonists.*

DRUG EFFECT TIMELINE FOR FTM MEDICATIONS

➔ *Refer to the Endocrine Society guideline, Table 13, page 3145 (reference 3 in the References section of this guidance) for specific expectations of masculinizing effects of medication therapy.*

In general, a person may expect the following to occur:

- Effects that develop within the first six months of treatment include increased skin oiliness and acne, fat redistribution, cessation of menses, clitoral enlargement, and vaginal atrophy, with onset within the first three months. Maximum effect usually occurs in one to two years, but may take up to five years in some cases.
- Effects that develop in the six-to-12 month time frame include increased facial and body hair, scalp hair loss, increased muscle mass and strength, and deepening of the voice, with maximum effect often occurring in one to two years.

FTM MEDICATIONS: DRUG RISKS

Table 4 lists conditions that can be exacerbated by gender-affirming testosterone therapy. See Appendix 1b for more information on the adverse effects of testosterone therapy.

TABLE 4. MEDICAL CONDITIONS EXACERBATED BY GENDER-AFFIRMING TESTOSTERONE THERAPY (FTM)

Very High Risk of Serious Adverse Outcomes	Moderate-to-High Risk of Adverse Outcomes
• Breast or uterine cancer • Erythrocytosis (hematocrit >50%)	• Severe liver dysfunction (transaminases >3x upper limit of normal)

FTM MEDICATIONS: MONITORING

Gender-affirming hormone therapy has the same risks associated with hormone replacement therapy in biological males and females. Some of the adverse effects experienced with chronic testosterone therapy are erythrocytosis, liver dysfunction, hypertension, excessive weight gain, salt retention, lipid changes, excessive or cystic acne, and adverse psychological changes. Appropriate monitoring is crucial. Weight, blood pressure, physical exams, risk factors, medications, complete blood counts, renal and liver function, and lipid and glucose metabolism should be monitored for all **TG** individuals receiving gender-affirming hormone therapy.

- Clinical and laboratory monitoring is appropriate prior to starting treatment, every three months during the first year, and then once or twice yearly thereafter, except as noted.
  - ➔ *Monitor for development of masculine characteristics, for target blood levels, and for adverse of effects of medication and other treatments.*
- Cardiovascular risk assessment is recommended periodically for all patients treated with hormones, in accordance with established guidelines and BOP guidance when available.
  - ➔ *Specific parameters that need to be monitored include weight and body mass index, blood pressure, lipids, and blood sugar/glycohemoglobin levels.*
- A pregnancy test is obtained prior to starting treatment for all biological females with child bearing potential.
- Serum testosterone levels are obtained before starting treatment with testosterone, and then every three months while on treatment.
  - ➔ *Target testosterone levels are 350–700 ng/d. Higher levels may be associated with increased risk of side effects and complications.*
  - ➔ *Timing of the testosterone level is determined by the route of administration. Trough testosterone levels are obtained prior to the next dose of **injectable** testosterone. Testosterone levels are recommended three to five hours after an **oral** dose, and any time after one week of therapy on **topical** testosterone.*
- Serum estradiol levels are obtained before starting hormone therapy, and then every three months while on treatment until estradiol levels are < 50 pg/ml and cessation of menses has been six months.
- A complete blood count (CBC) and liver panel are obtained prior to starting hormone therapy, every three months during the first year of treatment, once or twice yearly thereafter, or more frequently as clinically indicated.
  - ➔ *Dose adjustment or discontinuation of testosterone is indicated if the hematocrit is > 54%.*
- Screening for colon cancer is recommended in accordance with established guidelines and BOP guidance when available.
- Breast cancer screening guidelines for women are followed for **FTM TG** individuals treated with hormone therapy and who have not had mastectomies.
- Cervical cancer screening is performed annually in those who are treated with hormone therapy and have cervical tissue (i.e., no hysterectomy).

(List continues on next page.)

- Screening for osteoporosis with a DEXA scan may be appropriate in some cases.
  - *In the absence of sufficient data to formulate evidence-based guidelines, it is considered appropriate to assess bone mineral density prior to starting treatment in those with risk factors for osteoporosis, those who are at least five years status post-gonadectomy, and all those who are 60 to 65 years or older.*
  - *Bone density measurements for transgender men are compared with standards for biological males.*

12. GENDER-AFFIRMING (A.K.A. SEX REASSIGNMENT) SURGERY

Although individuals may live successfully as transgender persons without surgery, gender-affirming surgery may be appropriate for some and is considered on a case-by-case basis.

CRITERIA: In addition to the eligibility and readiness criteria for hormone therapy, general criteria for consideration of surgery include at least 12 months of successful use of hormone therapy, participation in psychotherapy as clinically indicated, full-time real life experience in their preferred gender, and consolidation of gender identity. The inmate must request consideration for and demonstrate via informed consent a practical understanding of gender-affirming surgery including, but not limited to, permanence, potential complications, and short- and long-term treatment plans.

Requests for surgery are submitted to the **BOP TCCT** for initial review and recommendation to the Medical Director, who is the approving authority. Each referral should include comprehensive medical and mental health summaries, a comprehensive psychosocial assessment (preferably by a licensed clinical social worker), and a criminal history and institutional adjustment report.

13. PATIENT EDUCATION & INFORMED CONSENT

Patient education and informed consent are crucial to the treatment process. Sample consent and counseling documents can be found in *Appendix 2* and *Appendix 3*. Psychology and medical staff should allow individuals to read the appropriate consent forms, as well as discuss the forms with the individuals to ensure that they understand them thoroughly. Informed consent must be documented within the electronic medical record.

See Section 7, Medical Assessment and *Section 8, Stepwise Approach to Medical and Mental Health Management of TG Individuals for more information*.

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APPENDIX 1A. TREATMENT SUMMARY CHART FOR MTF THERAPY

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL <200 PG/ML AND SERUM TESTOSTERONE <55 NG/DL ★						
Anti-Androgen Drugs	**Dose**	**Mode of Action**	**Adverse Effects**	**Contraindications**	**Interactions**	**Notes/Monitoring**
SPIRONOLACTONE	**Starting:** 25–50 mg BID **Typical:** 50 mg BID **Max:** 200 mg BID	Potassium-sparing antihypertensive that directly inhibits testosterone secretion and androgen binding to the androgen receptor	• Mild diuretic • Hyperkalemia • Excretion of sodium, calcium, and chloride • Decreased libido	• Renal insufficiency • Potassium >5.5 mmol/L • Avoid after orchiectomy	• Digoxin • ACE inhibitors • ARBs • Potassium-sparing diuretics	• **Baseline labs:** BMP • **Follow-up labs:** Serum potassium and renal function in 1 week, monthly for three months, and every three months during first year. • **When stable:** BMP every 6 to 12 months
FINASTERIDE	**Low:** 1 mg daily **High:** 5–10 mg daily	5α reductase inhibitor, which blocks the conversion of testosterone to the more active 5α dihydrotestosterone	Sexual dysfunction	None pertinent	Antiretrovirals and diltiazem may increase finasteride levels.	• **High dose:** Unable to take spironolactone • **Low dose:** Treatment of male pattern baldness • Use in combo with spironolactone for rare individuals not achieving desired effects • May be used after orchiectomy if hirsutism or male pattern baldness are present
APPENDIX 1A, PAGE 1 OF 3 *(See APPENDIX 1C for sources and abbreviations.)*						

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL <200 PG/ML AND SERUM TESTOSTERONE <55 NG/DL ★						
Anti-Androgen Drugs	**Dose**	**Mode of Action**	**Adverse Effects**	**Contraindications**	**Interactions**	**Notes/Monitoring**
GNRH AGONISTS: **GOSERELIN** **NAFARELIN** **LEUPROLIDE**	**Goserelin:** 3.6 mg SQ monthly **Nafarelin:** 600 µg intranasal daily **Leuprolide:** 3.75–7.5 mg IM monthly	Neurohormones that block the GnRH receptor, thus blocking release of FSH & LH, leading to highly effective gonadal blockade	• Loss of BMD • Hot flashes • Sexual dysfunction • Diarrhea	None pertinent	None noted	• MTF: Use anti-androgen to decrease estrogen use • Fully reversible when used in adolescents to delay puberty
PROGESTERONE, MEDROXYPROGESTERONE	**Starting:** 2.5 mg daily **Typical:** 5–10 mg daily **Max:** 20 mg daily	• Anti-androgen effect at high doses • May help breast development at cellular level	• Increased CV risk • Weight gain • Edema • Mood disorder • Increased facial and body hair	See below; same contraindications as estrogen.	Antiretrovirals	• Not as effective as spironolactone • Adjunct for individuals on maximum estrogen doses with unsatisfactory effects • **Monitoring:** Same as estrogen; see below
APPENDIX 1A, PAGE 2 OF 3 *(See APPENDIX 1C for sources and abbreviations.)*						

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL <200 PG/ML AND SERUM TESTOSTERONE <55 NG/DL ★					
Estrogen	**Dose**	**Adverse Effects**	**Contraindications**	**Notes**	**Monitoring**
ESTRADIOL	**Starting:** 2–3 mg daily **Typical:** 4 mg daily **Max:** 8 mg daily	**Common:** • Increase in weight, VTE, dyslipidemia, insulin resistance, prolactin levels, edema, N/V, migraine • Decrease in erections • Melasma and skin irritation from estradiol patches **Less Common:** • LFT abnormalities • Increase in CV events especially in those older than 50 taking progesterone with estrogens • Increased triglycerides in those taking oral estrogens • Increased risk of pancreatitis, cholelithiasis, diabetes mellitus, hypertension, and hyperkalemia (in spironolactone users) **Rare or plausible but have not been observed:** • Liver damage • Prolactinoma • Breast cancer (compared with men never exposed to estrogen)	**Absolute:** • Estrogen-dependent cancer **Precautions:** • History of VTE • Coronary artery disease • Hyperlipidemia • Diabetes mellitus • Cigarette smoking • Highly sedentary lifestyle • Migraine • Seizure disorder • Retinopathy • Heart failure • Valvular heart disease • Family history of estrogen-dependent tumor	• **Interactions:** CYP 3A4, 1A2 inhibitors/inducers • Transdermal formulations better for older individuals or those with risk factors for VTE • Stop estrogens two weeks prior to surgery or immobilizing event. Restart after mobilization or one week after surgery • Consider adding aspirin therapy to those at high risk for VTE • Individuals who enter the BOP on conjugated estrogen should be switched to a different form of estrogen due to inability to monitor estrogen levels with this preparation • IM injections cause greater peaks and troughs in estrogen levels making oral and transdermal preparations preferable	• **Baseline:** fasting glucose, lipids, LFTs, prolactin, BMP, BMD if at risk for fracture • **Follow-up:** glucose and lipids every 2–3 months after starting or dose increase and 1 year after starting • Check serum testosterone and estradiol every 3 months in first year then 1–2 times per year after for feminization and adverse events • Optional: LFTs and prolactin after 1 year • Routine prostate and breast cancer screening
ESTRADIOL SUBLINGUAL (ESTRADIOL MICRONIZED, ESTRACE)	**Starting:** 0.5–1 mg **Typical:** 2 mg daily **Max:** 4 mg daily				
ESTRADIOL VALERATE (DELESTROGEN)	**Starting:** 20–40 mg IM q2wk **Average:** 40 mg IM q2wk **Max:** 40–80 mg IM q2wk **Endocrine guidelines:** 2–10 mg IM q1wk				
ESTRADIOL CYPIONATE (DEPO-ESTRADIOL)	**Starting:** 20–40 mg IM q2wk **Average:** 40 mg IM q2wk **Max:** 40–80 mg IM q2wk **Endocrine guide:** 2–10 mg IM q1wk				
ESTRADIOL PATCH (CLIMARA, ESTRADERM, ALORA, VIVELLE-DOT)	**Starting:** 0.1 mg/24hr **Average:** 0.2 mg/24hr **Max:** 0.4 mg/24hr **Endocrine guide:** 0.1–0.4 mg twice weekly				
ESTRADIOL GEL (DIVIGEL, ELESTRIN, ESTRASORB, ESTROGEL)	Roughly equivalent to patch dosing				
CONJUGATED EQUINE ESTROGENS (PREMARIN)	**Starting:** 1.25–2.5 mg daily **Typical:** 5 mg daily **Max:** 10 mg daily				
APPENDIX 1A, PAGE 3 OF 3 *(See APPENDIX 1C for sources and abbreviations.)*					

APPENDIX 1B. TREATMENT SUMMARY CHART FOR FTM THERAPY

★ **GOAL LEVELS FOR FTM: SERUM ESTRADIOL <50 PG/ML AND SERUM TESTOSTERONE 320–1000 NG/DL** ★

Drug	Dose	Adverse Effects	Contraindications	Notes	Monitoring
TESTOSTERONE CYPIONATE (in cottonseed oil) **TESTOSTERONE ENANTHATE (in sesame oil)**	**Starting:** 50–100 mg q2wk or 25–50 mg/wk **Typical:** 200 mg q2wk or 100 mg/wk **Max:** 400 mg q2wk or 200 mg/wk	**Common:** • Increase in weight, oily skin, acne, and male pattern baldness • Vaginal atrophy • Infertility (possibly irreversible) • Dyslipidemia • Mood changes • Skin irritation with patch • Risk of exposing partners or children to testosterone with topicals **Less Common:** • Increase in edema, blood pressure, and aggressiveness • Erythrocytosis • Abnormal LFTs • Sleep apnea **Rare or plausible but not observed:** • Increased risk of CV disease, breast/ ovarian cancer, and endometrial hyperplasia	**Absolute:** • Pregnancy • Breast cancer (testosterone may have anti-proliferative effects on most, but not all, breast cancers) • Breastfeeding **Precautions:** • Erythrocytosis • Cardiac, hepatic, renal, or vascular disease with edema or risk of edema • Sleep apnea or high risk of sleep apnea due to obesity or chronic lung disease • Dyslipidemia	• **Interactions:** Warfarin Cyclosporine Insulin • Causes drop in blood glucose in DM individuals • May notice cyclic variation in mood with IM dosing Q 2–4 weeks. Use a lower, more frequent dose, or transdermal • Transdermal reaches same levels as IM, but in longer timeframe • Menses typically stop in early months of treatment, but may persist when using transdermals **Use in Corrections:** **Injectable testosterone is the preferred formulation in the correctional environment due to potential risk of abuse and/or diversion. Testosterone is a DEA Controlled Substance**	• **Baseline:** CBC, lipids, urine hCG, glucose, & LFTs (if PCOS suspected) • **Follow-up:** 2–3 months after starting or changing dose CBC, lipids • **1 year after start or change:** CBC, lipids, LFTs (optional) • Serum testosterone: every 2–3 months in first year then 1–2 times/year for virilization/AEs • Serum estradiol: q 2–3 months in first 6 months or until no uterine bleeding for 6 months • **When to check specific formulations:** **IM:** Testosterone levels just prior to next dose. Adjust to mid-normal range of 350–700 ng/dl **Patch:** Testosterone levels after week 1 • Continue screenings for cervical and breast cancer if tissue still present
TESTOSTERONE PATCH **Available strengths: 2 mg, 2.5 mg, 4 mg, 5 mg**	**Starting:** 2–2.5 mg/day **Typical:** 5 mg/day **Max:** 7.5 mg/day				
TESTOSTERONE GEL (TESTIM 1%, ANDROGEL 1%)	**Starting:** 2.5 mg every morning **Typical:** 5 mg every morning **Max:** 10 mg every morning				
TESTOSTERONE GEL (ANDROGEL 1.62%)	No published or anecdotal experience with these preparations				
TESTOSTERONE SOLUTION (AXIRON axillary solution)					
MEDROXYPROGESTERONE AND GNRH AGONISTS	See *page 2* of APPENDIX 1A for dosing and other information.			Used to suppress menstruation if persists after early months of testosterone treatment	

(See APPENDIX 1C for sources and abbreviations.)

APPENDIX 1C. TREATMENT SUMMARY CHARTS: SOURCES AND ABBREVIATIONS

SOURCES FOR TREATMENT SUMMARY CHARTS: *See References 2, 3, 4, 5, 8, 9, and 10.*

ABBREVIATIONS:

AEs	Adverse events
ARB	Angiotensin II receptor blocker
BMD	Bone mineral density
BMP	Basic metabolic panel, including glucose, calcium, sodium, potassium, CO_2, chloride, blood urea nitrogen, and serum creatinine
CBC	Complete blood count
CV	Cardiovascular
DM	Diabetes mellitus
FSH	Follicle-stimulating hormone
FtM	Female-to-male
GnRH	Gonadotropin-releasing hormone
hCG	Human chorionic gonadotropin
IM	Intramuscular
LFT	Liver function test
LH	Luteinizing hormone
MtF	Male-to-female
N/V	Nausea and vomiting
PCOS	Polycystic ovarian syndrome
q	"Every" (*Example:* q2wk = every 2 weeks)
SQ	Subcutaneous
VTE	Venous thromboembolism

APPENDIX 2. FEMINIZING GENDER-AFFIRMING HORMONE TREATMENT FOR TG PATIENTS – CONSENT AND COUNSELING FORM

A sample ***Consent and Counseling Form*** for feminizing gender-affirming hormone treatment for **TG** patients appears on the next five pages.

FEMINIZING GENDER-AFFIRMING HORMONE TREATMENT FOR TRANSGENDER PATIENTS

CONSENT AND COUNSELING FORM

INSTITUTION NAME: _____

PATIENT NAME: _____ **ID #:** _____

You want to take estrogen and other medications to feminize your body. Once you start these medications, some of them will need to be taken for the rest of your life in order to maintain their effects. Before using these medications, you need to know more about how they might affect you, including possible benefits, side effects, risks, and warning signs. We have listed them here for you. It's important that you understand all of this information before you start. We are happy to answer *any* questions you might have, so please ask!

WHAT ARE THE DIFFERENT MEDICATIONS THAT CAN HELP TO FEMINIZE YOU?

Estrogen is the female gender-affirming hormone and there are different types of estrogen that can help you appear more like a woman. There are also medications—called androgen antagonists or anti-androgens or androgen blockers—that can help you appear less like a man. Androgen is the male gender-affirming hormone.

WARNING — WHO SHOULD NOT TAKE ESTROGEN?

It should NOT be used by anyone who has a history of:

- An estrogen-dependent cancer
- Blood clots that could or did travel to the lungs

It should be used WITH CAUTION, and only after a full discussion of risks, by anyone who:

- Has a strong family history of breast cancer or other cancers that grow faster when estrogens are present
- Has diabetes
- Has eye problems such as retinopathy
- Has heart disease, heart valve problems, or a tendency to have easily clotted blood
- Has hepatitis
- Has high cholesterol
- Has kidney or liver disease
- Has migraines or seizures
- Is obese
- Smokes cigarettes

Please review and initial each statement to show you understand the benefits, risks, and changes that may occur from taking these medications. At the end of the document, indicate your preference regarding hormone therapy, then sign and date it.

FEMINIZING EFFECTS:

_____ I know that estrogen or anti-androgens—or both—may be prescribed to help me appear less like a man and more like a woman.

_____ I know that it can take several months or longer for the effects to become noticeable. I know that no one can predict how fast—or how much—change will happen.

_____ I know that if I am taking estrogen, I will probably develop breasts.

- I know it can take several years for breasts to get to their full size.
- I know the breasts will remain, even if I stop taking estrogen.
- I know I should examine my breasts for irregularities as soon as they start growing. I should also have a clinician examine them every year.
- I know I might have a milky discharge from my nipples (galactorrhea). If I do, I know I should have it evaluated by my clinician because it could be caused by the estrogen or by something else.
- I know that no one knows if taking estrogen increases the risk of breast cancer.

_____ I know that the following changes are usually not permanent—they are likely to go away if I stop taking the medicines:

- I know my body hair will become less noticeable and will grow more slowly, but it won't stop completely, even if I take the medicines for years.
- I know I will probably have less fat on my abdomen and more on my buttocks, hips, and thighs. It will be redistributed to a more female shape, changing from an "apple" shape to more of a "pear" shape.
- I know that if I already have male pattern baldness, it may slow down, but will probably not stop completely. It is also unlikely that hair that has been lost will grow back.
- I know I may lose muscle and strength in my upper body.
- I know my skin may become softer.

_____ I know that my body will make less testosterone. Upon release, this may affect my sex life in different ways and my future ability to cause a pregnancy:

- I know my sperm may no longer reach maturity. This could make me less able to cause a pregnancy. I also know I might never produce mature sperm again, but I know that it's also possible that my sperm could still mature. So, I know that I might get someone pregnant if we have vaginal intercourse, and we don't use birth control. The options for sperm banking have been explained to me.
- I know my testicles may shrink down to half their size. Even so, I know that I will need regular checkups for them.
- I know it is likely that my penis won't be hard in the morning as often as it has been before. it is also likely that I will have fewer spontaneous erections.
- I know I may lose the ability to obtain an erection for intercourse.
- I know I may have less sex drive.
- I know this treatment may (but is not assured to) make me permanently unable to make a woman pregnant.

_____ I know that some parts of my body will not change much by using these medicines.

- I know the hair of my beard and moustache may grow more slowly than before. It may become less noticeable, but it will not go away.
- I know the pitch of my voice will not rise, and my speech patterns will not become more like a woman's.
- I know my Adam's apple will not shrink.
- Although these medicines can't make these changes happen, there are other treatments that may be helpful.

RISKS OF TAKING FEMINIZING MEDICATIONS:

_____ I know that the side effects and safety of these medicines are not completely known. There may be long-term risks that are not yet known.

_____ I know that I should not to take more medicine than I am prescribed. I know it increases health risks. I know that taking more than I am prescribed won't make changes happen more quickly or more significantly. I know my body can convert extra estrogen into testosterone, and that can slow down or stop my appearing more womanly.

_____ I know these medicines may damage the liver and may lead to liver disease. I know I should be checked for possible liver damage as long as I take them.

_____ I know these medicines cause changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones. I know I can reach out to psychology services to help me find support resources. I also know that the BOP does not tolerate harassment, discrimination, and violence in any circumstances. If I feel I am the recipient of any of these actions, I will notify a BOP staff member.

RISKS OF TAKING ESTROGEN:

_____ I know that taking estrogen increases the risk of blood clots that can result in:

- Chronic problems with veins in the legs
- Heart attack
- Pulmonary embolism (blood clot to the lungs), which may cause permanent lung damage or death
- Stroke, which may cause permanent brain damage or death

_____ I know that the risk of blood clots is much worse if I smoke cigarettes, especially if I am over 40. I know the danger is so high that I should stop smoking completely if I start taking estrogen and that I should not start to smoke again when I am released from a BOP institution.

_____ I know that taking estrogen can increase the deposits of fat around my internal organs. This can increase my risk for diabetes and heart disease.

_____ I know that taking estrogen can raise my blood pressure. I know that if my blood pressure goes up, my clinician can work with me to try to control it with diet, lifestyle changes, and/or medication.

_____ I know that taking estrogen increases my risk of getting gallstones. I know that I should talk with my clinician if I get severe or long-lasting pain in my abdomen.

_____ I know that estrogen can cause nausea and vomiting. I know that I should talk with my clinician if I have long-lasting nausea or vomiting.

_____ I know that estrogen can cause headaches or migraines. I know I should talk with my clinician if I have headaches or migraines often, or if the pain is unusually severe.

_____ I know that it is not yet known if taking estrogen increases the risk of prolactinomas. These are non-cancerous tumors of the pituitary gland. I know they are not usually life-threatening, but they can damage vision and cause headaches. I know this possibility needs to be checked periodically by a clinician for at least three years after I start taking estrogen.

_____ I know that I am more likely to have dangerous side effects if:

- I smoke.
- I am overweight.
- I am over 40 years old.
- I have a history of blood clots.
- I have a history of high blood pressure.
- My family has a history of breast cancer.

RISKS OF TAKING ANDROGEN ANTAGONISTS:

_____ I know that spironolactone affects the balance of water and salts in the kidneys, which may:

- Increase the amount of urine I produce, making it necessary to urinate more frequently.
- Increase thirst.
- Reduce blood pressure.
- Cause (although rarely) high levels of potassium in the blood, possibly leading to changes in heart rhythms that may be life-threatening.

_____ I know that some androgen antagonists make it more difficult to evaluate test results for cancer of the prostate. I know that if I am over 50, I should have my prostate evaluated every year with a prostate-specific antigen test, as applicable.

PREVENTION OF MEDICAL COMPLICATIONS:

_____ I agree to take feminizing medications as prescribed, and I agree to tell my clinician if I have any problems or if I am unhappy with the treatment.

_____ I know that the dose and type of medication that is prescribed for me may not be the same as for someone else.

_____ I know that I need periodic physical exams and blood tests to check for any side effects.

_____ I know that feminization medications can interact with other drugs and medicines—including alcohol, diet supplements, herbs, other hormones, and street drugs—causing complications. I know that I need to prevent complications because they can be life-threatening. That's why I need to be honest with my clinician about whatever else I take or use. I also know that this will not interfere with my getting medical care; I will continue to get medical care here no matter what information I share about what I take.

_____ I know that it can be risky for anyone with certain conditions to take feminizing medicines. I agree to be evaluated if my clinician thinks I may have such a condition. Then, we will decide if it's a good idea for me to start or continue using these medications.

_____ I know that I should stop taking estrogen two weeks before any surgery or when I may be immobile for a long time. This will lower the risk of getting blood clots. I know that I can start taking estrogen again a week after I'm back to normal or when my clinician says it's okay.

_____ I know that using these medicines to appear more womanly is an "off-label" use. I know that this means that using these medicines for this purpose is not approved by the Food and Drug Administration (FDA). I know that the medicine and dose that is recommended for me is based on the judgment and experience of the clinician.

_____ I know that I can choose to stop taking these medicines at any time. I know that if I decide to do that, I should do it with the help of my clinician. This will help me make sure there are no negative reactions. I also know that my clinician may suggest that I cut the dose or stop taking it altogether if certain conditions develop. This may happen if the side effects are severe or if there are health risks that cannot be controlled.

MY SIGNATURE BELOW CONFIRMS THAT:

- My clinician has talked with me about:
  - The benefits and risks of taking feminizing medication.
  - The possible or likely consequences of hormone therapy.
  - Potential alternative treatments.
- I understand the risks that may be involved.
- I know that the information in this form includes the known effects and risks. I also know that there may be unknown long-term effects or risks.
- I have had enough opportunity to discuss treatment options with my clinician.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to take, refuse, or postpone therapy with feminizing medications.
- I am 18 years old or older.

BASED ON ALL THIS INFORMATION:

_____ I want to begin taking estrogen.

_____ I want to begin taking androgen antagonists (e.g., spironolactone).

_____ I do not wish to begin taking feminizing medication at this time.

_____ _____
Patient's Signature *Date*

_____ _____
Prescribing Physician's Signature *Date*

Your health is important to us. If you have any questions or concerns, please come to sick call and an appointment with your PA/Physician will be made.

APPENDIX 3. MASCULINIZING GENDER-AFFIRMING HORMONE TREATMENT FOR TG PATIENTS – CONSENT AND COUNSELING FORM

A sample ***Consent and Counseling Form*** for masculinizing gender-affirming hormone treatment for **TG** patients appears on the next four pages.

MASCULINIZING GENDER-AFFIRMING HORMONE TREATMENT FOR TRANSGENDER PATIENTS
CONSENT AND COUNSELING FORM

INSTITUTION NAME: _____

PATIENT NAME: _____ **ID #:** _____

You have expressed a desire to take testosterone to masculinize your body. Before beginning treatment, there are several details about treatment that you need to be familiar with, including the possible advantages, disadvantages, risks, warnings, and alternatives. These topics are covered below. It is important that you understand all of this information before initiating treatment. We are happy to answer *any* questions you might have, so please ask!

WHAT IS TESTOSTERONE?

Testosterone is the hormone responsible for male features. It builds muscle, causes the development of facial hair, and is responsible for the deepening of a person's voice during puberty. Testosterone also may increase sex-drive.

HOW IS TESTOSTERONE TAKEN?

Testosterone is usually injected every one to four weeks. It is not used as a pill because the body may not absorb it properly, and it can cause liver problems. Some people use skin creams and patches, but these are not used in the correctional environment.

The doses used for injections differ from product to product, and from patient to patient. Doses may range from 100 mg to 400 mg. The injections are administered into a large muscle to slow the release of the hormone. There can be unwanted swings in hormone levels. This can be controlled by changing how often the dose is given, how much of a dose is given, or by changing formulations.

WARNING — WHO SHOULD NOT TAKE TESTOSTERONE?

Testosterone should ***not*** be used by anyone who is pregnant or has uncontrolled coronary artery disease.

It should be used ***with caution and only after a full discussion of risks*** by anyone who has: acne, family history of heart disease or breast cancer, blood clot history, high levels of cholesterol, liver disease, or high red-blood-cell count. Caution should also be used in obese patients and persons who smoke.

MONITORING:

Periodic blood tests to check on the effects of the hormone will be required for treatment. Routine breast exams and pelvic exams with pap tests should be continued, when applicable.

BENEFITS AND RISKS OF TESTOSTERONE TREATMENT:

Benefits	Risks

• Appearing more like a man:
  • Larger clitoris*****
  • Coarser skin
  • Deeper voice*****
  • Increased body hair*****
  • Increased facial hair*****
  • Increased muscle mass
  • Increased strength
  • Elimination of menstrual periods
• Increased physical energy
• Protection against bone thinning (osteoporosis)
 	
*****_These are permanent changes._
	• Acne (may permanently scar)
	• Blood clots (thrombophlebitis)
	• Emotional changes
	• Headache
	• High blood pressure (hypertension)
	• Increased red-blood-cell count
	• Infertility
	• Inflamed liver
	• Interaction with drugs for diabetes and blood thinning — e.g., Coumadin and Warfarin
	• Male pattern baldness
	• Increased abdominal fat
	• Increased risk of heart disease
	• Swelling of hands, feet, and legs
	• Weight gain

Please review and initial each statement to show that you understand the benefits, risks, and changes that may occur from taking these medications. At the end of the document, indicate your preference regarding hormone therapy, then sign and date it.

MASCULINIZING EFFECTS OF TESTOSTERONE:

_____ I know that testosterone may be prescribed to make me appear less like a woman and more like a man.

_____ I know that it can take several months or longer for the effects to become noticeable.

_____ I know that no one can predict how fast or how much change will take place.

_____ ***I know that the changes may not be complete for two to five years after starting testosterone.***

_____ ***I know the following changes are likely to be permanent, even if I stop taking testosterone:***

- Bigger clitoris — typically about half an inch to a little more than an inch
- Deeper voice
- Growth of facial hair (moustache and beard)
- Hair loss at the temples and crown of the head and the possibility of becoming completely bald
- More, thicker, and coarser hairs on abdomen, arms, back, chest, and legs

_____ I know that the following changes are usually ***not permanent*** and will likely go away if I stop taking testosterone:

- Acne (however, acne scars will be permanent)
- Elimination of menstrual periods (typically stop one to six months after starting testosterone)
- Increased abdominal fat (redistribution of fat to a more masculine shape)
- Decreased fat on buttocks, hips, and thighs
- More muscle mass and strength
- Vaginal dryness

_____ I know that the effects of testosterone on fertility are unknown. I have been told that I may or may not be able to get pregnant even if I stop taking testosterone. I know I might still get pregnant even after testosterone stops my menstrual periods. I know my birth control options upon release (if applicable). I know I cannot take testosterone if I am pregnant.

_____ I know that some aspects of my body will not be changed:

- Losing some fat may make my breasts appear slightly smaller, but they will not shrink very much.
- Although my voice may deepen, other aspects of the way I speak will not change.

_____ I know that there are other treatments that may be helpful to make my breasts smaller or my speech manlier. If I have concerns, I can discuss treatment options with my clinician.

RISKS OF TESTOSTERONE:

_____ I know that the medical effects and safety of testosterone are not completely known. There may be long-term risks that are not yet known.

_____ I know not to take more testosterone than prescribed. I know this would be a risk to my health. I know that taking more testosterone than I am prescribed will not make changes happen more quickly or more significantly. I know that my body can convert extra testosterone into estrogen, which can slow down or reverse the progress of my transition.

_____ I know that testosterone can cause changes that increase my risk of heart disease. I know these changes include:

- Less good cholesterol (HDL), which is needed to protect against heart disease, and more bad cholesterol (LDL), which may increase the risk of heart disease
- Higher blood pressure
- Increased deposits of fat around my internal organs

_____ I know that my risk of heart disease is higher if people in my family have had heart disease, if I am overweight, or if I smoke.

_____ I know that I should have periodic heart-health checkups for as long as I take testosterone. I know I must watch my weight and cholesterol levels and have them checked by my clinician.

_____ I know that testosterone can damage the liver and possibly lead to liver disease. I know I should be checked periodically for possible liver damage for as long as I take testosterone.

_____ I know that testosterone can increase my red blood cell count and hemoglobin. I know the increase is usually only to the level that is normal for a man. I know normal levels would have no health risks; however, higher increases can cause problems that can be life-threatening. These problems include stroke and heart attack. As such, I know I need to have periodic blood checks for as long as I take testosterone.

_____ I know that taking testosterone can increase my risk for diabetes. It may decrease my body's response to insulin, cause weight gain, and increase deposits of fat around my internal organs. I know I should have periodic checks of my blood glucose for as long as I take testosterone.

_____ I know that my body can turn testosterone into estrogen. I know that no one knows if this could increase the risk of cancers of the breast, ovaries, or uterus.

_____ I know that taking testosterone can thin the tissue of my cervix and the walls of my vagina. This can lead to tears or abrasions during vaginal intercourse. I know it does not matter if my partner is a woman or a man. This raises my risk of getting a sexually transmitted infection, including HIV. I know I should speak frankly with my provider regarding the best ways to prevent and check for infections. I am aware that sex between inmates, or between inmates and staff, is not permitted within the BOP.

_____ I know that testosterone can give me headaches or migraines. I know it is best to talk with my clinician if I get them frequently or if the pain is unusually severe.

_____ I know that testosterone can cause emotional changes. For example, I could become more irritable, frustrated, or angry. I know my provider can help me find resources to explore and cope with these changes.

_____ I know that testosterone causes changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones. I know I can reach out to psychology services to help me find support resources. I also know that in the BOP, harassment, discrimination, and violence are not tolerated under any circumstances. If I feel I am the recipient of any of these actions, I will notify a BOP staff member.

PREVENTION OF MEDICAL COMPLICATIONS:

_____ I agree to take testosterone as prescribed, and I agree to tell my clinician if I have any problems or am unhappy with the treatment.

_____ I know that the dose and type of medication prescribed for me may not be the same as it is for someone else.

_____ I know that I need periodic physical exams and blood tests to check for any side effects.

_____ I know that testosterone can interact with other drugs and medicines, including alcohol, diet supplements, herbs, other hormones, and street drugs. This kind of interaction can cause complications. I know that I need to prevent complications because they can be life-threatening. I need to be honest with my clinician about other items I am taking. I also know that this will not interfere with my getting medical care; I will continue to get medical care here no matter what information I share about what I take.

_____ I know that it can be risky for anyone with certain conditions to take testosterone. I agree to be evaluated if my clinician thinks I may have one of these conditions. Then, we will decide if it is a good idea to start or continue using testosterone.

_____ I know that using testosterone to appear more masculine is an "off-label" use. I know this means it is not approved by the Food and Drug Administration (FDA) for this purpose. I know the medicine and dose recommended for me is based on the judgment and experience of the clinician.

_____ I know that I can choose to stop taking testosterone at any time. I know if I decide to stop, I should discontinue with the help of my clinician to ensure there are no negative reactions. I know my clinician may suggest I cut the dose or stop taking it altogether if certain medical conditions develop. This may happen if the side effects are severe or if there are health risks that cannot be controlled.

MY SIGNATURE BELOW CONFIRMS THAT:

- My clinician has talked with me about:
  - The benefits and risks of taking testosterone.
  - The possible or likely consequences of hormone therapy.
  - Potential alternative treatments.
- I understand the risks that may be involved.
- I know that the information in this form includes the known effects and risks. I also know that there may be unknown long-term effects or risks.
- I have had enough opportunity to discuss treatment options with my clinician.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to take, refuse, or postpone testosterone therapy.
- I am 18 years old or older.

BASED ON ALL THIS INFORMATION:

_____ I want to begin taking testosterone.

_____ I do not wish to begin taking testosterone at this time.

_____ _____

Patient's Signature *Date*

_____ _____

Prescribing Physician's Signature *Date*

Your health is important to us. If you have any questions or concerns, please come to sick call and an appointment with your PA/Physician will be made.

WPATH AND USPATH COMMENT ON THE CASS REVIEW

May 17, 2024

The recently published Cass Review is the result of a four-year investigation initiated by the United Kingdom's National Health Service England (NHSE) into the scientific basis of treating transgender youth and the experiences of those involved in transgender care in the UK. It contains 32 recommendations for a reorganization of transgender care for youth in England and Wales. The review took place after concerns arose around the increase in referrals, the evidence base for gender-affirming medical care, and the functioning of the NHS Tavistock Clinic's Gender Identity Development Service (GIDS), the only national care service with a long history of clinical experience and knowledge, which had operated since 1989 and was closed in March 2024. To date there are no new services in operation, and there will be none in the foreseeable future, despite what NHS England or Hillary Cass may claim. WPATH and USPATH are extremely concerned that this has left young transgender and gender diverse (TGD) people and families with little opportunity to obtain transgender care. This is a devastating situation for transgender youth and their families, whose rights are breached as they are being denied medically necessary care. We believe this to be a complete breach of the seven core values enshrined in the NHS Constitution.

Overall, WPATH and USPATH remain deeply concerned about the facts regarding the Cass Review's process and content, as well as its consequences for the provision of care for trans and gender diverse youth. Here are some of the reasons:

1. NHS England, which commissions and finances specialist medical services, including trans health care for youth and adults in England, appointed Hillary Cass in 2020 without any transparent or competitive process. Hillary Cass is a pediatrician with hardly any clinical experience or expertise in providing transgender healthcare for young people. Furthermore, Hillary Cass lacks significant research qualifications or research expertise in transgender health. Yet, the Cass Review purports to make "evidence-based" recommendations based on six systematic reviews carried out by the University of York in the UK, which do not contain any new research that would contradict the recommendations made in professional consensus guidelines of the American Academy of Pediatrics (AAP), the Endocrine Society, and WPATH to name a few.
2. The Cass Review is hailed by some as an "independent" review, referring to the fact that Hillary Cass had negligible prior knowledge or clinical experience of trans and gender diverse youth or indeed transgender medicine and surgery. One senior psychiatrist at a gender identity clinic in England told a national newspaper in the UK that the failure to include those with personal or professional experience "had concerned many within the field." They said: "The terms of reference stated that the

Cass Review 'deliberately does not contain subject matter, experts or people with lived experience of gender services' and Dr. Cass herself was explicitly selected as a senior clinician 'with no prior involvement … in this area.' Essentially, ignorance of gender dysphoria medicine was framed as a virtue. I can think of no comparable medical review of a process where those with experience or expertise of that process were summarily dismissed." WPATH and USPATH agree completely.

3. In contrast to what the Cass Review recommends, WPATH and USPATH firmly stand by the Standards of Care for the Health of Transgender and Gender Diverse People – version 8, which was published in 2022—and based on far more systematic reviews that the Cass Review—in collaboration with The School of Evidence-based Practice Center at Johns Hopkins University and considers that the (research and consensus-based) evidence is such to recommend that providing medical treatment including puberty-blocking medication and hormone therapy is helpful and often life-saving for young TGD people, while withholding such treatment may lead to increased gender dysphoria and adversely affect psychological functioning. Of note, many countries have reacted critically regarding the Cass Review, disagreeing with its unfounded medical opinion to severely limit the use of puberty-blocking medication and hormone therapy for TGD young people. These countries include Canada, the Netherlands, Belgium, Germany, Austria, Switzerland, and many states in the United States. In Germany, a new guideline on adolescent transgender care has been drafted (in collaboration with Austria and Switzerland) and is currently under review by 27 professional societies. As drafted, this guideline does not restrict puberty blockers and is in broad accordance with the WPATH SOC8 recommendations in its adolescent chapter. The Cass Review appears to be an outlier, ignoring more than three decades of clinical experience in this area as well as existing evidence showing the benefits of hormonal interventions on the mental health and quality of life of gender diverse young people (1-9).
4. WPATH and USPATH also have serious concerns regarding the ethics of the provision of puberty-blocking agents for young TGD people in the United Kingdom in the context of a research protocol only. Care and treatment that is consensus- and expert-based occurs in many areas of medicine, including pediatrics. The use of a randomized blinded control group, which would lead to the highest quality of evidence, is ethically not feasible. It is ethically problematic to induce people to participate in a research project as the only way to access a type of care that is evidence based, widely recognised as medically necessary, and often reported as lifesaving. There is no role in modern medicine for such practices, which are not commensurate with providing the highest standard of care for young people, as the Cass Review allegedly advocates for.

Regardless of what Dr. Cass' intentions may or may not have been, the Cass Review process itself intentionally and explicitly excluded any oversight from patients and their families and trans healthcare experts, and its content is not supported by a robust methodology. The Cass Review relies on selective and inconsistent use of evidence, and its recommendations often do not follow from the data presented in the systematic reviews. The Cass Review deprives young trans and gender diverse people of the high-quality care they deserve and causes immense distress and harm to both young patients and their families.

Editor's note: This statement has been adjusted to reflect the fact that the German guideline for adolescent transgender care is still under review.

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United States | Marking their own homework

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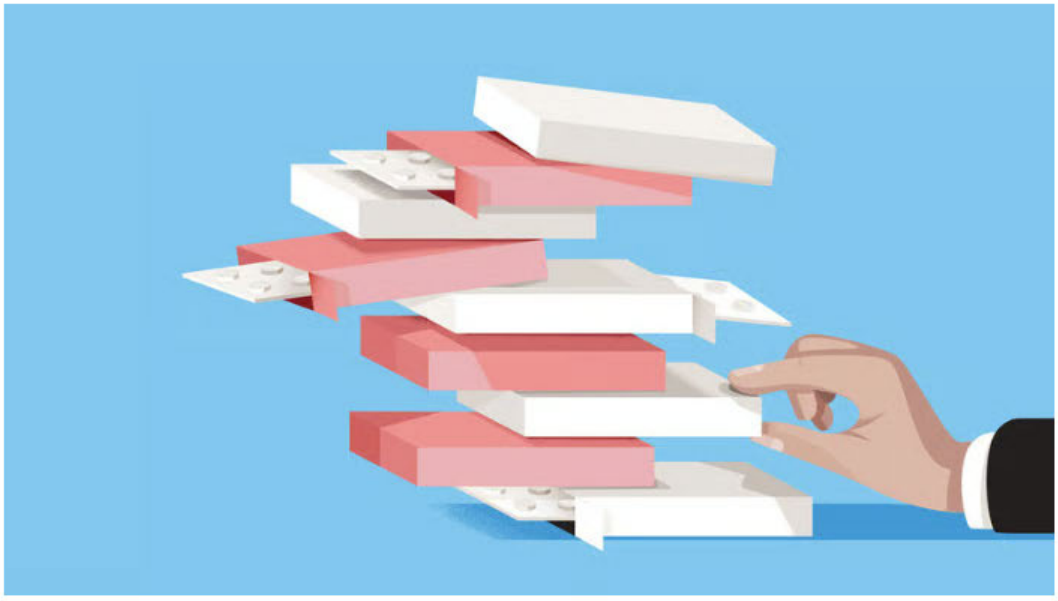

ILLUSTRATION: NATHALIE LEES

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IN APRIL HILARY CASS, a British paediatrician, published her review of gender-identity services for children and young people, commissioned by NHS England. It cast doubt on the evidence base for youth gender medicine. This prompted the World Professional Association for Transgender Health (WPATH), the leading professional organisation for the doctors and practitioners who provide services to trans people, to release a blistering rejoinder. WPATH said that its own guidelines were sturdier, in part because they were "based on far more systematic reviews".

Systematic reviews should evaluate the evidence for a given medical question in a careful, rigorous manner. Such efforts are particularly important at the moment,

given the feverish state of the American debate on youth gender medicine, which is soon to culminate in a Supreme Court case challenging a ban in Tennessee. The case turns, in part, on questions of evidence and expert authority.

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Court documents recently released as part of the discovery process in a case involving youth gender medicine in Alabama reveal that WPATH's claim was built on shaky foundations. The documents show that the organisation's leaders interfered with the production of systematic reviews that it had commissioned from the Johns Hopkins University Evidence-Based Practice Centre (EPC) in 2018.

From early on in the contract negotiations, WPATH expressed a desire to control the results of the Hopkins team's work. In December 2017, for example, Donna Kelly, an executive director at WPATH, told Karen Robinson, the EPC's director, that the WPATH board felt the EPC researchers "cannot publish their findings independently". A couple of weeks later, Ms Kelly emphasised that, "the [WPATH] board wants it to be clear that the data cannot be used without WPATH approval".

Ms Robinson saw this as an attempt to exert undue influence over what was supposed to be an independent process. John Ioannidis of Stanford University, who co-authored guidelines for systematic reviews, says that if sponsors interfere or are allowed to veto results, this can lead to either biased summaries or suppression of unfavourable evidence. Ms Robinson sought to avoid such an outcome. "In general, my understanding is that the university will not sign off on a contract that allows a sponsor to stop an academic publication," she wrote to Ms Kelly.

Months later, with the issue still apparently unresolved, Ms Robinson adopted a sterner tone. She noted in an email in March 2018 that, "Hopkins as an academic institution, and I as a faculty member therein, will not sign something that limits academic freedom in this manner," nor "language that goes against current standards in systematic reviews and in guideline development".

Not to reason XY

Eventually WPATH relented, and in May 2018 Ms Robinson signed a contract granting WPATH power to review and offer feedback on her team's work, but not to meddle in any substantive way. After WPATH leaders saw two manuscripts submitted for review in July 2020, however, the parties' disagreements flared up again. In August the WPATH executive committee wrote to Ms Robinson that WPATH had "many concerns" about these papers, and that it was implementing a new policy in which WPATH would have authority to influence the EPC team's output—including the power to nip papers in the bud on the basis of their conclusions.

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Ms Robinson protested that the new policy did not reflect the contract she had signed and violated basic principles of unfettered scientific inquiry she had emphasised repeatedly in her dealings with WPATH. The Hopkins team published only one paper after WPATH implemented its new policy: a 2021 meta-analysis on the effects of hormone therapy on transgender people. Among the recently released court documents is a WPATH checklist confirming that an individual from WPATH was involved "in the design, drafting of the article and final approval of [that] article". (The article itself explicitly claims the opposite.) Now, more than six years after signing the agreement, the EPC team does not appear to have published anything else, despite having provided WPATH with the material for six systematic reviews, according to the documents.

No one at WPATH or Johns Hopkins has responded to multiple inquiries, so there are still gaps in this timeline. But an email in October 2020 from WPATH figures, including its incoming president at the time, Walter Bouman, to the working group on guidelines, made clear what sort of science WPATH did (and did not) want published. Research must be "thoroughly scrutinised and reviewed to ensure that publication does not negatively affect the provision of transgender health care in the broadest sense," it stated. Mr Bouman and one other coauthor of that email have been named to a World Health Organisation advisory board tasked

with developing best practices for transgender medicine.

Another document recently unsealed shows that Rachel Levine, a trans woman who is assistant secretary for health, succeeded in pressing WPATH to remove minimum ages for the treatment of children from its 2022 standards of care. Dr Levine's office has not commented. Questions remain unanswered, but none of this helps WPATH's claim to be an organisation that bases its recommendations on science. ■

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This article appeared in the United States section of the print edition under the headline "Marking their own homework"

Correctional Health Policy Priorities Discussed on 11/12/2025

1. Continuity of Coverage & Benefits at Release (ACA/Medicaid/SNAP)	Protect and streamline continuity of coverage and benefits at release—maintain ACA gains, prevent unnecessary Medicaid/SNAP interruptions, and ensure warm handoffs to community care to reduce recidivism.
2. Elderly & Long-Term Care Placement (Incentives & Support)	Create federal incentives and support mechanisms for nursing homes and long-term care facilities to accept elderly or medically complex individuals leaving prison, including those with felony/sex-offense histories; support state-run options where needed.
3. Group Purchasing: Drugs & EHR Systems	Establish national group purchasing for pharmaceuticals and correctional EHR systems to leverage scale and reduce total cost of care and technology.
4. Hepatitis C Access & Elimination	Establish a national corrections-inclusive Hepatitis C elimination strategy by expanding funding and enabling large-scale purchasing to reduce drug costs and ensure universal access to curative therapy in custody and through reentry.
5. Legal/Policy Clarity (SSA 1905(a), 42 CFR 411.4(b), Transgender Care)	Clarify statutory and regulatory requirements affecting correctional healthcare—including SSA §1905(a) inmate exclusion and 42 CFR §411.4(b)—and provide clear federal guidance on standards of care for transgender individuals in custody.
6. Leverage Opioid Settlement Funds in Corrections	Direct a portion of opioid settlement funds to evidence-based correctional healthcare and reentry services for substance use disorders.
7. Medicaid Coverage Expansion (Outpatient/Off-site & Undo Carve-outs)	Remove Medicaid carve-outs and allow reimbursement for medically necessary off-site and outpatient services for incarcerated individuals—including imaging, chemotherapy, specialty visits—and permit community providers to bill Medicaid; maintain eligibility pre-adjudication.
8. Medicare Eligibility & Coverage for Elderly/Disabled (Outside Services)	Enable Medicare Part A/B coverage for incarcerated beneficiaries who are 65+ or disabled, at least for outside services, ending punitive suspensions and aligning with clinical need.
9. Protect 340B for Corrections	Preserve and strengthen correctional eligibility for the 340B Drug Pricing Program, opposing rebate-model shifts or policy erosions that would increase net drug costs for incarcerated populations.
10. Substance Use Treatment: Expand MAT (incl. Methadone & LAIs)	Expand access to medication-assisted treatment in corrections, including reducing barriers to methadone and supporting long-acting injectable formulations for OUD to improve adherence and reduce diversion.
11. Targeted Medicaid Strategy: Support 1115 Waivers Where Feasible	Support state pursuit of Medicaid §1115 waivers where administratively feasible and cost-effective, without a universal mandate, to pilot expanded coverage models for justice-involved people.
12. Training Pipeline: Correctional Medicine Residencies/Fellowships	Create and fund correctional medicine residencies, internships, and fellowships in partnership with academic health centers to build a sustained clinical workforce.
13. Workforce: HRSA Funding & Loan Repayment (incl. Mental Health)	Increase HRSA funding and explicitly designate jails and prisons as eligible shortage areas for loan repayment and recruitment programs, with emphasis on mental health clinicians.

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Corrected: Risk of Suicide and Self-Harm Following Gender-Affirmation Surgery

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This article has been corrected.

Correction date: June 11, 2024. Cite this correction as Straub J J, Paul K K, Bothwell L G, et al. (June 11, 2024) Correction: Risk of Suicide and Self-Harm Following Gender-Affirmation Surgery. Cureus 16(6): c182. doi:10.7759/cureus.c182.

This article has been corrected by the Editors-in-Chief to clarify the conclusions of the study. Two sentences have been revised as detailed below. The authors agree with these corrections.

- Original abstract conclusions: "Gender-affirming surgery is significantly associated with elevated suicide attempt risks, underlining the necessity for comprehensive post-procedure psychiatric support."

  Corrected to: "Patients who have undergone gender-affirming surgery are associated with a significantly elevated risk of suicide, highlighting the necessity for comprehensive post-procedure psychiatric support."

- Original first sentence of the Conclusions section: "The results of this study show that gender-affirmation surgery is associated with a significantly higher risk of suicide, death, suicide/self-harm, and PTSD compared to control groups in this real-world database."

  Corrected to: "The results of this study indicate that patients who have undergone gender affirmation surgery are associated with significantly higher risks of suicide, self-harm, and PTSD compared to general population control groups in this real-world database."

Abstract

Introduction

With the growing acceptance of transgender individuals, the number of gender affirmation surgeries has increased. Transgender individuals face elevated depression rates, leading to an increase in suicide ideation and attempts. This study evaluates the risk of suicide or self-harm associated with gender affirmation procedures.

Methods

This retrospective study utilized de-identified patient data from the TriNetX (TriNetX, LLC, Cambridge, MA) database, involving 56 United States healthcare organizations and over 90 million patients. The study involved four cohorts: cohort A, adults aged 18-60 who had gender-affirming surgery and an emergency visit (N = 1,501); cohort B, control group of adults with emergency visits but no gender-affirming surgery (N = 15,608,363); and cohort C, control group of adults with emergency visits, tubal ligation or vasectomy, but no gender-affirming surgery (N = 142,093). Propensity matching was applied to cohorts A and C. Data from February 4, 2003, to February 4, 2023, were analyzed to examine suicide attempts, death, self-harm, and post-traumatic stress disorder (PTSD) within five years of the index event. A secondary analysis involving a control group with pharyngitis, referred to as cohort D, was conducted to validate the results from cohort C.

Results

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Individuals who underwent gender-affirming surgery had a 12.12-fold higher suicide attempt risk than those who did not (3.47% vs. 0.29%, RR 95% CI 9.20-15.96, p < 0.0001). Compared to the tubal ligation/vasectomy controls, the risk was 5.03-fold higher before propensity matching and remained significant at 4.71-fold after matching (3.50% vs. 0.74%, RR 95% CI 2.46-9.024, p < 0.0001) for the gender affirmation patients with similar results with the pharyngitis controls.

Conclusion

Patients who have undergone gender-affirming surgery are associated with a significantly elevated risk of suicide, highlighting the necessity for comprehensive post-procedure psychiatric support.

Categories: Psychiatry, Psychology, Public Health
Keywords: self-harm, post traumatic stress disorder (ptsd), suicide, transgender, gender affirmation

Introduction

The prevalence of transgender individuals in the United States is approximately 0.3% to 0.6% of the adult population based on self-reporting studies [1]. Investigations that only include individuals with transgender diagnostic codes, hormone therapy, or gender-affirming surgery report a much lower rate of approximately 0.008% of the population [2]. People who identify as transgender are shown to have a higher risk of suicide in the United States and across many other countries [3-6].

In 2021, the Centers for Disease Control reported that 48,183 people died by suicide in the United States. Depression, substance abuse, other mental illness, legal/financial problems, harmful relationships, community risk factors, and easy access to lethal means are contributing factors to successful suicide. Transgender individuals have a higher prevalence of depression across several age groups, often due to life experiences that include discrimination, harassment, violence, misgendering, and enacted stigma that may generate poor mental health outcomes and harmful behaviors [4,7,8]. It is widely accepted that depression puts an individual at higher risk for suicidal ideation and suicide attempts [9]. Individuals at higher risk for suicide and post-traumatic stress disorder (PTSD) should have comprehensive psychiatric interventions and care throughout their lifetime. A better understanding of the relationship between suicide and gender affirmation remains particularly important.

There is ongoing controversy surrounding the benefits of gender-affirmation surgery on mental health [10-20]. This controversy reflects diverse perspectives within the medical and research communities, emphasizing the need for a more comprehensive understanding of the psychological outcomes of gender-affirming procedures. Despite the increasing acceptance of transgender individuals, questions persist about the psychological outcomes of gender-affirming procedures. Responses to the discussion surrounding the benefits of gender-affirmation surgery have been diverse, as evidenced by studies conducted by Branstrom and colleagues [11], Almazan et al. [13], and others [10,14-20].

The purpose of this study is to assess the risk of adverse outcomes, specifically suicide, death, self-harm, and PTSD in the five years following gender-affirmation surgery. Suicide risk over time among patients who received gender-affirmation surgery is compared to individuals in several control groups. The TriNetX (TriNetX, LLC, Cambridge, MA) database will be utilized to better understand the relationship between sex change and these outcomes.

This article was previously presented virtually as a meeting abstract at the 2023 Texas College of Emergency Physicians (TCEP) Research Forum on April 07, 2023.

Materials And Methods

TriNetX is a global health research network providing access to de-identified retrospective electronic medical records. The database consists of over 90 million patients from 56 healthcare organizations (HCOs) within the United States. This study utilized TriNetX to identify patients who had a “personal history of sex reassignment” and evaluate their relative risk for suicide attempt, death, suicide/self-harm, and PTSD. The term “sex reassignment” was based on the International Classification of Diseases, 10th Revision (ICD-10) code in the database but will be referred to as the current term “gender-affirmation surgery” for the remaining article. All outcomes were evaluated during the five years after gender-affirmation surgery.

Patients who have undergone gender-affirmation surgery of all sexes, races, and ethnicities were identified by using the ICD-10 code, ICD10CM:Z87.890. Sex, race, and ethnicity were derived from the electronic medical record. Patients who have undergone gender-affirmation surgery are identified by their affirmed gender. A total of four cohorts were identified for this study. Cohort A consisted of patients ages 18 to 60 who had both gender-affirmation surgery and an emergency visit. Cohort B was the study control group that consisted of patients ages 18 to 60 who had no history of gender-affirmation surgery but had an emergency visit. In this database, propensity matching is not possible for very large cohorts, more than 8.3 million patients with 12 covariates.

Additional control groups were chosen to perform propensity matching, which controls for confounders. Cohort C was the study's second control group and consisted of adult patients (18-60 years) who had no history of gender-affirmation surgery, had an emergency visit, and had a tubal ligation or vasectomy. Patients who had undergone tubal ligation were identified through the ICD-10 code, ICD10CM:Z98.51, while the vasectomy procedure was identified by Current Procedural Terminology (CPT), CPT:55250. A secondary sub-group analysis, cohort D, was performed utilizing acute pharyngitis (ICD10CM:J02) as a control group for patients aged 18-60 that was run on June 2, 2023. This was performed to ensure that the vasectomy or bilateral tubal ligation (BTL) group acted as an appropriate control. The relative risk for suicide attempt, death, suicide/self-harm, and PTSD was evaluated during the five years following gender-affirmation surgery in comparison to those without gender-affirmation surgery with the diagnosis of pharyngitis. Cohort A was used again and compared with cohort D, which included patients presenting to the emergency room after diagnosis of acute pharyngitis.

The outcome analysis between the three cohorts was performed for four events: suicide attempt (ICD10CM:T14.91), death (vital status: deceased), suicide/self-harm (ICD10CM:T14.91 or ICD10CM:X71-X83), and PTSD (ICD10CM:F43.1). An analysis was performed utilizing the measures contained in the TriNetX platform, which compared the individual outcomes between cohorts A and B and also cohorts A and C within the designated time frame. Patients who had the outcome before the time window were excluded from the analysis. The final TriNetX data reported RR, 95% CI, ORs, and a risk comparison expressed as a p-value. To control potentially confounding risk factors for the measured outcomes, the propensity matching tool in TriNetX was utilized. Factors involved in the data propensity matching are based on age at index, race, ethnicity, and sex. Propensity matching was only performed between the comparison of cohorts A and C, but not cohort B, due to the large sample size limitation.

Propensity score matching (PSM) is often used in observational studies to reduce confounding biases. It has been investigated and well-documented regarding its properties for statistical inference. PSM is a quasi-experimental method in which the researcher uses statistical techniques to construct an artificial control group by matching the affected group with a non-affected group of similar characteristics. Using these matches, the researcher can estimate the difference between both groups without the confounding variables' influence [21]. To justify our use of propensity matching for age, race, sex, and ethnicity, we considered established risk factors for suicide such as older age, male gender identity, and racial or ethnic minority status [3,4].

The cohort was analyzed descriptively using univariate and bivariate frequencies with chi-square and t-testing to assess differences. All eligible persons in the cohort were analyzed using both binary event estimation with RRs, 95% CIs, and probability values. Using the TriNetX database, a 1:1 propensity match using linear and logistic regression for age, sex, race, and ethnicity was employed for maximum generalization of the United States population. Greedy nearest-neighbor matching was used with a tolerance of 0.1 and a difference between propensity scores less than or equal to 0.1. Comparisons were made between cohorts before and after propensity matching. Statistical significance was set at a two-sided alpha <0.05. TriNetX provides data that have been de-identified, and as a result, an Institutional Review Board (IRB) review is not required for this study [22]. Three comparison reports were generated on February 4, 2023. Data gathered from HCOs was from February 4, 2003, to February 4, 2023.

Results

We identified 15,609,864 adult patients from TriNetX who were adults and had a visit to an emergency department within the United States Collaborative Network. Cohort A consisted of 1,501 adult patients who had a visit to the emergency department and a history of gender-affirmation surgery. Cohort B consisted of 15,608,363 patients who had an emergency visit but no history of gender-affirmation surgery. Cohort C consisted of 142,093 adult patients who had a visit to the emergency department and no history of gender-affirmation surgery but had a vasectomy or BTL.

Without propensity matching between cohorts A and B, patients with a history of gender-affirmation surgery exhibited a significantly higher risk for each possible outcome compared to patients without a history of gender-affirmation surgery (Table *1*). Patients who had a history of gender-affirmation surgery had a 12.12 times greater risk of suicide attempts (3.47% vs. 0.29%, RR 95% CI 9.20-15.96, $p < 0.0001$) vs. patients who had no history of gender-affirmation surgery. In patients with a history of gender-affirmation surgery, there was a 3.35 times greater risk of being deceased (4.9% vs. 1.5%, RR 95% CI 2.673-4.194, $p < 0.0001$). Patients with a history of gender-affirmation surgery had a 9.88 times higher risk of self-harm or suicide (4.5% vs. 0.5%, RR 95% CI 7.746-12.603, $p < 0.0001$). Lastly, patients who had a history of gender-affirmation surgery had a 7.76 times higher risk of PTSD (9.2% vs. 1.2%, RR 95% CI 6.514-9.244, $p < 0.0001$).

Outcomes	Cohort A	Cohort B	RR (95% CI)	p-value
Suicide attempts	3.50%	0.30%	12.12 (9.202, 15.958)	<0.0001
Deceased	4.90%	1.50%	3.348 (2.673, 4.194)	<0.0001
Suicide or self-harm	4.50%	0.50%	9.880 (7.746, 12.603)	<0.0001
PTSD	9.20%	1.20%	7.760 (6.514, 9.244)	<0.0001

TABLE 1: Outcomes following gender-affirmation surgery (cohort A) vs. no history of gender-affirmation surgery (cohort B)

PTSD, post-traumatic stress disorder

Before the propensity matching of cohorts A and C, there was a significantly higher risk for each outcome when considering patients with a history of gender-affirmation surgery compared to those without a history of gender-affirmation surgery but with a prior vasectomy or BTL (Table *2*). Patients with a history of gender-affirmation surgery had a 5.03 times higher risk of suicide attempts (3.5% vs. 0.7%, RR 95% CI 3.795-6.676, p < 0.0001), a 2.37 times higher risk of being deceased (4.9% vs. 2.1%, RR 95% CI 1.889-2.982, p < 0.0001), a 5.44 times higher risk of suicide or self-harm (4.5% vs. 0.8%, RR 95% CI 4.233-6.981, p < 0.0001), and a 3.74 times higher risk of PTSD (9.2% vs. 2.5%, RR 95% CI 3.125-4.463, p < 0.0001) compared to patients without a history of gender-affirmation surgery but with a prior vasectomy or BTL.

Outcomes	Cohort A	Cohort C	RR (95% CI)	p-value
Suicide attempts	3.50%	0.70%	5.03 (3.795, 6.676)	<0.0001
Deceased	4.90%	2.10%	2.37 (1.889, 2.982)	<0.0001
Suicide or self-harm	4.50%	0.80%	5.44 (4.233, 6.981)	<0.0001
PTSD	9.20%	2.50%	3.74 (3.125, 4.463)	<0.0001

TABLE 2: Outcomes following gender-affirmation surgery (cohort A) vs. vasectomy/tubal ligation (cohort C) before propensity matching

PTSD, post-traumatic stress disorder

After propensity matching of cohorts A and C, each cohort had 1,489 patients of similar age at index, race, and ethnicity (Tables *3*-*4*). Patients who had a history of gender-affirmation surgery compared to patients without a gender-affirmation surgery history but had a vasectomy or BTL showed significantly higher risks for each outcome (Table *3*). The adjusted suicide attempt risk for patients with gender-affirmation surgery compared to no history of gender-affirmation surgery but with a prior BTL or vasectomy was adjusted to a 4.71 times greater risk (3.50% vs. 0.74%, RR 95% CI 2.46-9.024, p < 0.0001). The risk of being deceased was 4.26 times greater in patients with a history of gender-affirmation surgery vs. patients with no history of gender-affirmation surgery but vasectomy or BTL (4.9% vs. 1.1%, RR 95% CI 2.520-7.191, p < 0.0001). Patients with a history of gender-affirmation surgery showed a 5.10 times higher risk of suicide or self-harm compared to patients with no history of gender-affirmation surgery but vasectomy or BTL (4.5% vs. 0.9%, RR 95% CI 2.816-9.227, p < 0.0001). Lastly, patients with a history of gender-affirmation surgery showed a 3.23 times higher risk for PTSD compared to patients with no history of gender-affirmation surgery but vasectomy or BTL (9.2% vs. 2.8%, RR 95% CI 2.278-4.580, p < 0.0001).

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Outcomes	Cohort A	Cohort C	RR (95% CI)	p-value
Suicide attempts	3.50%	0.74%	4.71 (2.46, 9.024)	<0.0001
Deceased	4.90%	1.10%	4.26 (2.520, 7.191)	<0.0001
Suicide or self-harm	4.50%	0.90%	5.10 (2.816, 9.227)	<0.0001
PTSD	9.20%	2.80%	3.23 (2.278, 4.580)	<0.0001

TABLE 3: Outcomes following gender-affirmation surgery (cohort A) vs. vasectomy/tubal ligation (cohort C) after propensity matching

PTSD, post-traumatic stress disorder

Demographics	Before propensity score matching		After propensity score matching	
	Cohort A (%)	Cohort C (%)	Cohort A (%)	Cohort C (%)
Total patients	1,501	142,093	1,489	1,489
Age at index ± SD	35.8 ± 11.6	41.1 ± 9.8	35.8 ± 11.6	36.3 ± 11.3
Female	760 (50.7%)	104,631 (76.1%)	760 (51.0%)	752 (50.5%)
Male	732 (48.8%)	32,830 (23.9%)	729 (49.0%)	737 (49.5%)
White	932 (62.1%)	90,431 (65.8%)	924 (62.1%)	892 (59.9%)
American Indian or Alaska Native	15 (1%)	483 (0.4%)	12 (0.8%)	32 (2.1%)
Native Hawaiian or other Pacific Islander	10 (0.7%)	147 (0.1%)	10 (0.7%)	10 (0.7%)
Hispanic or Latino	114 (7.6%)	15,780 (11.5%)	113 (7.6%)	111 (7.5%)
Black or African American	339 (22.6%)	27,253 (19.8%)	339 (22.8%)	345 (23.3%)
Asian	22 (1.5%)	2,073 (1.5%)	22 (1.5%)	19 (1.3%)
Not Hispanic or Latino	1,066 (71.1%)	87,544 (63.7%)	1,059 (71.1%)	1,060 (71.2%)
Unknown race	187 (12.5%)	17, 081 (12.4%)	187 (12.6%)	195 (13.1%)
Unknown ethnicity	320 (21.3%)	34,144 (24.8%)	317 (21.3%)	318 (21.4%)

TABLE 4: Demographics before and after propensity score matching

Cohort A: Adult patients who had a visit to the emergency department and a history of sexual reassignment.

Cohort C: Adult patients who had a visit to the emergency department and no history of sexual reassignment but had a vasectomy or bilateral tubal ligation.

The secondary sub-group analysis utilizing pharyngitis (N = 1,390,880) as a control revealed that patients presenting to the emergency department with a history of gender-affirmation surgery had a 7.95 times greater risk of suicide attempt than patients with pharyngitis (1.5% vs. 0.2%, RR CI 5.379-11.755, $p < 0.0001$), a 3.65 times greater risk of death (4.6% vs. 1.3%, RR CI 2.921-4.563, $p < 0.0001$), a 7.33 times greater risk of suicide or self-harm (2.7% vs. 0.4%, RR CI 5.448-9.850, $p < 0.0001$), and a 4.61 times greater risk of PTSD (9.2% vs. 2.0%, RR CI 3.901-5.438, $p < 0.0001$) compared to patients who were sent to the emergency department following acute pharyngitis. After propensity matching, mortality was 3.59 times greater in patients with a history of gender-affirmation surgery (4.6% vs. 1.3%, RR CI 2.224-5.806, $p < 0.0001$), and PTSD was 5.49 times greater (9.2% vs. 1.7%, RR CI 3.648-8.267, $p < 0.0001$) compared to patients with acute pharyngitis. There were too few suicides or self-harm outcomes to report results from the propensity-matched pharyngitis group. These results were similar to the results with cohort C.

Discussion

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The purpose of this study was to explore the relationship between gender-affirmation surgery and the risk of suicide outcomes compared to two control groups with data from 2003 to 2023. The significance of this investigation lies not only in its scale but also in its methodology, as it relies on real-world data rather than meta-analyses and self-reported surveys.

The first controlled group was a large number of patients who had emergency department visits but had not had gender-affirmation surgery. Propensity matching is not possible in the TriNetX database for large groups with millions of patients like the first control group. The second control group consisted of individuals who had not had gender-affirmation surgery but had either a vasectomy or BTL. This control group was selected to allow for propensity matching. Propensity matching was done for this comparison to control for the confounding influence of age, sex, and race/ethnicity. This is particularly important since the rate of successful suicide is much higher in men. At the start of this study, the hypothesis that was proposed predicted individuals who had undergone gender-affirmation surgery would have a greater risk of suicide, death, and self-harm compared to the two controls. This was confirmed by comparing the two control groups. In the second analysis, it was determined that patients who had undergone gender affirmation had a statistically significant increase in suicide attempts, death, self-harm, and PTSD after completion of gender affirmation in comparison with those who had undergone BTL or vasectomy and had not undergone gender-affirmation before propensity matching. After propensity matching our cohorts for age at index, race, and ethnicity, we also found a statistically significant increased risk of suicide attempts, death, self-harm/suicide, and PTSD. These outcomes confirmed the hypothesis. The secondary sub-group analysis utilizing pharyngitis as a control showed results that were comparable to the BTL/vasectomy control group, validating cohort C as an appropriate control group for propensity matching.

These data are supported by previous studies from multiple geographic regions of the globe, including Lebanon [3], Turkey [3], Pakistan [4], China [5], and Canada [6], as well as data from within the United States [3-4,6]. The large size of our study is an asset to our findings, which will help further our understanding of the relationship between sex change and suicide. To our knowledge, a study of this size has not been described in the literature. Using two control groups, a) those who had not experienced gender-affirmation surgery and had presented to the emergency department and b) a group that had not experienced gender-affirmation surgery, had visited the emergency department, and had a vasectomy or BTL, also helped effectively control for confounding variables utilizing propensity matching. Over the last 20 years, this study demonstrated a 12.12 times greater risk of suicide utilizing the first control group and a 4.71 to 5.03 times increased risk with the other control groups.

Transgender individuals, encompassing both those seeking gender-affirming surgery and those who have undergone it, demonstrate a significantly elevated risk of developing PTSD compared to the general population [10,23]. Among those who seek access to gender-affirming surgery, the commonality of discrimination, interpersonal assault, and a lack of social support have been identified as influential factors in the development of PTSD within this group [23]. Financial stress and insufficient insurance coverage prove to be significant obstacles for those trying to access gender-affirming surgery. Additionally, the limited availability of medical professionals with expertise in gender-affirming procedures, particularly in areas of lower socioeconomic status, further exacerbates the challenges faced by individuals seeking such care [10]. However, it is important to consider PTSD development in those who have undergone gender-affirming procedures. The emergence of PTSD following surgery often stems from the pre-operative challenges (such as harassment, limited social support, etc.) in conjunction with suboptimal surgical outcomes and insufficient psychiatric assistance.

This study has revealed a significantly elevated prevalence of PTSD in post-operative transgender individuals, with a 7.76-fold increase in comparison to cohort B and a 3.74-fold increased risk compared to cohort C after propensity matching. These findings were consistent with other studies investigated previously. A study conducted by Livingston et al. in 2022 used probabilistic and rule-based modeling on Veterans Health Administration (VHA) records from 1999 to 2021 to assess the differences in PTSD prevalence among 9,995 transgender and 29,985 cisgender veterans (1:3 ratio). They concluded that transgender veterans experienced PTSD at 1.5-1.8 times the rate of veterans identifying as cisgender, especially higher in recent users of VHA services [24]. There have proven to be many obstacles when comparing our findings to other studies assessing general population PTSD risk in those who have undergone gender-affirmation surgery. A 2018 systematic review conducted by Valentine et al. showed that many studies used assessment tools not particularly appropriate for evaluating mental health in transgender or gender non-conforming individuals [25]. The poor psychometric framework has led to many studies not acknowledging confounding and contextual variables, such as exposure to discrimination or minority identity when assessing PTSD in this demographic [10,25]. To avoid the repeated shortcomings of prior research, future studies should employ rigorous and reliable assessment tools such as cross-sectional studies or the collection of prospective data [25]. Improving transgender representation in emerging PTSD treatment trials is another step in improving the understanding and management of PTSD in transgender individuals [10].

In light of the examination of the relationship between gender-affirmation surgery and mental health outcomes discussed in this study, it is imperative to acknowledge the broader landscape of research on this topic. Our investigation contributes broad insight, examining real-world data over two decades and

encompassing a diverse cohort. However, to further expand upon the contextual significance, it is essential to compare findings from other studies that explore multifaceted aspects of mental health post-gender-affirmation surgery. A study published in the American Journal of Psychiatry by Branstrom et al. in October 2019 drew strong conclusions regarding the positive impact of gender-affirmation surgery on mental health [11]. However, the study faced criticism of its methodology, leading to a correction/retraction by the journal's editors that stated, "the results demonstrated no advantage of surgery about subsequent mood or anxiety disorder-related health care visits or prescriptions or hospitalizations following suicide attempts" [12]. In a subsequent study conducted in 2021, Almazan et al. compared the mental health outcomes of a group of patients who were not approved for gender-affirmation surgery with a group that had undergone the surgery [13].

Their findings suggested better mental health outcomes for those who underwent surgery, but notable limitations warrant careful interpretation. First, the study conducted a comparison between two groups: one that had not been approved for surgery, a process requiring two mental health screenings as per the World Professional Association for Transgender Health's standard of care recommendations, and another group that had already undergone surgery. Therefore, it is plausible that the surgery group could inherently have been healthier, irrespective of the surgery. Second, when the analysis was broadened to include lifetime outcomes, the positive association with the surgery became insignificant [14].

Although our study has revealed a statistically significant increase in suicide risk among those who have undergone gender-affirming surgery, it remains vital to recognize and support the positive impacts that these surgical interventions can have on the lives of transgender individuals. The results of a study by Park et al., published in October 2022 in the Annals of Plastic Surgery, provide a different perspective on the enduring effectiveness and consequences of gender-affirmation surgery [20]. While our research specifically examined the risk of suicide, death, self-harm, and PTSD in the five years following surgery, Park et al. surveyed the outcomes of 15 gender-affirming surgeries over a more extended period. Their results reveal an improvement in patient well-being, with high satisfaction levels, reduced dysphoria, and persistent mental health benefits even decades after surgery. Notably, the study highlights the durability of these positive outcomes and significantly reduced suicidal ideation following gender-affirmation surgery.

The number of non-gender-conforming individuals continues to increase globally. It is likely, therefore, that a growing number of medical professionals will care for an individual who has undergone gender-affirmation at some point in their career. Apart from additional assistance in surgical recovery, the most common aftercare needs for patients following gender-affirmation surgery is consultation with a mental health professional [26]. To properly address the mental health needs of transgender individuals, Lapinski et al. emphasize the significance of cultural competency, a patient-focused approach, and collaborative efforts involving psychiatric professionals [27-30]. Transgender individuals tend to see mental health care providers and face discrimination in clinical settings at a far higher rate than the cis-gendered population [27,28,30]. Competent medical care following gender-affirming surgery is vital in effectively managing PTSD and its respective mental health challenges for this population [27].

It is important to note that this study has several limitations. The retrospective cohort design can only demonstrate associations but not causality. However, the larger size of this study, in conjunction with propensity matching, gives this investigation a greater power to identify differences between groups. Additionally, with the extensive timeline of data collection, the findings are relevant and contemporary to modern situations. A limitation of the study design could include the fact that only adult data was analyzed, so the research cannot be generalized to those under the age of 18. The data were also only extracted from a population of residents from the United States. Patients who have undergone gender-affirmation surgery and our control groups may have refrained from disclosing their suicidal ideations or other psychiatric symptoms to their medical providers, potentially influenced by societal pressures or other factors such as perceived attitudes toward those with psychiatric complaints. It may be worth examining if groups considering gender-affirmation surgery who have not yet received the surgery share the same increased risk levels for suicidal actions and ideations. However, given the standard practice of undergoing psychiatric testing before being approved for gender-affirmation surgery, individuals contemplating the procedure may potentially pose a greater suicide risk compared to those who have been approved for surgery.

Conclusions

The results of this study indicate that patients who have undergone gender affirmation surgery are associated with significantly higher risks of suicide, self-harm, and PTSD compared to general population control groups in this real-world database. With suicide being one of the most common causes of death for adolescent and middle-aged individuals, it is clear that we must work to prevent these unfortunate outcomes. This further reinforces the need for comprehensive psychiatric care in the years that follow gender-affirmation surgery.

Appendices

Greedy nearest-neighbor matching

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The most common implementation of propensity matching is pair-matching, in which pairs of treated and control participants are formed. There are several common implementations of pair-matching. The most commonly used is greedy nearest-neighbor matching (NNM), which we used, in which a treated participant is selected at random and then matched to the control participant whose propensity score is closest to that of the treated participant. The process is described as greedy because, at each stage, the control is selected who is closest to the currently considered treated participant, even if that untreated participant would serve better as a control for a subsequently treated participant. This process is then repeated until a matched control participant has been selected for each treated participant. This process generally uses matching without replacement so that once a control participant is matched to a treated participant, that control participant is no longer available to match to a subsequently treated participant. A refinement to NNM is NNM with a caliper restriction. Using this approach, a control participant is an acceptable match for a treated participant only if the difference in their propensity scores is less than a maximum amount (the caliper width or distance). For technical reasons, one typically matches the logit of the propensity score and uses a caliper width that is defined as a proportion of the (0.1-0.2) SD of the logit of the propensity score. A crucial step in any study that uses PSM is to assess the degree to which matching the propensity score resulted in the formation of a matched sample in which the distribution of baseline characteristics is similar between treated and control participants. This assessment is critical as it allows both the researcher and readers to assess whether matching the estimated propensity score has removed systematic baseline differences between treatments. The use of the standardized difference, which is the difference in means in units of SD, is often used for assessing the similarity of matched treated and control participants. Some authors have suggested that a threshold of 0.10 (or 10%) be used to denote acceptable balance after matching. Once an acceptable balance has been achieved, analysts can unblind themselves to the outcome and compare outcomes between treated and control participants in the matched sample. The analyses conducted in the propensity score-matched sample can be similar to those that would be done in an RCT with a similar outcome.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

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Body

ABSTRACT

The long thoracic nerve's (LTN) superficial location on the chest wall renders it vulnerable to iatrogenic injury. Plastic surgeons' gender-affirming mastectomy volumes are rapidly increasing. This operation involves lateral chest contouring placing the distal LTN at risk of injury along the chest wall. Although proximal LTN injury can cause debilitating shoulder dysfunction, more distal injury can cause chronic postoperative shoulder pain and dysfunction without frank scapular winging, making diagnosis and treatment difficult. Therefore, injury is best avoided. In this study, the course of the LTN relative to the lateral border of the pectoralis major muscle was mapped to delineate and define a danger zone for LTN injury in gender-affirming mastectomy. The course of the LTN along the lateral chest wall relative to the pectoralis major lateral border was prospectively mapped using intraoperative nerve stimulation. Twelve individuals were enrolled. The LTN was mapped bilaterally and was most reliably located directly lateral to the intersection of the 4th rib and the lateral border of the pectoralis major muscle. The LTN was found a median of 4.3cm (interquartile range [IQR] = 0.9cm) lateral to the pectoralis major at the 3rd rib level, 5.0cm (IQR = 0.5cm) lateral to the pectoralis border at the 4th rib level, and 7.0cm (IQR = 0.5cm) lateral to the pectoralis border at the 5th rib level. In conclusion, this study defines a danger zone for LTN injury in gender-affirming mastectomy. With recent increases in the number of plastic surgeons performing gender-affirming mastectomies, awareness of this LTN danger zone is important to avoid iatrogenic injuries.

FULL TEXT

The long thoracic nerve (LTN) is a motor nerve responsible for the innervation of the serratus anterior (SA) muscle which stabilizes the scapula against the chest wall during upper extremity motion. The proximal LTN originates from the roots of the fifth, sixth, and seventh cervical rami, traversing dorsal to the brachial plexus and axillary artery, passes adjacent to the clavicle at the level of the first rib, and distally lies along the chest wall between ribs 2 through 9 on the superficial surface of the SA, [1] where it is particularly susceptible to injury in surgery. [2] [3] The rate of *distal* LTN injury and the subsequent deficits are not well described in the literature because proximal innervation is maintained to the upper slips of the SA preventing clinically apparent scapular winging. However, injury of the distal portion of the LTN and subsequent denervation of the lower SA can result in persistent shoulder pain and less pronounced symptoms of instability with either subclinical, asymptomatic, or partial scapular winging. [4] [5] While it is difficult to diagnose distal LTN injury clinically and therefore difficult to quantify, it is the senior author's experience seeing referrals for chronic postoperative pain following gender-affirming mastectomy involving significant lateral chest wall contouring that this problem is more common than realized.

The proximal portion of the infraclavicular LTN from the 1st through 3rd ribs has a known risk of iatrogenic injury during procedures such as scalenectomy, surgery for thoracic outlet syndrome, first rib resection, and mastectomy with axillary dissection. The distal portion of the LTN from rib levels 4 to 9 is in the surgical field in many procedures of the chest, such as thoracotomy, [6] and several studies defined a danger zone for LTN injury in thoracic surgery. [2] [7] [8] LTN injury during oncologic mastectomy has also been well documented in the surgical oncology literature, [9] [10]

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and landmarks to help identify and protect the LTN during oncologic surgery of the breast and axilla have been proposed. [11] While injuries to the LTN have been occasionally described in the plastic surgery literature, [12] [13] no studies to date discuss the anatomy of the LTN in the context of gender-affirming mastectomy.

Gender-affirming mastectomy is a surgical procedure that has seen large annual growth due to improvements in insurance coverage and accessibility of care for transgender patients. [14] This translates clinically to a significant increase in the number of mastectomy procedures being performed by plastic surgeons. Although many plastic surgeons are trained to perform breast reconstruction, oncologic mastectomy has typically been performed by general and oncologic breast surgeons. Mastectomy therefore represents a relatively recent addition to the breadth of practice for many plastic surgeons and the plastic surgery literature lacks any report of the anatomy of the LTN as it relates specifically to gender-affirming mastectomy procedures. In addition, gender-affirming mastectomy places the LTN at higher risk of injury than other breast procedures as it often requires significant lateral chest wall contouring to address the “bra roll” of the lateral chest which can be a significant source of dysphoria. Additionally, the incision itself is relatively superior in this operation with a lateral curve that extends even more superiorly to mirror the lateral border of the pectoralis major muscle bringing the operative field directly over the course of the LTN.

Given the increasing number of gender-affirming mastectomies performed each year and the anatomic factors predisposing the distal LTN to iatrogenic injury during this procedure specifically, there is a need to define a danger zone for iatrogenic LTN injury in gender-affirming mastectomy. The purpose of this study is to identify and define this danger zone using in situ nerve mapping in live patients positioned appropriately for this procedure and provide technical recommendations to decrease the risk of iatrogenic LTN injury in gender-affirming mastectomy procedures.

Patients and methods

Patient population and data analysis

After obtaining IRB approval (STUDY00026655), an observational cross-sectional study was performed involving 12 patients undergoing gender-affirming mastectomy by the senior author. All patients undergoing gender-affirming

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mastectomy during the study period (November 15, 2023 - February 15, 2024) with a BMI <35 were consecutively prospectively enrolled. Patients with a BMI >35 were excluded from the study due to the increased thickness of adipose tissue on the chest wall fascia in these cases making nerve stimulation unreliable. Methodology was conducted in accordance with the STROBE guidelines. Patient demographic data at the time of operation was documented and the location of the LTN was recorded relative to the lateral border of the pectoralis major muscle and the 3rd, 4th, and 5th rib levels bilaterally with intraoperative nerve stimulation as described below. Nerve stimulation was used to map the nerve rather than dissection of the nerve to avoid unnecessary risk of nerve injury associated with nerve dissection that is not clinically indicated. Data were analyzed using descriptive statistics. Shapiro-Wilk testing revealed the location of the nerve to be not normally distributed at rib level 4. The dataset was therefore treated as having a nonparametric distribution and the nerve location between the right and left sides was compared using Mann-Whitney U tests.

Nerve stimulation technique

Gender-affirming mastectomy was performed using a standard double incision technique. [15] At our institution, incision placement may vary slightly depending on patient preference but typically follows the inferior and lateral borders of the pectoralis major. Breast tissue is excised off of the pectoralis fascia and lateral to the pectoralis major muscle a thin layer of adipose tissue is left on top of the fascia of the SA and latissimus dorsi to minimize the risk of iatrogenic injury to the LTN. After the excision of the breast and lateral chest wall tissue, a Checkpoint Nerve Stimulator (Checkpoint Surgical, Independence, OH) was used at 0.5mA to aid in precise localization of the LTN along the fascia of the exposed anterior surface of the SA. This setting was selected as it allows for adequate nerve stimulation specifically and does not cause contraction from direct stimulation of muscle. If paralytic was used for anesthetic induction, it was reversed and robust muscle response was confirmed prior to intraoperative nerve mapping. The distance between the LTN and the lateral border of the pectoralis major was recorded at each rib level where the SA muscle was visible and the LTN was able to be identified and stimulated. The lateral border of the pectoralis major muscle was the chosen landmark because it is always identifiable in the surgical field and its location is easy to reliably locate (as opposed to the often described midaxillary line which has a more subjective location and is often difficult to identify in a draped field in an abducted arm position). This process was repeated bilaterally.

Results

In this study, 12 patients underwent gender-affirming mastectomy with bilateral intraoperative stimulation and mapping of the long thoracic nerve for a total of 24 mappings of the LTN danger zone. Table 1 displays the study cohort demographics. None of the included patients had undergone a previous chest operation prior to gender-affirming mastectomy.

Table 1

1077	**22 (9.5)**
Age[1077]**, y**	
BMI	27.7 (4.7)
188	
Fisher grade[188]	

[15] A.A. Salibian, E. Gonzalez, J.D. Frey, R. Bluebond-Langner; Tips and tricks in gender-affirming mastectomy; Plast Reconstr Surg; Vol. 147, 6; (Jun 01 2021), pp. 1288-1296.Salibian A.A., Gonzalez E., Frey J.D., Bluebond-Langner R. Tips and tricks in gender-affirming mastectomy. Plast Reconstr Surg. Jun 01 2021;147(6):1288-1296. doi:10.1097/PRS.0000000000007997

1077	**22 (9.5)**
Age[1077]**, y**	
1	0 (0)
2	1 (8)
3	5 (42)
4	6 (50)

Table 1 - Patient Demographics.

[a]Displayed as median (IQR).

[b]Displayed as n(%).

Table 2 displays the location of the LTN in relation to the lateral border of the pectoralis major muscle. The location of the nerve was not significantly different between sides (3rd rib: p = 0.65; 4th rib: p = 0.72; 5th rib: p = 0.73) and therefore the location of the nerve was grouped between sides. The LTN was most consistently identified in the surgical field with intraoperative stimulation at the 4th rib level (100% of study participants), followed by the 3rd rib level (75% of participants), and finally the 5th rib level (40% of participants). The distances from the lateral pectoralis border were used to map the danger zone within which the LTN is most likely to be injured. See Video, Supplemental Digital Content 1. The LTN was found a median of 4.3cm lateral to the pectoralis border at the 3rd rib level (IQR = 0.9cm; range: 3 to 6cm), 5.0cm lateral to the pectoralis border at the 4th rib level (IQR = 0.5cm; range: 4.5 to 7cm), and 7.0cm lateral to the pectoralis border at the 5th rib level (IQR = 0.5cm; range 6 to 7.5cm). Figure 1 depicts the danger zone boundaries within the surgical field, with the LTN depicted traversing through the middle of this zone along the lateral chest wall.

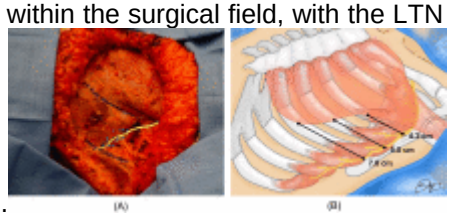

Figure 1 - Intraoperative photo demonstrating the anatomy of the long thoracic nerve as it courses through the danger zone between rib levels 3-5, with blue dots representing the measured points of each included patient in the study (A). Illustration of the nerve anatomy with measurements indicating the median distance the nerve was found lateral to the lateral border of the pectoralis major muscle (B).

Table 2

Rib Level	**3**	**4**	**5**
5875	4.3 (0.9)	5.0 (0.5)	7.0 (0.5)
Distance from pectoralis border (cm)[5875]			
Range, cm	3−6	4.7−7	6- 7.5
1293	83	100	58
Nerve identified at this level[1293]			

Table 2 - Location of the Long Thoracic Nerve in Relation to the Lateral Border of the Pectoralis Major Muscle.

[a]Presented as median (IQR).

[b]Presented as percentage of sides investigated.

Supplementary material related to this article can be found online at doi:10.1016/j.nanoen.2021.105929.

The following is the Supplementary material related to this article Video S1.

Supplemental Digital Content 1: Intraoperative Stimulation of the Long Thoracic Nerve.

Discussion

While the anatomy of the LTN is familiar to many surgeons performing breast surgery, some plastic surgeons trained in the era of integrated residency programs but before widespread insurance coverage of gender-affirming mastectomy procedures, limiting their training exposure to mastectomy operations performed for either oncologic or gender-affirming indications. Therefore, they may have had less formal training in performing mastectomies and less experience with the anatomy and identification of the LTN in this setting. Gender-affirming mastectomy also poses a heightened risk of LTN injury compared to many other common breast surgery procedures due to the dysphoria caused by lateral chest wall fullness or “bra rolls” which necessitates more extensive lateral chest wall contouring. This chest contouring often involves direct excision of the lateral chest wall adipose excess down to the level of the fascia overlying the SA and latissimus dorsi to achieve a cosmetically acceptable result. This resection often leaves only a thin layer of fascia over the SA to protect the LTN. Inadvertent violation of this fascia can easily occur, particularly in patients with significant soft tissue laxity or slender patients with only a thin fascial layer over the SA. 10 In addition, the adipose tissue of the lateral chest is frequently fed by large perforating vessels from the lateral thoracic artery along the chest wall. Overly aggressive cauterization of these vessels represents another potential source of injury to the LTN. Furthermore, incision placement in gender-affirming mastectomy procedures frequently results in a surgical field that is superior to other breast procedures such as mastopexy and breast reduction. Additionally, it is common practice to curve the upper incision superolaterally toward the axilla so the final scar mirrors the lateral border of the pectoralis major. Defining an LTN danger zone may help raise awareness and minimize the risk of iatrogenic injury of the LTN during gender-affirming mastectomy procedures. In addition, while this study focuses on gender-affirming mastectomy for the aforementioned reasons, the findings reported here may additionally be applied more broadly to non-oncologic mastectomies performed for other indications such as gynecomastia or granulomatous mastitis, and given the ease and reliability of finding the proposed landmarks intraoperatively compared to previously proposed landmarks for LTN identification in oncologic mastectomies, they may also prove to be useful for oncologic breast and axillary surgery.

In this study, the LTN was identified and stimulated in the surgical field at the level of the 3rd through 5th ribs. A recent study defined the danger zone of the distal portion of the LTN during thoracotomy to lie between the 4th to 6th rib spaces within 3 cm anterior and 1 cm posterior to the midaxillary line. 2 That study also documented that 76% of LTN branches entered the SA within the 4th to 6th intercostal spaces. 2 The danger zone defined here has a significant overlap with this area described in the thoracic surgery literature, though is described and defined using anatomic landmarks familiar to plastic surgeons and relevant to gender-affirming mastectomy specifically. In this study, the location of the LTN was identified within the gender-affirming mastectomy field and in relation to the lateral border of the pectoralis major muscle, a reproducible landmark for this operation. In prior literature on the LTN, the midaxillary line is often used which is a more subjective landmark often less clearly defined in the gender-affirming mastectomy operative field. Other less practical landmarks have also been proposed such as the scapular tip or the sternum. 1 2 7 One additional advantage of this study design was that previous studies have used cadavers to map the course of the LTN, 1 2 7 wherein this study used intraoperative nerve stimulation to identify the LTN location in situ. This study provides a more relevant context for where the nerve may be encountered when taking into account patient positioning, arm abduction, and expected surgical field.

Iatrogenic injury to the distal LTN is one potential etiology for chronic pain following gender-affirming mastectomy that is often overlooked. Previous studies have documented distal LTN injury or entrapment as a cause of chronic shoulder pain which can be neuropathic in origin or mechanical due to SA dysfunction (leading to anterior shoulder rocking or compensatory muscle pain). 5 Prevention of LTN injury is important as treatment options are poor if spontaneous recovery does not occur, 10 and counseling regarding LTN injury should be included in all gender-affirming mastectomy surgical consents. If the LTN is injured proximally in the neck or the axilla, a nerve transfer can be performed from the thoracodorsal nerve with the possible addition of a pectoral fascicle of the middle trunk. [16] [17] [18] However, the location most at risk of injury in gender-affirming mastectomy procedures is along the chest wall between ribs 3 to 5 as demonstrated here. When this part of the nerve is injured, nerve transfer may not be viable as the distal LTN target is damaged and may not be available as a distal nerve transfer target. An additional challenge in treatment is a lack of recognition or significant delay in diagnosis. If innervation is maintained to the upper slips of the SA, as in the case of a distal LTN injury, this may not result in scapular winging which is the clinical sign most physicians are trained to look for if suspecting injury to the LTN. A lack of winging does not rule out injury to the distal portion of the LTN. Diagnosis should be considered based on symptoms of persistent low-grade pain and physical exam signs of instability and confirmed with electromyography testing the lower slips of the serratus for evidence of denervation. 10

Technical recommendations to reduce the risk of iatrogenic injury

The anatomic danger zone defined in this study is most frequently encountered during the resection of the axillary tail of breast tissue or the frequently performed additional resection of adipose tissue on the lateral chest wall in gender-affirming mastectomy cases. Although addressing the lateral chest is important, it is critical to avoid over-resection of the adipose tissue/bra roll on the lateral chest wall, to leave the fascia of the SA completely intact and even to consider leaving a thin tissue layer superficial to the SA fascia to avoid injury to the LTN and its branches. Large perforating vessels are typically encountered originating from the lateral thoracic artery, and careful cauterization or clip application to these branches should be considered to avoid thermal injury to the nearby LTN. Finally, all efforts must be made to avoid entering the axilla during gender-affirming mastectomy procedures. Some patients, particularly those with a significantly elevated body mass index, may have ptotic axillary fat that enters the resection field. It is important to recognize the difference in the appearance of axillary fat and leave this in situ to minimize the risk of both inadvertent lymph node dissection and lymphedema as well as a more proximal iatrogenic injury to the LTN. While we do not recommend routine use of intraoperative nerve stimulation for nerve identification, it can be a helpful adjunct in cases that involve extensive chest wall contouring, or to rule out an LTN nerve injury if there is a significant violation of the SA fascia noted within the described danger zone.

Limitations

This study was limited to defining an anatomic danger zone and did not include prospective outcomes. Due to limitations with the intraoperative nerve stimulation technique, we were unable to perform LTN stimulation and mapping in patients with BMI >35. Therefore, the application of this LTN danger zone to this patient population should be used with caution. Furthermore, given the small sample size and nonparametric distribution of the nerve

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locations at some rib levels, nonparametric statistical tests were utilized which may increase the likelihood of type I error being present in the results.

Conclusion

Gender-affirming mastectomy frequently involves significant lateral chest wall contouring. The superficial location of the LTN and its branches on the anterior surface of the SA muscle places the nerve at risk of iatrogenic injury. The danger zone for injury to the LTN in gender-affirming mastectomy traverses from the 3rd to 5th rib, and extends from 3 cm to 7.5 cm lateral to the lateral border of the pectoralis major muscle. Strategies to minimize the risk of iatrogenic injury to the LTN in gender-affirming mastectomy include avoiding over-resection of tissue of the lateral chest wall, not violating the fascia of the SA, and avoiding thermal injury from aggressive cauterization of lateral thoracic perforating vessels.

Ethical approval statement

All patients gave written and verbal consent to participate in this study. This study was approved by our institution's Institutional Review Board (STUDY00026655).

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None.

Conflict of interest statement

PCF - none; DE - none; EAM - none; KI - none; BRP - none.

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Original Research

Examining gender-specific mental health risks after gender-affirming surgery: a national database study

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Abstract

Background: Transgender individuals face heightened psychological distress, including depression, anxiety, and suicidal ideation, partly due to stigma and lack of gender affirmation.
Aim: To evaluate mental health outcomes in transgender individuals with gender dysphoria who have undergone gender-affirming surgery, stratified by gender and time since surgery.
Methods: This retrospective study utilized the TriNetX database, analyzing U.S. patients aged ≥18 with gender dysphoria (International Classification of Diseases, Tenth Revision [ICD-10] F64) between June 2014 and June 2024. Six cohorts were created based on gender and surgery status: Cohorts A-D included patients with or without surgery, and Cohorts E-F allowed for gender comparison among those with surgery. Propensity score matching controlled for age, race, and ethnicity. Mental health outcomes included depression, anxiety, suicidal ideation, substance use disorder, and body dysmorphic disorder, assessed over two years post-surgery using clinician-verified ICD-10 codes. Body dysmorphic disorder (BDD) was analyzed separately and not conflated with gender dysphoria cohorts to ensure the distinction between these conditions**.** Statistical analysis employed risk ratios, with $P < 0.05$ deemed significant.
Outcomes: Primary outcomes were differences in mental health disorders, specifically depression, anxiety, suicidal ideation, body-dysmorphic disorder, and substance use disorder, among transgender individuals' post-surgery.
Results: From 107 583 patients, matched cohorts demonstrated that those undergoing surgery were at significantly higher risk for depression, anxiety, suicidal ideation, and substance use disorders than those without surgery. Males with surgery showed a higher prevalence of depression (25.4% vs. 11.5%, RR 2.203, $P < 0.0001$) and anxiety (12.8% vs. 2.6%, RR 4.882, $P < 0.0001$). Females exhibited similar trends, with elevated depression (22.9% vs. 14.6%, RR 1.563, $P < 0.0001$) and anxiety (10.5% vs. 7.1%, RR 1.478, $P < 0.0001$). Feminizing individuals demonstrated particularly high risk for depression (RR 1.783, $P = 0.0298$) and substance use disorders (RR 1.284, $P < 0.0001$).
Clinical implications: Findings suggest the necessity for gender-sensitive mental health support following gender-affirming surgery to address post-surgical psychological risks.
Strengths and Limitations: By leveraging ICD-10 codes, we provide a more accurate representation of patient demographics and clinical outcomes, minimizing recall and reporting biases that often limit survey-based research. Limitations include the inability to account for unmeasured confounders such as social support.
Conclusion: Gender-affirming surgery, while beneficial in affirming gender identity, is associated with increased risk of mental health issues, underscoring the need for ongoing, gender-sensitive mental health support for transgender individuals' post-surgery.

Keywords: transgender; gender identity; gender dysphoria; gender-affirming surgery; mental health; TriNetX.

Introduction

Transgender individuals—those who experience a mismatch between their gender identity and the sex assigned at birth—face a heightened risk of psychological distress and related challenges, including suicidal tendencies [1–4]. This increased risk is thought to arise partly from transgender individuals' heightened exposure to stigma-related stress, often referred to as minority stress [5, 6]. Additionally, it may be linked to the stress of not receiving gender affirmation, which involves the accurate acknowledgment and validation of their gender identity [3, 7]. For some transgender individuals, this distress reaches a clinical threshold known as gender dysphoria, defined as significant discomfort or distress stemming from an incongruence between one's experienced or expressed gender and their assigned sex at birth [8, 9]. To relieve the stress associated with the ongoing mismatch between one's gender identity and assigned sex, a growing number of transgender individuals pursue gender-affirming medical treatments, such as hormone therapy and gender-affirming surgeries.

Despite increasing support for gender-affirming medical interventions to alleviate distress in transgender individuals experiencing gender incongruence, the long-term mental health outcomes associated with these interventions remain largely unclear. Much of the available research is based on small sample sizes, cross-sectional designs, and self-reported data on treatment exposure and mental health outcomes,

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which can introduce biases and limit the reliability of findings [4, 10–13]. A meta-analysis of small-scale studies, primarily cross-sectional, suggested a positive association between self-reported hormone therapy and gender-affirming surgery with improved mental health outcomes [10]. However, these studies are often limited by short follow-up periods and lack of control for confounding variables, making it challenging to establish causative links over time.

Existing studies also fall short due to non-representative sampling and limited longitudinal data, leaving critical questions unanswered about the association between the duration since gender-affirming treatment and mental health outcomes among transgender individuals. Moreover, the absence of probability-based data on the prevalence of mood and anxiety disorders within this population, as compared to the general population, reflects a gap in understanding the true impact of these interventions [14].

Our study seeks to address these gaps by utilizing the TriNetX database and International Classification of Diseases, Tenth Revision (ICD-10) codes, which allow for a more comprehensive, clinician-verified assessment of gender dysphoria and related mental health outcomes across a large, nationally representative cohort. Unlike previous studies that rely on self-reported data and smaller, institution-based samples, our methodology leverages robust, real-world data to enable a more accurate and generalizable understanding of mental health outcomes following gender-affirming surgery. The objectives of this study are threefold: (1) to assess mental health outcomes in transgender individuals with gender dysphoria who have undergone gender-affirming surgery compared to those who have not, (2) to explore gender-specific mental health differences among those who have received gender-affirming surgery, and (3) to evaluate whether mental health outcomes vary based on the length of time since undergoing surgery. By addressing these objectives, this study aims to provide valuable insights into the mental health impacts of gender-affirming surgery, contributing to more informed and supportive care for transgender individuals.

Methods

Data source

This study utilized the TriNetX database, a global health research network managed by a private organization, providing access to de-identified patient data from over 64 U.S.-based healthcare organizations, including a mix of public and private institutions. The database encompasses data from more than 113.4 million patients, aggregated from electronic medical records (EMRs), claims, and other healthcare data sources, ensuring standardized and comprehensive documentation. Organizations contribute their data to support research initiatives, improve healthcare outcomes, and leverage analytics for quality improvement. This study was deemed exempt from Institutional Review Board (IRB) oversight as it exclusively involved de-identified patient data.

Study design and population

The retrospective study selected patients from June 12, 2014, to June 12, 2024 of U.S. patients. To be included, all patients had to be 18 years or older with a diagnosis of gender dysphoria, as identified by the ICD-10 code F64. This criterion was chosen based on literature highlighting elevated mental health concerns for transgender and nonbinary patients with gender dysphoria [15, 16]. Gender-affirming surgery cohorts consisted of patients with a documented diagnosis of gender dysphoria who had undergone specific gender-affirming surgical procedures. For transmen, this primarily included mastectomy (chest masculinization surgery, CPT codes 19 303 and 19 304), while for transwomen, this encompassed a range of feminizing procedures such as tracheal shave (CPT code 31899), breast augmentation (CPT code 19325), and vaginoplasty (CPT codes 57 335 and 55 970). These surgeries were identified using clinician-verified CPT codes within the TriNetX database, allowing for precise classification.

Classification of cohorts

We classified patients using the gender documented in the EMRs within the TriNetX database, recognizing that this documentation may reflect either natal sex or gender identity, depending on how it was recorded. To minimize potential misclassification, we identified transgender individuals using the ICD-10 code F64 (gender dysphoria) and categorized them into six cohorts.

- **Cohort A**: Patients documented as male (which may indicate natal sex or affirmed gender identity), aged ≥18 years, with a prior diagnosis of gender dysphoria, who had undergone gender-affirming surgery.
- **Cohort B**: Male patients with the same diagnosis but without surgery.
- **Cohort C**: Patients documented as female, aged ≥18 years, with a prior diagnosis of gender dysphoria, who had undergone gender-affirming surgery.
- **Cohort D**: Female patients with the same diagnosis but without surgery.
- **Cohort E**: Transgender male patients who underwent masculinizing gender-affirming regardless of a previous documented diagnosis of gender dysphoria
- **Cohort F**: Transgender female patients who underwent feminizing gender-affirming surgery regardless of a previous documented diagnosis of gender dysphoria.

Cohorts E and F include transgender patients who underwent gender-affirming surgery but lacked a documented diagnosis of gender dysphoria, unlike Cohorts A and C, which specifically require this diagnosis for inclusion. This distinction allows for the evaluation of mental health outcomes in a broader transgender population, encompassing individuals who sought surgery without meeting the formal diagnostic criteria for gender dysphoria. By comparing these cohorts, the study provides unique insights into how mental health outcomes may differ based on diagnostic status. While longitudinal data at the individual level were unavailable, mental health outcomes were assessed in a cross-sectional manner using diagnoses recorded before and after surgery within the database. Risk for mental health outcomes was assessed for all cohorts over two years following surgery, based on findings from the 2015 US Transgender Survey that highlighted significant adverse mental health outcomes occurring within this timeframe [17]. Mental health outcomes were determined using validated tools administrated by the doctors and healthcare organizations, with the results recorded using corresponding ICD-10 codes.

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Mental health outcome assessment

Mental health outcomes in this study were assessed using clinician-verified International Classification of Diseases, Tenth Revision (ICD-10) diagnostic codes, as recorded in the EMRs within the TriNetX database. These diagnoses were established by healthcare professionals during clinical encounters and documented in the EMRs of participating healthcare organizations. This approach eliminates the reliance on self-report measures, ensuring that diagnoses such as depression, anxiety, suicidal ideation, substance use disorder, and body dysmorphic disorder are based on clinical evaluations rather than patient-reported symptoms or survey items. By utilizing ICD-10 codes, we sought to enhance the validity and reliability of the data, addressing the limitations of bias and subjectivity inherent in self-reported mental health measures.

Study outcomes

The outcomes for our study were chosen based on studies that highlighted mental health outcomes that exist within the transgender patient population [18–20]. Patients included in the analysis had no documented mental health disorder diagnoses prior to the index date. The absence of longitudinal patient trajectories in the database limited within-patient tracking, and outcomes were evaluated cross-sectionally based on ICD-10 diagnoses documented at two time points: pre- and post-surgery. The database does not include explicit information on sex assigned at birth, relying instead on documented demographic data as "male" or "female."

Propensity score matching

To control for potentially confounding factors, propensity score matching was utilized. In our study, we propensity matched for age, race, and ethnicity, criteria identified in the literature as risk factors for mental health in this population [21, 22].

Statistical analysis

Data analysis was conducted using the TriNetX software platform, which facilitates statistical computations and cohort comparisons. Risk ratios (RRs) with 95% confidence intervals (CIs) were calculated to assess the relative risk of mental health outcomes between cohorts. Statistical significance was determined with a threshold of $P < 0.05$. Additional tables summarizing demographic and outcome data were generated using Microsoft Excel to provide a comprehensive overview of the results.

Results

Our team identified 107 583 patients aged ≥18 with a previous diagnosis of gender dysphoria using the TriNetX Database United States Collaborative Network. Initially, Cohort A included 2774 male patients with gender dysphoria and gender-affirming surgery; Cohort B included 48 090 male patients with gender dysphoria but no gender-affirming surgery; Cohort C included 3358 female patients with gender dysphoria and gender-affirming surgery; Cohort D included 67 579 female patients with gender dysphoria but no gender-affirming surgery; Cohort E included 3790 transgender male patients who underwent gender-affirming surgery but did not have a documented diagnosis of gender dysphoria; Cohort F included 4643 transgender female patients who underwent gender-affirming surgery but did not have a documented diagnosis of gender dysphoria. The demographics for each cohort before and after propensity score matching is attached to the supplementary tables.

After propensity score matching of cohorts A and B, each cohort had 2774 patients of similar race, ethnicity, and age at index (**Supplementary document:** Table S1). Compared to male patients with a diagnosis of gender dysphoria only, those with gender affirmation surgery were at significantly higher risk for depression, anxiety, suicidal ideation, and substance use disorders. However, neither cohort was at increased risk for body dysmorphic disorder (Table 1). Male patients with gender-affirming surgery had a 25.4% rate of depression, compared to 11.5% for those without surgery (RR 2.203, 95% CI 1.477-3.287, $P < 0.0001$). Male patients with surgery had 4.882 times the risk of anxiety (12.783% vs. 2.618%, RR 4.882, 95% CI 4.505-5.29, $P < 0.0001$) compared to those who did not receive surgery (12.783% vs. 2.618%, RR 4.882, 95% CI 4.505-5.29, $P < 0.0001$). Both groups had the same risk for body dysmorphic disorder (0.4% vs. 0.4%, RR 1.001, 95% CI 0.417-2.402, $P = 0.9974$).

After propensity score matching of Cohorts C and D, each cohort had 3358 female patients of similar age at index, race, and ethnicity (**Supplementary document:** Table S2). Female patients with gender dysphoria and a history of gender-affirming surgery had significantly higher risks for depression, anxiety, suicidal ideation, and substance use disorders compared to those with a diagnosis of gender dysphoria only. However, neither group was at an increased risk for body dysmorphic disorder (Table 2). Females with gender-affirming surgery had a 22.9% rate of depression, compared to 14.6% for those without surgery (RR 1.563, 95% CI 1.422-1.717, $P < 0.0001$). Compared to those without surgery, females who had undergone gender-affirming surgery had a 1.478 times higher risk of anxiety (10.496% vs. 7.098%, RR 1.478, 95% CI 1.214-1.797, $P < 0.0001$), a 2.357 times higher risk of suicidal ideation (19.811% vs. 8.402%, RR 2.357, 95% CI 1.579-3.515), and a 2.712 times higher risk of substance use disorder (19.322% vs. 7.123%, RR 2.712, 95% CI 1.439-3.217). Both groups had the same risk for body dysmorphic disorder (0.3%) (Table 2).

To assess gender disparities in mental health outcomes in transgender patients who underwent gender-affirming surgery but lacked a documented diagnosis of gender dysphoria, we compared Cohorts E and F. After propensity score matching, both cohorts included 3607 patients who were similar at index, in age, race, and ethnicity (**Supplementary document:** Table S3). Transgender men who had undergone gender-affirming surgery were at higher risk of most mental health issues compared to transgender women. Specifically, transgender men had a 1.58 times higher risk of anxiety (14.1% vs. 8. 9%, RR 1.580, 95% CI 0.845-2.134, $P = 0.0002$), a 1.186 times higher risk of suicidal ideation (5.5% vs. 4.6%, RR 1.186, 95% CI 0.97-1.449, $P = 0.0358$), and a 1.284 times higher risk of substance use disorder (14.4% vs. 11.2%, RR 1.284, 95% CI 1.137-1.45, $P < 0.0001$). Among the five outcomes, the relative risk was highest for depression among transgender men compared to transgender women (RR 1.783, 95% CI 1.327-2.389, $P = 0.0298$). Both cohorts were at the same risk for body dysmorphic disorder (Table 3).

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Table 1. Outcomes for male patients with a previous diagnosis of gender dysphoria following gender-affirming surgery (cohort A) vs. male patients with gender dysphoria only (cohort B) after propensity score matching.

Outcomes	Cohort A	Cohort B	RR (95% CI)	p-value
Depression	25.4%	11.5%	2.203 (1.477, 3.287)	<0.0001
Anxiety	12.8%	2.6%	4.882 (4.505, 5.29)	<0.0001
Suicidal ideation	3.4%	2.5%	1.356 (0.984, 1.868)	0.0002
Substance use disorder	19.0%	8.2%	2.299 (2.158, 2.45)	<0.0001
Body dysmorphic disorder	0.4%	0.4%	1.00 (0.417, 2.402)	0.9974

RR: relative risk; CI: confidence interval.

Table 2. Female patient outcomes following gender-affirming surgery with a previous diagnosis of gender dysphoria (cohort C) vs. female patient outcomes with a previous diagnosis of gender dysphoria only (cohort D) after propensity score matching.

Outcomes	Cohort C	Cohort D	RR (95% CI)	p-value
Depression	22.9%	14.6%	1.563 (1.422, 1.717)	<0.0001
Anxiety	10.5%	7.1%	1.478 (1.214, 1.797)	<0.0001
Suicidal ideation	19.8%	8.4%	2.357 (1.579, 3.515)	0.0401
Substance use disorder	19.3%	7.1%	2.712 (1.439, 3.217)	0.0193
Body dysmorphic disorder	0.3%	0.3%	1.00 (0.416, 2.406)	0.9995

RR: relative risk; CI: confidence interval.

Table 3. Outcomes of transgender males without documented gender dysphoria following gender-affirming surgery (cohort E) vs. transgender females without documented gender dysphoria following gender-affirming surgery (cohort F) after propensity score matching.

Outcomes	Cohort E	Cohort F	RR (95% CI)	p-value
Depression	44.2%	24.7%	1.789 (1.327, 2.389)	0.0298
Anxiety	14.1%	8.9%	1.580 (0.845, 2.134)	0.0002
Suicidal ideation	5.5%	4.6%	1.186 (0.97, 1.449)	0.0358
Substance use disorder	14.4%	11.2%	1.284 (1.137, 1.45)	<0.0001
Body dysmorphic disorder	0.3%	0.3%	1.00 (0.416, 2.405)	1.000

RR: relative risk; CI: confidence interval.

Discussion

The findings of this study underscore a pressing need for enhanced mental health guidelines tailored to the needs of transgender individuals following gender-affirming surgery. Our analysis reveals a significantly elevated risk of mental health disorders—including depression, anxiety, suicidal ideation, and substance use disorder—post-surgery among individuals with a prior diagnosis of gender dysphoria. Importantly, however, our results indicate no increased risk of body dysmorphic disorder following surgery, suggesting that these individuals generally experience satisfaction with their body image and surgical outcomes. Notably, the heightened risk of mental health issues post-surgery was particularly pronounced among individuals undergoing feminizing transition compared to masculinizing transition, emphasizing the necessity for gender-sensitive approaches even after gender-affirming procedures.

By excluding patients with documented pre-existing mental health diagnoses, this study sought to ensure that identified mental health outcomes likely represented new or emergent conditions rather than pre-existing disorders. This methodological approach was critical to focusing on the relationship between gender-affirming surgery and mental health. However, we acknowledge that this approach, relying solely on ICD-10 codes, may not fully account for undiagnosed or subclinical conditions prior to surgery. These emergent mental health issues may result from a multifactorial interplay of social, psychological, and physiological factors, including social support systems, environmental stressors, hormonal changes, surgical outcomes, and the broader psychosocial adjustments involved in transitioning.

Comparison with previous studies

When evaluating these findings within the context of previous research, it is crucial to recognize the limitations inherent in studies that rely primarily on survey data, such as those analyzed by Marano et al. and Almazan and Keuroghlian [13, 23]. These studies, using data from the U.S. Transgender Survey, underscore the psychosocial benefits of gender-affirming surgeries, including reductions in depression, anxiety, and suicidal ideation, while emphasizing the importance of aligning physical appearance with gender identity to improve mental health. However, survey-based studies are limited by self-reported data, which may introduce response bias and lack clinical validation, potentially limiting the generalizability of their findings [24]. Our study diverges by using a national database of de-identified clinical data, enabling a more comprehensive and representative examination of real-world mental health outcomes across diverse demographics. This approach allows us to capture more nuanced insights into mental health risks, particularly the heightened susceptibility to depression, anxiety, suicidal ideation, and substance use disorder in transwomen individuals' post-surgery. This divergence from survey-based findings highlights the need for gender-sensitive mental health strategies that extend beyond the surgical intervention itself.

Implications for mental health care

Despite the observed increase in mental health issues, gender-affirming surgery remains essential in aligning transgender individuals' physical appearance with their gender identity, offering significant psychological benefits [8, 18]. Research,

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such as that conducted by Park et al., has documented long-term satisfaction and mental health improvements in patients who have undergone gender-affirming surgeries over decades [25]. These enduring benefits underscore the necessity for mental health practitioners to recognize and address these specific challenges, ensuring that post-surgical mental health care is both accessible and gender-responsive.

It is also crucial to acknowledge that transgender individuals seek mental health support for a wide range of issues, not solely those related to gender identity. The lifelong impact of minority stress continues to affect transgender individuals' experiences of depression and anxiety even after transitioning [3, 26, 27]. Barriers to mental health care, including discrimination within healthcare settings, exacerbate these mental health challenges, fostering systemic distrust and reducing access to necessary services [28–30]. Our findings highlight that anxiety is particularly prevalent among transgender men post-surgery, while substance use disorder is more common among transgender women, reflecting gender-specific mental health risks. For transgender women, societal pressures to conform to traditional female roles and the pervasive devaluation of femininity may contribute to heightened stress, emotional distress, and, ultimately, increased reliance on substance use as a coping mechanism [31, 32]. Conversely, transgender men may encounter societal expectations to suppress emotions, aligning with traditional masculine norms, which can heighten anxiety as they navigate their new gender identity.

Hierarchical criteria and mental health diagnoses

An important consideration in interpreting our findings is the hierarchical nature of psychiatric diagnoses, as specified in the DSM. This framework often precludes standalone diagnoses of anxiety or depression if these symptoms are deemed to be better explained by another superior diagnosis, such as gender dysphoria [33]. Consequently, symptoms of anxiety or depression that co-occur with gender dysphoria may be subsumed under the latter diagnosis, particularly in pre-surgical contexts. Following gender-affirming surgery, the alleviation of distress related to gender incongruence may enable the reclassification of these symptoms as independent diagnoses. This diagnostic shift could contribute to the observed increase in mental health diagnoses post-surgery, not as a reflection of adverse surgical outcomes but rather as a reconceptualization of symptoms within the care pathway. Including this perspective enhances our understanding of the study's findings and emphasizes the need for nuanced mental health assessments tailored to the unique trajectories of transgender individuals. Future research should explore how changes in diagnostic frameworks and psychiatric practices influence mental health outcomes in this population.

Future directions

Further research should investigate the complex factors contributing to mental health disparities post-surgery, including social support, family acceptance, societal stigma, and pre-existing mental health conditions. Prospective, longitudinal studies are needed to track changes in mental health from pre-surgery through long-term follow-up, providing greater clarity on the causal impact of gender-affirming surgery. Additionally, examining how systemic factors, such as healthcare policy, insurance coverage, and provider training, influence access to care would offer critical insights into improving equity and effectiveness in mental health care for transgender individuals.

While the limitations of this study cannot be fully overcome with the current data available from the TriNetX database, it is important to carefully interpret the conclusions within the context of these constraints. The retrospective design and reliance on de-identified, aggregated data restrict our ability to establish causation or continuously follow individuals across healthcare systems. Furthermore, potential misclassification of mental health outcomes due to undocumented pre-existing conditions or incomplete follow-up outside the TriNetX network remains a limitation. Despite these challenges, our analytic design offers valuable insights into associations between gender-affirming surgery and mental health outcomes at a population level, leveraging clinician-verified ICD-10 codes to enhance diagnostic reliability compared to self-reported data. However, this approach cannot capture nuanced individual trajectories or address disparities in access to care that may influence the likelihood of receiving a diagnosis. Future research should employ longitudinal designs with continuous follow-up to better address these limitations, allowing for more robust evaluations of the relationship between gender-affirming care and mental health outcomes.

Study limitations

While this study offers critical insights into the mental health challenges experienced by transgender individuals following gender-affirming surgery, several limitations must be acknowledged. The TriNetX database, comprising de-identified patient records, restricts patient-level linkage for multiple diagnoses or tracking individual health trajectories, which limits our ability to perform true longitudinal or within-person analyses. Instead, our analysis relied on cross-sectional comparisons of mental health outcomes before and after surgery. While TriNetX aggregates patient data from multiple healthcare organizations within its network, this does not extend to patients who leave the network entirely, potentially leading to incomplete follow-up data. Additionally, data stored in unstructured formats, such as clinical notes, are not included, which may contribute to selection bias. A significant limitation is the potential selection bias inherent in the study population. Individuals pursuing gender-affirming surgery may represent a subgroup experiencing higher levels of psychological distress compared to those who do not seek surgery. This increased baseline distress could inherently elevate the risk of adverse mental health outcomes, independent of the surgical intervention itself. Future research should consider methods to account for these pre-existing differences to better understand the true impact of surgery on mental health outcomes.

One significant limitation is the binary classification of gender within the TriNetX database, which only records patients as "male" or "female" in its demographic data. This excludes non-binary individuals and others who do not align with binary gender categories, limiting the inclusivity and representativeness of the study. Furthermore, the database does not include explicit information on sex assigned at birth, legal gender changes, or affirmed gender identities, which prevents more nuanced subgroup analyses. This limitation underscores the importance of developing future data systems that allow for broader gender identity categories to support more inclusive research.

While our use of clinician-verified ICD-10 codes ensures objective and standardized diagnoses, these codes are reliant

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on the clinical expertise and practices of healthcare professionals, which may vary across organizations. This variability introduces potential inconsistencies in diagnosis accuracy. Moreover, differences in healthcare access likely influence the likelihood of receiving formal mental health diagnoses. Patients undergoing surgery often have greater access to healthcare services, including mental health care, compared to those who do not. This may lead to higher rates of mental health diagnoses in surgical cohorts, independent of actual differences in mental health status, introducing potential surveillance bias.

Another limitation is the potential misclassification of individuals in the "no-surgery" cohort. The TriNetX database captures surgical history only from participating organizations, which means that patients who underwent gender-affirming surgeries outside of these institutions may have been incorrectly categorized. This limitation may affect the accuracy of our comparisons between surgical and non-surgical cohorts. Future studies with access to centralized and comprehensive data sources are needed to improve the classification of surgical histories.

The criteria for identifying transgender individuals in this study were based on documented diagnoses of gender dysphoria (ICD-10 code F64). This approach excludes transgender or gender-diverse individuals who do not seek medical treatment for gender incongruence, limiting the generalizability of our findings. Additionally, the absence of a comparison group for individuals who sought but had not yet received gender-affirming treatments restricts the study's ability to assess the impact of treatment timing on mental health outcomes. Longitudinal studies that track outcomes before and after treatment are needed to address this gap.

Lastly, mental health treatment utilization serves as an imperfect proxy for mental health itself. Transgender individuals receiving treatment for gender dysphoria are frequently in healthcare settings, where they may encounter more mental health treatment opportunities, potentially skewing utilization rates. Finally, while our findings support the need for accessible gender-affirming treatments, the generalizability of these results may be further limited by systemic factors, including healthcare policies, insurance coverage, and regional differences in provider training. These barriers, which vary significantly across different healthcare systems, can affect transgender individuals' access to adequate mental health care and underscore the necessity for policies that ensure consistent, affirming care.

Conclusion

Our study reveals that both male and female patients with gender dysphoria who undergo gender-affirming surgery are at significantly higher risk for adverse mental health outcomes, including depression, anxiety, suicidal ideation, and substance use disorder, compared to those who do not undergo gender-affirming surgery. This trend persists even after controlling for confounding factors through propensity score matching. Notably, transgender men showed a greater relative risk for these mental health issues compared to transgender women following gender-affirming surgery. Despite the benefits of surgery in alleviating gender dysphoria, our findings underscore the necessity for ongoing mental health support for transgender individuals during their post-surgery trajectories. These results also highlight the critical need for gender-specific care tailored to the unique experiences of male and female populations, respectively, addressing both pre- and post-surgical mental health care to improve overall well-being and prevent any mental illness or diseases.

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Joshua Lewis (Conceptualization [lead], Data curation [lead], Methodology [lead], Writing—original draft [equal], Writing—review & editing [equal]), Amani Patterson (Writing—original draft [equal], Writing—review & editing [equal]), Maame Effirim (Writing—original draft [equal], Writing—review & editing [equal]), Manav Patel (Writing—original draft [equal], Writing—review & editing [equal]), Shawn Lim (Writing—original draft [equal], Writing—review & editing [equal]), Victoria Cuello (Writing—original draft [equal], Writing—review & editing [equal]), Marc Phan (Writing—original draft [equal], Writing—review & editing [equal]), Wei-Chen Lee (Data curation [supporting], Methodology [lead], Supervision [lead], Writing—original draft [equal], Writing—review & editing [equal]).

Supplementary material

Supplementary material is available at *The Journal of Sexual Medicine* online.

Conflicts of interest

The authors that there are no conflicts of interest regarding the publication of this paper.

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Ethical statement

The study was deemed IRB exempt from University of Texas Medical Branch Institutional Review Board.

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Original Research

MP04-18
THEMATIC ANALYSIS OF LIVED EXPERIENCE IN PATIENTS WITH ADULT ACQUIRED BURIED PENIS

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INTRODUCTION AND OBJECTIVE: There is a paucity of evidence documenting the lived experience of patients with adult acquired buried penis (AABP) and how this condition is affected by surgical treatment. The purpose of this study is to use patient interview data to describe the lived experience of patients with AABP to heighten clinicians' awareness of the most prominent challenges this population faces and the efficacy of surgery in addressing these.

METHODS: This mixed-methods study utilized validated survey instruments and semi-structured interviews to capture pre- and post-surgical outcomes for men with AABP. Semi-structured interviews were conducted at University of California, San Francisco with open-ended questions to elicit the impact of AABP on a patient's quality of life in several domains including urinary function, sexual function, interpersonal relationships, and mental health. Interviews were conducted in English and were transcribed and independently coded by authors (JH, NR, MS).

RESULTS: Fourteen (14) patients with AABP participated in the study, 10 of whom had undergone surgical treatment for their condition. Semi-structured interviewee responses were coded into 13 different themes (Table 1). The most common themes were problems with urinary and sexual function (14, 100%), which included urinary stream/spraying issues as well as inability to perform intercourse or achieve an erection; among patients who underwent surgery, the majority discussed improvement in urinary and sexual function (60% and 70% respectively). Most interviewees (79%) reported negative impacts of AABP on social life, primarily involving issues with using public restrooms and avoiding travel. Half of interviewees reported struggles with relationships and mental health, such as avoiding romantic relationships and fear of rejection with concomitant depression and/or anxiety, and issues with access to care.

CONCLUSIONS: Patients living with AABP experience profound negative impacts on quality of life including urinary and sexual function, social life, and mental health. Additionally, many patients face issues with access to care. Providers should be aware that AABP patients have complex needs requiring interdisciplinary management, and that surgery may improve quality of life.

Table 1: Thematic Analysis of Interviews with AABP Patients

Patient-reported themes, no. (%)	Pre-surgical (n=14)	Post-surgical improvement (n=10)
Urinary issues	14 (100)	6 (60)
Sexual function issues	14 (100)	7 (70)
Impacting social life	11 (79)	3 (30)
Contributing Factors		
Worse after weight change	11 (79)	3 (30)
Worse after multiple surgeries	9 (64)	0 (0)
Infection issues	9 (64)	0 (0)
Relationship issues	7 (50)	3 (30)
Poor mental health	7 (50)	4 (40)
Access to care issues	7 (50)	0 (0)
Physical Issues		
Chronic pain	4 (26)	0 (0)
Impaired mobility	2 (14)	1 (10)
Cosmesis issues	3 (29)	0 (0)
Affected employment	3 (21)	0 (0)

Source of Funding: None

MP04-19
PROSTATIC METAPLASIA OF THE VAGINA IN TRANSGENDER MEN

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INTRODUCTION AND OBJECTIVE: Gender-affirming surgery (GAS) of the reproductive tract in transgender males includes vaginectomy. In most centers, this is achieved by colpocleisis, with cautery ablation of the vaginal mucosa & suture ablation of the vaginal lumen. Having seen complications due to residual vaginal tissue following colpocleisis, we changed our technique to complete vaginectomy with full-thickness excision of vaginal tissue, allowing its histopathologic examination. Our institution recently reported prostatic metaplasia of vaginal epithelium in the first 6/7 patients treated in this manner. Having accrued 11 additional patients, we extend the analysis of this novel observation.

METHODS: The study was IRB approved. Pathology archives were searched for vaginectomy specimens as part of GAS from 1/1/18-2/15/21. Gross features were reviewed. Hematoxylin-and-eosin-stained slides were examined in all cases. The majority were immunohistochemically stained for NKX3.1, prostate-specific antigen (PSA) and androgen receptor. 3 control cases of vaginal tissue from patients without clinical evidence of androgen supplementation were compared.

RESULTS: 18 patients, ages 20-34, underwent vaginectomy or excision of vaginal remnants. Each had been assigned female gender at birth without history of endocrine or genetic abnormality. All had received long-term testosterone cypionate treatment (range, 26-60 mos). Grossly, there were no mucosal lesions identified at surgical or pathological examination. Microscopically, 17/18 cases demonstrated a patchy intraepithelial glandular proliferation along the basement membrane; the 18th had a nodular collection of prostate-type tissue within subepithelial stroma. Atrophy & transitional metaplasia of squamous epithelium was also seen. The glandular proliferation was positive for NKX3.1 (15/15; 100%), PSA (9/11; 82%), and androgen receptor (8/8; 100%). Control vaginal tissue showed no evidence of prostatic metaplasia or atrophy.

CONCLUSIONS: This study further characterizes the occurrence of prostatic-type tissue in the vagina of transgender men. Prostatic tissue was present in 18/18 transgender men receiving androgen therapy and our findings are consistent with a form of androgen-associated prostatic metaplasia. This finding may have important clinical implications since some transgender men may elect to retain their vaginas, while those who do undergo GAS may have residual tissue left behind, particularly if colpocleisis is performed. Long-term follow-up of this population, with recognition of this entity, is in order.

Source of Funding: N/A

MP04-20
RATES OF PSYCHIATRIC EMERGENCIES BEFORE AND AFTER GENDER AFFIRMING SURGERY

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INTRODUCTION AND OBJECTIVE: Despites rates of comorbid psychologic illness in cases of gender dysphoria being estimated to be 70% greater than the general population, there is a dearth of literature concerning this topic. In this study we aimed to assess rates of psychiatric emergencies before and after gender affirming surgery in a large population-based cohort.

METHODS: All persons undergoing feminizing (vaginoplasty) and masculinizing (metoidioplasty/ phalloplasty) genital gender affirming surgery were identified in California from 2012-2018 from the Office of Statewide Health Planning and Development datasets using appropriate ICD-9/10 codes. All emergency room and inpatient psychiatric

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encounters were identified (noting those involving suicide attempts). Rates of these encounters were calculated before and after gender affirming surgery (using date of first operation if staged). On average, patients had a balanced two years of observation before and after their surgery.

RESULTS: Overall, 869 and 357 patients were identified undergoing vaginoplasty and phalloplasty with 193 (22.2%) and 74 (20.7%) having at least one psychiatric encounter (Table 1). Although the overall proportion of those experiencing a psychiatric encounter was similar between the vaginoplasty and phalloplasty groups, suicide attempts were more common in the vaginoplasty group (4.4% vs. 1.7%, $p = 0.033$). The rate of a psychiatric encounter occurring after surgery if an episode prior surgery occurred was 33.9% and 26.5% for the vaginoplasty and phalloplasty groups. The overall rates of suicide attempts doubled (3.3 vs 1.5%, $p = 0.017$) after vaginoplasty (effect not observed after phalloplasty).

CONCLUSIONS: Rates of psychiatric emergencies are high both before and after gender affirming surgery. Although both the phalloplasty and vaginoplasty patients have similar overall rates of psychiatric encounters, suicide attempts are more common in the later. In fact, our observed rate of suicide attempts in the phalloplasty group is actually similar to the general population, while the vaginoplasty group's rate is more than double that of the general population. Patients undergoing GAS with a history of prior psychiatric emergences or feminizing transition are at higher risk and should be counseled appropriately.

Table 1: Psychiatric Encounters Before and After Gender Affirming Surgery

	Vaginoplasty (n=869)	Phalloplasty (n=357)
Overall*	193 (22.2%)	74 (20.7%)
Before Surgery only	74	36
After Surgery only	81	25
Before and after Surgery	38	13
Overall Risk Before	12.8%	13.7%
Overall Risk After	13.7%	10.6%
Presented Before	33.9%	26.5%
Did not Present Before	11.1%	8.1%
Suicide Attempt	38 (4.4%)	6 (1.7%)
Before Surgery only	9	3
After Surgery only	25	3
Before and after Surgery	4	0
Overall Risk Before	1.5%	0.8%
Overall Risk After	3.3%	0.8%
Presented Before	30.8%	0.0%
Did not Present Before	2.8%	0.8%

*Defined as experiencing at least one psychiatric encounter. 193 and 74 unique patients had at least one psychiatric encounter from the vaginoplasty and phalloplasty groups, respectively.

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Original Research

Gender-affirming treatment and mental health diagnoses in Danish transgender persons: a nationwide register-based cohort study

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Abstract

Importance: Gender affirming treatment aims to improve mental health.

Objective: To investigate longitudinal mental health outcomes in Danish transgender persons.

Design: National register-based cohort study in Danish transgender persons with diagnosis code of "gender identity disorder" during the period 2000-2021.

Participants: Five age-matched controls of the same sex at birth and five age-matched controls of the other sex at birth were included for each transgender person.

Main outcomes: Diagnosis codes of mental and behavioral disorders and/or prescription of psychopharmacological agents until June 2022.

Results: The cohort included 3812 transgender persons with median age (interquartile range) 19 (15; 24) years for persons assigned female at birth (AFAB, $N = 1993$) and 23 (19; 33) years for persons assigned male at birth (AMAB, $N = 1819$) and 38 120 controls. Follow up duration was up to 10 years with mean (standard deviation) 4.5 (4.3) years. In transgender persons AFAB compared to control women, the odds ratio (OR) (95% confidence interval) for mental and behavioral disorders was 6.7 (5.5; 8.1) before the index date, 9.9 (8.4; 11.7) at 1 year, 5.8 (4.4; 7.7) at 5 years, and 3.4 (2.1; 7.5) at 8 years follow up. In transgender persons AMAB compared to control men, corresponding ORs were 5.0 (4.0; 6.4), 11.3 (9.3; 13.7), 4.8 (3.5; 6.5), and 6.6 (4.2; 10.3) at 8 years follow up (all $P < .001$).

Conclusion: The OR for mental health disorders was higher in transgender persons compared to controls and remained elevated throughout follow up, especially in transgender persons AMAB.

Keywords: transgender, register based, depression, suicide, mental health, medicine prescription, gender-affirming surgery, gender-affirming hormone

Significance

The number of referrals for transgender care continues to increase and the main aim of gender-affirming treatment is to improve mental health. We investigated longitudinal outcomes of diagnosis codes of mental and behavioral disorders and prescription of psychopharmacological agents in 3812 Danish transgender persons following their first diagnosis of transgender identity. We found that the odds ratio for mental health disorders was more than five times higher in transgender persons compared to controls at baseline. The risk for mental and behavioral disorders in transgender persons increased rapidly during the first year after the index date followed by a decreasing trend, but the odds ratio remained elevated throughout follow-up, especially in transgender person's assigned male at birth.

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Introduction

The term transgender describes persons whose gender identity differs from the birth-assigned sex.[1] The proportion of transgender persons is estimated to be 0.6%-1.1% in Europe.[2,3] Gender dysphoria is associated with a 2- to 3-fold higher risk of mental illness including depression and anxiety compared with cisgender controls and prevalence of suicide attempts in transgender study populations approaches 50%.[4–6]

The aim of gender-affirming care is to add to improving mental health.[5,7] Limited prospective studies on mental health outcomes are available in representative study cohorts of transgender persons.[5,8,9] Prospective studies of up to 2 years duration documented decreased depression scores after initiation of gender-affirming hormone treatment, whereas measures of anxiety were unchanged.[9,10] In a recent Swedish register-based study,[8] a health care visit due to mood and anxiety disorder was 6 times more likely in 2679 persons with gender incongruence diagnosis compared to the general population. Years since initiating of gender-affirming hormone treatment was not related to likelihood of mental health treatment (adjusted odds ratio (OR) = 1.01, 95% confidence interval (CI) = 0.98, 1.03), whereas longer time since last gender-affirming surgery was associated with reduced mental health treatment (adjusted OR = 0.92, 95% CI = 0.87, 0.98).[8] The design of the study has been discussed[11] and the findings by Bränström et al. remain to be reproduced in other national study cohorts.

The annual number of persons seeking health care due to gender identity-related conditions continues to increase.[2,4] In Denmark, evaluation of gender dysphoria is highly specialized and takes place at three Danish Centers of Gender Identity.[12] Danish transgender care follows international guidelines and initiation of gender-affirming treatment is proceeded by psychological evaluation.[1,13] Gender-affirming hormone treatment is most often initiated before gender-affirming surgery.[1,13,14]

The objective of this study was to investigate mental health outcomes after initiation of gender-affirming care in Danish transgender persons.

Methods

The study was a register-based cohort study. In Denmark, a unique social security number (central person register, CPR) is issued to all citizens at birth or upon immigration to Denmark. The CPR individually enables linkage of data from all Danish health and social care registers.[15,16] The **National Patient Register** includes data on all somatic inpatient hospital contacts in Denmark since 1977, psychiatric inpatient hospital contacts in Denmark since 1995, and outpatient contacts since 1995.[17] The National Patient Register was used to extract International Classification of Diseases (ICD-10) diagnosis codes and dates for contacts. The **Civil Registration System** was established in 1968 and was used to extract data on sex, age, death date, and emigration date.[16] **The Danish Income Statistics Register** includes the income of anyone economically active in Denmark.[18] **The National Prescriptions Registry** contains a complete record of Anatomic Therapeutic Chemical (ATC) code, date drug was dispensed, and number of drug packets for all prescriptions filled at Danish pharmacies issued by prescribers, general practitioners, or specialists since 1995.[19]

Study population

Danish transgender persons were included according to national registers. We included persons aged 3 years or older with the ICD-10 diagnosis code of transgender during 2000-2021 in the National Patient Register. The diagnosis codes F64-F649 ("transsexual, gender identity disorder") were used from 2000 to 2017[20] and the diagnosis codes DZ768E-DZ768E4 ("contact regarding gender identity condition") were applied after 2017. Persons should have a valid Danish address at the time of inclusion. The index date was defined as the first date of transgender diagnosis within the study period.

Controls

Five age-matched controls of the same sex at birth and 5 age-matched controls of the other sex at birth were drawn for each transgender person from the Danish Civil Registration system. The controls were born in the same year and should be alive at the index date of their respective matched transgender person. The controls could not be included in the transgender group at the time of inclusion but were able to enter the transgender group later. Each control could only be included once. Controls were assigned the index date of their matched transgender person.

Assigned sex at birth in the transgender study cohort was determined as the earliest recorded CPR-encoded sex. Transgender persons were divided into persons AMAB (most often transgender women) and persons assigned female sex at birth (AFAB, most often transgender men). In Denmark, a citizen can apply for legal sex-change after the age of 18 years. Misclassification of assigned sex at birth could occur in persons immigrating to Denmark after sex-change abroad. Misclassification could also occur in individuals with a transgender diagnosis or legal sex-change before year 2000. Therefore, persons with surgical codes of salpingo-oophorectomy and/or hysterectomy were defined as AFAB, persons with a diagnosis codes of penis amputation and/or orchiectomy were defined as AMAB, which resulted in correction of assigned sex in 5 individuals (Figure 1).

Definition of study parameters

The primary study outcome was mental and behavioral disorders diagnosed according to ICD-10 (primary and secondary diagnosis) or the use of psychopharmacological agents.

Mental and behavioral disorders were defined by the ICD-10 codes F32-F33 (depression), F40-F41 (anxiety), X60-X84 (intentional self-harm), F10-F19 (psychoactive substance use), F20-F29 (psychotic disorders), F30-F31, and F34-F39 (bipolar and mood disorders) from hospital contacts.

Use of psychopharmacological agents was defined as more than one prescription and redemption of antidepressants (N06A), anxiolytics (N05B), or antipsychotics (N05A).

Results regarding the study outcomes on ICD10 diagnosis codes on mental and behavioral disorders and medicine prescriptions were presented as separate analyses instead of constructing a pooled study outcome.

Covariates

Age was calculated at the index date.

Personal income was extracted from the Income Statistics Register[18] in the calendar year of the index date (or the first

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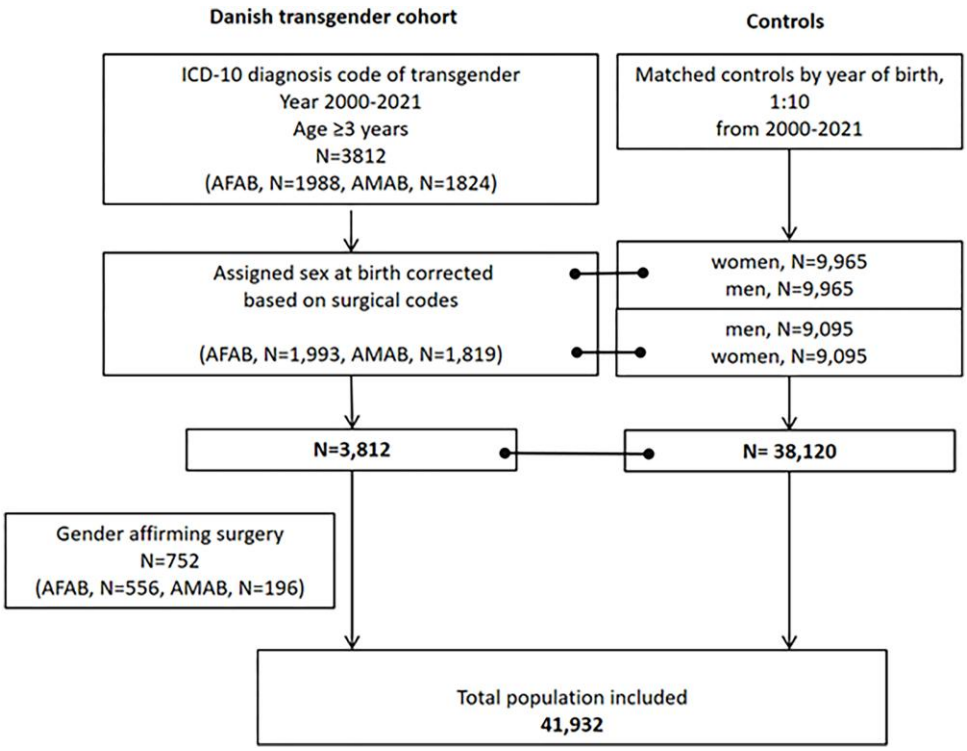

Figure 1. Flowchart of included study cohort. AFAB, assigned female at birth; AMAB, assigned male at birth.

calendar year before in case of missing income information) and included information on the available average income after tax and interest (including salary, retirement benefits, welfare payment, remuneration, company profits, etc.). The income was categorized into tertiles (high, middle, low) within age groups with 5-7 years intervals.

Presence of medical morbidity (defined as Charlson comorbidity index ≥1) was defined from hospital diagnoses within 5 years before the index date. The Charlson comorbidity index is based on 19 medical conditions[21] and was calculated from the ICD-10 operationalization by Quan et al.[22,23]

The event of gender-affirming hormone treatment was defined as a prescription followed by at least one purchase of feminizing and/or masculinizing treatment[7,12–14] following the index date. The use of gender affirming hormone treatment (GAHT) in Danish transgender persons until year 2018 has been published recently.[13]

The event of gender-affirming surgery was defined as surgical procedure codes for top or genital surgery, chondrolangyngoplasty, and liposuction following the index date. According to Danish legislation, gender-affirming surgery could only occur after the age of 18 years.

Ethics

No approval is necessary from the local Ethics committee or Institutional Review Board on register studies according to Danish law. The study complied with the Helsinki Declaration. The Data Protection Agency and Statistics Denmark approved the study with details published with OPEN ID: 939 https://open.rsyd.dk/OpenProjects/openProject.jsp? openNo=939&lang=da

Statistical analyses

Baseline characteristics in transgender persons were presented as frequencies for categorical variables and compared using chi-squared test. When estimating the incidence of study outcomes, subjects were considered at risk from the index date. The study population was followed until first occurrence of death, emigration, or end of study (December, 31, 2021), and for controls becoming cases until index date. The proportions of hospital contacts with psychiatric diagnoses and prescribed psychopharmacological agents were calculated within periods of years from the index date. The probability of hospital contacts with psychiatric diagnoses and prescribed psychopharmacological agents for cases compared with controls was calculated within periods of years from the index date using generalized estimating equations (GEE) with independent within-group correlation structure and binomial distribution. The probability of hospital contacts with psychiatric diagnoses and prescribed psychopharmacological agents for cases and controls over time were calculated within periods of years from the index date compared with 2 years before the index date using GEE with exchangeable within-group correlation structure and binomial distribution.

Sensitivity analysis

In main analyses, ICD-10 diagnosis codes for mental and behavioral disorders could occur as primary or secondary diagnosis. However, transgender persons could have hospital contacts for somatic diseases where mental and behavioral disorders were not the primary reason for hospital contact. Transgender persons undergo psychological assessment before initiation of gender-affirming hormone treatment, which can result in surveillance bias and over-diagnosis of mild

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Table 1. Baseline characteristics of Danish transgender cohort and controls and diagnoses of mental and behavioral disorders and use of psychopharmacological before the index date.

	Transgender AFAB $N = 1993$	Control women $N = 9965$	Control men $N = 9965$	Transgender AMAB $N = 1819$	Control men $N = 9095$	Control women $N = 9095$
Baseline						
Age, median (IQR)	19 (15;24)	19 (15;24)	19 (15;24)	23 (19;33)	23 (19;33)	23 (19;33)
Morbidity (yes)	88 (4.4%)	298 (4.0%)^{NS}	257 (3.6%)^{NS}	78 (4.3%)	311 (4.8%)^{NS}	340 (4.8%)^{NS}
Income low tertile	931 (46.7%)	3456 (34.7%)	3500 (35.1%)	1003 (55.1%)	3044 (33.5%)	3152 (34.7%)
Income middle tertile	725 (36.4%)	3607 (36.2%)	3169 (31.8%)	513 (28.2%)	2697 (29.7%)	3272 (36.0%)
ICD-10 mental and behavioral disorders						
Depression (F32-F33)	290 (14.6%)	286 (2.9%)	110 (1.1%)	193 (10.6%)	126 (1.4%)	311 (3.4%)
Anxiety (F40-F41)	220 (11.0%)	189 (1.9%)	91 (0.9%)	117 (6.4%)	95 (1.0%)	189 (1.9%)
Psychoactive substance use (F10-F19)	83 (4.2%)	147 (1.5%)	184 (1.8%)	97 (5.3%)	217 (2.4%)	172 (1.9%)
Psychotic (F20-F29)	186 (9.3%)	87 (0.9%)	98 (1.0%)	147 (8.1%)	103 (1.1%)	89 (1.0%)
Bipolar and mood (F30-F31, F34-F39)	35 (1.8%)	31 (0.3%)	18 (0.2%)	29 (1.6%)	30 (0.3%)	47 (0.5%)
Intentional self-harm (X60-X84)	51 (2.6%)	47 (0.5%)	14 (0.1%)	21 (1.2%)	15 (0.2%)	53* (0.6%)
Any psychiatric diagnosis	**573 (28.8%)**	**599 (6.0%)**	**404 (4.1%)**	**447 (24.6%)**	**449 (4.9%)**	**630 (6.9%)**
ATC[a]						
Antidepressants (N06A)	412 (20.7%)	528 (5.3%)	306 (3.1%)	331 (18.2%)	422 (4.6%)	797 (8.8%)
Anxiolytics (N05B)	54 (2.7%)	85 (0.9%)	64 (0.6%)	60 (3.3%)	116 (1.3%)	221* (2.4%)
Antipsychotics (N05A)	193 (9.7%)	179 (1.8%)	164 (1.6%)	180 (9.9%)	199 (2.2%)	197 (2.2%)
Any psychopharmacological use	**489 (24.5%)**	**621 (6.2%)**	**433 (4.3%)**	**436 (24.0%)**	**576 (6.3%)**	**960 (10.6%)**

Baseline characteristics include morbidity, diagnoses of depression, and medication history 5 years before the index date. Transgender cohort is divided according to assigned gender at birth. Morbidity is defined as Charlson comorbidity index ≥1 5 years before the index date. Statistical analyses were performed in AFAB vs. control women, AFAB vs. control men, AMAB vs. control men, and in AMAB vs. control women. All *P*-values <0.001 except $^{*}P < .05$, NS: $P > .05$. Bold refers to sum of any psychiatric diagnoses and sum of any psychofarmacologial use.
[a]≥2 redemptions of medicine.
Abbreviations: AFAB, assigned female at birth; ATC, anatomical therapeutic chemical code; IQR, interquartile range.

mood/anxiety/substance abuse disorders in the transgender study population and mental health disorders could be underreported in the control group. Therefore, we conducted a sensitivity analysis, allowing only primary diagnoses for mental and behavioral disorders as study outcome.

The primary study outcome included ICD-10 diagnosis codes for several mental and behavioral disorders. We investigated number of hospital contacts for suicide attempts (X60-X84) during follow-up as a sensitivity analysis.

In Denmark, organization of gender-affirming treatment differs between child and adolescent transgender persons and adult transgender persons. Therefore, we conducted a sensitivity analysis including only adult transgender persons aged at least 18 years old at the time of their first diagnosis code of transgender.

Danish legislation was changed during the study period. In 2014, Denmark allowed legal sex-change independent of genital surgery and in 2015, the Danish national guideline was revised with focus on shortened evaluation period and wider access to gender-affirming treatment. Therefore, we conducted a sensitivity analysis including only transgender persons with first diagnosis code of transgender from January, 1, 2015 and onward.

Data management and data analyses were conducted using Stata MP 17.0 through a remote virtual private network access to Statistics Denmark with analysts blinded to the personal identities of the study subjects.

Results

A flowchart of the Danish transgender population is shown in Figure 1. The transgender cohort included 3812 individuals, 1993 (52%) were AFAB, and 1819 (48%) were AMAB.

Baseline

The median age (interquartile range) at the index date was 19 (15; 24) years in transgender persons AFAB and 23 (19; 33) years in AFAB individuals (Table 1). Medical morbidity (Charlson comorbidity index ≥1) was present 5 years before the index date in 4.4% of persons with AFAB and 4.3% of persons with AMAB. The number of persons with low tertile income was 46.7% in persons with AFAB and 55.1% in persons with AMAB.

Diagnosis codes for mental and behavioral disorders from 5 years before the index date are presented in Table 1. The frequency of any psychiatric diagnosis was 28.8% in transgender persons AFAB, 6.0% in control women, and 4.1% in control

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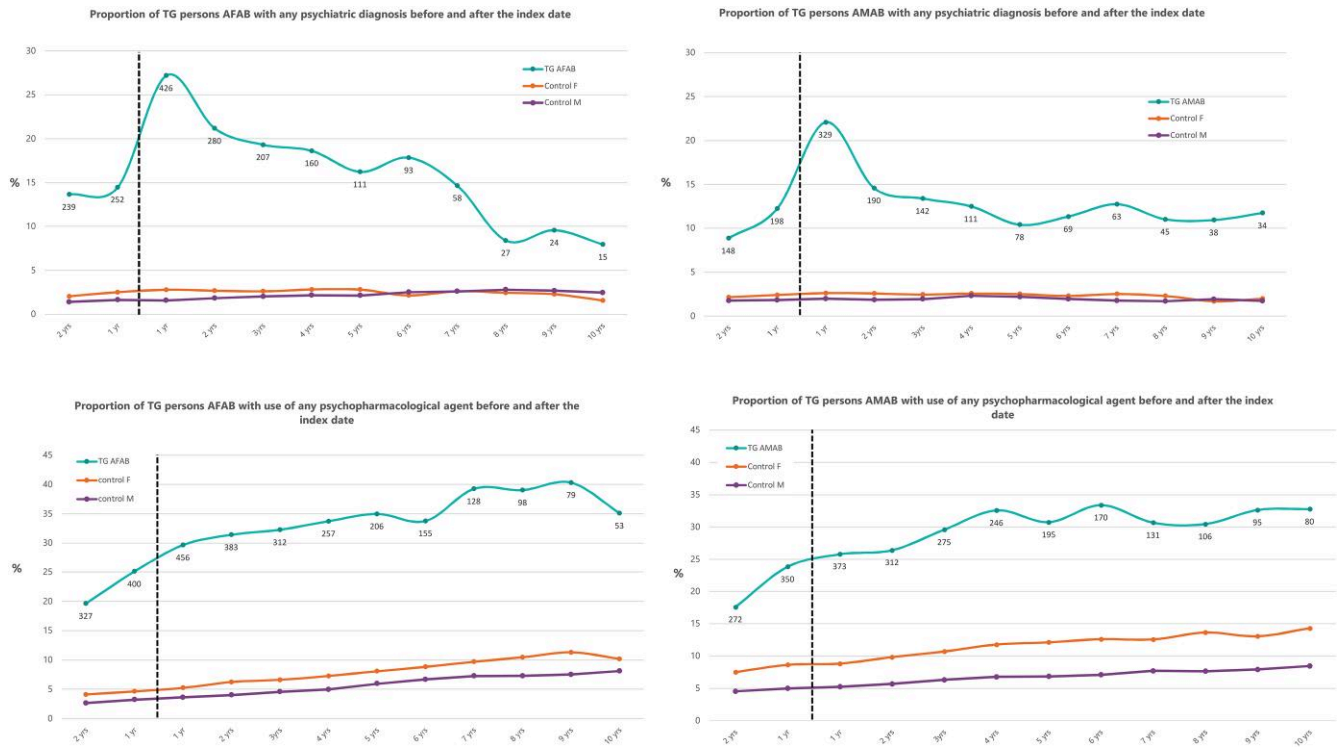

Figure 2. Number and proportion of psychiatric diagnoses and use of psychopharmacological agents before and after the index date in transgender persons and controls. Number and proportion of psychiatric diagnoses (top panels) and use of psychopharmacological agents (lower panels) in transgender persons and controls before the index date and until 10 years of follow-up. Index date = date of first transgender (TG) diagnosis. TG AFAB, Transgender person assigned female at birth; TG AMAB, Transgender person assigned male at birth.

men. In transgender persons AMAB, the prevalence was 24.6%, in control men 4.9% and in control women 6.9% (all $P < .001$ vs. controls). Prescription of psychopharmacological agents was present in 24.5% of transgender persons with AFAB and 24.0% in persons with AMAB (all $P < .001$ vs. controls).

Follow-up

The follow-up duration of the study cohort was up to 10 years with mean (SD) follow-up duration of 4.5 (4.3) years; AFAB 3.6 (3.4) and AMAB 5.3 (4.8) years.

Psychiatric diagnoses

The proportion of persons with hospital contacts for psychiatric diagnoses in the study cohort from 2 years before the index date and until 10 years of follow-up is presented in Figure 2. The proportion of transgender persons AFAB with psychiatric diagnoses was 13.6% before the index date, 27.2% 1 year after the index date, 16.2% after 5 years, and 8.4% after 8 years. In transgender persons AMAB, the corresponding proportions were 8.9%, 22.1%, 10.4%, and 11.0%.

The OR for psychiatric diagnoses in transgender persons compared to controls is presented in Appendix Figure S1. In persons AFAB compared to control women, the ORs (95% CI) for mental and behavioral disorders were 6.7 (95% CI: 5.5; 8.1) before the index date, 9.9 (95% CI: 8.4; 11.7) at 1 year, 5.8 (95% CI: 4.4; 7.7) at 5 years, and 3.4 (95% CI: 2.1; 7.5) at 8 years follow-up. In persons AMAB compared to control men, the ORs for mental and behavioral disorders was 5.0 (95% CI: 4.0; 6.4) before the index date, 11.3 (95% CI: 9.3; 13.7) at 1 year, 4.8 (95% CI: 3.5; 6.5) at 5 years, and 6.6 (95% CI: 4.2; 10.3) at 8 years follow-up.

The OR for psychiatric diagnoses compared to the pre-index date is presented in Figure 3. In persons AFAB, the OR at 1 year was 2.4 (95% CI: 2.0; 2.8), at 5 years 1.6 (95% CI: 1.3; 2.0), and at 8 years 1.1 (95% CI: 0.8; 1.5) compared to 2 years before baseline. In persons AMAB, the corresponding ORs were 3.0 (95% CI: 2.5; 3.6), 1.5 (95% CI: 1.2; 2.0), and 1.7 (95% CI: 1.3; 2.3).

Prescription of psychopharmacological agents

The proportion of transgender persons AFAB with a prescription of psychopharmacological agents was 19.6% before the index date, 29.7% 1 year after the index date, 35.0% after 5 years and 39.0% after 8 years, Figure 2. In transgender persons AMAB, the corresponding proportions were 17.6%, 25.8%, 30.8%, and 30.5%. The OR for the prescription of psychopharmacological agents in transgender persons compared to controls is presented in Appendix Figure S1. In persons AFAB compared to control women, the OR for prescription of psychopharmacological agents was 4.8 (95% CI: 4.1; 5.6) before the index date, 5.7 (95% CI: 5.0; 6.6) at 1 year, 4.4 (95% CI: 3.6; 5.4) at 5 years and 3.8 (95% CI: 2.9; 5.1) at 8 years follow-up. In transgender persons AMAB vs. control men, the corresponding ORs were 3.9 (95% CI: 3.3; 4.6), 5.0 (95% CI: 4.3; 5.8), 4.6 (95% CI: 3.7; 5.6), and 4.0 (95% CI: 3.1; 5.3). The OR for prescription of psychopharmacological agents compared to the pre-index date is presented in Figure 3. In persons AFAB, the OR at 1 year was 1.8 (95% CI: 1.6; 2.0), at 5 years 2.3 (95% CI: 2.0; 2.7) and at 8 years 2.5 (95% CI: 2.1; 3.1) compared to 2 years before baseline.

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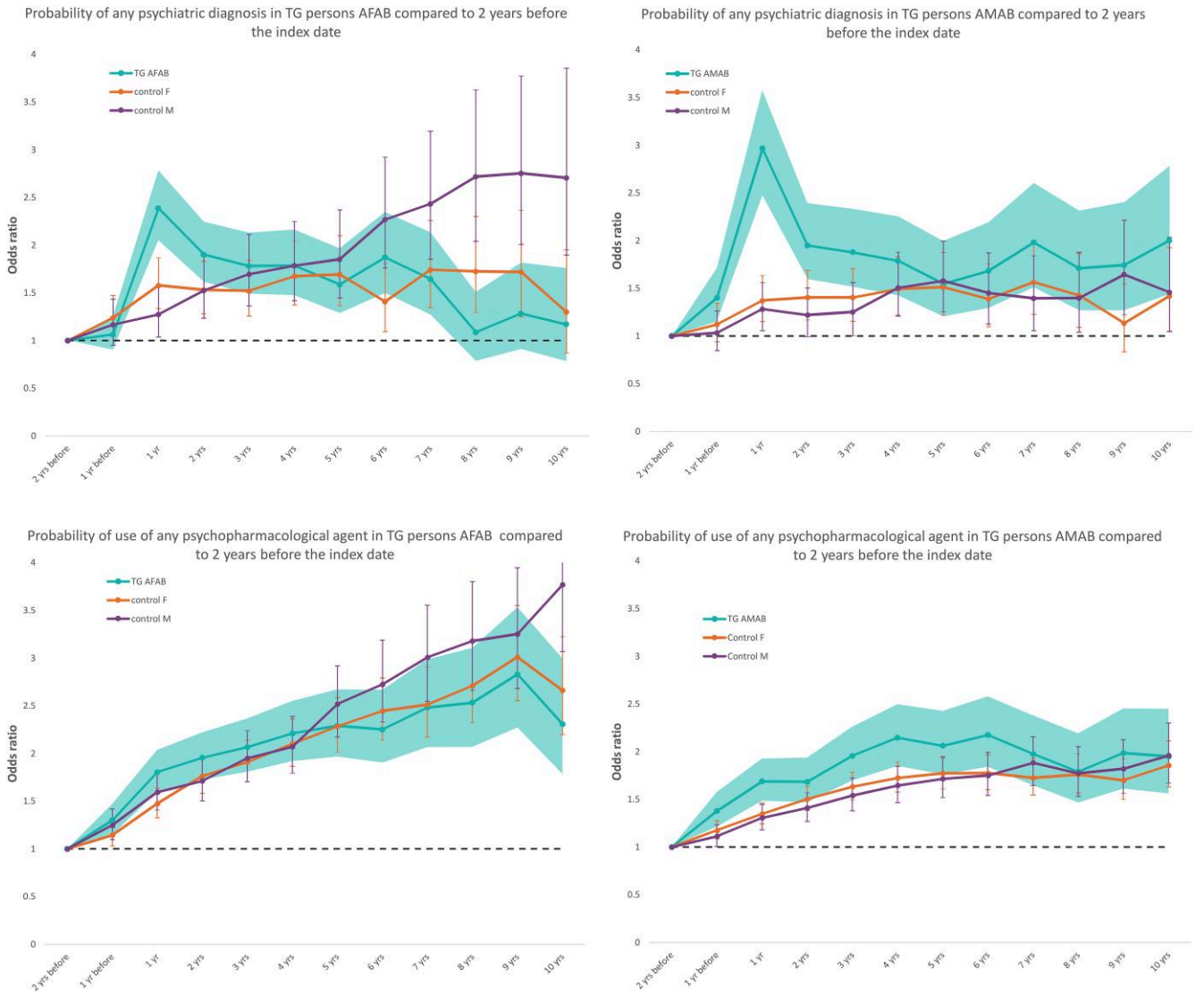

Figure 3. Probability of psychiatric diagnoses and use of psychopharmacological agents in transgender persons and controls compared to before the index date. Odds ratio (interquartile range) for psychiatric diagnoses (top panels) and use of psychopharmacological agents (lower panels) in transgender persons and controls during follow-up compared to 2 years before the index date. Index date = date of first transgender (TG) diagnosis. TG AFAB, Transgender person assigned female at birth; TG AMAB, Transgender person assigned male at birth.

In persons AMAB, the corresponding ORs were 1.7 (95% CI: 1.5; 1.9), 2.1 (95% CI: 1.8; 2.4), and 1.8 (95% CI: 1.5; 2.2).

Gender-affirming hormone therapy was prescribed in 2089 transgender persons (1046 AFAB and 1043 AMAB). The average follow-up duration from the index date to prescription of gender-affirming hormone therapy was 1.8 (95% CI: 1.7; 1.9) years in persons AFAB and 1.2 (95% CI: 1.0; 1.3) years in persons AMAB. Statistical analyses were repeated with a date for the first prescription of gender-affirming hormone therapy as the index date (Appendix Figure S2). In transgender persons AFAB, the OR for psychiatric diagnoses compared to 2 years before initiation of GAHT was 1.0 (95% CI: 0.8; 1.3) after 1 year, 1.1 (95% CI: 0.8; 1.5) at 5 years and 1.0 (95% CI: 0.6; 1.6) at 8 years. In persons AMAB, the corresponding ORs were 1.5 (95% CI: 1.2; 2.0), 1.5 (95% CI: 1.1; 2.1), and 1.5 (95% CI: 1.0; 2.3). In transgender persons AFAB, the OR for the prescription of psychopharmacological agents compared to before initiation of GAHT was 1.3 (95% CI: 1.1; 1.5) after 1 year, 2.0 (95% CI: 1.6; 2.5) at 5 years and 1.8 (95% CI: 1.4; 2.4) at 8 years. In persons AMAB, the corresponding ORs were 1.3 (95% CI: 1.1; 1.5), 2.0 (95% CI: 1.6; 2.4), and 1.8 (95% CI: 1.4; 2.3).

Gender-affirming surgery was performed on 752 transgender persons. Due to limited follow-up duration after the date of surgical procedures, the hypothesis that gender-affirming surgery improved mental health in the study cohort could not be investigated (data not presented).

Sensitivity analysis

Mental and behavioral disorders as primary diagnoses

Analyses were repeated where ICD-10 codes for mental and behavioral disorders should occur as a primary diagnosis to be included as a study outcome. The proportion of transgender persons AFAB with psychiatric diagnoses was 9.4% 2 years before the index date, 11.8% 1 year after the index date, and 11.8% after 5 years. In transgender persons AMAB, the corresponding proportions were 6.7%, 10.9%, and 7.8%. In transgender persons AFAB, the OR for psychiatric diagnoses compared to 2 years before the index date

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was 1.5 (95% CI: 1.2; 1.8) after 1 year and 1.7 (95% CI: 1.3; 2.1) at 5 years. In persons AMAB, the corresponding ORs were 1.9 (95% CI: 1.5; 2.3) and 1.4 (95% CI: 1.1; 1.9).

Suicide attempts

The number of hospital contacts for suicide attempts (X60-X84) during follow-up was 510 (97 individuals) in persons AFAB and 198 (47 individuals) in persons AMAB, which made the study underpowered to investigate changes in hospital contacts over time.

Transgender persons aged ≥18 years at first referral

The study cohort included 2670 transgender persons (1174 AFAB, 1496 AMAB) referred after the age of 18 years. In transgender persons AFAB, the OR for psychiatric diagnoses compared to 2 years before the index date was 1.5 (95% CI: 1.2; 1.9) after 1 year, 1.2 (95% CI: 0.8; 1.6) at 5 years, and 1.1 (95% CI: 0.7; 1.7) at 8 years. In persons AMAB, the corresponding ORs were 2.4 (95% CI: 1.8; 3.1), 1.3 (95% CI: 0.9; 1.8), and 1.5 (95% CI: 1.0; 2.3). In transgender persons AFAB, the OR for prescription of psychopharmacological agents compared to before the index date was 1.5 (95% CI: 1.3; 1.8) after 1 year, 1.5 (95% CI: 1.2; 1.9) at 5 years and 1.9 (95% CI: 1.4; 2.5) at 8 years. In persons AMAB, the corresponding ORs were 1.4 (95% CI: 1.1; 1.6), 1.8 (95% CI: 1.5; 2.2), and 1.5 (95% CI: 1.2; 1.9).

Transgender persons with first referral after January, 1, 2015

The study cohort included 2952 persons referred after January, 1, 2015 (1622 AFAB, 1330 AMAB). In this study cohort, transgender persons AFAB had OR for psychiatric diagnoses compared to 2 years before the index date of 2.3 (95% CI: 2.0; 2.7) after 1 year and 2.2 (95% CI: 1.7; 2.8) at 5 years. In persons AMAB, the corresponding ORs were 2.7 (95% CI: 2.2; 3.3) and 2.3 (95% CI: 1.7; 3.2). In transgender persons AFAB, the OR for prescription of psychopharmacological agents compared to before the index date was 1.9 (95% CI: 1.7; 2.2) after 1 year and 2.7 (95% CI: 2.2; 3.3) at 5 years. In persons AMAB, the corresponding ORs were 1.8 (95% CI: 1.5; 2.1) and 2.9 (95% CI: 2.3; 3.6).

Discussion

In this register-based study, we investigated mental health outcomes from hospital contacts and prescribed medications in Danish transgender persons after contact with a national center of gender identity. The present dataset was unique as we could access hospital contacts for mental health diagnoses and use of psychopharmacological agents in a national study cohort of transgender persons in a longitudinal perspective. Our data showed that the risk for mental and behavioral disorders in transgender persons increased rapidly during the first year after the index followed by a decreasing trend. Furthermore, the OR for mental and behavioral disorders in transgender persons and controls remained elevated throughout follow-up compared to 2 years before diagnosis, especially in transgender persons AMAB. The proportion of transgender persons with prescription of psychopharmacological agents increased from <20% at baseline to more than 30% who had prescriptions during follow-up. Transgender persons attending transgender care after the year 2015 showed similar findings compared to the whole study cohort. Furthermore, we found no evidence that inclusion of young and adolescent persons in the dataset affected our study results.

The present data add significant results to findings from a Swedish register-based study[11] investigating ICD-10 diagnosis codes for mood (ICD-10 codes F30-F39) and anxiety (F40-F42) disorders, admission for suicide attempts (codes X60-X84) and prescription of antidepressant and anxiolytic medication (codes N06A and N05B) in transgender persons compared to controls. Of notice, the control population included the background population in Sweden, which implied a median age of 31.5 years in transgender persons compared to 40.7 years in controls, furthermore, transgender persons were not divided according to assigned gender at birth, and study outcomes had to occur in year 2015 to be included.[11] In the present study, the ORs for all study outcomes of mental health were higher during follow-up in transgender persons AFAB and AMAB compared to controls, which corresponded to findings by Bränström et al.[11] We found that the OR for mental and behavioral disorders increased after the index date and then gradually decreased following 1 year after the index date in transgender persons AFAB compared to control women, whereas the ORs for mental and behavioral disorders reached a plateau in transgender persons AMAB. We conducted a sensitivity analysis including only the events where mental health disorders were coded as primary diagnosis. The 5-year results of these analyses were comparable to the main analyses, but the initial rise in events of mental health diagnoses at 1 year disappeared. This finding supports that systematic psychological evaluation after referral to a center of gender identity will increase awareness of mental health disorders in transgender individuals. Interestingly, ORs for mental health outcomes in this study were stable after initiation of gender-affirming hormone treatment, without sign of decrease after the date for first prescription of gender-affirming hormone. In accordance with this, Bränström et al.[11] reported that years since the initiation of hormone treatment were not significantly related to the likelihood of mental health treatment (adjusted OR = 1.01, 95% CI = 0.98, 1.03). However, Bränström et al. did not divide or stratify the study cohort according to masculinizing vs. feminizing treatment,[11] which could have affected their study results. Time since the last surgical treatment significantly reduced the risk of mental health outcomes (adjusted OR = 0.92, 95% CI = 0.87, 0.97)[11] and the likelihood of being treated for mood or anxiety disorder was reduced by 8% for each year since last gender-affirming surgery. In the present study, we did not have power to investigate changes in mental health after gender-affirming surgery. The mean follow-up duration of this study was 4.5 years, which resulted in a limited number of performed surgical procedures. In Denmark, genital constructive surgery is performed at one center only, and at least 12 months of hormone treatment and comprehensive multidisciplinary counseling are needed before the patient is registered on a waiting list for surgery.[1,24] The present study design therefore needs to be repeated with updated data extraction within the next 5-10 years to allow longer follow-up and investigate the hypothesis that gender-affirmation surgery is associated with a lower risk of mental health diagnoses in Danish transgender persons.

We observed that OR for psychiatric diagnoses before the index date was more than 5 in transgender persons compared to controls, the proportion of transgender persons with a diagnosis of mental and behavioral disorders was 26%, and

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prescription of psychopharmacological agents before the index date was observed in 24%. These findings are in agreement with previous studies reporting significantly impaired mental health in transgender study populations before transgender care with prevalence of depression around 50%.[9,10,25] The present transgender study cohort was defined by ICD-10 diagnosis code, which implied contact with a Danish center of gender identity, and supported that the present study cohort was comparable to other transgender study cohorts, which were included at centers of gender identity.[9,10,25] We defined mental health outcomes by ICD-10 diagnosis codes and/or use of psychopharmacological agents. Treatment with antidepressants is only indicated in case of moderate or severe depression, whereas psychotherapy should be applied in patients with milder depressive symptoms.[26] It is, therefore, possible that a considerable proportion of Danish transgender persons would have milder symptoms of depression without the need for psychopharmacological agents, which could not be investigated in a register-based study design. Our finding of increasing risk of psychiatric diagnoses in transgender persons 1 year after the index date could seem an unexpected study result, however, psychological counseling is advised before initiation of gender-affirming treatment, which would result in higher awareness for diagnosis and treatment of mental health disorders in transgender persons attending a center of gender identity and indicated a time of important life changes and social confrontation. For the same reason, we chose a time interval until 2 years before the index date for baseline reference in analyses of mental health outcomes during follow-up. Interestingly, Tordoff et al.[5] also described a transient impairment of mental health outcomes in the first several months of transgender care in 104 transgender and non-binary youth, which subsequently returned to baseline by 12 months. The authors suggested that delay in start of hormone medication could initially exacerbate mental health symptoms.[5] Furthermore, delayed onset of mental health improvements associated with hormone treatment could lead to transient worsening of mental health.[5] We found comparable mental health at baseline in transgender persons AFAB and transgender persons AMAB, but during follow-up, mental health was more impaired in transgender persons AMAB compared to transgender persons AFAB. In accordance, feminizing hormone treatment did not improve mental health in adolescents to the same extent as masculinizing hormone treatment.[10] Estrogen treatment is less potent than testosterone treatment regarding changes in body characteristics and changes occur with longer onset.[10,14] Feminizing hormone treatment stimulates breast development, however, the desired Tanner stage is not always obtained.[27] Higher degree of minority stress has also been reported in transgender women compared to transgender men,[28] which could be an additional explanation for lower mental health in persons AMAB during follow-up. As recently reported, cyproterone acetate is the most prescribed androgen blocker in many European countries.[4,13] In the Nordic countries, cyproterone acetate is prescribed in >40% of transgender women, whereas <10% are treated with spironolactone.[12] Cyproterone acetate is a synthetic progesterone (progestin) and blocks the gonadal axis and potentially improves breast development.[4] However, cyproterone acetate is associated with cardiovascular risks such as thromboembolism and hypertension[29,30] and progestin use has been associated with deteriorated mental health.[31,32] Further studies on mechanisms for differences in mental health outcomes between transgender women and transgender men are highly needed.

Strengths and limitations

An important strength of this study includes access to nationwide longitudinal data including all persons with contact to national centers of center identity in Denmark as ICD10 diagnosis codes of transgender are used in all contacts with national clinics. The study outcome was broad and included both ICD-10 diagnoses code of mental and behavioral disorders and the use of psychopharmacological agents. Systematic psychological evaluation of transgender persons after referral could lead to surveillance bias, therefore, baseline was defined as 2 years before the index date. We considered constructing a single pooled study outcome, but chose to present results of the study outcomes separately to ensure transparency of study results. Our finding of comparable changes in ICD10 diagnosis codes and medicine prescriptions in the transgender study cohort supports valid study results. Furthermore, several sensitivity analyses were conducted. Events of suicide attempts and self-harm could be considered hard endpoints, but unfortunately, we did not have sufficient study power in the present dataset to detect changes in these endpoints. Our study results highlight the need for larger data sets and longer follow-up in transgender persons.

Some limitations may apply to the present study. Transgender persons without hospital contact would not be included in the data set and persons who terminated transgender care before year 2000 are not included. Non-binary persons with no wish for gender-affirming care at a center for gender identity would not be included in the dataset. Therefore, the study cohort represents a selected group of transgender persons. Use of gender-affirming hormone treatment was defined by medicine prescriptions and self-prescribed hormone treatment by online purchase or through private contacts would not be included. Furthermore, transgender persons without prescription for gender-affirming hormone prescription could be persons with shorter follow-up (still undergoing initial psychological evaluation), non-binary persons with no wish for gender-affirming hormone, or could have contraindications for hormone treatment due to severe physical or mental illness. The follow-up duration of this study did not enable us to test possible reasons for not initiating gender-affirming hormone treatment in the study cohort. Further studies regarding mental health in different sub-cohorts of transgender persons are highly relevant. Furthermore, gender-affirmation surgery with insertion of breast implants is possible at Danish private clinics, which could leave some surgical breast augmentation procedures outside the dataset. Persons were divided according to assigned sex at birth, and misclassification of sex could occur in foreigners if they immigrated to Denmark after the date of legal sex-change. Therefore, persons AFAB included persons with surgical codes of salpingo-oophorectomy and/or hysterectomy and persons AMAB included persons with surgical codes of penis amputation and/or orchiectomy. Waiting time for gender-affirming surgery resulted in limited follow-up duration after surgery and we did not have study power to detect mental health after gender-affirmation surgery.

Conclusion

In this study, mental health was stabilized during gender-affirming care, but mental health was still impaired in transgender persons compared to age-matched controls.

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Supplementary material

Supplementary material is available at *European Journal of Endocrinology* online.

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Contributors

Dorte Glintborg, Marianne Skovsager Andersen, Jens-Jakob Kjer Møller: Idea, design, writing manuscript. Jens-Jakob Kjer Møller: Data analysis. Øjvind Lidegaard, Guy T'Sjoen, Malene Hilden, Mie-Louise Julie Ørsted Larsen; Katrine Hass Rubin: Design, criticism of manuscript.

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Cohort profile: Study of Transition, Outcomes and Gender (STRONG) to assess health status of transgender people

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ABSTRACT

Purpose The Study of Transition, Outcomes and Gender (STRONG) was initiated to assess the health status of transgender people in general and following gender-affirming treatments at Kaiser Permanente health plans in Georgia, Northern California and Southern California. The objectives of this communication are to describe methods of cohort ascertainment and data collection and to characterise the study population.

Participants A stepwise methodology involving computerised searches of electronic medical records and free-text validation of eligibility and gender identity was used to identify a cohort of 6456 members with first evidence of transgender status (index date) between 2006 and 2014. The cohort included 3475 (54%) transfeminine (TF), 2892 (45%) transmasculine (TM) and 89 (1%) members whose natal sex and gender identity remained undetermined from the records. The cohort was matched to 127 608 enrollees with no transgender evidence (63 825 women and 63 783 men) on year of birth, race/ethnicity, study site and membership year of the index date. Cohort follow-up extends through the end of 2016.

Findings to date About 58% of TF and 52% of TM cohort members received hormonal therapy at Kaiser Permanente. Chest surgery was more common among TM participants (12% vs 0.3%). The proportions of transgender participants who underwent genital reconstruction surgeries were similar (4%–5%) in the two transgender groups. Results indicate that there are sufficient numbers of events in the TF and TM cohorts to further examine mental health status, cardiovascular events, diabetes, HIV and most common cancers.

Future plans STRONG is well positioned to fill existing knowledge gaps through comparisons of transgender and reference populations and through analyses of health status before and after gender affirmation treatment. Analyses will include incidence of cardiovascular disease, mental health, HIV and diabetes, as well as changes in laboratory-based endpoints (eg, polycythemia and bone density), overall and in relation to gender affirmation therapy.

Strengths and limitations of this study

- ► Perhaps the most important strength of this study is systematic cohort identification without a need for participant opt-in.
- ► Additional strengths inlude accurate determination of gender identity and comprehensive ascertainment of hormonal and surgical treatment received at Kaiser Permanente.
- ► Notable weaknesses of the study include relatively short follow-up, dearth of information on gender affirmation treatment received outside of the health plans and lack of data on outcomes not captured in the medical records.

INTRODUCTION

Transgender people are a diverse group of individuals whose biological sex does not match their gender identity.[1] Typically, sex is assigned at birth based on the appearance of the genitalia.[2] In contrast, an individual's gender identity is defined as being a male/man, female/woman or of a different gender.[2 3] Many transgender people may not self-identify based on binary definitions;[4] however, a person whose gender identity differs from a male natal sex assignment is often referred to as male-to-female or trans woman, and a person whose gender identity differs from a female natal sex is often referred to as a female-to-male or trans man.[5 6] More recently, the terms transfeminine (TF) and transmasculine (TM) have become preferred as they also apply to individuals who do not identify with binary gender categories.[7]

Transgender individuals sometimes seek medical gender affirmation, which may involve administration of cross-sex hormone therapy (HT) to achieve desired masculinisation or

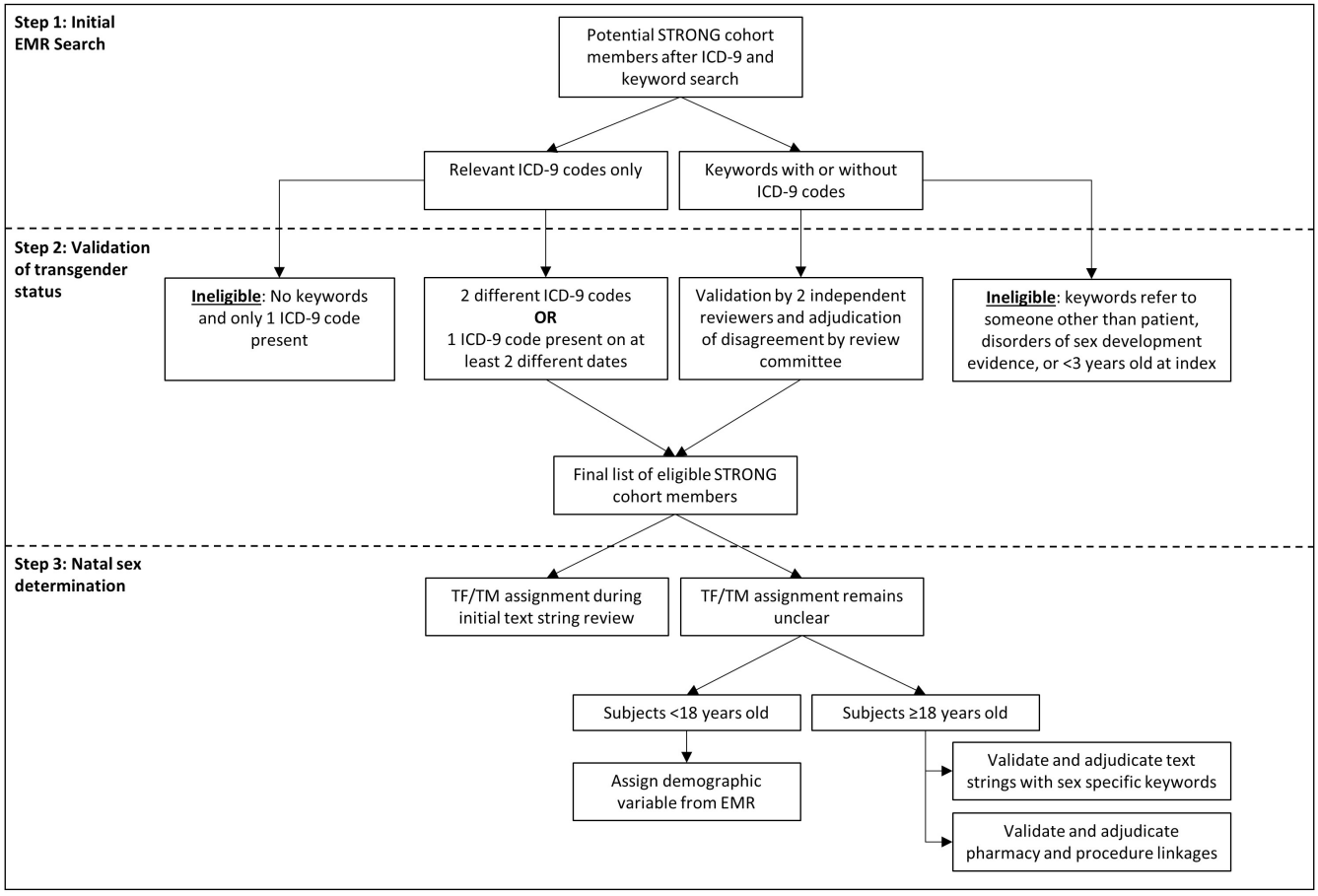

Figure 1 STRONG transgender cohort ascertainment flow diagram. EMR, electronic medical record; ICD-9; International Classification of Diseases, Ninth edition; STRONG, Study of Transition, Outcomes and Gender; TF, transfeminine; TM, transmasculine.

feminisation, and/or surgical change of the genitalia and other sex characteristics.[8 9] Although several organisations have established guidelines for clinical care of transgender patients,[9 10] many issues in transgender health and gender affirmation therapy remain unresolved due to lack of direct evidence.[11] Consequently, many current practices and standards of care are based on expert opinion, case reports or extrapolation of research findings from other populations. For example, current recommendations regarding risk of venous thromboembolism in TF patients receiving oestrogen are based on the observed effects of hormone replacement therapy in postmenopausal women.[12 13] Similarly, expected health risks in TM are inferred from comorbidities associated with polycystic ovary syndrome.[14]

Critical knowledge gaps include the effect of HT and surgery on gender dysphoria (the feeling of distress when natal sex does not match gender identity[15]) and other mental health issues, haematological side effects of HT and risk of cardiovascular disease, metabolic or endocrine disorders and cancer following hormonal or surgical gender affirmation.[16] A direct evaluation of some of these issues requires longitudinal studies with large numbers of TM and TF participants with sufficient follow-up and variable history of surgical interventions and cross-sex HT use.[17] These considerations motivated the design of the longitudinal cohort for 'Study of Transition, Outcomes and Gender (STRONG)'. This paper provides a summary of the challenges facing transgender health research, describes the main elements of the STRONG study design and data collection and discusses lessons learnt during the implementation of this project. In this 'cohort profile' communication, we offer a detailed documentation of methods used to assemble, validate and characterise the STRONG cohort and offer an overall description of the study population that will provide data for a multitude of subsequent hypothesis-testing studies.

METHODOLOGICAL CHALLENGES FACING TRANSGENDER HEALTH STUDIES

The methodological challenges in observational studies of transgender health fall into five categories: (1) attaining sufficient sample size and statistical power; (2) systematic and comprehensive identification of eligible study participants and comparable reference groups; (3) determination of natal sex and/or gender identity; (4) assessment of current and past gender affirmation treatment and (5) engagement of patient and physician stakeholders at all stages of research.[17]

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Table 1 ICD-9 codes and keywords used to identify potentially eligible STRONG transgender cohort members among KPGA, KPSC and KPNC members

ICD-9 diagnostic codes	ICD-9 V codes*+internal KP codes	Keywords
302.5—trans-sexualism 302.50—trans-sexualism with unspecified sexual history (aka 'trans-sexualism not otherwise specified') 302.51—trans-sexualism with asexual history 302.52—trans-sexualism with homosexual history 302.53—trans-sexualism with heterosexual history 302.85—gender identity disorder in adolescents or adults 302.6—gender identity disorder in children 302.3—transvestic fetishism	V49.89+121141596—other conditions influencing health: transgender V45.77+121141596—acquired absence of genital organs: history of sex reassignment surgery V07.8+12124952—other specified prophylactic measure: male-to-female hormone supplementation V07.8+12124310—other specified prophylactic measure: female-to-male hormone supplementation	'Transgender' 'Transsexual' 'Transvestite' 'Gender identity' 'Gender dysphoria' 'Gender reassignment'

*ICD-9 V codes are used for supplementary classification of factors influencing health status.[40 41] As V codes may cover several conditions, they have to be used in conjunction with internal KP codes to ensure specificity.
ICD-9, International Classification of Diseases Ninth edition; KP, Kaiser Permanente; KPGA, Kaiser Permanente health plan located in Georgia; KPNC, Kaiser Permanente health plan located in Northern California; KPSC, Kaiser Permanente health plan located in Southern California; STRONG, Study of Transition, Outcomes and Gender.

Transgender people represent a hard-to-reach population, and to date most existing cohorts assessing transgender health were assembled in specialised clinics that provide gender affirmation care.[18 19] This approach provides good options for collecting detailed treatment data and biospecimens but may exclude individuals who have not sought or who have already completed treatment, and makes it difficult to select comparable reference groups.[20] In addition, establishing a large clinic-based cohort requires coordination across multiple sites, is costly and may still have small numbers resulting in studies of relatively low statistical power.[17]

Besides clinic-based studies, previous efforts to identify transgender individuals for health research also involved population surveys[21] and reviews of electronic records for relevant International Classification of Diseases (ICD) codes.[22 23] While surveys offer generalisable population estimates, they may be affected by recall bias and low response rates and require large-scale efforts to identify sufficient numbers of transgender people. Reliance on ICD codes allows identifying large samples from insurance claims or electronic medical records (EMRs), but may exclude eligible study participants who do not have or do not wish to receive a transgender-specific diagnosis.[24]

A critical aspect of transgender research is accurate identification of gender identity. In recent years, the US Department of Health and Human Services issued a directive that EMR systems should enable providers to record gender identity and sexual orientation.[25] This directive should improve documentation over time; but in the meantime, determination of TF or TM status presents a methodological challenge because the available demographic data can reflect natal sex or gender identity, without specifying which is which. Assessing TM/TF

Table 2 Keywords used for STRONG transgender cohort natal sex assignment

Transfeminine	Natal sex keywords	'Testes', 'testicular', 'penis', 'penile', 'prostate', 'prostatic', 'PSA', 'scrotum', 'neovagina', 'neo vagina', 'neo-vagina', 'sperm', 'erection'
	Hormonal therapy keywords	'Estrogen', 'anti-androgen', 'progesterone', 'aldactone', 'avodart', 'cenestin', 'climara', 'cyprostat', 'cyproterone', 'delestrogen', 'depo-estradiol', 'divigel', 'dutasteride', 'elestrin', 'enjuvia', 'estrace', 'estradiol', 'estroderm', 'estrogel', 'estrosorb', 'flutamide', 'finasteride', 'lupron', 'medroxyprogesterone', 'premarin', 'premphase', 'prempro', 'propecia', 'proscar', 'prometrium', 'provera', 'spironolactone'
	Procedure keywords	'Castration', 'orchiectomy', 'penectomy', 'vaginoplasty', 'breast augmentation', 'breast enlargement', 'laryngeal shave', 'feminization', 'electrolysis', 'hair transplant', 'collagen', 'silicone', 'voice therapy'
Transmasculine	Natal sex keywords	'Ovary', 'ovaries', 'ovarian', 'cervix', 'uterus', 'uterine', 'vagina', 'PAP smear', 'menstrual bleeding', 'menses'
	Hormonal therapy keywords	'Android', 'androderm', 'androgel', 'axiron', 'delatestryl', 'depo-testosterone', 'striant', 'testim'
	Procedure keywords	'Vaginectomy', 'phalloplasty', 'metoidioplasty', 'mastectomy', 'hysterectomy', 'oophorectomy'

PAP, Papanicolau; PSA, prostate specific antigen; STRONG, Study of Transition, Outcomes and Gender.

Box Data available for Study of Transition, Outcomes and Gender transgender cohort

Data categories and specific elements

Demographic and membership characteristics
- Age, sex and race/ethnicity
- Health plan site
- Area-based socioeconomic status factors*
- Enrolment/disenrolment intervals
- Insurance plan type

General health indicators
- Height/weight (body mass index)*
- Smoking status*
- Comorbidities

Gender affirmation procedures
- Current Procedure Terminology and/or International Classification of Diseases code
- Date of procedure
- History of gender affirmation procedures (clinical notes)

Pharmacy records (hormone therapy, psychiatric medications)
- Medication prescribed
- Filled prescription for medication
- Dose
- Form
- Dates of prescription and fill

Visit-associated diagnoses
- Cardiovascular disease
- Diabetes
- HIV
- Mental health problems

Cancer diagnoses
- Stage
- Site
- Histology
- Date of diagnosis

Laboratory results
- Laboratory test
- Value
- Date

Vital status
- Date of death
- Cause of death

Note: *Assessed at index date (date of first evidence of transgender status in electronic medical record).

status can be achieved by asking two questions about natal sex and gender identity[26]; however, reliance on self-report requires contact with individual participants and is subject to non-response, which increases the risk of selection bias.

Insurance coverage for gender affirmation therapy has increased over time[27–29]; however, it remains sporadic and incomplete, and many transgender people seek care outside of regular healthcare plans.[30] This presents a specific challenge for any study that aims to ascertain hormonal exposures and surgical procedures, particularly for transgender people with no or inadequate insurance coverage and for persons who initiated gender-affirming therapy years ago.

In a rapidly developing field, such as transgender health, even experienced researchers may lack specific expertise required to prioritise research questions and select the most relevant patient-centred outcome measures. Thus, it is important to involve members of the transgender community and their physicians to ensure that the proposed research questions, study design and data collection methods are relevant, appropriate and feasible.[31] Conversely, as the research methods and interpretation of findings are becoming increasingly complex, researchers should communicate with stakeholders directly to convey information relevant to their decision-making.[32]

In sum, transgender health research faces significant methodological challenges and logistical barriers. These challenges and barriers contribute to the lack of knowledge about the health risks in this population and preclude development of evidence-based recommendations for transgender healthcare.[11]

COHORT DESCRIPTION

Study goals, design and setting

STRONG was initiated in September 2013 with the primary long-term goal of assessing the health status of transgender individuals overall, among TF/TM subgroups, and in both subgroups after different types of gender-affirming treatment. It was designed as an EMR-based retrospective/prospective cohort study of transgender members enrolled in three Kaiser Permanente (KP) health plans located in Georgia (KPGA), Northern California (KPNC) and Southern California (KPSC). These health plans are prepaid integrated care systems and currently provide comprehensive health services to approximately 8 million members. Individuals and their families may enrol through an employer, state or federal programmes such as Medicaid and Medicare, or directly. The populations of enrollees are sociodemographically diverse and broadly representative of the communities in the corresponding areas.[33 34]

The three KP organisations are members of several research consortia including the Healthcare Systems Research Network[35] and the Mental Health Research Network.[36] They share similarly structured databases organised into 'Virtual Data Warehouses' (VDW), with files stored behind security firewalls at each site. The files have identical variable names, formats and specifications that allow using centrally generated and/or distributed programs to create harmonised analytic datasets.[37] VDW files are linked by unique individual identifiers, allowing researchers to construct historical and prospective cohorts.[38]

The study was conducted in partnership with the Emory University, which served as the coordinating centre. All activities described in this manuscript were reviewed and approved by the Institutional Review Boards (IRBs) of the four institutions.

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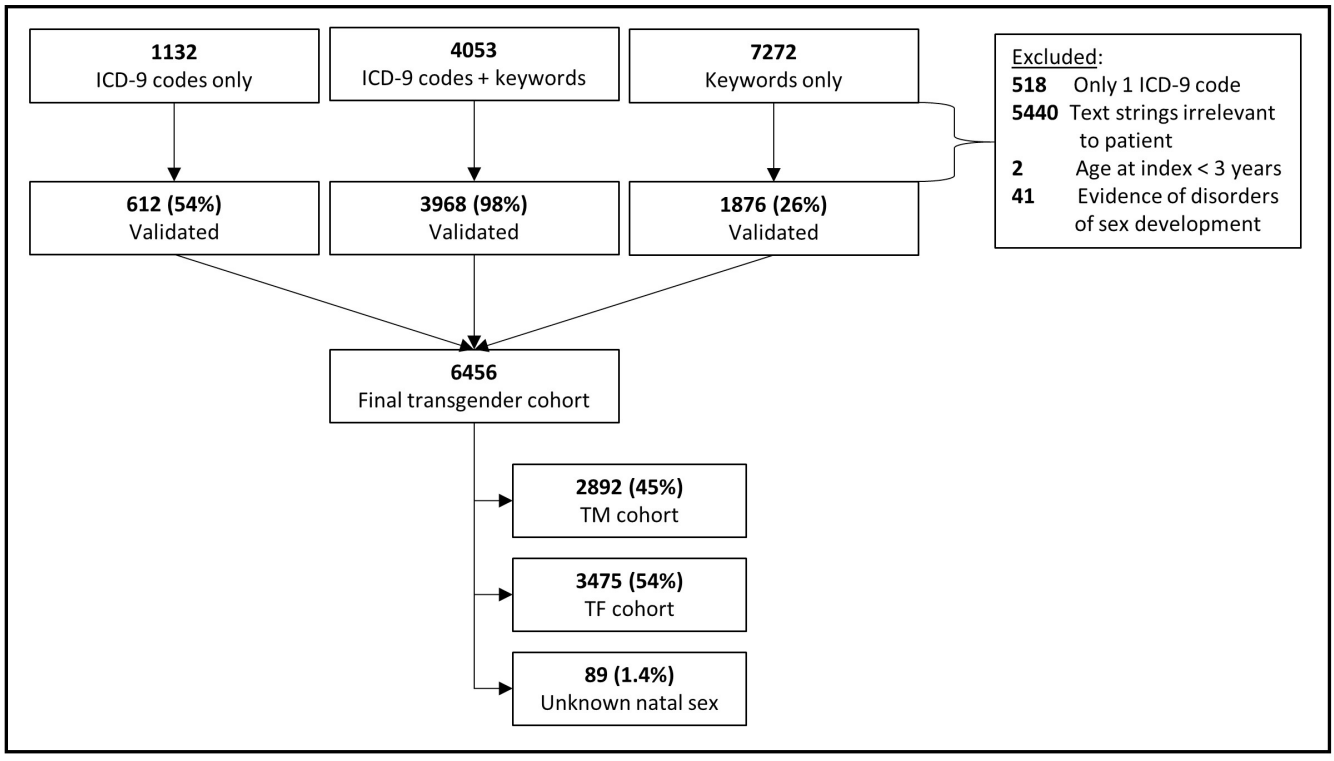

Figure 2 Results of STRONG transgender cohort ascertainment and validation. ICD-9; International Classification of Diseases Ninth edition; STRONG, Study of Transition, Outcomes and Gender; TF, transfeminine; TM, transmasculine.

The stakeholder involvement was achieved by assembling a project advisory group. To recruit the Stakeholder Advisory Group members, investigators at each site were charged with identifying a leading clinician specialising in transgender care. The physicians were then asked to nominate one or two patients to serve as representatives of the transgender community. The resulting Stakeholder Advisory Group included 12 members. The stakeholders made a number of important contributions to the project at various stages of study design, planning and implementation, as described below.

Cohort ascertainment

Figure 1 shows the three-step algorithm used to identify transgender cohort members. It includes initial EMR search to identify cohort candidates (step 1), validation of transgender status (step 2) and determination of TM/TF status (step 3).

Step 1: Initial EMR search

A computer programme written using Statistical Analysis Software (SAS) V.9.4 (SAS Institute Inc., Cary, NC) was used to search the EMRs of KPGA, KPNC and KPSC members of all ages enrolled between 1 January 2006 and 31 December 2014 to identify two types of evidence supporting transgender status: (1) relevant International Classification of Diseases, Ninth edition (ICD-9) codes and (2) presence of relevant specific keywords in free-text clinical notes (table 1). The program was developed and pilot-tested at KPGA and then distributed to the remaining sites. Cohort ascertainment was undertaken before the health plans switched to ICD-10 codes.

The diagnostic ICD-9 codes suggestive of transgender status were selected based on consultations with the STRONG Stakeholder Advisory Group and methodologies described in earlier studies.[23 39] Transvestic fetishism (ICD-9 code 302.3) was included based on previous observations that men who initially meet criteria for this diagnostic category may later experience persistent gender dysphoria consistent with transgender status.[22]

We also used ICD-9 V codes, which allow for supplementary classification of factors influencing health status.[40 41] As V codes may cover several conditions, we used them in conjunction with internal KP codes to ensure specificity. For example, a combination of ICD-9 code V49.89 and KP code 121141596 means 'Other conditions influencing health: transgender'.

The second method of transgender ascertainment involved another custom-written program that identified the relevant keywords in free-text clinical notes recognising that both appropriate and inappropriate terms could be found in the EMR. During pilot testing, an expanded list of keywords provided by the stakeholders was used; that list was gradually shortened after stepwise removal of keywords that did not contribute additional cases. The resulting list provided a complete cohort ascertainment with the shortest program running time.

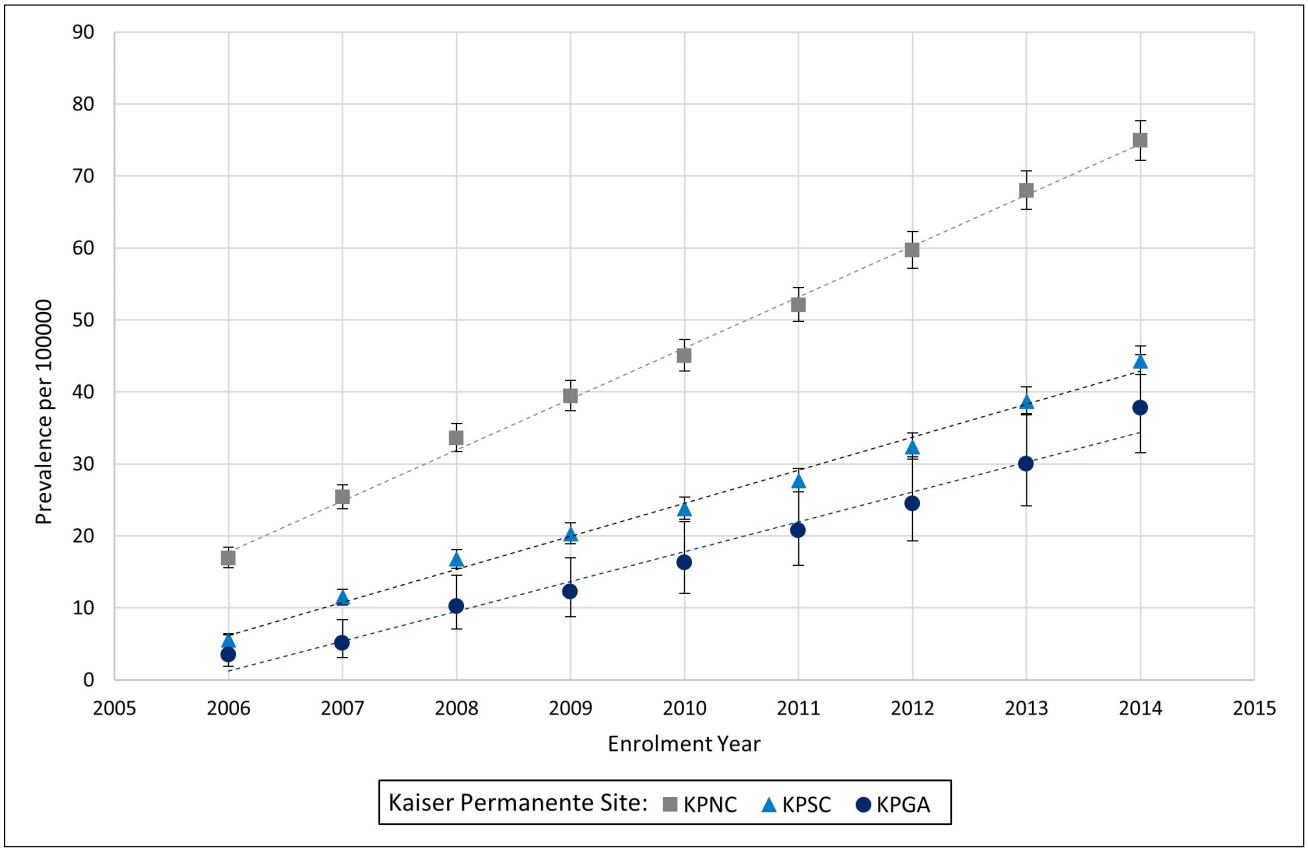

Figure 3 Prevalence of transgender status by site and year of health plan enrolment. Dotted lines represent linear trends. KPGA, Kaiser Permanente health plan located in Georgia; KPNC, Kaiser Permanente health plan located in Northern California; KPSC, Kaiser Permanente health plan located in Southern California.

Step 2: Cohort validation

A separate program extracted short strings of text that included 100 characters before and 50 characters after each keyword of interest. When clinical notes contained relevant keywords (with or without an ICD-9 code), transgender status was confirmed through an examination of the deidentified text strings by two trained reviewers. Disagreements among reviewers were adjudicated by a review committee that included two physician investigators (MG and VT) and the project manager (RN).

Cohort candidates with no keywords but at least two different diagnostic codes or the same code on different dates were considered eligible. The validity of this approach was confirmed using unstructured chart review during pilot testing of the study protocol, as described previously.[24]

Members who had evidence of disorders of sex development (ie, abnormalities of chromosomal, gonadal or anatomic sex[42]) and those younger than 3 years of age at the index date were excluded.

Step 3: Determination of TF/TM status

Each eligible study participant was categorised as TF or TM using several methods. We used all keyword text strings and ICD-9 codes extracted for step 1 to identify additional words such as 'male-to-female', 'female-to-male' and gender affirmation V codes (V07.8+12124952 and V07.8+12124310). During the validation of transgender status, the reviewers were also instructed to categorise each eligible person as 'natal male', 'natal female' or 'unclear'.

For persons whose TF/TM status was unclear after the initial review and for persons with ICD-9 codes only, another free-text program was developed to search for keywords reflecting natal sex anatomy (eg, 'testes' or 'ovaries'), history of specific procedures (eg, orchiectomy or hysterectomy) or evidence of hormonal therapy (eg, oestrogen or testosterone). The keywords used for assigning TM/TF status are included in table 2. Text strings containing TF-specific and TM-specific keywords were reviewed and adjudicated as discussed above.

Gender affirmation treatment status

During the initial STRONG cohort validation (step 2) and natal sex determination (step 3), reviewers were instructed to check a box for 'Evidence of treatment' if the text strings provided an indication of receipt or referral for HT, surgery or other relevant procedures (eg, electrolysis). Disagreements were adjudicated as described previously.

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Table 3 Characteristics of the STRONG transgender cohort

Participant characteristics	Overall transgender cohort, n (%)	TF cohort, n (%)*	TM cohort, n (%)*
Health plan site			
KPNC	3842 (60)	1949 (56)	1831 (63)
KPSC	2440 (38)	1431 (41)	982 (34)
KPGA	174 (2.7)	95 (2.7)	79 (2.7)
Race/ethnicity			
Non-Hispanic white	3532 (55)	1828 (53)	1669 (58)
Non-Hispanic black	510 (7.9)	248 (7.1)	256 (8.9)
Asian	515 (8.0)	305 (8.8)	203 (7.0)
Hispanic	1232 (19)	710 (20)	503 (17)
Other/unknown	667 (10)	384 (11)	261 (9.0)
Age†			
3–17 years	1347 (21)	588 (17)	745 (26)
18–25 years	1431 (22)	655 (19)	753 (26)
26–35 years	1329 (21)	600 (17)	707 (24)
36–45 years	939 (15)	577 (17)	347 (12)
46–55 years	779 (12)	552 (16)	219 (7.6)
>55 years	631 (9.8)	503 (14)	121 (4.2)
Smoking status†			
Current	1011 (16)	506 (15)	489 (17)
Former	873 (14)	461 (13)	401 (14)
Never	4029 (62)	2196 (63)	1795 (62)
Unknown	543 (8.4)	312 (9.0)	207 (7.2)
BMI†			
Underweight	150 (2.3)	96 (2.8)	52 (1.8)
Normal weight	2404 (37)	1356 (39)	1025 (35)
Overweight	1648 (26)	915 (26)	710 (25)
Obese	1690 (26)	777 (22)	886 (31)
Unknown	564 (8.7)	331 (9.5)	219 (7.6)
Medicaid status†			
Yes	265 (4.1)	138 (4.0)	123 (4.3)
No	6029 (93)	3251 (94)	2702 (93)
Unknown	162 (2.5)	86 (2.5)	67 (2.3)
Census-level education status			
<30% of residents have high school or less	2634 (41)	1405 (40)	1194 (41)
30%–50% of residents have high school or less	2233 (35)	1218 (35)	979 (34)
>50% have high school or less	1467 (23)	795 (23)	655 (23)
Unknown	122 (1.9)	57 (1.6)	64 (2.2)
Total, n (%)	6456 (100)	3475 (54)	2892 (45)

*Excludes 89 persons with unknown natal sex.
†Assessed at index date (date of first evidence of transgender status in electronic medical records).
KPGA, Kaiser Permanente health plan located in Georgia; KPNC, Kaiser Permanente health plan located in Northern California; KPSC, Kaiser Permanente health plan located in Southern California; STRONG, Study of Transition, Outcomes and Gender; TF, transfeminine; TM, transmasculine.

In addition to text string reviews, gender affirmation treatment status was determined by linkage with cross-sex hormone prescriptions using national drug codes, as well as ICD-9, ICD-10 and Current Procedure Terminology (CPT) codes reflecting surgeries and other interventions (online supplementary tables 1–6). TF drugs (eg, oestradiol, spironolactone) in a natal male and TM drugs (eg, testosterone) in a natal female were considered as evidence of HT.

As a result of these steps, cohort members were categorised based on evidence of HT and surgical or other gender affirmation procedures. Gender affirmation

Table 4 Gender affirmation status of the STRONG transgender cohort members

Gender affirmation evidence and type	Overall transgender cohort, n (%)	TF cohort, n (%)*	TM cohort, n (%)*
Evidence of treatment			
Any†	4040 (63)	2244 (65)	1792 (62)
None	2416 (37)	1231 (35)	1100 (38)
Cross-sex hormone therapy			
Specific evidence at KP	3544 (55)	2030 (58)	1514 (52)
Evidence in the text only	187 (2.9)	112 (3.2)	72 (2.5)
No evidence	2725 (42)	1333 (38)	1306 (45)
Gender affirmation surgery			
Top surgery at KP only	369 (5.7)	12 (0.3)	357 (12)
Orchiectomy at KP with or without top	52 (0.8)	52 (1.5)	0 (0)
Hysterectomy and/or oophorectomy at KP with or without top	311 (4.8)	0 (0)	311 (11)
Genital reconstruction at KP with or without other surgery	299 (4.6)	181 (5.2)	118 (4.1)
Evidence in the text only	432 (6.7)	253 (7.3)	179 (6.2)
No evidence	4993 (77)	2977 (86)	1927 (67)
Procedures to alter secondary sex characteristics			
Specific evidence at KP	678 (11)	385 (11)	293 (10)
Evidence in the text only	58 (0.9)	52 (1.5)	6 (0.2)
No evidence	5720 (89)	3038 (87)	2593 (90)
Total	6456 (100)	3475 (100)	2892 (100)

*Excludes 89 persons with unknown natal sex.
†Includes non-specific history and referral for treatment.
KP, Kaiser Permanente; STRONG, Study of Transition, Outcomes and Gender; TF, transfeminine; TM, transmasculine.

procedures were categorised as: bottom (eg, vaginoplasty for TF or vaginectomy for TM); top (eg, breast augmentation for TF or mastectomy for TM); interventions to change secondary sex characteristics (eg, electrolysis) or not specified (ie, evidence of surgery in the text only).

Selection of the reference cohort

Up to 10 male and 10 female KP enrollees without evidence of transgender status were matched to each member of the final validated transgender cohort on year of birth (within 5-year groups for adults and 2-year groups for children and adolescents), race/ethnicity, KP site and membership year at the index date. Index date was defined as the date of the first recorded evidence of transgender status in the EMR. For some transgender cohort members, the number of reference males or females was less than 10 due to duplicate matches; however, no transgender participant had less than seven referents of either sex. A cluster ID for each matched group was assigned to allow stratified analyses (eg, by HT type or gender-affirming surgery).

Data integration and follow-up

Patient identification numbers for both the transgender and reference cohorts were linked to multiple data sources to obtain ICD-9 and ICD-10 diagnostic codes for the conditions of primary interest (eg, mental health conditions, cardiovascular diseases and diabetes); disease registries to ascertain incident cancers and HIV diagnoses; psychiatric and behavioural healthcare utilisation; pharmacy records to track mental health treatment and HT receipt over time; and dates and results of laboratory tests including bone scans, blood chemistry analyses, hormone levels and blood cell counts (box). Mortality was ascertained from linkages to death registries. All members of the cohort were assigned a study ID by the programmer at each KP site and no personally identifiable information was included in the aggregated analytic file. To date, cohort follow-up extends through the end of 2016.

FINDINGS TO DATE

Initial review of the EMRs identified 12 457 potential transgender individuals. Of these, 7272 (58%) were identified through keywords only, 1132 (9%) through ICD-9 codes only and the remaining 4053 (33%) had both ICD-9 codes and keywords (figure 2). Among these candidates, 6456 were confirmed as transgender: 10% from ICD-9 codes alone, 29% from keywords alone and 61% from both codes and keywords. Based on validation results, the positive predictive values for keywords, diagnostic codes and both were 26%, 54% and 98%, respectively. The leading reason for non-eligibility was the use of a keyword

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Table 5 Frequency of health outcomes in the STRONG TF cohort relative to matched comparison groups

Health outcomes	TF cohort, n (%)*	Reference males, n (%)*	Reference females, n (%)*
Cardiovascular disease			
Venous thromboembolism	86 (2.5)	670 (1.9)	677 (2.0)
Stroke	88 (2.5)	943 (2.7)	674 (2.0)
Myocardial infarction	61 (1.8)	664 (1.9)	319 (0.9)
Peripheral artery disease	106 (3.1)	879 (2.6)	645 (1.9)
Unstable angina	64 (1.8)	656 (1.9)	336 (1.0)
Mental health†			
Anxiety	1337 (38)	4323 (13)	7485 (22)
Depression	1705 (49)	4721 (14)	8726 (25)
Self-inflicted injury‡	75 (2.2)	100 (0.3)	204 (0.6)
Suicidal ideation	175 (5.0)	157 (0.5)	194 (0.6)
Substance abuse disorder	524 (15)	2860 (8.3)	1680 (4.9)
Cancer primary site			
Colorectum	10 (0.3)	107 (0.3)	91 (0.3)
Lung and bronchus	9 (0.3)	58 (0.2)	59 (0.2)
Lymphatic and haematopoietic	22 (0.6)	168 (0.5)	106 (0.3)
Melanoma	10 (0.3)	227 (0.7)	180 (0.5)
Prostate	25 (0.7)	451 (1.3)	0 (0.0)
Other chronic conditions†			
HIV§	186 (5.4)	190 (0.6)	15 (0.0)
Diabetes	313 (9.0)	3358 (9.8)	2619 (7.6)
Vital status			
Alive	3372 (97)	33 562 (98)	33 839 (98)
Dead	103 (3.0)	818 (2.4)	551 (1.6)
Total	3475 (100)	34 380 (100)	34 390 (100)

*Percentages do not add to 100% due to overlapping categories.
†Based on at least two diagnoses in the EMR.
‡Combined diagnoses of self-inflicted injury, self-inflicted injury/poisoning and possible self-inflicted injury.
§HIV status ascertained from disease registries in Kaiser Permanente health plans located in Northern and Southern California and from two or more International Classification of Diseases codes in the EMR in Kaiser Permanente health plan located in Georgia.
EMR, electronic medical record; STRONG, Study of Transition, Outcomes and Gender; TF, transfeminine.

(eg, transgender) referring not to the patient, but to the patient's relative or partner. In other situations, the keywords of interest were used as part of standard text, such as when listing indications for hormone use. Natal sex and/or gender identity was successfully determined for all but 89 (1.4%) of the transgender cohort members.

The transgender cohort was matched to 127 608 enrollees with no evidence of transgender status. Of those 63 825 were women and 63 783 were men.

Figure 3 displays proportions of transgender enrollees over time at each of the three participating sites. In 2006, the prevalence estimates (95% CIs) per 100 000 enrollees were 3.5 (1.9 to 6.3), 5.5 (4.8 to 6.4) and 17 (16 to 19) in KPGA, KPSC and KPNC, respectively. By 2014, the corresponding estimates increased to 38 (32 to 45) in KPGA, 44 (42 to 46) in KPSC and 75 (72 to 78) in KPNC. The composition of the transgender population has also changed. Whereas in 2006, the TF:TM ratio among newly identified cohort members was approximately 1.7:1, in 2014 the same ratio was 1:1.

As shown in table 3, about 60% of all participants were from KPNC, 38% were from KPSC and less than 3% were from KPGA. With respect to race and ethnicity, blacks and Asians each comprised about 8% of the study population, 19% were Hispanics and 55% were non-Hispanic whites. Compared with TF, TM subjects were younger (76% vs 53% under the age of 36) and included a greater proportion of subjects who were obese (31% vs 22%). Proportions of smokers, insurance status and area-based measures of education were similar in TM and TF study subjects.

Nearly two-thirds of the transgender cohort had some evidence of gender-affirming treatment (table 4). Approximately 55% of all transgender cohort members had evidence of HT received at KP. This proportion was slightly higher (58%) in TF than in TM participants (52%).

Table 6 Frequency of health outcomes in the STRONG TM cohort relative to comparison groups

Health outcomes	TM cohort, n (%)*	Reference males, n (%)*	Reference females, n (%)*
Cardiovascular disease			
Venous thromboembolism	45 (1.6)	266 (0.9)	356 (1.2)
Stroke	42 (1.5)	360 (1.3)	250 (0.9)
Myocardial infarction	17 (0.6)	210 (0.7)	88 (0.3)
Peripheral artery disease	38 (1.3)	309 (1.1)	242 (0.8)
Unstable angina	20 (0.7)	215 (0.8)	123 (0.4)
Mental health†			
Anxiety	1323 (46)	3583 (13)	6089 (21)
Depression	1594 (55)	3806 (13)	6813 (24)
Self-inflicted injury‡	121 (4.2)	109 (0.4)	181 (0.6)
Suicidal ideation	193 (6.7)	160 (0.6)	186 (0.7)
Substance abuse disorder	418 (14)	2391 (8.4)	1523 (5.3)
Cancer primary site			
Breast	20 (0.7)	¶	217 (0.8)
Cervix	7 (0.2)	0 (0.0)	172 (0.6)
Melanoma	8 (0.3)	109 (0.4)	71 (0.2)
Other chronic conditions†			
HIV§	9 (0.3)	117 (0.4)	10 (0.0)
Diabetes	153 (5.3)	1329 (4.7)	1213 (4.2)
Vital status			
Alive	2853 (99)	28237 (99)	28366 (99)
Dead	39 (1.3)	283 (1.0)	183 (0.6)
Total	2892 (100)	28520 (100)	28549 (100)

*Percentages do not add to 100% due to overlapping categories.
†Based on at least two diagnoses in the EMR.
‡Combined diagnoses of self-inflicted injury, self-inflicted injury/poisoning and possible self-inflicted injury.
§HIV status ascertained from disease registries in Kaiser Permanente health plans located in Northern and SouthernCalifornia and from two or more International Classification of Diseases codes in the EMR in Kaiser Permanente health plan located in Georgia.
¶Counts <5 are suppressed.
EMR, electronic medical record; STRONG, Study of Transition, Outcomes and Gender; TM, transmasculine.

About 23% of the transgender cohort had some evidence of gender affirmation surgery. Top surgery receipt at KP was far more common among TM cohort members than among their TF counterparts (12% vs 0.3%). Similar proportions of TM and TF cohorts had genital surgeries (4%–5%) or procedures aimed at altering other secondary sex characteristics (11%).

Tables 5 and 6 present the number of cases for various health outcomes in the STRONG population through the end of 2016. These frequencies should not be interpreted as evidence of increased or decreased risk because they do not account for person-time of follow-up, time ordering of the conditions and transgender status and do not take into consideration exposures to cross-sex hormones or surgical procedures. Nevertheless, these data indicate that both TF and TM cohort members, as well as their corresponding referents, have sufficient numbers of cardiovascular events, mental health conditions, HIV, diabetes and several common cancers to permit meaningful analyses. Additional analyses will include changes in laboratory-based endpoints including polycythemia and bone density. These analyses are beyond the scope of this communication, which is focused on the study methods rather than specific findings. The planned analyses will include comparisons of transgender and reference cohorts as well as within-transgender cohort examination of health status before and after surgery and initiation of HT.

STRENGTHS AND LIMITATIONS

In this communication, we describe STRONG, a health system-based observational study that was designed to examine the health status of transgender people and to evaluate the possible risks and health benefits of various gender-affirming treatments. STRONG aimed to overcome five previously described methodological challenges facing transgender health research.

Sample size and power considerations

Adequate sample size can be feasibly achieved with the use of large well-defined populations that offer an

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adequate sampling frame.[38] In practical terms, at least in the USA, this can be done by basing the study in large integrated health systems with millions of members and comprehensive EMRs. The EMR data from the health systems allow assembling cohorts of hard-to-reach populations and ample options for selection of referent groups. The STRONG cohort, which included almost 6500 transgender people and nearly 130 000 referents, represents one of the largest studies of its kind available to date. Nevertheless, a number of important analyses by different subtypes of gender affirmation treatment may not be feasible due to sparse stratum-specific data.

Systematic identification of eligible study participants

We demonstrated that by using a relatively simple algorithm—based on standard codes and supplemented with analysis of digitised provider notes—it is possible to comprehensively identify transgender enrollees of large community-based health plans. The use of keyword-containing text strings enhanced cohort ascertainment relative to ICD code-alone-based approaches. On the other hand, reliance on keywords without text validation would have erroneously included a substantial number of persons who are not transgender. A review of records to confirm transgender status added considerable time and resources; however, it is still more efficient and more comprehensive than the traditional unstructured chart review. In conducting cohort validation, we reviewed up to three clinical note excerpts on 11 325 people. This task was accomplished within 6 months.

A comprehensive identification of all transgender people in the KP population (with and without evidence in the medical records) would require contacting more than 8 million members to inquire about their natal sex and gender identity; this does not appear feasible at this time.

Determination of natal sex and/or gender identity

Our study definitively ascertained natal sex and/or gender identity for nearly 99% of cohort members. We obtained information on TM/TF status from three sources: keyword text strings, pharmacy records and procedure codes. In most instances, these sources were in agreement; however, in some cases the results were discordant. Each disagreement was used as an opportunity to check data accuracy and allowed reducing misclassification, which would have been substantial if STRONG relied on demographic data in the EMR. For example, among adult TF study subjects, 41% were documented as 'female' and 59% were documented as 'male'. The corresponding proportions of people classified as 'female' and 'male' among adult TM cohort members were 59% and 40%, respectively, with 1% recorded as unknown in the EMR. By contrast, in 96% of persons under the age of 18, the demographic variable reflected natal sex.

A limitation of the current data is the inability to accurately identify persons who reject binary gender categories. These individuals are likely to be found among cohort members who do not have a transgender-specific diagnosis and receive no HT or surgical treatment; however, at the present time EMRs alone are not sufficient for determination of non-binary gender identity. This will be possible in the near future after KP introduces new data capture systems with separate fields for natal sex, gender identity, preferred pronouns, organ inventory and history of gender-affirming procedures.

Assessment of current and past gender affirmation treatment

Although the information on gender affirmation received within the KP system is high quality, one of the main limitations of STRONG data is the lack of information on HT and surgical treatment received outside the KP system. This restricts our ability to identify a subcategory of transgender cohort members with no history of gender affirmation treatment of any kind. For this reason, the most definitive analyses are limited to people who initiated therapy at KP. These individuals can be identified among those STRONG participants whose EMR demonstrates a gap between index date and the first prescription for HT. This 'HT initiation' group represents about 35% of TM and 32% of TF subjects.

The broadening of coverage for gender affirmation services at KP occurred relatively recently. As the proportion of transgender people among enrollees has been increasing and many patients now initiate and receive gender affirmation therapy exclusively within the system, it is important to both expand the cohort and extend the follow-up of current participants.

Engagement of patient and physician stakeholders

A critical feature of STRONG is patient-centredness. During the study implementation, we held monthly stakeholder calls and had three inperson Stakeholder Advisory Group meetings. These interactions had direct impact on study design and implementation. For example, the list of keywords used for STRONG cohort ascertainment was proposed, pilot-tested and refined in close consultation with the study stakeholders. Following advice from stakeholders, we expanded eligibility criteria to include transgender and gender non-conforming youth (persons under 18 years of age). This change allowed a number of additional analyses and offers important opportunities for future follow-up. STRONG stakeholders also helped to develop a comprehensive list of hormonal medications and procedures used for gender affirmation. The publications describing our formative research,[24 43–45] the current communication and the reports in preparation, all include stakeholders as coauthors.

CONCLUSIONS

Although the body of literature addressing transgender health issues has been growing,[46] most studies focus on substance use, sexual health, sexually transmitted infections and, to a lesser extent, mental health conditions.[47] By contrast, limited data are available on general health

status, or the incidence of chronic age-related conditions including cardiovascular disease, endocrine disorders and cancer.

To date, most data on morbidity and mortality in transgender populations come from clinical centres in Europe.[19 48–50] These studies are characterised by detailed clinical data; however, they are limited by relatively small sample sizes.

In terms of overall design and size, STRONG is comparable to US-based studies that used the Veterans Health Administration (VHA) data.[22 51] Unlike our study, however, the VHA data did not distinguish between TF and TM subjects and were limited to transgender persons identified via ICD-9 codes, without keywords.

We recognise that transgender people enrolled through an integrated healthcare system will yield a cohort of persons with health insurance. Weighing against this concern is the demonstrated ability to cost-effectively identify a large cohort of transgender subjects and referents with high degree of internal validity. The availability of a well-defined underlying population with detailed EMR ensures that participation does not require subject opt-in and allows selecting a complete cohort (rather than a sample) of eligible subjects. Moreover, as KP now provides 'one-stop' delivery of transgender care, the likelihood of capturing full details of gender affirmation treatment is increased. These internal validity advantages weigh heavily as a counter against concerns about representativeness.

In summary, STRONG is well positioned to fill existing knowledge gaps and make important contributions to the current literature. Lessons learnt while conducting this project provide support to future transgender health-related research. The methodology can be implemented at other healthcare institutions with EMRs, particularly in organisations participating in the Healthcare Systems Research Network (total population of almost 20 million) with little site-specific customisation. With extended follow-up and expanded cohort size, the data will permit additional analyses of rare health endpoints across various categories of surgical procedures, and different HT formulations, routes of administration and doses.

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Contributors VPQ and MG prepared the original draft of the manuscript. RN conducted data analyses and put together tables and figures. RC and LC were responsible for the preparation and application of data collection programs and ascertainment of study variables. EH, VPQ, DG, MJS and DT led study implementation at participating sites and were actively involved in study planning and design. TAB-C, AM and BR were responsible for the day-to-day project management at each site. DR and TLL provided methodological input on various aspects of study design, including identification of sources of bias and ways of addressing threats to validity. VT and JS provided input on clinical aspects of the study and were responsible for adjudication of study eligibility, gender identity and gender affirmation. KW developed, pilot-tested and supervised the cohort validation and gender identity ascertainment review protocols and programming. SG, CV and SW are members of the Stakeholder Advisory Group who assisted with the development of inclusion and exclusion criteria, assessment of gender identity and interpretation of the data. All authors provided critical review of the manuscript for important intellectual content and approved the final version.

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Ethics approval Emory University IRB.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Once the initial data analyses are complete, we will be open to collaborations with outside investigators as permitted by the IRBs of participating sites as well as by local, state and federal laws and regulations. In particular, we will encourage collaborations with researchers whose expertise is under-represented on our research team. To become a collaborator, a researcher will be required to submit an application, which will undergo both a scientific and an IRB review. In view of the complexity of the database, interested investigators will be asked to form a collaborative arrangement with the STRONG investigators rather than simply receive the data themselves. No additional data are available.

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Treatment for Pediatric Gender Dysphoria

Review of Evidence and Best Practices



Department of Health and Human Services

November 19, 2025

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Foreword

Over the past decade, the number of children and adolescents who question their sex and identify as transgender or nonbinary has grown significantly. Many have been diagnosed with a condition known as “gender dysphoria” and offered a treatment approach known as “gender-affirming care.” This approach emphasizes social affirmation of a child’s self-reported identity; puberty suppressing drugs to prevent the onset of puberty; cross-sex hormones to spur the secondary sex characteristics of the opposite sex; and surgeries including mastectomy and (in rare cases) vaginoplasty. Thousands of American children and adolescents have received these interventions.

While sex-role nonconformity itself is not pathological and does not require treatment, the use of pharmacological and surgical interventions as treatments for pediatric gender dysphoria has been called “medically necessary” and even “lifesaving.” Motivated by a desire to ensure their children’s health and well-being, parents of transgender-identified children and adolescents often struggle with how best to support them. Many of these children and adolescents have co-occurring psychiatric or neurodevelopmental conditions, rendering them especially vulnerable. When they seek professional help, they and their families should receive compassionate, evidence-based care tailored to their specific needs.

Society has a special responsibility to safeguard the well-being of children. Given that the challenges faced by these patients intersect with deeply contested issues of moral and social significance—including social identity, sex and reproduction, bodily integrity, and sex-based norms of expression and behavior—the medical practices that have recently emerged to address their needs have become a focus of significant controversy.

This Review is published against the backdrop of growing international concern about pediatric medical transition. Having recognized the experimental nature of these medical interventions and their potential for harm (which has been inadequately studied, especially with respect to long-term outcomes), health authorities in a number of countries have imposed restrictions. For example, the U.K. has banned the routine use of puberty blockers as an intervention for pediatric gender dysphoria.

Health authorities have also recognized the exceptional nature of this area of medicine. That exceptionalism is due to a convergence of factors. One is that the diagnosis of gender dysphoria is based entirely on subjective self-reports and behavioral observations, without any objective physical, imaging, or laboratory markers. The diagnosis centers on attitudes, feelings, and behaviors that are known to fluctuate during adolescence.

Additionally, the natural history of pediatric gender dysphoria is poorly understood, though existing research suggests it will remit without intervention in most cases. Medical professionals have no way to know which patients may continue to experience gender dysphoria and which will come to terms with their bodies.

Nevertheless, the “gender-affirming” model of care includes irreversible endocrine and surgical interventions on minors with no physical pathology. These interventions carry risk of significant harms including infertility/sterility, sexual dysfunction, impaired bone density accrual, adverse cognitive impacts, cardiovascular disease and metabolic disorders, psychiatric disorders, surgical complications, and regret, and there has been inadequate research into the frequency and severity of these harms. Meanwhile, systematic reviews of the evidence have revealed deep uncertainty about the purported benefits of these interventions.

The controversies surrounding the medical transition of minors extend beyond scientific debate; they are deeply cultural and political. Public discourse is dominated by intensely polarizing narratives. Some view the medical transition of minors as a pressing civil rights issue, while others regard it as a profound medical failure and a sobering reminder that even modern medicine is vulnerable to serious error. In the midst of this highly charged debate, children and adolescents, and their families—who seek only to support their flourishing—have found themselves caught between competing perspectives. They require, and are entitled to, accurate, evidence-based information to guide their decisions.

This Review of evidence and best practices was commissioned pursuant to Executive Order 14187, signed on January 28, 2025. It is not a clinical practice guideline, and it does not issue legislative or policy recommendations. Rather, it seeks to provide the

most accurate and current information available regarding the evidence base for the treatment of gender dysphoria in this population, the state of the relevant medical field in the United States, and the ethical considerations associated with the treatments offered.

The Review is intended for policymakers, clinicians, therapists, medical organizations and, importantly, patients and their families. It summarizes, synthesizes, and critically evaluates the existing literature on best practices for promoting the health and well-being of children and adolescents with distress related to their sex or to social expectations associated with their sex. Treatment of adults constitutes a separate topic and is not addressed in this Review. A summary of the Review's main findings is presented below.

Executive Summary

Part I: Background

- Gender dysphoria is a condition that involves distress regarding one's sexed body and/or associated social expectations. Increasing numbers of children and adolescents in the U.S. and other countries are diagnosed with gender dysphoria. Internationally, there is intense disagreement about how best to help them.
- The term "rapid onset gender dysphoria" (ROGD) has been suggested to describe a new clinical presentation of gender dysphoria. Despite sharp disagreement about the concept's validity, symptoms consistent with ROGD have been recorded in clinics in the U.S. and other countries.
- In the U.S., the current approach to treating pediatric gender dysphoria aligns with the "gender-affirming" model of care recommended by the World Professional Association for Transgender Health (WPATH). This model emphasizes the use of puberty blockers and cross-sex hormones, as well as surgeries, and casts suspicion on psychotherapeutic approaches for management of gender dysphoria.
- The understandable desire to avoid language that may cause discomfort to patients has, in some cases, given rise to modes of communication that lack scientific grounding, that presuppose answers to unresolved ethical controversies, and that risk misleading patients and families. This Review uses scientifically accurate and neutral terminology throughout.
- In many areas of medicine, treatments are first established as safe and effective in adults before being extended to pediatric populations. In this case, however, the opposite occurred: clinician-researchers developed the pediatric medical transition protocol in response to disappointing psychosocial outcomes in adults who underwent medical transition.
- The protocols were adopted internationally before the publication of the first outcome studies. In recent years, in response to dramatic shifts in the number

and clinical profiles of minor patients, as well as to multiple systematic reviews of evidence, health authorities in an increasing number of countries have restricted access to puberty blockers and cross-sex hormones, and, in the rare cases where they were offered, surgeries for minors. These authorities now recommend psychosocial approaches, rather than hormonal or surgical interventions, as the primary treatment, and in some cases have restricted the latter to nationally-overseen research protocols.

- There is currently no international consensus about best practices for the care of children and adolescents with gender dysphoria.

Part II: Evidence Review

- Evidence-based medicine is widely recognized by health authorities worldwide as the foundation of high-quality care. Consistent with its principles, this Review undertook a methodologically rigorous assessment of the evidence underpinning pediatric gender medicine.
- Specifically, this Review conducted an overview of systematic reviews—also known as an “umbrella review”—to evaluate the direct evidence regarding the benefits and harms of treatment for children and adolescents with gender dysphoria. Existing systematic reviews of evidence, including several that have informed health authorities in Europe, were assessed for methodological quality. The umbrella review found that the overall quality of evidence concerning the effects of any intervention on psychological outcomes, quality of life, regret, or long-term health, is very low. This indicates that the beneficial effects reported in the literature are likely to differ substantially from the true effects of the interventions.
- Evidence for harms associated with pediatric medical transition in systematic reviews is also sparse, but this finding should be interpreted with caution. Inadequate harm detection in pediatric gender medicine may reflect the relatively short period of time since the widespread adoption of the medical/surgical treatment model; the failure of existing studies to systematically track and report harms; and publication bias. Despite the lack of robust evidence from population

level studies, important insights can be drawn from established knowledge about human physiology and the effects and mechanisms of the pharmacological agents used.

- The risks of pediatric medical transition include infertility/sterility, sexual dysfunction, impaired bone density accrual, adverse cognitive impacts, cardiovascular disease and metabolic disorders, psychiatric disorders, surgical complications, and regret.

Part III: Clinical Realities

- In the U.S., the most influential clinical guidelines for the treatment of pediatric gender dysphoria are published by WPATH and the Endocrine Society. A recent systematic review of international guideline quality did not recommend either guideline for clinical use after determining they "lack developmental rigour and transparency."[1]
- Problems with the development of WPATH's *Standards of Care*, Version 8 (SOC-8) extend beyond those identified in the systematic review of international guidelines. In the process of developing SOC-8, WPATH suppressed systematic reviews its leaders believed would undermine its favored treatment approach. SOC-8 developers also violated conflict of interest management requirements and eliminated nearly all recommended age minimums for medical and surgical interventions in response to political pressures.
- Although SOC-8 relaxed the eligibility criteria for access to puberty blockers, cross-sex hormones, and surgeries, there is compelling evidence that U.S. gender clinics are not adhering even to those more permissive criteria.
- The "gender-affirming" model of care, as practiced in U.S. clinics, is characterized by a child-led process in which comprehensive mental health assessments are often minimized or omitted, and the patient's "embodiment goals" serve as the primary guide for treatment decisions. In some of the nation's

[1] Taylor, Hall, Heathcote et al. (2024a, p. 7).

leading pediatric gender clinics, assessments are conducted in a single session lasting two hours.

- The voices of whistleblowers and detransitioners have played a critical role in drawing public attention to the risks and harms associated with pediatric medical transition. Their concerns have been discounted, dismissed, or ignored by prominent advocates and practitioners of pediatric medical transition.
- U.S. medical associations played a key role in creating a perception that there is professional consensus in support of pediatric medical transition. This apparent consensus, however, is driven primarily by a small number of specialized committees, influenced by WPATH. It is not clear that the official views of these associations are shared by the wider medical community, or even by most of their members. There is evidence that some medical and mental health associations have suppressed dissent and stifled debate about this issue among their members.

Part IV: Ethical Considerations

- The principle of autonomy in medicine establishes a moral and legal right of competent patients to refuse any medical intervention. However, there is no corollary right to receive interventions that are not beneficial. Respect for patient autonomy does not negate clinicians' professional and ethical obligation to protect and promote their patients' health.
- The evidence for benefit of pediatric medical transition is very uncertain, while the evidence for harm is less uncertain. When medical interventions pose unnecessary, disproportionate risks of harm, healthcare providers should refuse to offer them even when they are preferred, requested, or demanded by patients. Failure to do so increases the risk of iatrogenic harm and reduces medicine to consumerism, threatening the integrity of the profession and undermining trust in medical authority.
- Proponents of pediatric medical transition claim that regret is vanishingly rare, while critics assert that regret is increasingly common. The true rate of regret is

not known and better data collection is needed. That some patients report profound regret after undergoing invasive, life-changing medical interventions is clearly of importance. However, regret alone (just like satisfaction alone) is not a valid indicator of whether an intervention is medically justified. Patients may regret medically justified treatments or feel satisfied with unjustified ones.

- A natural response to the absence of credible evidence is to call for more and better research. Even if high quality research such as randomized controlled trials on pubertal suppression or hormone therapy were feasible, however, conducting it may conflict with well-established ethical standards for human subjects research.

Part V: Psychotherapy

- The rise in youth gender dysphoria and the corresponding demand for medical interventions have occurred against the backdrop of a broader mental health crisis affecting adolescents. The relationship between these two phenomena remains a subject of scientific controversy.
- Suicidal ideation and behavior are independently associated with comorbidities common among children and adolescents diagnosed with gender dysphoria. Suicidal ideation and behavior have known psychotherapeutic management strategies. No independent association between gender dysphoria and suicidality has been found, and there is no evidence that pediatric medical transition reduces the incidence of suicide, which remains, fortunately, very low.
- There is a dearth of research on psychotherapeutic approaches to managing gender dysphoria in children and adolescents. This is due in part to the mischaracterization of such approaches as “conversion therapy.” A more robust evidence base supports psychotherapeutic approaches to managing common comorbid mental health conditions. Psychotherapy is a noninvasive alternative to endocrine and surgical interventions for the treatment of pediatric gender dysphoria. Systematic reviews of evidence have found no evidence of adverse effects of psychotherapy in this context.

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Disclosures of Interest (as of November 14, 2025)

Evgenia Abbruzzese has received payments for legal consultations related to pediatric gender medicine.

Farr Curlin has received payments for expert testimony and honoraria for speaking engagements related to pediatric gender medicine.

Kristopher Kaliebe has received payment for expert testimony related to pediatric gender medicine as well as an honorarium to attend a conference related to pediatric gender medicine.

Michael Laidlaw has received payment for expert testimony related to gender dysphoria as well as an honorarium to attend a conference related to pediatric gender medicine.

Leor Sapir has received payments for legal consultations and honoraria for speaking engagements related to pediatric gender medicine.

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PART 1

BACKGROUND

Chapter 1 Introduction

Currently, an estimated 3.3% of adolescents in the United States identify as transgender, and an additional 2.2% question whether they might be.[1] Many have received hormonal or surgical treatment for accompanying distress. A 2023 study published in the *Journal of the American Medical Association* found that between 2016 and 2020, 3,215 patients between the ages of 12 and 18 received surgical "breast or chest procedures" relating to their transgender identity.[2] A more recent study reported that approximately 0.1% of American 17-year-olds, or one in 1,000, was receiving cross-sex hormones between 2018 and 2022.[3] A national estimate of clinics offering pediatric medical transition interventions found at least 271 such institutions in the U.S. as of March 2023.[4]

This Review assesses the existing literature on best practices for promoting the health of children and adolescents with gender dysphoria (GD; serious distress at one's sexed body and associated social expectations[5]) or milder forms of such distress. Treatment of GD in adults is a separate topic and is not covered here.

In the United States, a number of institutions follow the guidelines of the World Professional Association for Transgender Health (WPATH) and the Endocrine Society (ES) for treating gender-dysphoric children and adolescents. This approach is usually called "gender-affirming care." Diane Ehrensaft, Director of Mental Health at UCSF's Child & Adolescent Gender Center, is a leading proponent. As Ehrensaft explains,

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[1] Suarez et al. (2024, Table 2).
[2] Wright et al. (2023).
[3] Hughes et al. (2025).
[4] Borah et al. (2023, p. 375-376). Some of these clinics were closed due to state age restriction laws.
[5] As an American Psychological Association report put it, quoting the American Psychiatric Association, gender dysphoria is an "aversion to some or all of those physical characteristics or social roles that connote one's own biological sex" (Schneider et al., 2009, p. 28). As explained in Zucker et al. (2016), "gender dysphoria" is a "technical term" that refers to symptoms of distress, but is also, as of the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (2013), a "diagnostic term" (p. 218). Gender Dysphoria is a formal diagnosis in the current (text revision) version of the DSM-5, the DSM-5-TR (American Psychiatric Association, 2022). For the relevant diagnostic criteria for children, adolescents, and adults in the DSM-III, IV, and 5, and in the current *International Classification of Diseases* (ICD-11), see Appendix 2 of this Review. The term "gender dysphoria" is used throughout this Review to refer to sex-related distress or discomfort, unless the context makes clear that the formal diagnosis is the topic.

> [gender-affirming care] is defined as a method of therapeutic care that includes allowing children to speak for themselves about their self-experienced gender identity and expressions and providing support for them to evolve into their authentic gender selves, no matter at what age. Interventions include social transition from one gender to another and/or evolving gender nonconforming expressions and presentations, as well as later gender-affirming medical interventions (puberty blockers, cross-sex hormones, surgeries).[6]

This Review is needed because—as later chapters will detail—the emphasis on medicalization makes the field of pediatric gender medicine (PGM) highly controversial. WPATH and ES guidelines recommend commencement of puberty blockers (PBs; drugs that halt pubertal development) at the earliest signs of puberty (Tanner Stage 2), which may begin as early as age 8 in girls and 9 in boys. According to these guidelines,[7] cross-sex hormones (CSH; estrogen for boys and testosterone for girls) are started sometime thereafter; surgeries (e.g., breast removal for girls) are also recommended for some adolescents.[8] All these interventions are associated with significant risks, and most cause irreversible physical or physiological effects.[9]

Do PBs, CSH, and surgeries constitute best practice for this population? Guidelines and policies promulgated by professional medical societies in the U.S. differ from some European guidelines that recommend psychotherapy, *not* hormones or surgeries, for children and adolescents with GD. This Review, then, is written against a backdrop of intense disagreement in the international medical community. The number of young people with GD has surged, and many are suffering, as are their families. The question of how to best help these patients hinges on a comprehensive assessment of the evidence base for different treatment approaches, together with ethical considerations. Bringing ethical principles to bear on the evidence is one goal of this Review. While the need for respect and compassion resonates with all reasonable Americans, an invasive

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[6] Ehrensaft (2017a, p. 62). The gender-affirming approach can be applied to adults too; this Review is entirely focused on the pediatric variety.
[7] Coleman et al. (2022); Hembree et al. (2017).
[8] The latest version of WPATH's clinical practice guideline has no recommended age limits for surgical procedures, with the exception of 18 years old for phalloplasty (the construction of a neophallus in females with skin taken from the patient's arm or leg).
[9] See Chapter 7.

treatment with lifelong ramifications deserves the highest level of dispassionate scrutiny.[10]

The diagnostic description of GD has changed since the condition appeared in the third edition (1980) of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), as has the terminology used to name it. But one thing has not changed. The DSM-III was clear that "Gender Identity Disorder of Childhood" was "not merely the rejection of stereotypical sex role behavior as, for example, in 'tomboyishness' in girls or 'sissyish' behavior in boys"[11]; the current DSM has a similar emphasis: "The diagnosis is not meant to merely describe nonconformity to stereotypical gender role behavior (e.g., "tomboyism" in girls, "girly-boy" behavior in boys, occasional cross-dressing in adult men)."[12] Non-conformity to sex-role stereotypes is as old as history, and present to some degree in every known culture.[13] This feature of the human experience is not pathological and needs no treatment. What may require treatment is the suffering experienced by those alienated from their sexed bodies.

PGM is a complex topic. This Review, therefore, will cover the field's history and evolution in some detail, from the inception of the medicalized approach in the Netherlands (Chapter 3)[14] to current treatment practices in the U.S. and other countries (Chapter 4, Chapter 9). The Review describes an international trend of retreat from the present "gender affirming" approach and reviews the reasons underlying it.

This Review finds that clinical practice in this field of medicine is exceptional and concerning (Chapter 11). The influential PGM guidelines followed in the U.S. are especially problematic. They were developed in ways that contravene best practices for

[10] The U.K.'s Cass Review pointed out that although some conceptualize controversies about pediatric gender medicine primarily from political/social standpoints, healthcare guidance should "[work] in an evidence-based way" (Cass, 2024a, p. 20).
[11] American Psychiatric Association (1980, p. 264).
[12] American Psychiatric Association (2013, p. 458).
[13] See Chapter 3, footnote 1.
[14] The general treatment paradigm of puberty blockers, cross-sex hormones, and surgeries originated in the Netherlands in the 1990s as an experimental research protocol, and, based on one small study that claimed to demonstrate significant benefits to mental health, was rapidly incorporated internationally into standard practice. As described in the Cass Review's interim report, the "affirmative model" is a "model of gender healthcare that originated in the USA which affirms a young person's subjective gender experience while remaining open to fluidity … This approach is used in some key child and adolescent clinics across the Western world" (Cass, 2022a, p. 78).

guideline development (Chapter 9, Chapter 10). This Review also finds evidence of extreme toxicity and polarization surrounding this field of medicine. ("There are few other areas of healthcare where professionals are so afraid to openly discuss their views … where name-calling echoes the worst bullying behaviour."[15]) Additionally, this Review describes the inadequate response of professional medical and mental health associations to new evidence and controversies (Chapter 12).

Section 1.1 of this opening chapter emphasizes the exceptional nature of PGM. Section 1.2 outlines the role that evidence-based medicine (EBM) plays in the Review; Section 1.3 does the same for medical ethics.

1.1 Exceptionalism

The field of PGM is exceptional due to the convergence of several distinct features.

First, the *diagnostic criteria* for GD are based solely on subjective reports and behavioral observations in patients with no objective physical pathology; there are no verifiable physiological or biochemical markers−such as abnormal imaging, lab, or clinical findings−to confirm the GD diagnosis.[16]

Second, the condition's *natural course* (also known as "natural history")—i.e., what happens when the condition remains untreated—appears to tend toward resolution absent medical and/or social transition interventions for a significant number of affected youths (Chapter 4). While the condition will persist in some affected adolescents into adulthood, the Cass Review, commissioned by England's National Health Service (NHS), found that while "a diagnosis of gender dysphoria has been the basis for initiating medical treatment … this is not predictive that the individual will go on to have longstanding trans identity."[17]

Third, the treatments recommended by the medicalized approach are invasive, usually irreversible, and their purported benefits are based on poor quality evidence. In addition

[15] Cass (2024a, p. 13).
[16] Laidlaw et al. (2019). The same goes for the ICD's diagnosis of "gender incongruence": for discussion, see Section 13.4.
[17] Cass (2024a, p. 146).

to infertility and impairment of sexual function, the anticipated harms include adverse effects on bone health, cardiovascular function, and possible negative impacts on brain development (Chapter 7).

When taken separately, *none* of these features is unique in medicine. Nearly all mental health and some physical health diagnoses are made on the basis of self-reports and behavioral observations. Also, there are other pediatric conditions such as mild ear infections and strep throat that are self-limiting but still treated to reduce discomfort, promote faster recovery, or prevent complications. Lastly, there are instances in which patients are offered treatments even if the benefits of those treatments are profoundly uncertain and harms are expected. For example, craniotomies are performed to remove certain malignant brain tumors, even though these interventions carry a high risk of permanent adverse effects and the overall prognosis remains poor even with treatment. (In such cases, however, the alternative to intervention is a significantly shorter life expectancy.) What makes PGM exceptional is not any one of these features, but their combination.

Is the fundamental goal of treatment to manage gender dysphoria, a condition recognized in the DSM's catalogue of mental disorders? Or is it to manage common comorbidities such as depression, anxiety, and suicidal ideation? Or, alternatively, is it to help individuals realize their "embodiment goals" (cosmetic desires)? The stated rationales for these interventions have shifted over time, following decades of research that failed to provide credible evidence of benefit (Chapter 5). This unclarity surrounding the treatments' fundamental aims is yet another way in which PGM is exceptional. In contrast, there is broad consensus about the purpose of medical intervention for conditions like appendicitis, diabetes, or severe depression.

1.2 Evidence

When assessing a medical intervention, one of the most important questions is: Is it safe and effective? Does drug X reduce all-cause mortality for cancer patients? Does talk therapy alleviate depression? Does knee surgery relieve arthritis pain with few postoperative complications? Even if the treatment is effective, it may not be safe, and there may be better alternatives.

In the case of invasive treatments for GD, medical authorities in the United States have issued statements indicating that the matter is settled. According to the American Medical Association (AMA):

> Improving access to gender-affirming care is an important means of improving health outcomes for the transgender population. Receipt of gender-affirming care has been linked to dramatically reduced rates of suicide attempts, decreased rates of depression and anxiety, decreased substance use, improved HIV medication adherence and reduced rates of harmful self-prescribed hormone use.[18]

In 2022, the then Assistant Secretary for Health at the U.S. Department of Health and Human Services, Admiral Rachel Levine, gave an even more unqualified endorsement:

> Gender-affirming care is medical care. It is mental health care. It is suicide prevention care. It improves quality of life, and it saves lives. It is based on decades of study. It is a well-established medical practice.[19]

However, according to the U.K.'s April 2024 Cass Review, the most comprehensive assessment of PGM to date:

> This is an area of remarkably weak evidence, and yet results of studies are exaggerated or misrepresented by people on all sides of the debate to support their viewpoint. The reality is that we have no good evidence on the long-term outcomes of interventions to manage gender-related distress.[20]

Whether the approach endorsed by the AMA is based on adequate evidence is the subject of intense controversy. What is considerably less controversial is the best framework for assessing the efficacy of treatments. That framework is EBM, adopted by this Review.

[18] American Medical Association (2022).
[19] Levine (2022).
[20] Cass (2024a, p. 13).

1.2.1 Evidence-based medicine

The physician and researcher Gordon Guyatt—who coined the term "evidence-based medicine" in 1991—describes EBM as follows:

> Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research. Evidence-based medicine requires new skills of the physician, including efficient literature searching and the application of formal rules of evidence evaluating the clinical literature.[21]

EBM sees carefully controlled clinical trials as especially important, along with "systematic reviews" (SRs), methodical syntheses and evaluations of all relevant available evidence. Various "hierarchies of evidence" have been proposed, with SRs at the top and the opinions of individual clinicians, which, although usually valuable, are subject to a variety of biases, at the bottom. EBM has been widely accepted by health authorities around the world.[22]

In keeping with EBM principles, this Review is informed by a methodologically rigorous assessment of the evidence underpinning PGM. An overview of SRs was conducted, and its findings are presented in Chapter 5 and in Appendix 4. In brief, the overview independently confirms Cass's observation that "this is an area of remarkably weak evidence."

Given its emphasis on clinical trials, EBM is less sensitive to evidence about known mechanisms of drug action or relevant biology more broadly. This limits the ability of SRs to uncover potential causal pathways or to understand observed associations or their absence (Chapter 6). Accordingly, Chapter 7 supplements the overview of SRs with evidence from basic science, including physiology. As detailed in that chapter, the risk of harm from the medicalized approach to treating pediatric GD is serious.

[21] Guyatt et al. (1992, p. 2420). See also Akobeng (2005).
[22] E.g. Darzi (2008); Margolis (2018); Carande-Kulis (2022).

It is important to recognize that evaluating the evidence for a treatment's efficacy does not, on its own, determine whether the treatment ought to be offered. SRs or other sources of high-quality evidence are not rigid formulas for making medical decisions; rather, they are essential components of the decision-making process. The principle is explicitly acknowledged in EBM. Medical evidence is not sufficient to justify clinical recommendations or decisions; other considerations—such as patient values and preferences—also play a critical role.[23] However, as emphasized below, these preferences do not override physicians' ethical and professional duties.

1.2.2 History lessons

An unreasonable skepticism toward medical expertise can lead to patient harm and even death.[24] On the other hand, while physicians are often capable of remarkable healing, they are not immune to human error or bias. However well-intentioned, doctors are not infallible. Even the consensus of professional medical associations can, at times, be mistaken.

Peanut allergies are a recent example. In 2000, the American Academy of Pediatrics (AAP) advised that infants deemed "high risk" should avoid peanuts—and that breastfeeding mothers do the same. In practice, this guidance was widely interpreted as a recommendation for all infants to avoid peanuts as a precaution. Peanut allergies increased dramatically, and in 2017 the AAP reversed course, recommending early *introduction* of peanuts for the highest-risk infants.[25]

This is just one of many examples.[26] Medical error is more prevalent than many Americans realize. Consensus does not guarantee correctness—in fact, it can sometimes entrench error. Nor should it be assumed that all treatment recommendations are motivated by altruism, as the opioid overprescription crisis has starkly demonstrated. This is not to suggest that medical consensus is inherently untrustworthy, but rather that it should be approached with critical scrutiny, not

[23] Djulbegovic & Guyatt (2017, p. 416); see also Guyatt et al. (2000).
[24] Centers for Disease Control (2025).
[25] Makary (2024, Chapter 1).
[26] Apart from Makary (cited above), see Prasad & Cifu (2019, Chapters 1, 2) and Patashnik et al. (2017, Chapter 2).

unquestioning acceptance. The physicians and researchers Vinay Prasad and Adam Cifu succinctly make this point:

> We expect that medical therapy will change and evolve with time. Good treatments will replace bad ones, and then better ones will replace those. Antibiotics have replaced arsenic, and anesthesia has replaced a bullet held bracingly between the teeth. Recently, however, change has occurred in surprising ways. If you have followed the news about prostate cancer screening, mammography for women in their forties, hormone replacement, cholesterol-lowering medications, and stents for coronary-artery disease, you might think doctors cannot get anything straight. These common practices were not replaced by better therapies; they were found to be ineffective. In some cases, they did more harm than good. You might be worried that some medical practices are nothing more than fads. In some cases, you would be right.[27]

1.3 Ethics

Finding safe and effective treatments is only part of medicine's mission. Questions of ethics—and the complex theoretical issues they raise—emerge immediately alongside clinical decision-making. What if a treatment is effective but the patient doesn't want it? When is informed consent needed before starting treatment? Should doctors ever lie to their patients? What is the difference between cosmetic procedures and those that alleviate a medical problem? What should we do when clinicians disagree with pediatric patients or their parents about the best medical course of action? These and numerous similar questions are the topic of the academic field known as *medical ethics*.[28]

EBM is only decades old, but medical ethics is as old as medicine itself. The Hippocratic Oath, originating in the fourth century BCE, and attributed to the ancient Greek physician Hippocrates, is a pledge to uphold ethical principles in medicine. The Hippocratic writings include: "I will use treatment to help the sick according to my ability

[27] Prasad & Cifu (2019, p. 11).
[28] An alternative name is *biomedical ethics*. *Bioethics* is a broader field encompassing ethical issues in the life sciences beyond healthcare. Although medical ethics is an academic discipline, medical ethicists often work in clinics and hospitals, supporting patients and their families, and assisting clinicians in developing policies.

and judgment, but I will never use it to injure or wrong them."[29] This commitment laid the foundation for the medical maxim *Primum non nocere*: First, do no harm.[30] Together with the duty of non-maleficence (avoiding harm), the duty of beneficence (promoting the patient's well-being) "undergirds all medical and health care professions and their institutional settings."[31] These duties have been continually affirmed by professional medical societies. For example, the World Medical Association's Declaration of Geneva, first published in 1948 and last revised in 2017, requires physicians to respect the "autonomy and dignity" of patients but recognizes the primacy of non-maleficence and beneficence: "The health and well-being of my patient will be my first consideration."[32]

Importantly, the physician's duties of non-maleficence and beneficence are not overridden by the patient's desire for a particular course of treatment. In 2002, the American Board of Internal Medicine Foundation, the American College of Physicians Foundation, and the European Federation of Internal Medicine articulated this point in a "Physician Charter." Among the three "fundamental principles" of the charter is the "Principle of patient autonomy," defined as follows:

> Physicians must have respect for patient autonomy. Physicians must be honest with their patients and empower them to make informed decisions about their treatment. Patients' decisions about their care must be paramount, *as long as those decisions are in keeping with ethical practice and do not lead to demands for inappropriate care*.[33]

One central question this Review attempts to answer is whether pediatric medical transition—and in particular the provision of hormonal or surgical interventions to children and adolescents—is consistent with widely-accepted principles of medical ethics. This is examined in Chapter 13. Another treatment approach—psychotherapy (talk therapy)—is examined in Chapter 14.

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[29] Beauchamp & Childress (2019, p. 155). Graduating medical students today recite a variety of oaths, sometimes composing them themselves (Weiner, 2018).
[30] The Latin phrase does not trace back to ancient times: it may have been devised by the seventeenth century English physician Thomas Sydenham (1624-1689), the "English Hippocrates" (Smith, 2005).
[31] Beauchamp & Childress (2019, p. 155).
[32] Parsa-Parsi (2017, p. 1971).
[33] American Board of Internal Medicine Foundation (2002, emphasis added).

The innovation and responsiveness of the U.S. medical system has made it the envy of the world. However, errors are unavoidable in healthcare. The test of a medical system is not its ability to avoid mistakes, but rather how it responds once mistakes become apparent.

Chapter 2 Terminology in Pediatric Gender Medicine

The choice of words can affect medical decision-making. Medical providers have a professional duty to apprise their patients of their conditions and the treatment options in language that is accurate, ethically neutral, and in no way misleading.[1] In the case of pediatric gender medicine (PGM), language has distorted the clinical picture, obscuring important distinctions. This chapter addresses that issue. Section 2.1 examines commonly used terminology, while Section 2.2 clarifies the specific terms adopted in this Review.

2.1 Terminology in pediatric gender medicine

Concerns about proper terminology and disclosure of all relevant information are common in medicine generally, particularly in the context of physician-patient interactions.[2] PGM, however, presents unique challenges. In this context, the understandable desire to avoid exclusionary or pathologizing language—combined with beliefs firmly embedded in the field—has led to a vocabulary and a mode of communicating that is scientifically ungrounded, that presupposes answers to ethical controversies, and that is in other ways misleading.[3]

Nearly all the core terms used in PGM exhibit these kinds of issues. As mentioned in Chapter 1, the preferred label for the treatment approach endorsed by the World Professional Association for Transgender Health (WPATH), the Endocrine Society (ES), the American Academy of Pediatrics (AAP) and the American Medical Association (AMA) is “gender-affirming care.” The surgical removal of breasts (mastectomy) in physically healthy females is called “gender-affirming chest surgery” or “top surgery.”[4] “Affirming” has a positive connotation, and someone who objects to “gender-affirming

[1] Importantly, accuracy and neutrality are not enough. “80% of patients given drug A recovered” is ethically bland; suppose it is also true. Absent further context that statement is misleading if 80% of patients *not* given drug A also recovered. Another example: if a physician truthfully tells a patient, “You either have cancer or a harmless cyst,” knowing that the patient has cancer, the patient has been misled.
[2] Shaw et al. (2022).
[3] For related examples in the field of women’s health, see Gribble (2025). See also Bartick et al. (2025); the authors make the point that “transgender and gender-diverse people need clear and unambiguous health communications, including those related to sex-based needs, conditions, and symptoms, as much as any other group” (p. 5).
[4] E.g. Coleman et al. (2022, p. S130).

surgery" sounds lacking in compassion. The euphemisms "chest surgery" and "top surgery" gloss over the relevant fact that breasts are removed.

Word choices can obscure patients' young ages. Terms such as "people" or "folks" are sometimes used by proponents of medicalized interventions instead of "children" or "adolescents." It is frequently emphasized that prepubertal children are not prescribed hormones or surgeries. That is true. However, clinical guidelines recommend initiating puberty blockers (PBs) at pubertal onset, which can occur at 8 or 9 years old—meaning that such interventions may be started during childhood. In discussions of this recommendation, "young people" or "adolescents" are sometimes substituted for "children."[5] Again, this helps camouflage the fact that sometimes serious medical interventions are performed on children's healthy bodies.[6]

Some adolescents transition and later detransition, reverting to living as their sex, changing their name back and making other necessary social adjustments. If the adolescent has undergone some degree of medical transition, the process of detransitioning can present significant challenges.[7] These difficulties are sometimes downplayed through the use of "retransitioning"[8] instead of "detransitioning," or writing

[5] E.g., from a National Association of Social Workers fact sheet: "MYTH: Gender-affirming hormones, or hormone replacement therapy (HRT), are given to *children*," and: "During and after puberty, some medical treatments may be available [for] the *youth*" (National Association of Social Workers, n.d., emphasis added). According to the AAP, childhood spans ages 2-12 (Hardin et al., 2017).

"Adolescent" is often used for children in the early stages of puberty, when a layperson would use "child." As a member of WPATH put it in an email: "I would avoid children and hormones, and stick to medical definitions: when a young person reaches … puberty, [they are] therefore classed as adolescents (whether they are 9 or 12)," quoted in Boe v. Marshall, No. 2:22-cv-00184: 557-9/700-2 (2024, p. 16). See also Ryan (2025): "Dr. Olson-Kennedy generally avoids using the words 'child,' 'children' or 'kids'"; and Levine et al. (2022b, p. 117). The Endocrine Society made a simple factual error when it stated that "medical intervention is reserved for older adolescents and adults" (Endocrine Society, 2023).

[6] Another phrase is "wrong puberty": e.g., "pubertal blockers … block the progression of puberty so the young person doesn't go through the wrong puberty" (Jacoby, 2022). Apart from presupposing the correct treatment, it is misleading to suggest that the "right puberty" induced by estrogen in males or testosterone in females amounts to a cross-sex version of puberty, because puberty centrally and definitionally involves maturation of the capacity for reproduction. The Endocrine Society guideline adopts this language, writing of the "induction of female puberty" in males (Hembree et al., 2017, Table 8); see also Section 7.4.1.

[7] MacKinnon, Expósito-Campos et al. (2023).

[8] Olson et al. (2022). "Retransitioning" does have a legitimate use, to describe the process of transitioning again, going from detransitioning to living as the other sex (MacKinnon, Expósito-Campos et al., 2023, p. 1).

of “dynamic desires for gender-affirming medical interventions.”[9] This conceptualizes an experience that can be profoundly distressing for the patient as simply another stop along their “gender journey.”[10]

The lead author of the AAP’s 2018 policy statement (reaffirmed in 2023), “Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents,” has even described detransition as part of the “gender affirming” approach itself, thus making treatment failure impossible to conceive.[11]

The problems go deeper. The terminology of “sex,” “male,” and “female” is indispensable if the medical and ethical issues are to be discussed responsibly. And yet proponents of medicalization go to extraordinary lengths to avoid the plain use of these words, and related words such as “boy” and “girl.” When “sex” is defined, the definition is rarely correct,[12] and in any case the preferred phrase is “sex assigned at birth.” According to the ES’s “Clinical Practice Guideline for the treatment of Gender-Dysphoric/Gender-Incongruent Persons,” “the terms biological sex and biological male or female are imprecise and should be avoided.”[13] Pediatric female patients are not “girls” or “young women,” but rather “AFAB individuals” (people “assigned female at

[9] Turban, Brady et al. (2022).
[10] Jorgensen (2023b): “we should be cautious about adopting euphemisms that might mask iatrogenic harm” (p. 2180).
[11] “Rafferty [the lead author of the AAP 2018 policy statement] told me patients who live with harms or regrets do not signal a failure of the affirmative care model. If a child or patient doesn’t like the effects of an intervention, or begins to feel different in their identity, then the provider continues to affirm by discontinuing treatment. ‘They’re not treatment failures if that’s what’s affirming’ he said” (Block, 2023d).
[12] E.g. the entry for “sex” in Hembree et al. (2017, Table 1) conflates sex with characteristics highly correlated with sex in humans (“sex chromosomes,” “sex hormones,” etc.); the entry in Rafferty et al. (2018, Table 2) erroneously says that sex is “an assignment that is made at birth.” For the orthodox conception of sex in biology, see, e.g., Dawkins (1976, pp. 183–184); Parker (2011); Futuyama & Kirkpatrick (2017, p. 249). The orthodox conception is in an Endocrine Society “Scientific Statement” (Bhargava et al., 2021), and in a Health and Human Services document (Health and Human Services, 2025).
[13] Hembree et al. (2017, Table 1). Hembree et al. don’t take their own recommendation completely to heart, writing at one point that “in females [i.e. “biological females”] … the effect of prolonged treatment with exogenous testosterone on ovarian function is uncertain” (p. 3880). This ES guideline is an update of “Endocrine treatment of transsexual persons: An Endocrine Society clinical practice guideline,” published in 2009. In that earlier guideline the conventional meaning of sex is used, and the authors use the allegedly imprecise phrase “biological females” (Hembree et al., 2009, p. 3139). The AMA also claims that “sex assigned at birth” is “more precise” than “sex” (American Medical Association, 2021, p. 14).

birth"). Some authorities in PGM say that the patients wanting mastectomies are in fact "young men."[14]

"Assigned sex at birth" is not a harmless euphemism. It suggests an arbitrary decision—not unlike "assigned seating"—rather than the observation of a characteristic present long before birth, namely the child's sex. Moreover, if the phrase "assigned sex" were intended merely as a gentler way of referring to sex in conversations with patients and families, one would expect more direct language to be used in the specialty medical literature. In professional contexts, where clarity is paramount, euphemisms are generally avoided. Yet "assigned sex" is ubiquitous in clinical and academic publications. Not only that: use of such terminology is now *mandated* by certain medical journals.[15] The American Psychological Association (APA) style guide, for example, classifies "birth sex" and "natal sex" as "disparaging terms" which problematically "imply that sex is an immutable characteristic."[16] As law professor Jessica Clarke observes, "'Sex assigned at birth' is not a euphemism for 'biological sex' but a critique of the very concept."[17]

The term "gender identity" is an especially important example of how words can sow confusion. When first introduced in the 1960s, it meant "the sense of knowing to which sex one belongs, that is, the awareness 'I am a male' or 'I am a female'."[18] Almost

[14] "I don't advocate removal [of] breast tissue from young women. I advocate for chest reconstruction in young men" (Olson-Kennedy, 2019, p. 38); this use of language has the effect of making mastectomies for adolescent girls sound unalarming. See also Ehrensaft (2017b, p. 7): "transgender boys are boys and transgender girls are girls."

[15] *The Lancet*'s "Information for Authors" mandates the use of "sex assigned at birth," instead of "biological sex," "birth sex," or "natal sex" because "it is more accurate and inclusive." The same document also incorrectly states that sex is not "binary," that it exists "along a spectrum," and that a person's sex can change (The Lancet, 2025).

[16] American Psychological Association (2024a). The APA has the "problematic implication" backwards: terminology that suggests a person's sex is a *mutable* characteristic is misleading to patients and should be avoided.

[17] Clarke (2022, p. 1828). The language of "assigned sex" was used in the 1950s for exceedingly rare cases of disorders of sex development (DSDs), where a baby with ambiguous genitalia could be raised as either a boy or a girl (Money, 1955).

[18] Stoller (1964, p. 220); see also Greenson (1964, p. 217). For discussion see Byrne (2023b, 2023a); Haig (2023); D. F. Janssen (2023).

everyone has a gender identity in this sense, and moreover one that is congruent with their sex: males know that they are male, and females know that they are female.[19]

However, today the phrase "gender identity" is used in a significantly different way. For example, WPATH defines "gender identity" in the glossary to their current clinical practice guideline (SOC-8) as:

> A person's deeply felt, internal, intrinsic sense of their own gender.[20]

This new definition is unclear. For instance, what does "gender" mean in this context? The glossary in SOC-8 offers little clarification—though it does correctly acknowledge that the word is highly ambiguous. One meaning of "gender" given in the glossary is "gender identity." But "gender" in the definition above cannot mean "gender identity," otherwise the definition would be circular. Another meaning provided is "gender expression," but this too leads to circularity, because "gender expression" is itself defined in the same glossary in terms of "gender."[21]

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[19] Some children distressed about their sexed bodies are mistaken about whether they are male or female, but some are not. Accordingly, being mistaken about one's sex is not required for a diagnosis of Gender Dysphoria in Childhood in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM): "A strong *desire* to be of the other gender" is enough. Although the diagnostic criteria for children also mention "an insistence that one *is* the other gender," this is not a necessary criterion, and is altogether absent from the DSM criteria for Gender Dysphoria in Adolescents and Adults (American Psychiatric Association, 2022, pp. 512–513, emphasis added).

[20] Coleman et al. (2022, p. S252). Along the same lines: "On one level, gender identity is something deeply felt and can be difficult to put into words. I often refer to this as one's *transcendent* sense of gender. You simply *feel* a certain gender" (Turban, 2024, p. 38); "Gender identity is a person's inner sense of belonging to a particular gender, such as male or female" (Ehrensaft, 2017b, p. 7). This latter definition would sound strange if "particular gender" was replaced by "particular sex": the implication would then be that there are more sexes beyond male and female.

[21] Another definition of "gender" given in SOC-8 is "social gender role, including understandings and expectations culturally tied to people who were assigned male or female at birth" (Coleman et al., 2022, p. S252). Consider the suggestion that this is the intended sense of "gender" in WPATH's definition of "gender identity." That is, "gender identity" is defined as: "a person's deeply felt, internal, intrinsic sense of their own social gender role." Now it is true that a person might have a sense of their "social gender role." A woman, say, might be aware that in her culture certain expectations apply to women. However, here the language of "deeply felt/internal/intrinsic" is quite inappropriate, which is one piece of evidence that the present suggestion is wrong. More importantly, there is no room for any "mismatch" between a person's sex and their social gender role. A woman may (perhaps rightly) disapprove of the expectations that her culture imposes on females; that is, she may disapprove of her social gender role. Since she has this gender role because she was "assigned female" at birth, her "gender" in this sense will *always* match her sex. But evidently WPATH wishes to define "gender identity" in such a way as to allow for *mismatches* with a person's sex. Hence, the "gender role" sense of "gender" is of no help in defining "gender identity" either. [Note continued on next page.]

In short, “gender identity” as it appears in SOC-8 and related literature is ill-defined.[22] It may be true that a person’s gender identity is subjective, or undetectable by blood tests or neuroimaging,[23] or otherwise beyond the reach of science, but the more critical point is that no tolerably clear definition of “gender identity” has been offered in the first place.[24] This is a serious problem, because the term figures centrally in the justification for medical intervention.

The term “transgender” is typically explained in terms of gender identity. Transgender people are those whose gender identities do not “align with” or “match” their sex (or “sex assigned at birth”).[25] Since “each of us has a gender identity, though many of us never give it much thought,”[26] the rest of humanity have gender identities that match their sex; these people are said to be “cisgender.” It is important to realize that “transgender” is

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Another way of explaining “gender” is to give a list of representative “genders” with the expectation or hope that the reader will see the pattern. In principle, this sort of explanation can be satisfactory. However, WPATH’s previous guideline offered the following examples: “male (a boy or a man), female (a girl or woman) … boygirl, girlboy, transgender, genderqueer, eunuch” (Coleman et al., 2012, p. 221). Notice that the list includes the category *transgender*, which is itself explained in terms of gender identity and hence gender, introducing a circularity. Another point is that if *eunuch* is a (contemporary) gender, then “gender” as it figures in WPATH’s definition of “gender identity” cannot possibly be explained in terms of “social gender role” (see the first paragraph of this note). Eunuchs had a special social role in Imperial China; they have no such role today. WPATH’s current guideline has an entire chapter on eunuchs, so clearly WPATH thinks the gender *eunuch* is not an anachronism.

[22] Here are two other examples. First, the AAP’s 2018 policy statement defines gender identity as “[a] person’s deep internal sense of being female, male, a combination of both, somewhere in between, or neither” (Rafferty et al., 2018, Table 1). The policy statement also says that a “transgender” person is someone “whose gender identity does not match their assigned sex.” Clearly “gender identity” as the AAP defines it cannot mean what it originally did, because a transgender man, for instance, might not be mistaken about being female. How to interpret “female” and “male” in the AAP’s definition is far from clear. Second, the philosopher Rach Cosker-Rowland explains gender identity as “our sense of ourself as a particular gender, as a woman, as a man, as non-binary, or as *another gender*” (Cosker-Rowland, 2025, p. 3, emphasis changed); Cosker-Rowland leaves “gender” unexplained.

[23] See, e.g. Baldinger-Melich et al. (2020); Levin et al. (2023); Bakker (2024).

[24] The original 1960s explanation of gender identity (see above) was perfectly clear, but that is not the contemporary conception in gender medicine.

[25] Boe v. Marshall*,* No. 2:22-cv-00184: 558-16 (2024); Ehrensaft (2017b); Olson-Kennedy (2022). According to the previous WPATH guideline (SOC-7): “The gender identity of transgender people differs to varying degrees from the sex they were assigned at birth” (Coleman et al., 2012, p. 221). Remarkably, sometimes “transgender” is defined to include commonplace gender non-conformity, *regardless* of any “mismatched” gender identity. For instance, according to SOC-8, if a person’s “gender expressions are not what is typically expected for the sex to which they were assigned at birth,” they are transgender (Coleman et al., 2022, p. S252).

[26] Forcier et al. (2020, p. 2). Similarly: “Gender identity … is a core and *universal* component of human identity” (Boe v. Marshall*,* No. 2:22-cv-00184: 592-12, 2024, p. 6, emphasis added).

not a clinical term and does not correspond to a medical diagnosis.[27] Indeed, proponents of the medicalized approach emphasize that some transgender people neither desire nor need medical or surgical interventions of any sort.

It is often claimed that gender identity is "innate or fixed at a young age," and so "cannot be changed."[28,29] Putting that idea together with the definition of "transgender," the result is that being transgender is a close-to-immutable trait. (The same goes for being cisgender.) A "transgender child," in this framework, is a child whose unalterable gender identity does not align with their sex, while cisgender children are the other kind.[30] Once this binary paradigm of "trans kids" and "cis kids" is accepted, therapeutic exploration of the underlying causes of a child's discomfort with his or her sexed body is readily dismissed as "conversion therapy," an unethical attempt to interfere with the development of the child's authentic self.[31,32]

According to many authorities in PGM, there is a test to determine whether a child is transgender or cisgender. This is because children "know who they are." Specifically, they know their "gender."[33] If a child's "gender" matches their "assigned sex," they are

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[27] Thus a recent article on assessing "transgender and gender diverse adolescents" for puberty suppression recommends reassuring patients that the goal is not to determine whether they "are actually transgender" (Turban et al., 2025, p. 14). But see Section 13.3.

[28] Adkins (2016, p. 4); Ehrensaft (2017b, p. 7); Olson-Kennedy (2022, p. 9). However, an earlier paper on the PMT approach, which has Ehrensaft and Olson-Kennedy as co-authors, states that it is a "myth" that gender identity is "immutable" (Hidalgo et al., 2013, p. 288), indicating at least some confusion about key terms.

[29] In his expert witness report for *Boe v. Marshall*, Aron Janssen, a gender clinician and vice chair of clinical affairs at Lurie's Pritzker Department of Child and Adolescent Psychiatry, wrote that gender identity, "a person's innate sense of their gender," "cannot be altered through medical or psychological interventions" (Boe v. Marshall*,* No. 2:22-cv-00184: 592-12, 2024, p. 6).

[30] Some PMT authorities would dispute this characterization and claim that a transgender child's gender identity *does* match their sex—what it *doesn't* match is their "birth-assigned sex" (Ehrensaft, 2017b, p. 9).

[31] "Psychotherapy may be beneficial but should not be a requirement for gender-affirming treatment, and conversion treatment should not be offered" Coleman et al. (2022, p. S10). On "conversion therapy," see Section 14.5.2.1.

[32] Two books that discuss the "transgender child" are Gill-Peterson (2018) and Meadow (2018). On Gill-Peterson, see Byrne (2024b, pp. 243–244). For an early expression of skepticism, see Brunskell-Evans & Moore (2018).

[33] [R]esearch substantiates that children who are prepubertal and assert an identity of TGD [transgender and gender-diverse] *know their gender* as clearly and as consistently as their developmentally equivalent peers who identify as cisgender and benefit from the same level of social acceptance" (Rafferty et al., 2018, emphasis added). Also: "Individuals whose sex assigned at birth is opposite to the gender they *know themselves to be* are often referred to as *transgender*" (Turban & Ehrensaft, 2018, p. 1, first emphasis added); "studies show that trans children and adolescents know themselves and their gender" (Ashley, 2022b, p. 15).

cisgender; if not, they are transgender. So, to determine whether a child is transgender or cisgender, one only need ask.

An immediate problem is posed by the undeniable phenomenon of temporary youthful transgender identification. (See Section 4.3.1.4.) Attempting to address this difficulty, Aron Janssen, vice chair of clinical affairs at the Pritzker Department of Child and Adolescent Psychiatry at Lurie Children's Hospital in Chicago, and chair of the American Academy of Child and Adolescent Psychiatry's Sexual Orientation and Gender Identity Issues Committee, stated in a deposition that although gender identity is "static" and "fixed," "one's understanding of it can evolve over time."[34]

Dysphoric children and socially transitioned children are routinely referred to as "transgender children." In some cases, this is for convenience or as a gesture of respect.[35] However, its use may subtly influence clinical reasoning. The label "transgender" implies a mismatch between gender identity and the person's sexed body, and that mismatch can supposedly cause gender dysphoria (GD).[36] Since an adolescent's gender identity cannot be changed, the obvious solution to relieve the distress is to change their body.[37]

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[34] Boe v. Marshall*,* No. 2:22-cv-00184: 558-16 (2024, pp. 104–110). Some PMT clinicians maintain that such change in understanding is not likely: "there is [a] small but non-zero possibility of one's understanding of their gender identity evolving over time" (Turban et al., 2025, p. 2). According to UCSF's Diane Ehrensaft, "My own clinical experience told me that you could discern one group of children from the other prior to adolescence, not with 100% accuracy, but not far from it" (Ehrensaft, 2014, p. 578). As Ehrensaft puts it in her book *The Gender Creative Child*, "we can tell the apples (the transgender children) from the oranges (the gender-nonconforming but not trans kids), sometimes as early as when they are three years old. So, why hold the apples back if they already know who they are?" (Ehrensaft, 2016, p. 55). Put without the framing of "trans kids," the clinical issue is whether one can discriminate between gender dysphoric children whose dysphoria will resolve without any medical intervention, and those whose dysphoria will persist into adulthood (see Section 4.3.2).

[35] E.g. Olson et al. (2022).

[36] According to WPATH, gender dysphoria is "distress that is *caused by* a discrepancy between a person's gender identity and that person's sex assigned at birth" Coleman et al. (2012, p. 221, emphasis added). The quotation continues, "(and the associated gender role and/or primary and secondary sex characteristics)"; so at least in theory, one way of relieving gender dysphoria would be to change the "associated gender role."

[37] The AAP policy statement includes more young people as candidates for medicalization than just those with mismatched or incongruent gender identities. The title of the policy statement is "Ensuring Comprehensive Care and Support for Transgender *and Gender-Diverse* Children and Adolescents" (Rafferty et al., 2018, emphasis added). Transgender youth, the policy statement says, are "a subset of gender-diverse youth." The policy statement explicitly equates "gender diverse" with "gender nonconforming" (the latter term being deprecated only because of its allegedly pejorative connotation).

2.2 Terminology in this Review

While communication with patients and families must always be sensitive and compassionate, describing sex as a matter of "assignment" is, at best, confusing and accordingly not truly respectful. Patients and their legal caregivers are entitled to the facts regarding their medical situation; this is essential for informed participation in the medical decision-making process. Just as importantly, evidence assessments must use accurate and precise language when referring to sex, in order to maintain scientific integrity and support sound clinical judgment.

Treatment of children and adolescents with GD presents an especially complex case of doctor-patient communication because doctors understandably do not want to alienate their patients; trust is the bedrock of shared decision-making.

There is growing international awareness of the importance of using accurate sex-based language. As the recent U.K.'s *Review of Data, Statistics and Research on Sex and Gender* (RSG) asserts:

> Analysts must be able to use clear and familiar language in reporting findings on sex. Terms such as women, men, boys and girls are synonymous with (respectively) adult human females and males and children of each sex. Similar considerations apply to terms such as mothers and fathers, sons and daughters.[38]

The RSG also recommends against using the phrase "sex assigned at birth," remarking that it is "misleading."[39]

The RSG notes that the word "gender" has "multiple distinct meanings, including: a synonym for sex; social structures and stereotypes associated with sex; and gender

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Thus, gender-nonconforming youth *in general* are singled out as potential recipients of sex-related hormone therapy and surgery. The same points apply to WPATH's SOC-8, *Standards of Care for the Health of Transgender and* Gender Diverse *People*, which also deprecates the use of "gender-nonconforming" (Coleman et al., 2022, p. S11, emphasis added); SOC-7 (Coleman et al., 2012) has "gender-nonconforming" in its title.

[38] Sullivan (2025, p. 11). The Review was commissioned by the previous Conservative government and welcomed by the present Labour Secretary of State for Health and Social Care (Scott, 2025).

[39] Sullivan (2025, p. 7).

identity."[40] For this reason, the RSG cautions against using the word when misunderstandings could arise. A prime example is WPATH's definition of "gender identity" discussed above, which uses the word "gender" without an adequate explanation. Because of its unclarity and ambiguity, "gender" will generally be avoided in this Review. "Gender identity" inherits the obscurity of "gender" and will not be used either.[41] As discussed, the term "transgender child" suggests that medical intervention is the default or primary course of action. For this reason, it will be avoided.[42]

The Review will use "social transition" for the process of changing one's sex-associated name, presenting oneself as a member of the other sex, being referred to with third-person pronouns for the other sex,[43] and so on.

"Gender dysphoria" is in the DSM and at present has no accepted alternative; therefore, it will be used despite problems with the word "gender." "Gender nonconformity" is a familiar and well-understood phrase, so it will also be used (although some may prefer "sex-stereotype nonconformity"). As already indicated, "pediatric gender medicine" (PGM) will be used for the clinical field that treats children and adolescents with GD, sometimes with medical interventions. Instead of the term "gender-affirming care" this Review will use "PMT" (pediatric medical transition), as in phrases such as "the PMT approach." This is more accurate and carries no positive or negative connotation. The PMT approach does not always involve hormones or surgeries, but some of its proponents do tend to view even social transition as an initial step toward medical transition. The older term "cross-sex hormones" (CSH)[44] is more neutral and informative than "gender-affirming hormone therapy." Surgeries to alter sex characteristics[45] for

[40] Sullivan (2025, p. 5).
[41] It should be emphasized that not everyone accepts that they have a gender identity. As the RSG puts it: "Questions on gender identity should recognize that the concept of gender identity as such will be unfamiliar, unclear or irrelevant to some respondents, and that many respondents may not perceive themselves as having a gender identity. Questions should not assume that respondents will agree that they have a gender identity" (Sullivan, 2025, p. 9). The RSG illustrates how "gender identity" is now firmly embedded, not just in gender medicine, but also in social statistics (and, it could be added, pedagogy). For an illuminating discussion of the history, see Brubaker (2025).
[42] Needless to say, terminology that makes other treatment pathways prominent is equally undesirable.
[43] Or *they* or neo-pronouns (*xe*/*xem* and the like).
[44] Even this terminology is not perfect: estrogens are normally present in males, although at lower levels than in females; vice versa for androgens (including testosterone).
[45] Sex characteristics are either *primary* (the external and internal reproductive organs), or *secondary* (characteristics that emerge at puberty, such as breasts in females and facial hair in males).

adolescents will be given medically standard, clinical, neutral descriptions—e.g. “mastectomy.” Finally, the older term “sex reassignment surgery” (SRS) will be used rather than the more recent “gender confirmation surgery.”

Chapter 3 History and Evolution of Adult and Pediatric Gender Medicine

Medical transition for gender dysphoric youth is a comparatively recent practice and grew out of the clinical experience of transitioning mature adults. It is common in medicine to extend medical treatments to children once they have been proven safe and effective in adults. In this case, however, the opposite occurred. The rationale for transitioning adolescents emerged from the observation that medical transition in adults often failed to produce the desired positive outcomes. This chapter explains how this came about and provides additional historical context.

Sections 3.1, 3.2, and 3.3 briefly review the history of medicalized transitions, which are barely a century old. Sections 3.4 and 3.5 explain how the observed failure of medical transition to produce positive psychosocial outcomes for adults led clinicians in the Netherlands to propose an early intervention model, resulting in the "Dutch Protocol." The final section describes how the Dutch Protocol evolved into the "gender affirming care" approach to pediatric medical transition (PMT), a shift that was accompanied by significant changes in the pediatric patient population presenting with gender dysphoria (GD)—both in terms of size and demographic composition.

3.1 *The Transsexual Phenomenon*

Extremely gender-nonconforming people, including those who live their lives either as members of the other sex, or as a so-called "third gender," have been documented throughout human history.[1] One famous example is the French diplomat and spy Chevalière d'Eon (1728-1810), who dressed and "passed" as a woman during the final 32 years of his life. Everyone was convinced, including the last king of France, Louis XVI.[2] In the early 20th century, the English physician and sexologist Henry Havelock Ellis coined *eonism*, after the Chevalière, for "people who took pleasure in behaving and

[1] See, e.g., Bullough et al. (1997); R. Green (1966); Herdt (1996); Peled (2016); Vasey & VanderLaan (2014). Many earlier cultures and some contemporary ones have "third genders": some people of one sex (typically feminine same-sex attracted males) occupy social roles (somewhat) similar to those of the other sex. It is a mistake to take this phenomenon to be akin to the contemporary Western "transgender moment"—see Vasey (2022).
[2] Kates (2001, p. 218).

dressing like the opposite sex and yet were not sexually inverted; that is, their sexual feelings were not directed towards persons of their own sex."[3] "Eonism" later came to label a broader category, including individuals with strong cross-sex wishes who were same-sex attracted.[4] In 1949, an American physician, David Cauldwell, used the term "transexual" to label "individuals who are physically of one sex and apparently psychologically of the opposite sex."[5]

"Transsexualism" was popularized by Harry Benjamin, a German-American endocrinologist and the father of transgender medicine. Benjamin's 1966 book, *The Transsexual Phenomenon*, was the first comprehensive English-language discussion of medicalized treatment for people who "want to undergo corrective surgery … so that their bodies would at least resemble those of the sex to which they feel they belong and to which they ardently want to belong."[6] Cross-sex hormones (CSH) followed by surgery, Benjamin thought, could "change a miserable and maladjusted person of one sex into a happier and more adequate, although by no means neurosis-free, personality of the opposite sex."[7]

In the first half of the 20th century, there were few recorded instances of transsexuals. One of the first people to undergo sex-reassignment surgery (SRS) was Einar Wegener, a Danish artist who modeled while cross-dressed for his wife Gerda Gottlieb, a talented painter. In pursuit of the body modifications he so desperately desired, Wegener sought help from the sexologist Magnus Hirschfeld, a long-time friend of Harry Benjamin's and founder of the Institute for Sexual Science in Berlin.[8] Castration, penectomy, and ovarian implantation were performed on Wegener in Berlin and Dresden in 1930, with

[3] Havelock Ellis (1937, p. 1, Part Two); quoted in Byrne (2024b, pp. 113–114). According to d'Eon's biographer, the historian Gary Kates, "d'Eon was neither a transvestite nor a transsexual … there is simply no indication that d'Eon hated his own body or that he wanted, or even imagined he would be better off with, the body of a woman" (Kates, 2001, p. xxii); quoted in Byrne (2024b, p. 229).
[4] See, e.g., Hamburger et al. (1953) (a report on Christine Jorgensen's case; see the following section). See also Benjamin (1967b, p. 107) and Blanchard (1989, p. 240).
[5] Quoted in Meyerowitz (2009, p. 44). This quotation is from Cauldwell's 1950 *Questions and Answers on the Sex Life and Sexual Problems of Trans-Sexuals*, which hyphenates "transsexual." Cauldwell used "psychopathic transexual" (one "s") in 1949 (Cauldwell, 2006, p. 41).
[6] Benjamin (1966, p. 14)
[7] Benjamin (1966, p. 164).
[8] Li (2023a, 2023b, pp. 113–114).

additional procedures the following year. These were unsuccessful. Einar Wegener, transformed into Lili Elbe, died in September 1931, after an "abyss of suffering."[9]

3.2 From George to Christine

Transsexualism was not then a phenomenon. That changed in 1952, when the news broke that George Jorgensen, a 24-year-old American of Danish descent had undergone sex reassignment surgery (SRS) in Denmark:

> [H]er celebrity began December 1, 1952, when a banner headline screaming "EX-GI BECOMES BLONDE BEAUTY: OPERATIONS TRANSFORM BRONX YOUTH" greeted readers of the *New York Daily News*. Hearst Publications' popular Sunday newspaper supplement, *American Weekly*, subsequently paid twenty thousand dollars for an exclusive interview with Jorgensen that brought her story to millions of American homes, and whetted the appetite of the world press. When she returned to the United States in 1953, an unprecedented three hundred reporters were on hand to meet her plane at New York International Airport … Her "sex-change" was viewed by many as a miracle of God in which not Christ, but Christine—Man reborn as Woman—heralded a new dispensation of human history.[10]

Jorgensen met Harry Benjamin in New York that year, and they enjoyed a long friendship. In a 1965 letter, just before the publication of *The Transsexual Phenomenon*, Benjamin wrote: "Without you, Christine, none of this would have happened."[11]

Growing up in the Bronx, the young George was teased for his "girlish qualities," and was greatly conflicted by his homosexuality:

> One question was especially troubling for George: He had learned at church and from his school friends that homosexual relationships were considered sinful and immoral. In the Jorgensen household, the word was never spoken. Among his

[9] Elbe et al. (2020, p. 203); quoted in Joyce (2021, p. 17). Lili apparently had no regrets, writing in June 1931, "The price which I have paid seems to me very small" (Elbe et al., 2020, p. 198). On regret, see Section 13.4. The 2015 movie *The Danish Girl*, starring Eddie Redmayne, is loosely based on Einar/Lili's story.
[10] Stryker (2000, pp. v–vi). See also Li (2023b, pp. 152–153).
[11] Jorgensen (1967, p. xi).

> neighbors, “homos” or “queers” were thought to be unacceptable, even dangerous people. Hence, a series of romantic attractions to other young men became his greatest teenage conflict. Try as he might to avoid these crushes, George persistently fell in love with other male youths of his age. This conflict would contribute to episodes of depression, low self-esteem, low aspiration for success, and much personal unhappiness.[12]

George himself fixated on a hormonal explanation for his femininity and same-sex attraction—a “glandular imbalance”[13]—and was also (wrongly) convinced that his genitals were “underdeveloped.”[14] It is a plausible conjecture that George found an English translation of Lili Elbe’s autobiography while hunting in New York City libraries, “hoping to find other keys to my dilemma.”[15] In any event, in search of the hormonal and surgical treatment he felt he needed, George went to Denmark on a one-way ticket in 1950. There the “Bronx youth” became a patient of Christian Hamburger, a Copenhagen endocrinologist:[16]

> Perhaps Hamburger felt a special compassion for homosexuals because his sister was a lesbian. Despite Denmark’s comparatively liberal national policies, Hamburger surely knew from his sister’s experience how discrimination against gays and lesbians could be profoundly troubling for a homosexual. He could offer no medical intervention to help his sister, but he believed there might be some steps he could take to help George Jorgensen, and he was willing to try.[17]

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[12] Docter (2013, pp. 25–26).
[13] Docter (2013, p. 63).
[14] Docter (2013, p. 46).
[15] Jorgensen (1967, p. 80); for the conjecture, see Docter (2013, p. 38).
[16] Hamburger had a distinguished career (Pedersen-Bjergaar, 1964). Contrasting with Hamburger’s academic record, before Benjamin became interested in transsexuality he was a prominent proponent of endocrine “rejuvenation therapy,” a medical fad. In 1931 he filed a lawsuit against the editor of the *Journal of the American Medical Association* (*JAMA*) “for calling his treatment quackery,” and lost (Pettit, 2013, p. 1070). See also Li (2023b).
[17] According to Hertoft & Sørensen (1979), a “sex change” was not the original plan: “the Danish team regarded Chris Jorgensen as a homosexual man suffering from his homosexuality and since he himself asked for castration, they would not deny him this operation. Not until afterwards, when the press published the case, did the team behind the procedure accept it as a sex change. The rest of the story is well known” (p. 168). Hamburger is said to have denied that Jorgensen was a homosexual in Christine’s autobiography (Jorgensen, 1967, p. 101). See also Docter (2013, p. 81).

In a case report he later wrote for the *Journal of the American Medical Association* (*JAMA*) Hamburger described George's desire "with medical assistance to be able to obtain permission to live on 'as nearly a woman as possible.'"[18] Hamburger prescribed estrogen, and George's application for castration to the Danish Ministry of Justice was approved in 1951.[19] Castration was followed by penectomy and a later unsatisfactory attempt at creating an artificial vagina. "As a nationally recognized personality, Christine Jorgensen's flame burned with exceptional brilliance for about thirty years,"[20] dimming in the 1980s. A heavy drinker and smoker, Christine died of cancer in 1989, at the age of 62.

3.3 "Dear Dr. Hamburger"

After the "sensational publicity" over George Jorgensen's metamorphosis into Christine, Hamburger received "a unique collection of letters from a considerable number of men and women who desire to change their sex."[21] He analyzed all 756 of them, from 465 people, and published the results in a European endocrinology journal, *Acta Endocrinologica*. His correspondents wrote from all over the world. Over three quarters were men, and some of the letter writers were young teenagers. Not everyone mentioned their sexual orientation, but the women were the most forthcoming, with 71% offering at least some information. Fewer than half the men gave "any information about their sexual impulses."[22] Homosexuality predominated[23] among the men and was universal among the women:

> It is remarkable that not one single woman admits to heterosexuality, which is the case in 22 per cent of all male letter writers … Not a single woman mentions attraction to men; on the contrary. Women who have experienced shorter or longer periods of married life, felt the physical part of matrimony to be intolerable. Completely different are the transvestic men: they do not appear to have felt any

[18] Hamburger et al. (1953, p. 393).
[19] Jorgensen (1967, pp. 114–116).
[20] Docter (2013, p. 255).
[21] Hamburger (1953, p. 361).
[22] Hamburger (1953, p. 368).
[23] Of the 45% of men who disclosed information about their sexual orientation, Hamburger classified 65% as homosexual (Hamburger, 1953, Table 3).

> aversion to the female body, although the erotic attraction, if any, is stated to have declined with passing years, or to have led to impotence.[24]

A 16-year-old American girl wrote:

> I've always acted like a boy and did the things they did. When I was smaller I used to wear my brothers [sic] clothes and I even do now sometimes when no one is home. This isn't the worst of it though, ever since I've been in High School I've been in love with a girl! and as much as I try to forget this love the more I realize I don't want to forget it. - - - I've also read about transvestites who only wanted to dress like the opposite sex but that's not how I feel. I want to dress like a boy yes, but it's not so bad that I can't control it.[25]

Childhood gender-nonconformity is strongly associated with later homosexuality.[26] Because childhood- or early-onset GD[27] involves extreme gender-nonconformity, young children distressed by their sexed bodies will likely grow up to be same-sex attracted. As the current *Diagnostic and Statistical Manual* (DSM-V-TR) puts it, "Studies have shown a high incidence of sexual attraction to those of the individual's birth-assigned gender, regardless of the trajectory of the prepubescent child's gender dysphoria."[28] Harry Benjamin put his own spin on George Jorgensen's homosexuality: "since the psychological status of a transsexual male is that of a female, it is natural that sex attraction centers on a male."[29]

Despite the sensational publicity, in the 1960s the "transsexual phenomenon" was still in its infancy. By 1965, Benjamin had seen 307 cases of which he deemed 220 "true transsexuals," the remainder being classed as "transvestites." Almost 90% of the transsexuals were male. Only 62 males and 11 females had had surgery.[30] Reflecting

[24] Hamburger (1953, p. 369).
[25] Hamburger (1953, p. 370).
[26] Bailey & Zucker (1995); R. Green et al. (1987); Steensma et al. (2013).
[27] Ristori & Steensma (2016); Singh et al. (2021). For other forms of GD, see Bailey & Blanchard (2017); Zucker et al. (2016). See also Section 4.3.1.
[28] American Psychiatric Association (2022, p. 516).
[29] Benjamin (1967a, p. ix).
[30] Benjamin (1966, p. 163).

this imbalance, *The Transsexual Phenomenon* had only one slim chapter on "the female transsexual."

By 1979, the demand for "sex change" became significant enough for clinicians caring for this patient population to form a professional association, the Harry Benjamin International Gender Dysphoria Association (HBIGDA), which published the first *Standards of Care* in 1979. In that short typewritten document, "Principle 2" of 32 was: "Hormonal and surgical sex reassignment are procedures requiring medical justification and are not of such minor consequence as to be performed on an elective basis."[31]

In the third edition of the DSM in 1980, the disorder of "transsexualism" was said to be "apparently rare."[32] In 1994 DSM-IV reported: "Data from smaller countries in Europe with access to total population statistics and referrals suggest that roughly 1 per 30,000 adult males and 1 per 100,000 adult females seek sex-reassignment surgery."[33] The "transgender tipping point"[34] had not yet arrived.

3.4 Outcomes of adult transitions

Pediatric medical transition began in the Netherlands, which had offered adult treatment in an academic hospital starting in the 1970s, with the costs of a medical transition reimbursed through the Dutch national health insurance system.[35] The availability of comprehensive and reliable medical records gave clinicians the opportunity to study how patients fared, and a paper detailing the results was published in 1988: "Sex reassignment surgery: A study of 141 Dutch transsexuals." The research was led by the psychologist Peggy Cohen-Kettenis, who had worked earlier with adult transsexuals at the Department of Sexology at Utrecht University. In 1987, she moved to the

[31] Harry Benjamin International Gender Dysphoria Association (1979).
[32] For the diagnostic criteria, see Appendix 2. The first two versions of the DSM fleetingly included "transvestism" (American Psychiatric Association (1952, p. 39) and "transvestitism" (American Psychiatric Association (1968, p. 44). See also Drescher & Yarbrough (2024).
[33] American Psychiatric Association (1994, p. 535). See also Dhejne et al. (2014). According to the first *Standards of Care*, "As of the beginning of 1979, an undocumentable estimate of the number of adult Americans hormonally and surgically sex-reassigned ranges from 3,000 to 6,000" (Harry Benjamin International Gender Dysphoria Association, 1979).
[34] The title of a *Time* cover story in 2014 (Steinmetz, 2014).
[35] Bakker (2021, p. 29).

Department of Child and Youth Psychiatry at the Academic Hospital Utrecht (now UMC Utrecht), where she began to see children and adolescents with GD.[36]

Cohen-Kettenis and her co-author and student Bram Kuiper sent recruitment letters to all 229 patients diagnosed by the Netherlands Gender Care Foundation (NGCF) as "transsexuals and who … had at least started hormone therapy." The 141 who agreed to participate were "36 FMs (female-to-male transsexuals) and 105 MFs (male-to-female transsexuals)."[37] They were at varying stages of medical transition. Some had completed surgery, while others had just started on CSH; follow-up time from the start of treatment ranged from one month to more than 10 years. The patients' average ages were late-20s (the FMs) and mid-30s (the MFs). They were assessed by interview, and all but three were interviewed in their homes.

On the positive side, 65% reported feeling happy or very happy, while 11% said they were unhappy or very unhappy. Almost all the FMs and nearly 80% of the MFs described their ability to "pass as a member of the newly assumed gender" as good or very good. None of those who had had surgery "felt any significant doubts about the decision to get rid of their own primary and secondary sex characteristics and to have the body surgically adjusted to the characteristics of the opposite sex," except for one FM who nonetheless had no regrets about living as a man.[38]

On the other hand, while the self-reported subjective outcomes were good, objective measures told a different story. One in seven MFs and one in 36 FMs had attempted suicide after treatment began. (Of the total number of patients seen at the NGCF in the previous 10 years, three had committed suicide after treatment.) 60% of the MFs and 37% of the FMs were unemployed and 59% of the MFs and 33% of the FMs had no romantic partners.[39] Commenting on previous studies of SRS, the researchers noted: "it is possible to discern a trend in these reports that the subjective well-being of the

[36] Bakker (2021, p. 113).
[37] Kuiper & Cohen-Kettenis (1988, p. 442).
[38] Kuiper & Cohen-Kettenis (1988, p. 450).
[39] Kuiper & Cohen-Kettenis (1988, p. 447).

transsexuals has increased, whereas an 'improvement' in their actual life situation is not always observed."[40]

Did medical transition at least alleviate gender dysphoria? Interestingly, there was no relationship between reported happiness and stage of transition:

> Although a fair number of persons attribute their feelings of happiness to SRS, there appears to be no direct relation between the subjective well-being and the phase of therapy. Those who have completed SRS are not happier or less happy than those who are still in the initial phase of therapy. In other words, a person's positive evaluation of his/her life-in-its-totality is not directly related to his/her progress in physical adjustment to the opposite sex.[41]

The researchers speculated that this might be due to an expectation effect:

> However, it does not seem justifiable to conclude that it is irrelevant to a person's happiness whether physical adjustment has or has not taken place and that the operations could therefore just as well have been omitted. One has to bear in mind that in general the [FMs and MFs who had not completed treatment] are happy in the knowledge that the operations will be performed within a reasonable time. They are taking a loan on the future.[42]

Although the researchers claimed that "there is no reason to doubt the therapeutic effect of sex reassignment surgery," they were clear that there were significant costs:

> SRS is no panacea. Alleviation of the gender problems does not automatically lead to a happy and lighthearted life. On the contrary, SRS can lead to new problems.[43]

Why were the MFs, in particular, doing so poorly? Three possible explanations were floated. One was that "passing" is easier for FMs, because of the power of

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[40] Kuiper & Cohen-Kettenis (1988, p. 440). Dhejne et al. (2011) examined the long-term outcomes of 324 people in Sweden receiving sex-reassignment surgery (SRS) over the period 1973-2003 (191 MFs, 133 FMs). Dhejne et al. concluded: "Persons with transsexualism, after sex reassignment, have considerably higher risks for mortality, suicidal behaviour, and psychiatric morbidity than the general population."
[41] Kuiper & Cohen-Kettenis (1988, p. 454).
[42] Kuiper & Cohen-Kettenis (1988, p. 454).
[43] Kuiper & Cohen-Kettenis (1988, p. 455).

testosterone.[44] Second, "society in general is inclined to take a milder view of women who dress and/or behave like men."[45] Finally, the MFs had transitioned later and were more likely to have married and to have children, with a consequent "heavier burden of a past life as a person of the original gender."[46,47]

One possibility that the Dutch researchers did not consider was that the FMs were doing better because their romantic relationships were easier to preserve after transition. As Hamburger reported from his correspondence in 1953, "No less than 10 women say, in so many words, that they want their sex changed in order to be able to marry their female friend or to have the relationship legalized."[48] Also apparently ignored was the related possibility that transition may appeal to young gay men and lesbians suffering from social disapproval of their homosexuality.[49]

3.5 The rationale for youth gender transition

Medically transitioning earlier gave patients a better chance to "pass" and reduced the "burden of a past life," so perhaps intervening at younger ages would improve transsexuals' quality of life. Cohen-Kettenis thought so. As sociologist Michael Biggs explains,

> Cohen-Kettenis believed that transsexuals would experience better outcomes if they started treatment before adulthood. By the mid-1990s, she was referring some patients aged 16 and 17 to the Amsterdam clinic for endocrinological intervention prior to cross-sex hormones … Johanna, for example, "fulfilled all necessary requirements for early treatment": she did not favor girly things (though neither did her sisters), she was fond of soccer, she never dated in school (perhaps not surprising given that she was homosexual), and her parents discovered her wearing a tight t-shirt to conceal her breasts … Brought to the clinic at 17, she was prescribed progestin for four months and then testosterone.

[44] This works both ways. First, testosterone can dramatically transform the female body; second, the effects of pubertal testosterone on the male body are hard or impossible to undo. See Section 7.4.
[45] Kuiper & Cohen-Kettenis (1988, p. 455).
[46] Kuiper & Cohen-Kettenis (1988, p. 456).
[47] See also Smith et al. (2005, p. 97).
[48] Hamburger (1953, p. 370).
[49] See Barnes (2023, pp. 159–164).

> Within two years Jaap (as Johanna had become) underwent mastectomy, hysterectomy, and oophorectomy, and obtained a new birth certificate.[50]

In 1991 Cohen-Kettenis and her colleague Louis Gooren lowered the eligible age for CSH to 16, but Cohen-Kettenis was not yet recommending puberty blockers (PBs).[51] The Dutch pediatric endocrinologist Henriette Delemarre-van de Waal had treated the first patient with blockers some years earlier, in 1987. "FG" was a girl with early-onset gender dysphoria:

> From the age of 5, FG "had made it very clear that I was supposed to be a boy." It later transpired that FG was sexually attracted to women. FG's father, an Italian with traditional views on gender, disapproved of his daughter's masculinity, and serious conflict ensued. Extensive psychotherapy did not improve matters; FG wrote a suicide note at the age of 12.[52]

At age 13, FG was prescribed puberty blockers and remained on them until age 18, after which many surgeries followed, including mastectomy and hysterectomy.

FG had come to the Utrecht gender clinic three years after starting PBs; as Cohen-Kettenis recounts:

> I'll never forget that first boy treated with Decapeptyl[53] by Henriette Delemarre. He made an impression with his boyish appearance at 16—naturally, because he hadn't entered puberty. Henriette and I embarked upon the adventure. No one knew what the long-term effects of administering puberty blockers would be. Yes, I was nervous: suppose you've got it wrong with an adolescent like that and you have to reverse it![54]

With the collaboration of Cohen-Kettenis and Delemarre-van de Waal, the "Dutch Protocol" for youth medical transition was born.[55] As of 1997, for carefully selected

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[50] Biggs (2023b, p. 350).
[51] Bakker (2021, p. 118).
[52] Biggs (2023b, p. 350).
[53] The brand name of triporelin, a gonadotropin releasing hormone agonist (GnRHa); triptorelin acts on the pituitary gland, blocking puberty in adolescents. See Section 7.3.
[54] Bakker (2021, p. 115).
[55] Delemarre-van de Waal & Cohen-Kettenis (2006).

"juvenile transsexuals," with early-onset GD worsening at puberty, PBs could be given as early as 12.[56] Cross-sex hormones could be administered at 16, with surgeries at 18.[57] Patients were required to be otherwise mentally healthy and have family support.

FG was followed up 22 years later at age 35:[58]

> FG did not regret transition, but scored high on the measure for depression. Owing to "shame about his genital appearance and his feelings of inadequacy in sexual matters," he could not sustain a romantic relationship with a girlfriend. Ironically, a "strong dislike of one's sexual anatomy" is one of the diagnostic criteria for gender dysphoria in children (according to DSM-5), and so in this respect it is not clear how the dysphoria had been resolved … Now aged 48, FG has given two recent interviews. FG's situation seems to have improved, and he now has a serious girlfriend. He describes puberty suppression as "life-saving" in his case … but also recommends that it should require a significant assessment process.[59]

3.6 The spread of the Dutch Protocol and the rise of "gender-affirming care"

In the United States, HBIGDA endorsed puberty blockers in their sixth version of their clinical guideline, the *Standards of Care* (SOC-6, 2001):

> Two goals justify this intervention: a) to gain time to further explore the gender identity and other developmental issues in psychotherapy; and b) to make passing easier if the adolescent continues to pursue sex and gender change. In order to provide puberty delaying hormones to an adolescent, the following criteria must be met:

[56] Bakker (2021, p. 121).
[57] In fact, surgery was mandatory until 2014 (Gregory, 2021).
[58] Cohen-Kettenis et al. (2011).
[59] Biggs (2023b, p. 355).

1. throughout childhood the adolescent has demonstrated an intense pattern of cross-sex and cross-gender identity and aversion to expected gender role behaviors;

2. sex and gender discomfort has significantly increased with the onset of puberty;

3. the family consents and participates in the therapy.[60]

SOC-6 also erroneously characterized PBs as "fully reversible" (see Chapter 7). As Biggs points out, "the published evidence for the benefits of puberty suppression then comprised a single case study of one patient—FG—awaiting final surgery."[61]

In the U.S., PBs were first prescribed for GD at Boston Children's Gender Management Service (GeMS, now Gender Multispeciality Service) around 2007, with the U.K.'s Gender Identity Development Service (GIDS) following four years later.[62] GeMs did not set a minimum age limit, and in 2015 neither did the U.K.'s National Health Service.[63] The relatively strict gatekeeping of the Dutch Protocol soon gave way to a more patient-led approach (see Section 4.1. and Chapter 11). This occurred not just in the U.S. but other countries, including the U.K.:

> From 2014, puberty blockers moved from a research-only protocol to being available through routine clinical practice … In addition, the strict inclusion criteria of the Dutch protocol were no longer followed, and puberty blockers were given to a wider range of adolescents … These included patients with no history of gender incongruence prior to puberty, as well as those with neurodiversity and complex mental health presentations.[64]

HBIGDA became the World Professional Association of Transgender Health (WPATH) in 2007. Reflecting in 2009 on the "new paradigms [that] have emerged about the nature

[60] Harry Benjamin International Gender Dysphoria Association (2001, p. 10).
[61] Biggs (2023b, p. 353).
[62] GIDS was closed in March 2024; see also Barnes (2023).
[63] Biggs (2023b, p. 354).
[64] Cass (2024a, p. 73).

of transgender identity and experience," Lin Fraser, then President-elect of WPATH, wrote:

> The new model views gender as a continuum rather than a male/female dichotomy and calls for individualized gender trajectories, which may or may not include hormonal therapy and sex reassignment surgery.[65]

The seventh version of the *Standards of Care* (SOC-7) was published in 2012 and was a significant departure from SOC-6, moving away from medical gatekeeping and towards the "gender-affirming" model. For example, SOC-6 recommended that CSH be given only to patients aged 18 or older, who either had "real-life experience" ("living in the desired gender") or had been in psychotherapy for at least three months. SOC-7 had no age limit for CSH, only requiring that the adolescent give "informed consent" and that the parents or guardians have also "consented to the treatment and are involved in supporting the adolescent." Recommendations for psychotherapy or real-life experience were absent. SOC-7 effectively relegated the role of mental health professionals to provide assessments needed by insurance companies for reimbursement.

Another change was apparent from SOC-7's title. SOC-6 was the standards of care "for Gender Identity Disorders," but SOC-7 was "for the Health of Transsexual, Transgender, and Gender Nonconforming People." "Non-binary" would have to wait its turn, appearing for the first time in the current guideline, SOC-8 (2022), with a chapter dedicated to it.[66] The first version of the *Standards of Care* was authored by just six people and comprised slightly over 3,000 words; SOC-8 has more than 100 contributors and more than 100,000 words.

In 2011, Cohen-Kettenis and colleagues published a follow-up study of 70 adolescent patients who received PBs in the Netherlands between 2000 and 2008. The results

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[65] Fraser (2009, pp. 113–114, citations omitted). One of the citations omitted from the quotation is *The Apartheid of Sex: A Manifesto on the Freedom of Gender*, by Martine Rothblatt. Chapter 1 of that book is called "Five Billion Sexes," and begins: "There are two sexes, male and female, right? Wrong! In fact, there is a continuum of sex types, ranging from very male to very female, with countless variations in between" (Rothblatt, 1995, p. 1).

[66] A 2020 survey of U.S. youth aged 13-24 who identified as LGBTQ found that, of the 11,914 who identified as transgender or non-binary, more than 60% identified as the latter (A. E. Green et al., 2022, p. 645).

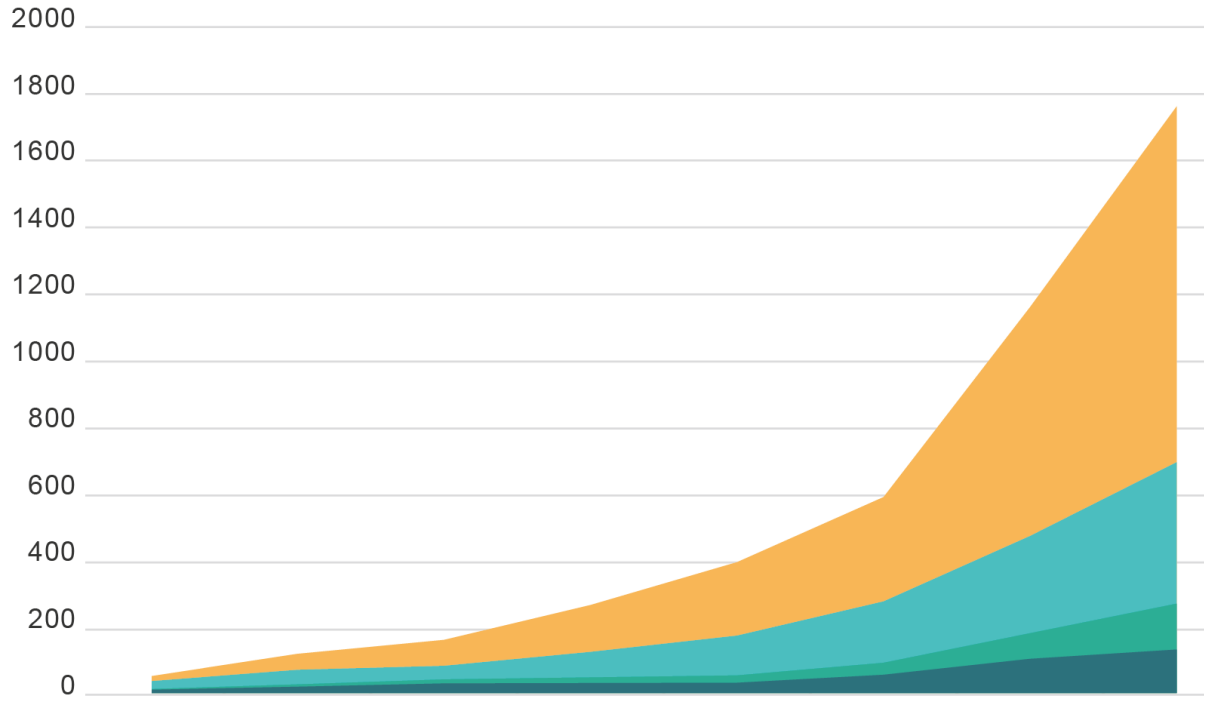
were interpreted as encouraging: “Behavioral and emotional problems and depressive symptoms decreased, while general functioning improved significantly during puberty suppression.”[67] A 2014 study of the same patient cohort after sex reassignment surgery—but with just 55 of the original 70 subjects—contained a similarly positive conclusion: “After gender reassignment, in young adulthood, the GD was alleviated and psychological functioning had steadily improved.”[68] These two studies form the foundational evidence base of the Dutch Protocol, and are widely cited to support it. (As subsequent analysis revealed, they do not: see Section 4.3.6.)

The previously observed tendency for early-onset GD patients to be gay continued with the Dutch cohort. Of the initial group of 70, only one reported heterosexuality; the other 69 reported either homosexuality (62), bisexuality (six), or “don’t know yet” (one).[69] (See also Section 13.3.1.)

Around the time Cohen-Kettenis and colleagues published their first study, clinicians started to observe a rapid increase in the pediatric patient population. More notably, the demographic profile of these patients was shifting, with adolescent females emerging as the predominant group. This trend is illustrated in Figure 3.1, which charts referrals to GIDS from 2009 to 2016.

[67] de Vries et al. (2011, p. 2276).
[68] de Vries et al. (2014, p. 696).
[69] de Vries et al. (2011, Table 1).

Figure 3.1: Sex ratio in children and adolescents referred to GIDS in the U.K. (2009-16)[70]



	2009	2010	2011	2012	2013	2014	2015	2016
Adolescent F	15	48	78	141	221	314	689	1071
Adolescent M	24	44	41	77	120	185	293	426
Children F	2	7	12	17	22	36	77	138
Children M	10	19	29	30	31	55	103	131

In a related trend, Western countries began reporting a growing number of adolescents who, often unexpectedly, disclosed a transgender identity—frequently to the surprise of their parents.[71] The number of pediatric patients seeking medical transition can only be roughly estimated,[72] but the demand in European countries has outstripped supply, with waitlists approaching 2 years or longer. In response to the growing demand, the U.S.—characterized by its decentralized and privatized healthcare system—saw the

[70] Reproduced from Cass (2024a, p. 70); original in de Graaf et al. (2018, Figure 1).
[71] See Section 4.3.1.4.
[72] According to the Human Rights Campaign (HRC), "there are more than 300,000 high school-aged (ages 13-17) transgender youth in the United States today, *many of whom need gender-affirming care*" (Human Rights Campaign, n.d.), emphasis added). See also Williams Institute (2024).

emergence of many new specialty gender clinics, along with a proliferation of independently practicing clinicians.[73] According to a recent conservative estimate, as of March 2023 there were 271 clinics offering PMT in the U.S., though 70 were inactive due to legislative restrictions.[74]

As clinical experience with treating youth with GD across the world has grown, concerns about the PMT model have become increasingly apparent. In response, public health authorities in several European countries have launched formal investigations into the practice. The most comprehensive is the U.K.'s 2024 Cass Review, mentioned in Chapter 1. As a result of such inquiries, some European health authorities are now restricting eligibility for medical transition and implementing new research requirements and safeguards. In the U.S., where government health authorities play a more limited role, and medical practice is primarily regulated at the state level, many states have turned to legislative measures to restrict or prohibit pediatric medical transition.[75]

As Hilary Cass observed in 2022, "it is not helpful to exceptionalise gender identity issues."[76] The consensus in pediatric gender medicine (PGM) of 10 years ago was driven by that exceptionalization, which has now begun to change. The following chapter explains why this change is underway.

[73] Levine et al. (2022a, p. 708).
[74] Borah et al. (2023, pp. 375–376).
[75] Harmon (2024).
[76] Cass (2022b).

Chapter 4 International Retreat from the "Gender-Affirming" Model

Since the publication of the Dutch Protocol in 2006, the practice of "gender-affirming" (or "affirmative" care) has rapidly expanded. Now, a global reversal is underway. Several national health authorities have restricted hormonal and surgical interventions for minors. Section 4.1 provides a brief overview of the rise of pediatric medical transition (PMT) as the primary response to childhood and adolescent gender dysphoria (GD). Section 4.2 summarizes the ongoing practice reversal that is now taking place in an increasing number of countries. Section 4.3 explores the reasons behind these reversals.

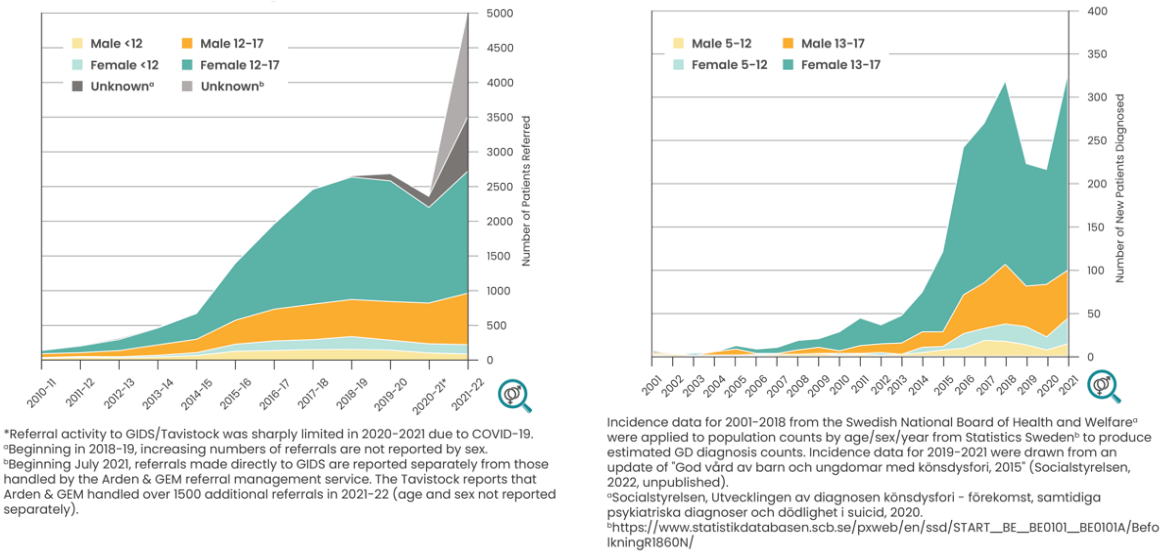
4.1 The rise of the affirmative care model

Following the publication of the Dutch Protocol in 2006,[1] puberty blockers (PBs) and cross-sex hormones (CSH) were incorporated into the Endocrine Society's 2009 clinical practice guideline (CPG),[2] which recommended that hormonal interventions should be used for certain pediatric patients with GD. This approach was also recommended by the World Professional Association for Transgender Health's (WPATH) guidelines in 2012.[3] Notably, these endorsements occurred before the final analysis of psychological outcomes from the original Dutch cohort was published in 2014[4]—and several years before the first systematic reviews of evidence (SRs) commissioned by public health authorities began to appear in 2019 and 2020.[5] During this same period, the number of children and adolescents reporting symptoms of GD and seeking medical intervention surged—a trend that has since become widespread across Western countries. At the same time, the epidemiological profile of patients changed markedly: while earlier

[1] Delemarre-van de Waal & Cohen-Kettenis (2006). Outcomes from the first patient cohort treated according to the protocol were published in 2011 and 2014 (de Vries et al., 2011, 2014).
[2] Hembree et al. (2009).
[3] The 2012 guidelines were the organization's seventh CPG (Coleman et al., 2012). The fifth and sixth CPGs, published in 1998 and 2001, briefly mentioned the potential use of "LHRH agonists" (Levine et al., 1998; Harry Benjamin International Gender Dysphoria Association, 2001), but the use of PBs as the central part of the treatment for adolescents did not emerge until the seventh version.
[4] de Vries et al. (2014).
[5] National Institute for Health and Care Excellence (2020b, 2020a); Pasternack et al. (2019).

cohorts consisted mainly of prepubertal boys, more recent referrals have been dominated by teenage girls (see Figure 4.1 below).

Figure 4.1: Child and adolescent referrals for GD (U.K., left; Sweden, right)[6]



*Referral activity to GIDS/Tavistock was sharply limited in 2020-2021 due to COVID-19.
[a]Beginning in 2018-19, increasing numbers of referrals are not reported by sex.
[b]Beginning July 2021, referrals made directly to GIDS are reported separately from those handled by the Arden & GEM referral management service. The Tavistock reports that Arden & GEM handled over 1500 additional referrals in 2021-22 (age and sex not reported separately).

Incidence data for 2001-2018 from the Swedish National Board of Health and Welfare[a] were applied to population counts by age/sex/year from Statistics Sweden[b] to produce estimated GD diagnosis counts. Incidence data for 2019-2021 were drawn from an update of "God vård av barn och ungdomar med könsdysfori, 2015" (Socialstyrelsen, 2022, unpublished).
[a]Socialstyrelsen, Utvecklingen av diagnosen könsdysfori - förekomst, samtidiga psykiatriska diagnoser och dödlighet i suicid, 2020.
[b]https://www.statistikdatabasen.scb.se/pxweb/en/ssd/START__BE__BE0101__BE0101A/BefolkningR1860N/

The scientific foundation for the rapid expansion of PMT was largely underpinned by two Dutch studies, published in 2011 and 2014,[7] which followed the same patient cohort. The first study, which focused on the use of PBs,[8] reported psychological outcomes in 70 adolescents who had completed the PB phase and were beginning CSH. The findings suggested modest "pre-post" improvements in some mental health measures following PB treatment—but notably, no improvement in GD itself, as assessed by the newly developed Utrecht Gender Dysphoria Scale (UGDS).

For more than a decade, many of the study's methodological flaws remained largely overlooked. One of the study's limitations was its retrospective selection of 70 subjects from a larger "intent-to-treat" group of 111 using non-randomized methods. This selection process inadvertently biased the sample toward cases with the most favorable prognoses, thereby limiting the generalizability of the study's findings.[9]

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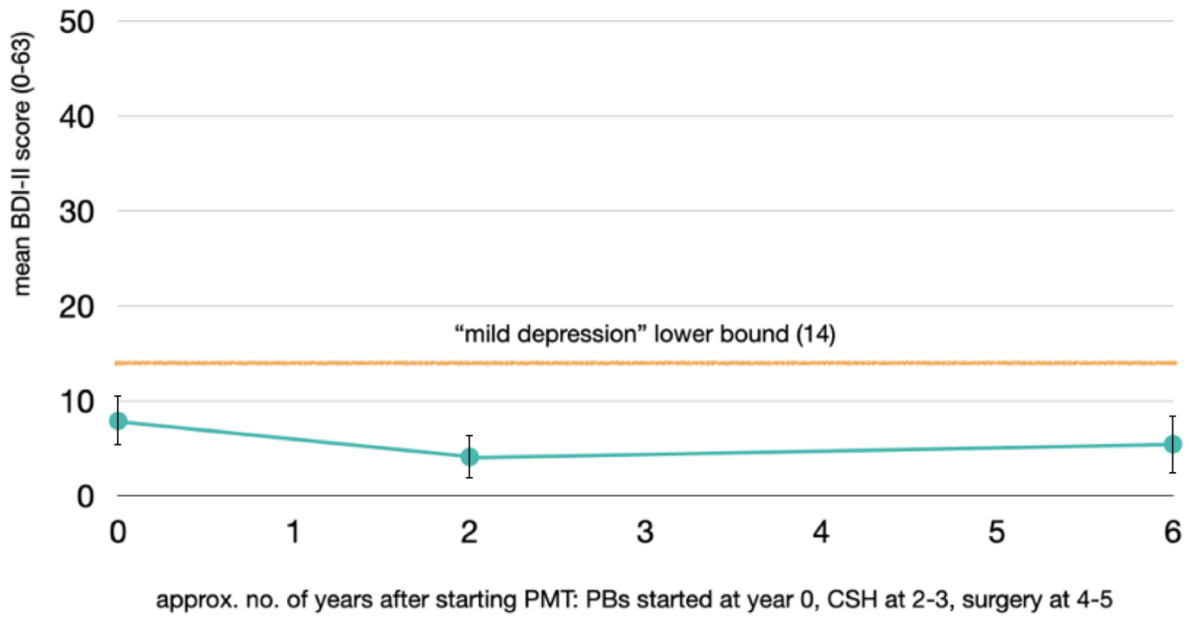
[6] Source: Society for Evidence-Based Gender Medicine (SEGM).
[7] de Vries et al. (2011, 2014).
[8] de Vries et al. (2011).
[9] The study's inclusion criteria defined eligibility for analyzing the effects of puberty blockers (PBs) based on the start date of the subsequent phase—CSH. This approach introduced significant bias by excluding,

In 2014, a follow-up study was published assessing the participants' functioning after CSH and surgery.[10] The sample size was further reduced to just 55 participants, and critical measures of psychological health—such as depression, anxiety, and overall functioning—were assessed in as few as 32 participants. Moreover, although the reported improvements reached statistical significance, their clinical relevance was limited (see the depression scores plotted in Figure 4.2: the orange line indicates the *threshold* for "mild depression," with 63 being the maximum score; mean scores remained below the mild depression threshold at baseline and throughout treatment).

Figure 4.2: Depression scores in Dutch cohort[11]



Noting the high-functioning status of the adolescent/young adult cohort at the end of the study, the authors concluded that the Dutch Protocol provided patients with "the

from the outset, any subjects who discontinued treatment, underrepresenting psychologically complex cases who remained in the "diagnostic" PB phase for longer periods, and skewing the sample toward older subjects. Because eligibility hinged on starting CSH at 16, only those who reached this threshold were included—potentially explaining why the average age for initiating PBs in the study was 15, despite the protocol recommending initiation around age 12 (Abbruzzese et al., 2023).

[10] de Vries et al. (2014).

[11] Graph of data contained in de Vries et al. (2011) and de Vries et al. (2014); 95% confidence intervals added.

opportunity to develop into well-functioning adults."[12] The study failed to consider that the subjects were already high-functioning at baseline—comparable to Dutch peers without GD.[13] This was likely attributable, at least in part, to the original Dutch Protocol's stringent selection criteria.

Moreover, the study failed to account for or appropriately consider potential signals of harm. One participant died due to post-surgical treatment complications associated with early pubertal suppression,[14] at least three were diagnosed with uncontrolled diabetes or morbid obesity while on hormones, and at least one subject discontinued treatment.

These and other serious limitations—including subject selection bias and methodological flaws (such as the post-treatment reversal of the UGDS[15])—remained largely unacknowledged, even as the study became the foundational pillar[16] of PMT protocols worldwide. Attempts to replicate the Dutch findings regarding PBs in the U.K. were unsuccessful[17]—and the publication of those unfavorable results was delayed for several years.[18] It has also been reported that the attempts to replicate the benefits of PBs in a National Institutes of Health (NIH)-funded study in the U.S. yielded less-than-favorable results.[19]

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[12] de Vries et al. (2014, p. 696).
[13] As explained in Abbruzzese et al. (2023), the requirement of psychological stability was built into the protocol, and earlier research from the same clinic had stated that "when both pre- and posttest group means were compared with Dutch normative data, all scores turned out to be within the average range" (Smith et al., 2001, p. 277).
[14] de Vries et al. (2014) noted that "1 transfemale died after her vaginoplasty owing to a postsurgical necrotizing fasciitis" (p. 697). A 2023 analysis of the original Dutch papers found that the researchers "did not mention the fact that this death was a consequence of puberty suppression: the patient's penis, prevented from developing normally, was too small for the regular vaginoplasty and so surgery was attempted with a portion of the intestine, which became infected" (Biggs, 2023b, p. 8). See also Negenborn et al. (2017).
[15] The reversal of the GD scale post-surgery may have entirely invalidated the study's key finding of the resolution of GD post-treatment (Abbruzzese et al., 2023). Of note, another clinical research study in this field (López de Lara et al., 2020) also switched GD and body image scales.
[16] One of the authors of the original Dutch research noted, in 2022, that those papers are "still used as main evidence for provision of early medical intervention including puberty blockers in transgender youth" (de Vries, 2022, p. 109). The Cass Review's final report described that instead of the usual, slow evolution of clinical practice over "many years before strongly positive research findings are incorporated … the reverse happened in the field of gender care for children. Based on a single Dutch study … the practice spread at pace to other countries …" (Cass, 2024a, p. 13).
[17] Carmichael et al. (2021).
[18] See Chapter 6.
[19] Ghorayshi (2024c).

Spurred on by the belief in the success of the Dutch Protocol and its central premise—reliance on PBs —the expanding availability of PMT services was met by a surge in demand: "first gradually, then suddenly."[20] By 2015, nearly every European country was reporting a dramatic increase in the number of gender-dysphoric youth seeking hormonal interventions at pediatric gender medicine (PGM) clinics—a trend whose underlying cause remains the subject of ongoing debate. The endorsement of PMT was further solidified by the publication of the 2017 Endocrine Society (ES) guidelines,[21] co-authored by psychologist Peggy Cohen-Kettenis—the pioneer of the original Dutch Protocol—who had first introduced the recommendations for PMT into the 2009 ES guidelines, and later reinforced them in the 2012 WPATH *Standards of Care 7* guidelines (SOC-7).[22]

One striking characteristic of the surge of adolescents presenting with a wish to undergo medical transition is the disproportionate number of female adolescents without prior childhood history of GD who present with high rates of comorbid mental health conditions. This pattern drew the attention of Finnish researchers, who were the first to publish on these changing demographics and to raise concerns that the Dutch Protocol might not be helping—and might even be harming—patients.[23] Finland subsequently became the first country to revise its national guidelines,[24] sharply limiting medical interventions based on the findings of an SR.[25] In the years that followed, other countries began conducting their own evaluations of the evidence and arrived at similar conclusions. A global trend has since emerged, away from use of PBs, CSH, and surgeries in youth with GD. This ongoing reversal is explored in greater detail in the following section.

4.2 The international practice reversals

Starting in 2020, PMT began to face growing scrutiny from public health authorities worldwide, resulting in substantial reversals of clinical protocols in an increasing number

[20] Abbruzzese et al. (2023, p. 12).
[21] Hembree et al. (2017).
[22] Coleman et al. (2012); Hembree et al. (2009).
[23] Kaltiala et al. (2020); Kaltiala-Heino et al. (2015).
[24] Council for Choices in Health Care Finland (2020a, 2020b, 2020c).
[25] Pasternack et al. (2019).

of countries. The most influential effort to date has been the Cass Review—a four-year independent evaluation of PGM that was published in April 2024.[26] The findings of the Cass Review led to the closure of the U.K.'s PGM clinic, the Gender Identity Development Service (GIDS), which had been given a rating of "inadequate" by the Care Quality Commission in 2021.[27] The Cass Review recommended a restructuring of the care delivery model—away from the centralized "gender clinic" model of care toward a more holistic framework centering psychosocial support, to be delivered through regional hubs. The Cass Review's findings also led the U.K. to ban the use of PBs outside clinical trials,[28] and to significantly restrict CSH.[29] While CSH are still officially an available treatment, the National Health Service (NHS) recently revealed that since the Cass Review was published, no minor has been found eligible to receive CSH according to the updated policy.[30] In the U.K., minors have never received GD-related surgery through the NHS.

Finland was the first country to curtail PMT, issuing revised national guidelines in 2020.[31] In 2022, Sweden's National Board of Health and Welfare concluded that, for most young people, the potential harms of hormonal interventions outweigh the benefits, and subsequently restricted both to research settings or exceptional cases.[32] Denmark followed Sweden's lead in 2023, restricting the use of endocrine intervention in minors,[33] and Norway's public health agency (the Norwegian Healthcare Investigation Board) advised that PBs and CSH should be considered experimental treatments.[34] Most recently, hormonal interventions have been restricted in Brazil,[35] Chile,[36] the province of Alberta in Canada,[37] and the state of Queensland in Australia.[38]

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[26] Cass (2024a).
[27] Care Quality Commission (2021).
[28] Department of Health and Social Care (2024).
[29] National Health Service England (2024c).
[30] Spencer (2025).
[31] Council for Choices in Health Care Finland (2020a, 2020b, 2020c).
[32] Socialstyrelsen (2022a, 2022b, 2022c).
[33] Hansen et al. (2023). See also Society for Evidence-Based Gender Medicine (2023b).
[34] Block (2023b).
[35] AFP (2025).
[36] Lane (2024).
[37] Government of Alberta (2024).
[38] Australian Associated Press (2025).

At the same time, several other countries are in the process of determining how best to care for youth with GD. In Australia, following Queensland's statewide pause in January 2025 on initiating PBs and CSH for new patients under 18, the Australian Government commissioned the National Health and Medical Research Council with developing new clinical practice guidelines for youth with GD. The guidelines are expected to be completed within three years, with interim recommendations on PBs available in 2026.[39] In Italy, the Italian Bioethics Committee updated its position on the use of PBs for GD,[40] and a formal guideline development process is underway.[41] France is expected to release new national guidelines in 2025, which are expected to spark considerable debate due to anticipated endorsement of PMT[42]—a position previously criticized by the French National Academy of Medicine.[43]

Germany recently published guidelines[44] that continue to generate considerable debate in German-speaking countries, including Austria and Switzerland. The controversy stems from concerns about the non-evidence-based nature of the recommendations, their a priori reliance on WPATH positions, and deep divisions in the professional community[45] regarding the appropriate approach to caring for youth with GD. Even the Netherlands—the birthplace of the Dutch Protocol—has not been immune to debate.[46] In May 2024, the Dutch Minister for Medical Care formally requested that the Health Council of the Netherlands produce an independent scientific advisory report on healthcare for minors with GD. This ongoing review will include an evaluation of the Dutch Protocol and a comparison with other countries' guidelines.[47]

[39] Australian Government National Health and Medical Research Council (2025).
[40] Italian National Bioethics Committee (2024). See also Society for Evidence-Based Gender Medicine (2024d).
[41] Curridori (2024).
[42] Sugy (2024).
[43] Society for Evidence-Based Gender Medicine (2022a).
[44] German Society for Child and Adolescent Psychiatry, Psychosomatics and Psychotherapy (DGKJP) (2025).
[45] Zepf, Buchmann, et al. (2024).
[46] Society for Evidence-Based Gender Medicine (2023c).
[47] Health Council of the Netherlands (2024).

4.2.1 The Cass Review and its reception

The Cass Review has had a profound influence on international debates. Commissioned by NHS England, the Cass Review assessed the safety, efficacy, and delivery of PGM services for children and adolescents. Conducted over four years under the leadership of Hilary Cass, pediatrician and a past president of the Royal College of Paediatrics and Child Health, the review engaged a broad range of stakeholders and relied on SRs from the National Institute for Health and Care Excellence (NICE)[48] and the University of York,[49] as well as additional research. The Cass Review identified significant limitations in the evidence base for PBs and CSH. It recommended that PBs be offered only as part of a clinical trial until further data are available, and that all potential interventions should be tested within a research context.[50] The review emphasized a multidisciplinary, developmentally-informed model of care for youth with GD that prioritizes psychological support and the development of "an explicit clinical pathway … for non-medical interventions."[51]

Recent criticisms of the Cass Review—particularly claims that it fails to meet CPG standards—reflect a misunderstanding of the Cass Review's purpose and scope. The Cass Review was not a CPG; it was an "independent review." This is a U.K.-specific process of conducting a service-level evaluation intended to inform policy, not prescriptive clinical decisions. Such processes are invoked when an area of clinical care begins to operate in ways that compromise care quality and threaten patient safety.[52]

Criticism of the Cass Review appears to stem largely from a U.S.-based group of motivated advocates for the continued legality of PMT.[53] The critiques are ridden with

[48] National Institute for Health and Care Excellence (2020a, 2020b).
[49] Hall et al. (2024); Heathcote et al. (2024); Taylor, Hall, Heathcote et al. (2024a, 2024b); Taylor, Hall, Langton et al. (2024a, 2024b); Taylor, Mitchell, Hall, Heathcote et al. (2024); Taylor, Mitchell, Hall, Langton et al. (2024).
[50] "The overarching conclusion from the evidence presented in this Review is that the puberty blocker trial, which is already in development, needs to be one part of a much broader research programme that seeks to build the evidence on all potential interventions, and to determine the most effective way of supporting these children and young people" (Cass, 2024a, p. 197). See "Recommendation 6" (Cass, 2024a, p. 35).
[51] Cass (2024a, p. 157).
[52] Cheung et al. (2025).
[53] Of these, the white paper McNamara et al. (2024), produced by the Yale Integrity Project, has been most influential.

misrepresentations of the Cass Review and contain multiple factual errors.[54] In the U.K., the Cass Review has been widely accepted as a foundational document for realigning pediatric gender medicine (PGM) with the principles of evidence-based medicine (EBM) and child safeguarding.[55] It has been welcomed by both major political parties in the U.K., and was fully accepted by the NHS for implementation, which is well underway.[56]

4.3 Rationale for international reversals

A defining feature of these global reversals has been the rejection of the "gender clinic" model, which typically promotes PMT. Internationally, this model is increasingly being supplanted by more traditional, holistic approaches to adolescent distress. Rather than referring youth with GD to specialty clinics oriented toward transition, emerging models emphasize standard mental health services, where young people receive comprehensive psychosocial and psychotherapeutic support—and, when indicated, psychiatric care.

The global reversals away from PMT can be attributed to six main factors: a significant shift in the patient population; uncertainty surrounding the natural history and prognosis of GD; increasing recognition of the risks associated with medical interventions; a more accurate understanding of the suicide risk; the collapse of the original treatment rationale; and a weak underlying evidence base. The following subsections (1-6) examine each of these factors in turn.

4.3.1 Changes in the patient population

The population of young people for whom the Dutch Protocol was originally developed differs significantly from those presenting for care today.

4.3.1.1 Epidemiological shifts

Over the past decade, the population presenting to PGM clinics has changed in two key ways: a rapid increase in numbers and a significant shift in demographic composition. Before hormonal interventions became widely available, pediatric referrals for GD were

[54] Cheung et al. (2025); McDeavitt et al. (2025).
[55] Abbasi (2024).
[56] National Health Service England (2024a).

relatively rare,[57] and the majority were prepubertal boys with early-onset GD.[58] Over the past decade, the increase in patients has been described as exponential,[59] a trend driven primarily by adolescent females who typically have no childhood history of GD.[60]

4.3.1.2 Mental illness and neurodevelopmental diagnoses

The current patient population has a high rate (relative to the general population) of comorbid mental health problems, including depression, anxiety, suicidality, self-harm, and eating disorders; as well as neurodevelopmental conditions like autism spectrum disorder (ASD).[61] Importantly, register-based research conducted in Finland, which has national databases, found that 75% of patients presenting to PGM clinics in the mid-2010s had severe mental health problems that appeared to have *predated* the emergence of GD.[62] High rates of comorbid mental illness have been documented in the U.S. and other countries.[63]

The high prevalence of ASD among youth presenting with GD has been recognized for some time.[64] At the U.K.'s clinic, ~35% of patients had comorbid moderate-to-severe autistic traits (compared to <2% of the general population).[65] Although some researchers have postulated that the social difficulties in youth with these co-occurring conditions may not result from ASD but instead from GD and may be ameliorated by targeting this distress,[66] limited research thus far has not supported this hypothesis.[67] In

[57] For example, the U.K.'s clinic had 12 total referrals in 1994 and 24 in 1996; the number of referrals between its opening in 1989 and the year 2000 was 150 (Barnes, 2023, pp. 15–16).
[58] Steensma et al. (2018).
[59] E.g. Coleman et al. (2022, p. S9, S43); Baker & Restar (2022); de Vries et al. (2021); Olson-Kennedy, Okonta et al. (2018). The figure in McDeavitt et al. (2025) shows that the rate of increase in referrals to the U.K.'s clinic (for example) is well-approximated by an exponential. A Reuters investigation did not describe exponential growth but did find that referrals to PGM clinics have sharply increased in the U.S. (Respaut & Terhune, 2022).
[60] See Kaltiala-Heino et al. (2015, 2018); Taylor, Hall, Langton et al. (2024b); Thompson et al. (2022a); Wagner et al. (2021); Wood et al. (2013); Zhang et al. (2021). One study in this field claimed that there was no disproportionate increase in female adolescents (Turban, Dolotina et al., 2022). However, this finding was based on a survey in which there was "uncertainty as to whether transgender students responded to the sex question with their sex or gender identity" (Johns et al., 2019).
[61] See Becerra-Culqui et al. (2018); Kaltiala-Heino et al. (2015), (2018); Kozlowska et al. (2021); Taylor, Hall, Langton, Fraser, et al. (2024b); Thompson et al. (2022b).
[62] Kaltiala-Heino et al. (2015).
[63] E.g., Becerra-Culqui et al. (2018); Kozlowska et al. (2021).
[64] E.g. de Vries et al. (2010); Strang et al. (2018).
[65] Barnes (2023, p. 156).
[66] E.g., Ehrensaft (2016); Edwards-Leeper & Spack (2012); J. L. Turban (2018).
[67] Russell et al. (2021).

2018, recognizing the clinical entity of co-occurring GD and ASD traits, researchers published preliminary guidelines for this specific population of children and adolescents,[68] recommending that "due to differences in social communication, insight and flexible thinking … extended diagnostic periods should be considered in cases where [ASD] is suspected or diagnosed."[69]

4.3.1.3 Nonbinary identities

The original Dutch research did not study patients with nonbinary identities; such patients were not deemed to be appropriate candidates for medical transition.[70] However, nonbinary identities now feature prominently in contemporary clinical settings and research populations. In a 2020 research project funded by the Trevor Project, for example, 63% of the 11,914 survey respondents identified as nonbinary.[71] In a study of youth who received mastectomies, 11% identified as nonbinary or "other."[72] This creates a new set of ethical challenges, as patients seek interventions that have never before been contemplated, including keeping patients in puberty-suppressed states for extended periods of time to allow them to maintain a sex-ambiguous appearance. The risks of such interventions may be considerable.[73]

4.3.1.4 Social influence

The role of social influence is a likely factor in these epidemiological changes. In 2018, physician and researcher Lisa Littman popularized the phrase "rapid onset gender dysphoria," or ROGD, in the peer-reviewed literature, describing the clinical picture of

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[68] Strang et al. (2018).

[69] See description in Russell et al. (2021, p. 2074). In contrast to the 2018 Dutch guidelines that recommended more caution for patients with co-occurring ASD, leading specialists in the United States have criticized parents who are reluctant to consent to PMT for their autistic children. They have proposed clinicians "depend on drawings" for severely autistic, nonverbal adolescents who cannot speak but are able to draw pictures (Transparency Podcast, n.d.). See also: whistleblower account of therapist Tamara Pietzke (Section 11.4.3).

[70] de Vries et al. (2006, p. 88): "Adolescents whose wish for sex reassignment seems to originate from factors other than a genuine and complete cross-gender identity are served best by psychological interventions."

[71] A. E. Green et al. (2022).

[72] Ascha et al. (2022).

[73] In 2020, researchers published a case report in which clinicians considered the possibility of keeping an "agender" patient with low bone density on PBs for at least seven years in order to provide affirmation for this identity (Pang, Notini, et al., 2020). Contemporary WPATH guidelines have eliminated barriers to hormonal interventions and surgeries for minors with nonbinary and other identities.

"adolescent-onset or late-onset gender dysphoria where the development of gender dysphoria is observed to begin suddenly during or after puberty in an adolescent or young adult who would not have met criteria for gender dysphoria in childhood."[74] This phenomenon has also been described in research from the U.K.,[75] the Netherlands,[76] Finland,[77] and Canada.[78] Other terms have been used—e.g. "adolescent onset gender dysphoria," "postpuberty adolescent-onset transgender histories"[79]—for pubertal-onset gender dysphoria disproportionately affecting female adolescents.

Research into experiences of detransition and regret (detransition refers to stopping or reversing transition after having received medical and/or surgical interventions; it can overlap with but is not synonymous with regret) have suggested social influence or pressure have played a role in the transient transgender identifications of some patients.[80] Concerns about the possible role of social influence underlying epidemiological shifts in presentations have been articulated elsewhere in the literature,[81] including by some proponents of PMT.[82] WPATH's guidelines note that "susceptibility to social influence impacting gender may be an important differential to consider" for some adolescents; the guidelines also acknowledge "situations in which a young person experiences very recent or sudden self-awareness of gender diversity and a corresponding gender treatment request, or when there is concern for possible excessive peer and social media influence on a young person's current self-gender concept."[83]

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[74] Littman (2018, p. 2). This research surveyed 256 parents of children with adolescent-onset GD, finding that in roughly half the cases, the rapid onset of GD appeared to have coincided with the onset of similar distress within the children's friend groups, and with an increase in social media/Internet use. "Rapid onset gender dysphoria" appeared in scholarly work a year earlier, in a poster abstract by Littman in the *Journal of Adolescent Health* and (following Littman's research) also in Marchiano (2017).
[75] de Graaf et al. (2018); Hutchinson et al. (2020).
[76] de Vries (2020).
[77] Kaltiala-Heino et al. (2018); Kaltiala-Heino & Lindberg (2019).
[78] Zucker (2019).
[79] Kaltiala-Heino & Lindberg (2019); de Vries (2020).
[80] Littman (2021); Littman et al. (2024).
[81] Bailey & Diaz (2023); Wood et al. (2013).
[82] Edwards-Leeper & Anderson (2021); Shrier (2021b).
[83] Coleman et al. (2022, p. S45, S58).

4.3.2 Unclear natural history and prognostic uncertainty

Prior to the widespread availability of hormonal interventions, most cases of childhood GD resolved naturally by the end of puberty, with the majority of patients having a homosexual sexual orientation in adulthood.[84] The Dutch Protocol was developed on the assumption that only GD that persisted into adolescence would likely be permanent.[85] As referrals shifted toward patients with adolescent-onset distress, this assumption of permanence was generalized to all adolescent GD regardless of whether it *intensified* in adolescence or *appeared for the first time* in adolescence. The belief that any GD in adolescence is likely permanent and warrants medical treatment remains "central to the rationale for medical intervention" in adolescents.[86]

4.3.2.1 New evidence about the natural history of gender dysphoria

Recent close examination of the literature has called into question the assumptions regarding the permanence of adolescent GD.[87] Although the natural history of GD—i.e., its course absent medical interventions—is currently impossible to measure given the wide availability of interventions, new evidence tentatively suggests that GD has a low diagnostic stability. For example, a German longitudinal analysis of an insurance claims database showed that over 70% of adolescent females aged 15-19 no longer had the

[84] The largest such study was Singh et al. (2021), which included a comprehensive overview of prior research on persistence of childhood GD (pp. 2–4). Some have argued that changes to diagnostic criteria—from the older "Gender Identity Disorder" (for which dysphoria, described as "discomfort," was a criterion) to the contemporary "Gender Dysphoria" diagnosis—render findings of older studies irrelevant (Temple Newhook et al., 2018). These arguments have been effectively countered (Zucker, 2018). (For the diagnostic criteria, see Appendix 2.) Low persistence rate of childhood GD has been recognized in the literature: e.g. "gender variant children, even those who meet the criteria for GID prior to puberty, for the most part are not gender dysphoric at a later age" (de Vries & Cohen-Kettenis, 2012, p. 306); also see Ristori & Steensma (2016, p. 6); Cohen-Kettenis & Gooren (1999).

[85] E.g. Cohen-Kettenis & Pfäfflin (2003); de Vries et al. (2006); de Vries & Cohen-Kettenis (2012); de Vries et al. (2014).

[86] Rosenthal (2021a, p. 585): "Longitudinal studies have indicated that the emergence or worsening of gender dysphoria with pubertal onset is associated with a very high likelihood of being a transgender adult. This observation is central to the rationale for medical intervention in eligible transgender adolescents."

[87] Byrne (2024a).

diagnosis five years later.[88] Another recent study from the Netherlands found that "gender non-contentedness" continues to decline steadily into the early twenties.[89]

4.3.2.2 Concerns about identity development

There is considerable concern that "pubertal suppression may alter the course of gender identity development, essentially 'locking in' a gender identity that may have reconciled with biological sex during the natural course of puberty."[90] This concern is not new. Some early critics of the Dutch approach pointed out that initiation of hormonal interventions in early to mid-puberty "might affect the further development of gender identity, or … even iatrogenically induce persistence [of GD]."[91] In 2024, the European Academy of Pediatrics cautioned that puberty suppression may undermine long-term autonomy by creating a path dependency that leads to cross-sex hormones and surgery.[92] Several studies have suggested continuation rates from PBs to CSH exceed 90%.[93] The perception of PBs has shifted—from being seen as a reversible "pause button" to more like a "gas pedal" that accelerates medical transition.

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[88] Bachmann et al. (2024) was an insurance claims study looking at the International Classification of Diseases, tenth version (ICD-10) code F64 ("Gender Identity Disorder"), which was the billing code used in Germany over the course of the study period (Society for Evidence-Based Gender Medicine, 2024c). A recent *BMJ* analysis of claims data and medical records concluded that for some groups, including young people, "GD is not a permanent diagnosis" (Sun et al., 2023).

[89] Rawee et al. (2024, p. 1813). "Gender non-contentedness" was defined based on endorsement of item 110 in the Youth Self Report/Adult Self Report (YSR/ASR), "Wishes to be the opposite sex." Although item 110 is not synonymous with the diagnosis of GD, it is frequently used as a rough proxy for the clinical diagnosis as it captures the primary criterion of the desire to be the opposite sex. See Zucker (2005).

[90] Jorgensen et al. (2022, p. 1005). See also the Cass Review's final report: "Blocking [puberty] means that young people have to understand their identity and sexuality based only on their discomfort about puberty and a sense of their gender identity developed at an early stage of the pubertal process. Therefore, there is no way of knowing whether the normal trajectory of the sexual and gender identity may be permanently altered" (Cass, 2024a, p. 178).

[91] Korte et al. (2008, p. 839).

[92] Brierley et al. (2024).

[93] E.g., Brik et al. (2020); Carmichael et al. (2021); Karakılıç Özturan et al. (2023a); van der Loos, Klink et al. (2023); Wiepjes et al. (2018). Some have claimed that "the most likely explanation for why most youth who receive early, supportive interventions [i.e., puberty blockers] continue onto gender-affirming hormone therapy [is] that they are indeed transgender. It is not ... puberty-pausing medications that drive a persistent transgender identity" (McNamara et al., 2024, pp. 20–21). However, the very research studies that comprise the evidence base in this area recognized the possibility that the intervention may induce persistence; e.g., "Due to the observational character of the study, it is not possible to say if [puberty blocker] treatment itself influenced the outcome" (Brik et al., 2020, p. 2611); "[there is] the potential that treatment could influence the continuation of their GD" (Carmichael et al., 2021).

Social transition in childhood may have similar effects, with some low-quality studies suggesting the majority of children who socially transition[94] before puberty progress to medical interventions.[95] These patients "are likely [to] seek blockers or hormones."[96] Prepubertal transition was not recommended in the original Dutch approach (the researchers actually recommended *against* the practice),[97] but was originally championed by American clinicians.[98]

Prepubertal social transition is now recommended for certain patients, including in the Netherlands.[99] However, there are no reliable methods to distinguish which patients will experience long-term GD.[100] There is growing concern about administering irreversible treatments that may lead to lifelong medical dependency for a condition that, in many cases, may naturally resolve.

4.3.3 Concerns about treatment-associated risks and harms

Awareness of the risks and potential harms of PMT is growing.[101] Concern has been raised about the unknown or potentially harmful effects of suppressing normally timed puberty on adolescent physical and mental health, especially with regard to bone mineralization and brain development.[102] Hormonal interventions can lead to infertility and impaired sexual function, and in some cases, if the patient proceeds to genital

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[94] In this context, social transition refers to "a 'complete' binary social transition ... including changing their pronouns to the binary gender pronouns that differed from those used at their births" (Olson et al., 2022, p. 2), not to changes in hairstyle, clothing, etc.
[95] Olson et al. (2022, 2024). See also Society for Evidence-Based Gender Medicine (2022b).
[96] Olson et al. (2022, p. 4).
[97] E.g., "In a qualitative follow-up study, several youths indicated how difficult it was for them to realize that they no longer wanted to live in the role of the other gender and to make this clear to the people around them… Another reason we recommend against early transitions is that some children who have done so (sometimes as preschoolers) barely realize that they are of the other natal sex. They develop a sense of reality so different from their physical reality that acceptance of the multiple and protracted treatments they will later need is made unnecessarily difficult. Parents, too, who go along with this, often do not realize that they contribute to their child's lack of awareness of these consequences" (de Vries and Cohen-Kettenis, 2012, p. 308).
[98] E.g. Ehrensaft (2016); Olson et al. (2016).
[99] Bazelon (2022a).
[100] Cass (2024a, pp. 22, 134, emphasis added). "… clinicians have told us *they are unable to determine with any certainty* which children and young people will go on to have an enduring trans identity … Many clinicians, both nationally and internationally, have [acknowledged] that there is *no reliable way to accurately predict* which young people might benefit from a medical transition and which might benefit from alterative pathway(s) or interventions(s)."
[101] See Chapter 7 for detailed discussion.
[102] E.g., Baxendale (2024); Biggs (2021).

procedures, riskier operations.[103] Surgical procedures themselves carry the risk of complications.

The emergence of detransitioners has brought renewed attention to a risk acknowledged in the original Dutch Protocol, which is that initiating medical transition while a young person's identity is still developing carries the risk of "false positives"—patients who undergo irreversible hormonal and/or surgical interventions but ultimately do not continue to identify as transgender.[104] In the past five years, a growing body of research and peer-reviewed literature has examined the phenomena of detransition and regret.[105] Personal accounts from detransitioned patients who report having been harmed by PMT have played a significant role in drawing public and regulatory attention to these issues.[106]

4.3.4 More appropriate understanding of suicide

Proponents of PMT often describe it as lifesaving.[107] Some physicians recommending PMT have urged anxious parents to consent to irreversible interventions for their distressed children, warning that not doing so may increase the risk of suicide.[108] Such claims are not supported by the evidence and have been criticized as unethical.[109]

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[103] See Lee et al. (2023), for example.
[104] Delemarre-van de Waal & Cohen-Kettenis (2006, p. S132). "It is conceivable that lowering the age limit increases the incidence of 'false positives.'"
[105] E.g. Entwistle (2020); Littman (2021); MacKinnon, Expósito-Campos et al. (2023); Roberts et al. (2022).
[106] According to a Reuters investigation, a patient told her gender clinic at age 16 that she was "sure of my identity … I thought nothing would change my mind." After starting CSH she experienced worsening mental health and had several suicide attempts and psychiatric hospitalizations. She detransitioned at age 20 and identifies as a lesbian: "I do wish my doctors had said to me, 'It's OK to feel disconnected from your body. It's OK to like girls. It's OK to be gender non-conforming'" (Respaut et al., 2022). For an overview of the role of detransitioner Keira Bell in drawing regulatory attention to pediatric gender medicine in the U.K., see Cass (2024a, pp. 78–80).
[107] E.g., ACLU (2021); Boerner (2022, 3/31/2025 update); Georges et al. (2024); Lee & Rosenthal (2023); Sandhu et al. (2025); Szilagyi (2022b); The Lancet Child & Adolescent Health (2021). See also Section 1.2.
[108] In 2011, Johanna Olson-Kennedy, pediatrician and leader in the field of pediatric gender medicine, told ABC News that "We often ask parents, would you rather have a dead son than a live daughter?" (ABC News, 2011). See also Singal (2018).
[109] E.g., Clayton (2023); Levine et al. (2022a).

Adolescents and adults with GD do exhibit higher rates of suicidality—including suicidal thoughts, self-harm, and suicide attempts—compared to the general public.[110] However, completed suicide among adolescents with GD remains rare.[111] Moreover, there is no evidence that elevated suicidality can be attributed solely to GD, as it frequently co-occurs with other mental health conditions. A 2020 report by the Swedish National Board of Health and Welfare (Socialstyrelsen) concluded that "people with gender dysphoria who commit suicide have a very high rate of co-occurring serious psychiatric diagnoses, which in themselves sharply increase risks of suicide … it is not possible to ascertain to what extent GD alone contributes to suicide."[112]

Table 4.1 reports suicide rates from four PGM clinics and notes whether the suicides were in patients who had received hormonal interventions.

[110] E.g., Biggs (2022); Erlangsen et al. (2023); Heino et al. (2023); Marconi et al. (2023); Van Cauwenberg et al. (2021); Wiepjes et al. (2020).
[111] Biggs (2022); Ruuska et al. (2024); Society for Evidence-Based Gender Medicine (2023a).
[112] Socialstyrelsen (2020); see also Ruuska et al. (2024). Additionally, de Graaf et al. (2022) found that adolescents with GD or transgender identification had similar self-reported suicidality measures to comparator adolescents without GD who were receiving specialized mental healthcare for other psychiatric diagnoses.

Table 4.1: Suicide mortality in youth referred to pediatric gender medicine clinics (with estimated per 1,000 patient-years rates)

Study; Country	Age range	Years	Referred youths	Suicides	%	Per 1K patient-years	Were patients who died by suicide taking PBs and/or CSH?
Van Cauwenberg et al. (2021); Belgium	12–18	2007–2016	148	5	3.38	11.26	All suicides among patients taking CSH
Chen et al. (2023); U.S.	12–20	2016–2021	315	2	0.63	3.17	All suicides among patients taking CSH
Ruuska et al. (2024); Finland	<23	1996–2019	2,083	7	0.34	0.51	Unknown (38% of cohort treated with PBs and/or CSH)
Biggs (2022); U.K.	<18	2010–2020	15,032	4	0.03	0.13	Unknown (59% of cohort treated with PBs and/or CSH)

Table adapted from Society for Evidence-Based Gender Medicine (2024a).

Further, the evidence for whether PMT reduces *suicidality*-related outcomes in adolescents—such as self-reported frequency of suicidal thoughts, or healthcare utilization for self-harm or suicide attempts—is inconsistent.[113] When the focus turns to preventing *suicide mortality*, there is no evidence that hormonal interventions are effective. A large, register-based study from Finland found that overall suicide mortality in patients with GD was rare and that when mental health comorbidities were controlled for, the rate did not differ from that of the general population. The study authors concluded that hormonal interventions did not appear to have impacted suicide risk.[114]

[113] Small to medium-size studies have reported improvement over time in self-report scores related to suicidality (Achille et al., 2020; Allen et al., 2019) or decrease in healthcare utilization for suicidal or self-harm behavior (Kaltiala et al., 2020; Khatchadourian et al., 2014); other larger studies found the percent of patients with suicidal thoughts/behaviors increased after initiating PBs/CSH (Kuper et al., 2020) and increases in healthcare utilization related to suicidality (Hisle-Gorman et al., 2021). Kuper et al.'s before-after comparison is compromised by the unequal time periods over which suicidality was measured.
[114] Ruuska et al. (2024).

An SR of suicide prevention for youth with GD rated the evidence as low quality,[115] and WPATH's own SR of mental health outcomes, which focused on adult populations, acknowledged that "It was impossible to draw conclusions about the effects of hormone therapy on death by suicide."[116] As summarized in the Cass Review's final report, "it has been suggested that hormone treatment reduces the elevated risk of death by suicide in this population, but the evidence found [does] not support this conclusion."[117] Consequently, claims that PMT is "lifesaving" appear to be unsupported by the evidence.

These findings also have been confirmed by the Appleby Report, commissioned by the U.K. government, which reviewed suicides among young people with GD. The report strongly criticized the way suicide and GD have been discussed on social media, characterizing it as insensitive, distressing, dangerous, and in violation of established guidance on the safe reporting of suicide. Appleby emphasized that many of the public claims made about suicide do not meet basic standards for statistical evidence. The report also urged a shift away from viewing PBs as the primary marker of supportive care, warning that such a narrow focus oversimplifies complex clinical needs.[118]

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[115] Christensen et al. (2025). Similar findings were also reported in a recent narrative review focused on adults (Jackson, 2023). With respect to surgeries, evidence is limited. A recent systematic review of mastectomies in young females found very low certainty evidence with respect to effect on death by suicide (Miroshnychenko et al., 2024).

[116] Baker et al. (2021, p. 12). Another more recent systematic review also found very low certainty evidence for the effect of CSH on death by suicide (Miroshnychenko, Ibrahim et al., 2025).

[117] Cass (2024a, p. 33). An example of commonly cited evidence—e.g., American Psychological Association (2024b); The Lancet Child & Adolescent Health (2021), via reference to Rew et al., (2021); Turban (2020)—in support of this suggestion is Turban, King et al. (2020), a cross-sectional analysis of Internet-based survey data that found that respondents who had accessed PBs had lower lifetime suicidal ideation when compared to those who had wanted PBs but not accessed them. The online survey, the 2015 U.S. Transgender Survey (USTS) (James et al., 2015), had multiple methodological weaknesses. For example, it was a convenience sample, likely not representative of transgender adults in the U.S, and respondents may have confused PBs for CSH (Biggs, 2020; Clayton et al., 2021). Additionally, the survey relied on adult respondents' retrospective recall of childhood and adolescence, and such memories "are subject to confabulation, modification, bias, and simply forgetting;" for example, "31% of respondents recalled realizing they were transgender by age 5, including some who recalled they were transgender at the age of 1 and 2—long before autobiographical memories begin" (Kulatunga Moruzi & Lawler, 2024, pp. 11, 4). The Turban et al. study has also been criticized for its inaccurate assumption that PBs for GD were available in the U.S. starting in 1998, and it has been pointed out that on multivariate analysis, there were no statistically significant between-group differences on five other measures of suicidality, including history of suicide attempts (Biggs, 2020; Clayton et al., 2021).

[118] Appleby (2024).

4.3.5 Collapse of clinical rationale

An original rationale for prescribing PBs, as outlined in the Dutch Protocol, was to provide adolescents with "time to think" by pausing puberty, thereby allowing for the exploration of identity without the added distress of physical development.[119] However, as noted earlier, data suggest that the vast majority of adolescents who start PBs go on to take CSH.[120] This means that PBs may not function as a neutral pause, but rather the first step on the path to medical transition. This has prompted many experts to abandon the "time to think" rationale, a reversal reflected in more recent WPATH guidelines and professional statements.[121] PBs and CSH are now understood to be a continuous treatment pathway.[122]

Given the risk profile of PBs as outlined in Chapter 7, and the possibility that their use may lead to lifelong medical dependency carrying additional long-term risks, their role in the current treatment paradigm is unclear. In male patients, testosterone suppression can be achieved with anti-androgens alongside estrogen for feminization. In female patients, testosterone alone effectively suppresses estrogen, while also inducing masculinization. Therefore, if PBs are not being used to provide time to think, their rationale in this context remains uncertain.[123]

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[119] Delemarre-van de Waal & Cohen-Kettenis (2006).

[120] See Section 4.3.2.2.

[121] Although WPATH's 2012 guidelines stated (consistent with the original Dutch research) that PBs would "[give] adolescents more time to explore their gender nonconformity and other developmental issues," (see Coleman et al., 2012, p. 177), this clinical rationale is absent in the latest version of the organization's guidelines, Coleman et al. (2022). A recent article by leaders in the field about eligibility and screening evaluations for patients interested in PBs made no mention of the "time to think" rationale (Turban et al., 2025). See also amicus brief acknowledging that PBs and CSH should not be considered separate treatment pathways because they constitute a "care continuum" and "the vast majority of adolescents with gender dysphoria who receive puberty blockers progress to cross-sex hormone therapy" (U.S. v. Skrmetti (No. 23-477), Expert Researchers and Physicians, Amicus curiae brief, 2024).

[122] There are exceptions to this understanding; some research papers and organizations still claim PBs provide time to think (e.g. Fisher et al., 2024; U.S. v. Skrmetti (No. 23-477), American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations, Amicus curiae brief, 2024, p. 13).

[123] The Cass Review found that although there may be "a very narrow indication for the use of puberty blockers in birth-registered males as the start of a medical transition pathway in order to stop irreversible pubertal changes," there were no other reasonable, proven rationales for use of PBs, and, notably, no indication for use of PBs in females (Cass, 2024a, p. 180). Experts have questioned "the rationale for depriving an adolescent of sex hormones for years during puberty and risking the effects on bones and brains" (Ryan, 2024b).

4.3.6 Lack of reliable evidence of benefit

The original intent behind the use of hormonal interventions in pediatrics was to improve mental health outcomes[124] by preventing sexual development and causing the development of physical characteristics typical of the other sex. This approach was based on the hypothesis that avoiding "an unfavorable physical appearance"[125] would "improve the ability to 'pass' as the desired gender."[126] While these interventions do alter physical appearance, SRs have not found credible evidence that they lead to meaningful improvement in mental health.[127] Multiple SRs have concluded that the evidence supporting the benefits of pediatric transition interventions—from PBs to CSH and surgery—is of "very low certainty." (See Chapter 5.) This means that findings from studies reporting mental health improvements[128] are not considered reliable. In contrast, all medical interventions carry the potential for harm.

Ultimately, medical interventions should be used when the balance of benefits clearly outweighs the risks. Every public health authority that has conducted a systematic

[124] Researchers were originally motivated to initiate hormonal interventions in children and adolescents because they were concerned about poor mental health in adult patients and hoped to mitigate this by preventing development of sex characteristics that were distressing for these adults (discussed in more detail in Chapter 3).
[125] Delemarre-van de Waal & Cohen-Kettenis (2006).
[126] Costa et al. (2015).
[127] The other original clinical rationale was decreasing need for future surgeries. One study has reported that female patients who started PBs early in puberty were less likely to receive mastectomies than patients who started PBs later, suggesting relative lack of breast tissue precluded need for mastectomy. However, this study also found greatly increased odds of intestinal vaginoplasty in male patients who received PBs in early puberty (van de Grift et al., 2020). One adolescent mastectomy study suggested chest-related dysphoria increased after testosterone use (Olson-Kennedy, Warus, et al., 2018). Theoretically, increasing chest dysphoria could lead to pursual of mastectomy. In the adult literature there have been reports of females undergoing hysterectomy due to pelvic pain caused by reproductive organ atrophy (e.g., Zwickl et al., 2023).
[128] Across the studies looking at mental health outcomes, statistically significant improvements have been inconsistently reported. Of longitudinal mental health outcome studies in this field, some reported improvements in one or more mental health outcomes (Achille et al., 2020; Allen et al., 2019; Chelliah et al., 2024; Chen et al., 2023; de Vries et al., 2011, de Vries et al., 2014; Fisher et al., 2024; Kaltiala et al., 2020; Kuper et al., 2020; Lavender et al., 2023; López de Lara et al., 2020; Olson-Kennedy et al., 2025); the largest study found worsening in mental health outcomes (Hisle-Gorman et al., 2021), while others reported no change (Becker-Hebly et al., 2020; Cantu et al.. 2020; Carmichael et al., 2021; Eisenberg et al., 2024; Khatchadourian et al., 2014; Russell et al., 2021; Tordoff et al., 2022). One study reported similar improvement in a group treated with PBs and a group treated with psychotherapy only (Costa et al., 2015).

review of the evidence has concluded that the benefit/risk profile of PMT is either unknown or unfavorable.

PART 2

EVIDENCE REVIEW

Chapter 5 Overview of Systematic Reviews

This chapter reviews the best available information regarding the risks, benefits, and uncertainties of interventions commonly used to address gender dysphoria (GD) in youth. It summarizes the findings of the overview of systematic reviews (SRs) (also known as an "umbrella review") conducted for this Review. Section 5.1 defines some terminology and describes the methodology used to produce the overview of SRs. Sections 5.2-5.6 summarize the overview's findings for the following interventions: social transition; puberty blockers (PBs); cross-sex hormones (CSH); surgery; and psychotherapy. The chapter concludes with a discussion section (5.7).

Chapter 6 explains the limitations of SRs and the need—especially in the context of pediatric gender medicine (PGM)—to consider other types of scientific evidence. Chapter 7 is an overview of those other types of evidence, including evidence from basic science, from known mechanisms of drug action, and from endocrinological disorders that approximate the effects of medical transition. This broader base of evidence allows for a more comprehensive assessment of potential harms. Chapter 8 briefly summarizes the implications of these findings for decision-makers.

5.1 Methodology

A fundamental principle of evidence-based medicine (EBM) is that optimal decision-making "requires awareness of the best available evidence, which ideally will come from systematic summaries of that evidence."[1] The cornerstone of EBM is the *systematic review*,

> [which] attempts to collate all empirical evidence that meet prespecified eligibility criteria in order to answer a specific research question. It uses explicit, systematic methods that are selected with a view to minimizing bias, thus providing more reliable findings from which conclusions can be drawn and decisions made.[2]

[1] Guyatt et al. (2015, p. 10).
[2] Higgins et al. (2019, p. xxiii).

The conclusions of any individual study will be limited by study design and other factors. Collating, synthesizing, and assessing all relevant studies on the topic of interest, using systematic and reproducible methods to minimize biases and mistakes, makes more reliable conclusions possible.

SRs sit atop of the "hierarchy of evidence."[3] However, not all literature reviews are SRs, even when titled as such, so it is important to evaluate the process used in the production and reporting of any evidence review that claims to be an SR. For example, the "Cornell Review" has been extensively cited in the field of PGM to support a claim of low regret, but that review's findings are undermined by poor methodology.[4] Similarly, a recent review commissioned by lawmakers in Utah has been cited as showing the safety of PBs and CSH, but this review lacks a methodologically valid evidence appraisal, among other problems.[5]

An overview of SRs essentially applies the methodology of SRs to SRs themselves, making the SRs the unit of analysis, rather than individual primary studies. In the present case, an overview of SRs was prepared because the field is already saturated with SRs, many of which evaluate the same studies. By assessing the quality of these SRs, an overview allows for a clearer understanding of the overall strength, consistency, and gaps in the evidence base.

The methodology of the overview followed the recommendations for overviews of SRs in the *Cochrane Handbook for Systematic Reviews of Interventions*.[6,7] Medline, Embase, and the psychological database PsycINFO were searched for SRs on the effects of social transition, PBs, CSH, surgeries, and psychotherapy for youth with GD

[3] See Appendix 3.
[4] Cornell University & What We Know Project (2017). The relevance of the Cornell Review to PMT is anyway slight, because the target population was mature adults, and thus is not clearly applicable to children and adolescents with GD (see Section 4.3.1.1). The Cornell Review was not included in the present overview for this reason. The review claimed that "regrets are most likely to result from a lack of social support after transition or poor surgical outcomes using older techniques." But evidence from included studies was not properly synthesized, nor was evidence quality assessed. The findings should therefore be interpreted with caution.
[5] University of Utah College of Pharmacy, Drug Regimen Review Center (2025); cited by Dowshen et al. (2025). See Section 5.7.3 and Appendix 4, Section 2.4.
[6] Higgins et al. (2019).
[7] See Appendix 4 for the detailed methodology and results of this overview.

up to age 26 years.[8] A complementary literature search was also conducted for "grey literature"[9] and reference lists of eligible SRs. Two reviewers independently screened titles and abstracts, and then full texts, to determine study eligibility. Reviewers resolved disagreement by discussion. The Risk of Bias Assessment Tool for Systematic Reviews (ROBIS) was used to assess the included SRs.[10] Data extraction and risk of bias assessment were completed by one reviewer and checked by a second. ROBIS assesses the quality of the SR in four domains: (1) study eligibility criteria; (2) identification and selection of studies; (3) data collection and study appraisal; and (4) synthesis of findings. Additionally, ROBIS assesses the overall risk of bias in an SR's process. SRs with concerns identified in the four domains can still be assessed at low risk of bias if the SRs have properly addressed those concerns in the evidence interpretation.

The following five sections of this chapter summarize the outcome data across SRs published in English and classified at low risk of bias. The evidence synthesis was organized by the outcomes of interest for each treatment strategy. These outcomes included GD, mental health and well-being, physiologic effects (e.g., suppression of sex hormones for PBs), need for or progression to further treatment, safety outcomes including side effects and adverse outcomes, and regret. For each outcome, this overview summarized the effect estimates and the quality of evidence (the confidence in the effect estimates), following the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology.

In GRADE, quality of evidence is equivalent to certainty of evidence.[11] Quality of evidence can be downgraded for various reasons: risk of bias (study limitations), inconsistency (unexplained variation in results), indirectness (evidence not directly

[8] SRs in this area have usually involved patients under 18 or under 26. To encompass the inclusion of those aged 18, the Review made the decision to search for SRs for patient populations below the age of 26. This balances the comprehensiveness and the directness (applicability) of evidence review. Though there is concern regarding the directness of evidence, the evidence for <18 and patients who are older than 18 years did not identify any significant differences in outcomes.
[9] "Gray literature" refers to research and information produced outside of traditional academic publishing channels and therefore may not be formally peer-reviewed or indexed in major databases.
[10] Whiting et al. (2016).
[11] "The quality of evidence is very low" is equivalent to "the certainty of evidence is very low" (Balshem et al., 2011; Guyatt et al., 2008).

applicable), imprecision (wide confidence intervals or small samples), and publication bias (selective reporting).[12] Conversely, quality may be upgraded if there is a large effect size, a clear dose-response relationship, or if confounding factors would likely reduce the observed effect but the effect was nonetheless observed.[13]

Evidence is then classified into four categories by level of quality: high, moderate, low, or very low.[14] High quality evidence means that "we are very confident that the true effect lies close to that of the estimate of the effect." Very low quality evidence indicates that "we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect." This overview summarizes the GRADE ratings from the original SRs for the respective outcome wherever it is available. Nevertheless, two modifications were made:

1. Where a formal GRADE appraisal had not been performed by the SR, but expressions such as "we are very uncertain" or "no conclusions could be drawn" were used in the SR's conclusions, these were considered equivalent to a "very low quality" GRADE assessment.[15]

2. Where SRs disagreed on GRADE assessment for the same outcome, this overview resolved the disagreement with *de novo* assessment following the GRADE methodology and reported the rationale.

After screening, 17 SRs met the inclusion criteria. These examined the effects of social transition (n = 2),[16] PBs (n = 9),[17] CSH (n = 8),[18] surgery (n = 3),[19] and psychotherapy (n

[12] Balshem et al. (2011); Guyatt et al. (2008); Guyatt, Oxman, Kunz, Brozek et al. (2011); Guyatt, Oxman, Kunz, Woodcock, Brozek, Helfand, Alonso-Coello, Falck-Ytter et al. (2011); Guyatt, Oxman, Kunz, Woodcock, Brozek, Helfand, Alonso-Coello, Glasziou et al. (2011); Guyatt, Oxman, Montori, et al. (2011); Guyatt, Oxman, Vist et al. (2011).
[13] Guyatt, Oxman, Sultan et al. (2011).
[14] Balshem et al. (2011). See also Appendix 3.
[15] Balshem et al. (2011); Santesso et al. (2020).
[16] Dopp et al. (2024); Hall et al. (2024).
[17] Chew et al. (2018); Dopp et al. (2024); Ludvigsson et al. (2023); Miroshnychenko, Roldan et al. (2025); Ramos et al. (2021); Rew et al. (2021); Taylor, Mitchell, Hall, Heathcote et al. (2024); Thompson et al. (2023); Zepf, König et al. (2024).
[18] Chew et al. (2018); Dopp et al. (2024); Karalexi et al. (2020); Ludvigsson et al. (2023); Miroshnychenko, Ibrahim et al. (2025); Taylor, Mitchell, Hall, Langton et al. (2024); Thompson et al. (2023); Zepf, König et al. (2024).
[19] Dopp et al. (2024); Miroshnychenko et al. (2024); Thompson et al. (2023).

= 5)[20] among children or adolescents with GD. Of the 17 included SRs, 10 were rated as having a low risk of bias overall.[21] SRs rated as a "low risk of bias" nevertheless may still have limitations in one or more domains. Seven SRs were rated as having a high risk of bias overall,[22] often due to limited or poorly defined research questions and eligibility criteria, lack assessment for risk of bias, and inadequate synthesis of findings. The variation in methodological rigor highlights the need for cautious interpretation of findings, especially from reviews rated at high risk of bias.

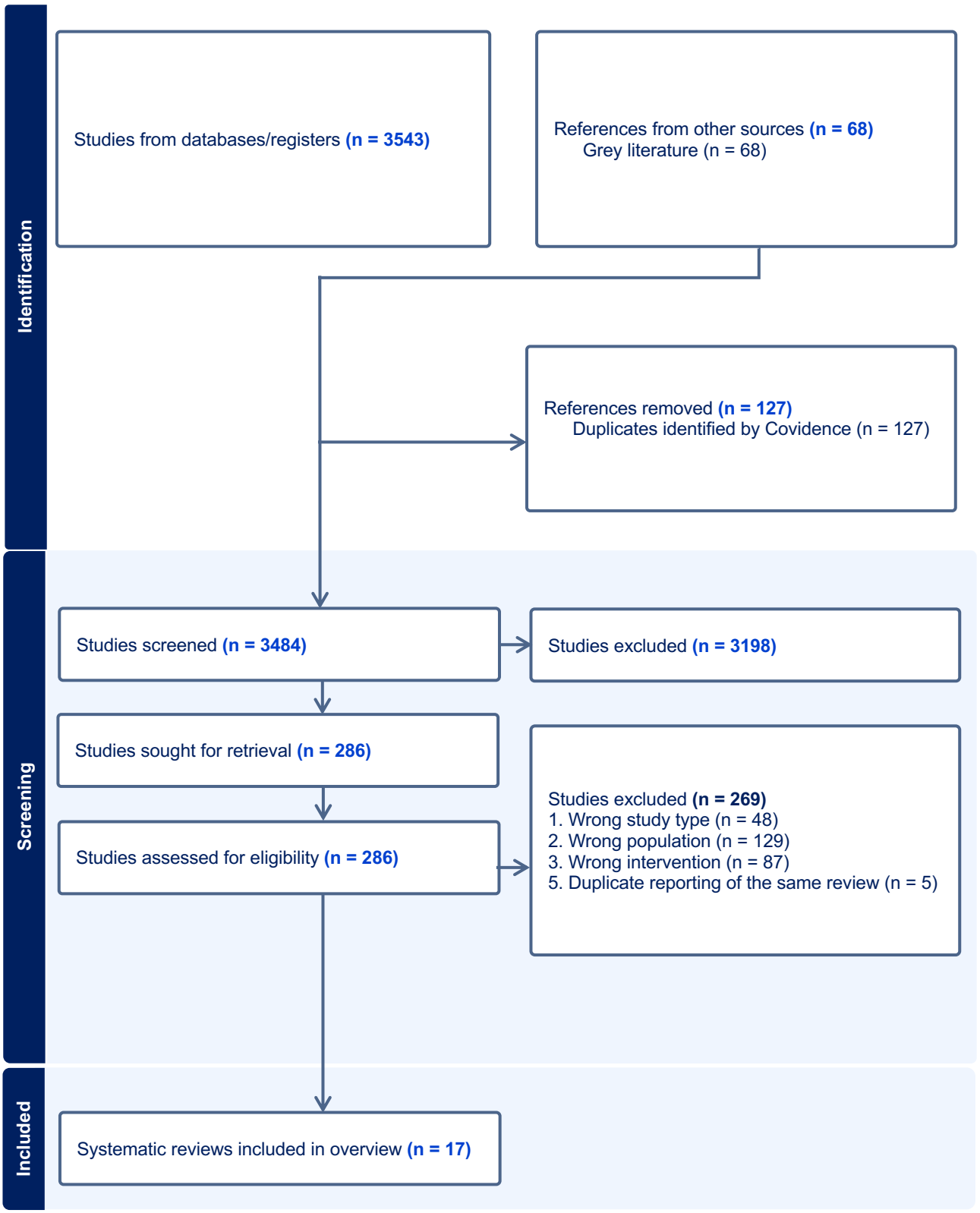
Of note, this overview excluded two SRs performed by the National Institute for Health and Care Excellence (NICE) in October 2020 to inform the Cass Review.[23] These were excluded because several subsequent SRs commissioned from the University of York to inform the Cass Review were published. The latter SRs are more comprehensive and updated the findings of the two NICE SRs.

This overview also excluded the 2021 SR by Baker et al.,[24] because participants in most of the included studies for that SR were mature adults. Notably, the Baker et al. review was cited to support Statement 2.1 in the World Professional Association for Transgender Health's *Standards of Care for the Health of Transgender and Gender Diverse People*, Version 8 (WPATH SOC-8).[25] That statement—"We recommend health care systems should provide medically necessary gender-affirming health care for transgender and gender diverse people"—was then cited in support of the recommendations in SOC-8's Adolescent chapter. Because of the way this SR has been relied on in the field of PMT, Baker et al. was subjected to a separate ROBIS analysis which found it to be at high risk of bias due to limitations in ROBIS domains of "data collection and study appraisal" and "synthesis and findings." The ROBIS assessment of

[20] Dopp et al. (2024); Expósito-Campos et al. (2023); Heathcote et al. (2024); Malpas et al. (2022); Thompson et al. (2023).
[21] Dopp et al. (2024); Hall et al. (2024); Heathcote et al. (2024); Ludvigsson et al. (2023); Miroshnychenko et al. (2024); Miroshnychenko, Ibrahim et al. (2025); Miroshnychenko, Roldan et al. (2025); Taylor, Mitchell, Hall, Heathcote et al. (2024); Taylor, Mitchell, Hall, Langton et al. (2024); Zepf, König et al. (2024). SRs conducted by the same research group generally followed the same methodology approach.
[22] Chew et al. (2018); Expósito-Campos et al. (2023); Karalexi et al. (2020); Malpas et al. (2022); Ramos et al. (2021); Rew et al. (2021); Thompson et al. (2023).
[23] National Institute for Health and Care Excellence (2020b, 2020a).
[24] Baker et al. (2021).
[25] Coleman et al. (2022).

Baker et al. is included in Section 2.3 of Appendix 4, while Appendix 3 provides an introduction to SRs and EBM. Figure 5.1 below provides a flow diagram for the searching, screening, and inclusion process.

Figure 5.1 Searching, screening, and inclusion process



5.2 Outcomes of social transition

Social transition involves changing one or more aspects of one's presentation or expression, such as name, appearance, or behavior, with the goal of being perceived and treated as a member of the other sex, or to avoid being perceived and treated as a member of one's own sex. As noted in the Cass Review, even though social transition is undertaken outside healthcare settings, "it is important to view [social transition] as an active intervention because it may have significant effects on the child or young person in terms of their psychological functioning and longer-term outcomes."[26]

This overview identified two SRs evaluating the impact of social transition. Both are assessed at low risk of bias.[27] The results suggest that the impact of social transition on long-term GD, psychological outcomes and well-being, and future treatment decisions such as hormones or surgeries remains poorly understood. Evidence on regret associated with social transition is extremely limited. The certainty of evidence for these outcomes is very low.

Significant evidence gaps remain in the evaluation of social transition as an intervention for children and adolescents with GD. Most available studies are cross-sectional and there are no prospective longitudinal studies with appropriate comparison groups, making it unclear whether observed associations reflect the effects of social transition or other underlying factors. Additionally, published studies often do not disentangle the effects of social transition from concurrent interventions such as psychotherapy or medical treatments, further complicating interpretation.

5.3 Outcomes of puberty blockers

Gonadotropin-releasing hormone agonists (GnRHa), known as "puberty blockers" (PBs), are used to prevent or arrest the development of sex characteristics in

[26] Cass (2024, p. 158). Social transition may also involve breast binding for females or "tucking" (moving the testes into the inguinal canals and positioning the penis and scrotum in the perineal region) for males. This is a (non-medical) physical intervention with potentially adverse health effects, unlike haircuts or clothing changes. As a recent review puts it, "For chest binding, a significant number of negative health implications have been reported, with rates as high as 97.2%" (Bumphenkiatikul, 2025, p. 5). This review did not attempt to synthesize the quality of the evidence for either harms or benefits, however.
[27] Dopp et al. (2024); Hall et al. (2024).

peripubertal and pubertal children and adolescents with GD. This overview identified nine SRs that assessed the treatment effects of PBs. Among these four were English-language SRs[28] assessed at low risk of bias. The eligibility criteria and number of included studies varied in these four SRs, and the certainty of evidence is very low regarding the effect of PBs on GD (or gender incongruence), improvement in mental health, and safety. There is high certainty evidence that PBs exert physiological effects (such as sex hormone suppression) and often cause infertility when followed by CSH, depending on the patient's pubertal stage and sex.[29] Low certainty evidence suggests that PBs may compromise bone health.[30] A high proportion of youth proceed to CSH after PBs, though the certainty of evidence regarding any causal role PBs play in this progression is very low.

Important gaps remain in both the range and quality of outcomes assessed across the existing literature. Many primary studies were not adequately designed for measuring or reporting on the outcomes related to PBs. For example, few primary studies included in the SRs assessed the impact of PBs on outcomes such as GD or mental health. Although PBs are frequently described as a "pause button,"[31] no studies have systematically examined their role in the decision-making process or the outcomes of those who discontinue treatment.

When outcomes were assessed, the focus was largely on short-term psychological or physiological changes, or surrogate outcomes—such as suicidal ideation or bone mineral density, rather than on endpoints like suicides or fractures. The evidence is particularly limited regarding long-term outcomes related to fertility, growth, and neurocognitive development.

[28] Dopp et al. (2024); Ludvigsson et al. (2023); Miroshnychenko, Roldan et al. (2025); Taylor, Mitchell, Hall, Heathcote et al. (2024).
[29] See subsequent discussion of fertility in Chapter 7.
[30] See subsequent discussion of physiologic mechanisms whereby induced hypogonadotropic hypogonadism negatively impacts bone development.
[31] See, for example, a puberty blocker fact sheet from Cambridge Health Alliance/Harvard Medical School Teaching Hospital (Cambridge Health Alliance, n.d.).

While studies suggest a high proportion of youth proceed to CSH after puberty suppression,[32] there is minimal evidence on the impact of this combined pathway compared to CSH alone, or on how this pathway affects longer-term outcomes such as undergoing surgery. Furthermore, no studies have clearly examined the physical or psychosocial trajectories of the small minority of those who undergo PBs but do not proceed to CSH. As a result, there is little data on what happens after treatment ends, and the assumption that the effects of PBs are reversible remains largely untested. Another important limitation is that most of the primary studies have not distinguished the effects of PBs on females versus males. Overall, the absence of long-term, high-certainty evidence on these critical outcomes (including suicides, fractures, fertility, growth, and neurocognitive development) leaves substantial uncertainty about the effects of PBs.

5.4 Outcomes of cross-sex hormones

Estrogen for males and testosterone for females are used off-label to induce physical changes in the sex characteristics of youth with GD. This overview identified eight SRs on the treatment effects of CSH, among which four were in English language and assessed at low risk of bias.[33] The certainty of evidence is very low regarding the effect on GD or incongruence, improvement in mental health, and safety metrics including fertility and bone health. There is high certainty evidence that CSH exert physiological effects.

As with PBs, important evidence gaps exist for CSH. Many studies were not specifically designed to capture the full range of long-term outcomes and have primarily concentrated on short-term psychological or physiological changes. Key outcomes such as effects on GD, other mental health outcomes, and quality of life have been inconsistently measured and, when reported, often are derived from small,

[32] In the systematic reviews that were assessed at low risk of bias, only two studies (Carmichael et al., 2021; Karakılıç Özturan et al., 2023a) reported data on this outcome, each reporting progression rates from PBs to CSH of >95%. Other studies not captured by this overview, cited elsewhere in this Review, also reported >90% progression rate from PBs to CSH: Brik et al. (2020); van der Loos, Klink et al. (2023); Wiepjes et al. (2018).

[33] Dopp et al. (2024); Ludvigsson et al. (2023); Miroshnychenko, Ibrahim et al. (2025); Taylor, Mitchell, Hall, Langton et al. (2024).

observational studies with limited follow-up. Critically important long-term outcomes remain poorly understood. Sexual dysfunction, despite being highly relevant to long-term well-being, has been infrequently assessed. Although a few studies have reported cardiovascular event rates, long-term follow-up is needed to evaluate cumulative risk.[34]

Evidence on fertility is sparse, with little data on whether reproductive effects vary by age at treatment initiation or whether these effects are reversible. Furthermore, the compounded effects of sequential (and sometimes concurrent, especially among males) treatment with PBs followed by CSH—such as their impact on bone health recovery, final adult height, or the likelihood of requiring surgical interventions—have not been adequately investigated. As with PBs, the lack of methodologically rigorous, long-term studies significantly limits researchers' understanding of the broader health implications of CSH use during adolescence. A lack of primary studies that separately evaluate the effects of estrogen in males and testosterone in females is a significant limitation, as hormone-sex interactions may meaningfully influence outcomes.

5.5 Outcomes of surgery

Masculinizing mastectomy for adolescent females is the most frequently performed surgery in the context of youth with GD. This overview identified three SRs on surgeries for children or adolescents with GD, with most primary studies considering mastectomy only.[35] Two SRs were assessed at low risk of bias.[36] There is high certainty evidence that mastectomy is associated with predictable surgical complications such as necrosis and scarring. The certainty of evidence is very low regarding the effect of surgery on GD or incongruence, improvement in mental health including suicidality and depression, and long-term outcomes such as sexual function, quality of life, and regret.

There are substantial gaps in the evidence on surgeries for adolescents with GD. Most studies are case series or small observational designs, with limited or no comparator

[34] This is particularly true for pediatric medical transition (due to starting CSH in adolescence, the duration of treatment will be longer than for previously studied populations of adults).
[35] Dopp et al. (2024) included 18 studies; more than half of the included studies were on mastectomy. Miroshnychenko et al. (2024) included 39 studies and only assessed the effects of mastectomy. The other SR included 25 participants receiving surgeries, of which 24 received mastectomy. See Dopp et al. (2024); Miroshnychenko et al. (2024); Thompson et al. (2023).
[36] Dopp et al. (2024); Miroshnychenko et al. (2024).

groups, and thus are unable to isolate the effects of surgery from prior medical or psychosocial interventions. Outcomes such as effects on GD, mental health, and quality of life are inconsistently reported and often lack validated measures. Long-term outcomes, including the durability of psychological benefits, sexual function, need for revision surgeries, as well as satisfaction and well-being into adulthood, remain poorly characterized. Furthermore, while regret is a frequent topic of public discussion, existing studies do not provide robust data on the factors influencing regret. There are also knowledge gaps for other types of surgeries, including genital surgeries.

5.6 Outcomes of psychotherapy

Discussions about the role of psychotherapy in the treatment of youth with GD suffer from internal inconsistencies in the field of gender medicine, whereby psychotherapy is both recognized as an important tool but is also stigmatized if its aim is the resolution of GD (see Chapter 14). The overview identified a total of five SRs assessing psychotherapy among children or adolescents with GD. Only two were assessed at low risk of bias.[37]

The evidence on the effects of psychotherapy is limited. A 2024 review conducted by Dopp et al. included one randomized controlled trial (RCT) evaluating the effects of "coping-oriented brief videos" on suicidality, which did not provide direct evidence about the effect of psychotherapy in youth with GD. There are no other RCTs. Both SRs found that psychotherapy interventions were delivered through a range of formats, highlighting considerable heterogeneity in delivery. Formats for both face-to-face and online interventions varied widely, including individual, group, family-based, and combined approaches. Face-to-face interventions took place in diverse settings, such as specialist gender services, community programs, community mental health clinics, a weekend retreat, and an acute residential treatment program. These heterogeneities limit the generalizability of evidence. For mental health outcomes, the certainty of evidence was very low. However, no harms were reported.

[37] Dopp et al. (2024); Heathcote et al. (2024).

The overview found no evidence on the effect of psychotherapy on GD itself. This evidence gap may be due to a conflation of psychotherapy with "conversion therapy." As noted by the Cass Review, "[the] role of psychological therapies in supporting children and young people with gender incongruence or distress has been overshadowed by an unhelpfully polarised debate around conversion practices."[38] There has been very limited evidence on the role of psychotherapy in treating mental health problems co-occurring with childhood or adolescent GD,[39] including depression, anxiety, eating disorders, self-harm, and suicidality. Early reports often did not isolate the effects of psychotherapy from those of other concurrent interventions such as social transition, PBs, or CSH, making it difficult to attribute observed outcomes to psychotherapy alone. There is little understanding of which therapeutic approaches may be more or less effective for specific subgroups. The lack of robust research was acknowledged by the Cass Review, which noted that "there has been a failure to systematically consider how psychosocial interventions should be used and to research their efficacy."[40]

Of note, although the direct evidence for psychotherapy in children and adolescents with GD is limited, there is available evidence to support the role of psychotherapy in treating children and adolescents with other mental health problems, including depression, anxiety, eating disorders, self-harm, and suicidality (See Section 14.5.1).

5.7 Discussion

5.7.1 Findings of this overview

This overview of SRs includes 17 SRs evaluating the effects of interventions for children or adolescents with GD. For social transition, the certainty of benefits and harms is very low due to problems in the study designs. While studies suggest that early social transition is associated with a high rate of persistence of GD and a >90% rate of continuation to PBs and CSH,[41] from a methodological perspective there is uncertainty due to very low-quality evidence about causal explanations/pathways. Specific to medical transition, this overview highlights a consistent pattern across interventions for

[38] Cass (2024a, p. 150).
[39] See Chapter 14.
[40] Cass (2024a, p. 155).
[41] Hall et al. (2024).

children or adolescents with GD: while PBs, CSH, and surgeries reliably produce expected physiological changes, there remains substantial uncertainty about their psychological and long-term health impacts. High-quality evidence confirms that PBs suppress pubertal development and CSH induce changes to sex characteristics. There is low quality evidence suggesting that PBs compromise bone health.[42] However, the quality of evidence for outcomes such as GD, mental health, quality of life, and regret remains very low across all intervention types. The interpretation of many of the SRs' findings should be approached with caution, particularly given the sources of uncertainty, the robustness of this overview's conclusion, and the methodological limitations inherent in the evidence reviews.

5.7.2 Sources of uncertainty in evidence

Across the included SRs, the quality (certainty) of evidence is predominantly limited by lack of methodologically rigorous studies. For instance, across all primary studies included in the nine SRs on PBs, there were no eligible randomized controlled trials.

The lack of proper controls is another common methodological limitation in the studies. This overview found that across all primary studies in the nine SRs on PBs, only six were observational studies with parallel control groups that compared PBs with no PBs among children or adolescents with GD.[43] However, the overall certainty of evidence was influenced not only by methodological shortcomings, but also by factors such as small sample size and small or no effects, which signify imprecision in GRADE terminology. For instance, the sample sizes of the six comparative observational studies addressing PBs were small, with three studies which each included fewer than 100 participants. One SR downgraded the quality of evidence on the effect of PBs on global function for imprecision, noting that the evidence "suggests both a possibility of a benefit or a harm in the outcome."[44]

Inconsistent study findings are another frequently cited concern that lowers the quality of evidence. For instance, one SR of CSH found "limited or inconsistent evidence

[42] Physiological mechanism for PBs' effect on bone mineralization is discussed in Chapter 7.
[43] Becker-Hebly et al. (2021); Costa et al. (2015); Grimstad et al. (2021); Jensen et al. (2019); McGregor et al. (2024); Tordoff et al. (2022).
[44] Miroshnychenko, Roldan et al. (2025).

regarding GD, body satisfaction, psychosocial and neurocognitive outcomes, fertility, height/growth, bone health and cardiometabolic effects."[45] Similar limitations were observed across studies evaluating other medical and surgical interventions for youth with GD.

Thus, it is important to clarify that the absence of high- or even moderate-quality evidence is not only due to a lack of randomized controlled trials (RCTs). The quality of evidence could have been improved through well-conducted observational studies,[46] which can provide moderate and even high-quality evidence when effects are large, consistent, and clearly attributable to the intervention.

5.7.3 Robustness of this overview's conclusion

Although this overview focused on English-language SRs assessed at low risk of bias, another low risk of bias SR, published in German, reached similar conclusions, reinforcing the overall patterns identified here.[47] As stated earlier, this overview did not include the NHS-commissioned SRs on PBs and CSH in 2020, as they were superseded by the SRs published in 2024 to inform the Cass Review. However, these two earlier SRs also concluded that the evidence was of very low quality,[48] and their inclusion would not have altered the conclusions of this overview.

A report commissioned by lawmakers in Utah was publicly released at the end of May 2025.[49] Assessment of the "Utah Review" with ROBIS[50] demonstrates that it would not have met the criteria for inclusion in the evidence synthesis (which only included SRs with low risk of bias). The Utah Review's review of primary studies did not properly define the research question, conduct a comprehensive literature search, or critically appraise all included studies. Most critically, it failed to perform two key aspects of a systematic review, a formal evidence synthesis and an assessment of evidence certainty, and therefore does not qualify as a systematic evidence review. It concluded,

[45] Taylor, Mitchell, Hall, Langton et al. (2024).
[46] See the checklist for ways to improve observational research in this field in Ludvigsson et al. (2023).
[47] Zepf, König et al. (2024).
[48] National Institute for Health and Care Excellence (2020b, 2020a).
[49] University of Utah College of Pharmacy, Drug Regimen Review Center (2025). This report postdated the initial publication of the present Review.
[50] See Appendix 4, Section 2.4, and Whiting et al. (2016).

without sound methodological basis, that “the consensus of the evidence supports that the treatments are effective.”[51] The Utah Review also contained a review of clinical guidelines and SRs; these both had significant limitations. For example, the guideline review retrieved only four guidelines, and the SR review omitted recently published SRs.

It is also important to note that while the current overview focused on SRs assessed at low risk of bias, this designation does not imply that these SRs were without methodological limitations. The “low risk of bias in the systematic review” in ROBIS allows for some flexibility. The included SRs still had shortcomings, such as limited search strategies, outdated literature searches,[52] or lack of precision in evidence assessments. In contrast, SRs assessed at high risk of bias consistently exhibited serious methodological flaws, including poorly defined eligibility criteria, absence of risk of bias assessments for included studies, and unsystematic synthesis approaches. These SRs were judged to be too biased to inform reliable conclusions. The findings presented in this overview, therefore, reflect a deliberately cautious approach, drawing only from the most trustworthy sources currently available.

Finally, rather than extending beyond what the evidence can support, this overview is confined to summarizing the conclusions of SRs. As a result, it may not include some of the most recently published studies (due to the timing of the SRs’ literature searches). However, a targeted search[53] of recently published studies did not reveal any published or ongoing studies that would significantly change the conclusions, especially those pertaining to benefits. This is due to ongoing problems such as an absence of comparison groups, inadequate sample sizes, and limited follow-up. Should the contemplated U.K. RCT trial of PBs[54] receive ethics approval, it might improve the

[51] University of Utah College of Pharmacy, Drug Regimen Review Center (2025, p. 90).
[52] According to the Cochrane Handbook, reviews should be as up-to-date as possible. However, as recency is not the sole consideration, SRs with outdated search strategies can still be considered at low risk of bias overall (Higgins et al., 2019).
[53] A targeted search in this field identified recent publications based on observational studies from the U.S. (Hidalgo et al., 2024; Olson-Kennedy et al., 2025; Wittlin et al., 2025), Canada (Lawson et al., 2024), the Netherlands (van der Meulen et al. 2025), and the U.K. (Morandini et al., 2023). These studies have similar limitations (including study design, small sample size, short-term follow up, etc.) to the primary studies included in the SRs.
[54] National Institute for Health and Care Research (2024).

evidence base for short-term (24 month) effects of PBs on certain outcome measures. However, based on the elements of the study design publicly disclosed to date, it might not provide information about the effect of treatment when PBs are followed by CSH—a clinical trajectory which appears to occur more than 90% of the time.[55] Such combination use would have a different risk/benefit profile than the use of PBs alone, both in terms of possible benefits and possible harms. Finally, the anticipated short-term follow-up will not adequately address the key question of long-term outcomes.

Without a meaningful shift toward more robust research designs—such as RCTs that test each intervention as it is currently provided (sequential treatment of PBs followed by CSH), prospective cohorts with suitable comparators, or natural experiments—the quality of evidence likely will remain low.[56] Conducting new SRs to answer the same research questions in the near future is unlikely to yield novel insights. This dearth of robust research and evidence has direct implications for clinical guidance and policy development, where expectations of benefit must be weighed against the persistent uncertainty of the evidence documented in the literature.

5.7.4 Limitations and strengths of this overview

All SRs and overviews of SRs have limitations. SRs aim to capture all relevant research that meets predefined eligibility criteria. However, this objective may be undermined by reporting (or non-reporting) bias—a form of bias that arises when the decision to publish, delay, or selectively report study results is influenced by the statistical significance, size, or direction of the findings.[57]

As discussed in Chapter 6 of this Review, research in the field of PGM suffers from significant publication and reporting bias. The extent of the problem is difficult to quantify due to widespread poor methodology and a lack of consistency in reporting effect

[55] Brik et al. (2020); Carmichael et al. (2021); van der Loos, Klink, et al. (2023); Wiepjes et al. (2018).
[56] There is debate about whether high-quality research on effects of PBs/CSH in minors should be pursued. Ethical deliberations factor into this debate. Some have argued that research should focus on patients who already received PBs, CSH or surgery (Ryan, 2024b). The Cass Review called for more robust research into psychotherapeutic approaches to GD, which is a promising treatment approach so-far neglected by research (Cass, 2024a).
[57] Guyatt, Oxman, Montori, Vist et al. (2011).

sizes.[58] Notably, publication bias has not been considered as a reason for downgrading the certainty of evidence in the included SRs.

Another limitation is that SRs serve to answer well-defined research questions which have prespecified outcomes, but cannot detect signals or generate hypotheses. Many studies in PGM focus on psychological outcomes but only inconsistently track other outcomes that may be signals of the intervention's adverse effects. When outcomes are not reported using rigorous methodological standards—such as being clearly listed in a dedicated outcomes table—but instead are only mentioned in the discussion section, SR methodologies are unlikely to flag the study as relevant to that outcome during the screening process. As a result, important adverse effects may go unnoticed. This issue is discussed at some length in the next chapter.

A key characteristic of SRs and overviews of SRs is their emphasis on population-level epidemiological data,[59] often with limited integration of mechanistic evidence or considerations of biological plausibility. This narrow scope limits the ability of this overview to elucidate potential causal pathways or to fully interpret observed associations—or their absence.

This overview of SRs has other limitations. Like all overviews, it is constrained to synthesizing published SRs and does not reanalyze primary studies. The scope of this overview was intentionally narrow, focusing on young patients and excluding indirect evidence from adult populations that may provide insight into long-term effects.

Strengths included systematic evaluation of the risk of bias across SRs using the ROBIS tool. Thus, this overview offers a transparent assessment of the reliability of each SR's conclusions. It also allows for comparison across SRs with overlapping but differently scoped studies, helping to identify consistent findings, methodological gaps, and areas of agreement or divergence.

[58] Publication bias is notoriously hard to measure, and the existing statistical tools have significant limitations (Afonso et al., 2024).
[59] Guyatt et al. (1992, 2015).

5.7.5 Conclusion

This overview synthesizes the best available clinical evidence from population-level data, highlighting a consistent pattern across interventions for children and adolescents with GD. The benefits and harms of social transition remain unknown; PBs, CSH, and surgeries consistently produce certain physical and physiological effects; and there is considerable uncertainty regarding their psychological and long-term health outcomes. Likewise, there is uncertainty regarding the effects of psychotherapy for GD.

Chapter 6 Limitations of Systematic Reviews

As reported in the overview of systematic reviews (SRs), the quality of evidence for benefits of the interventions used in pediatric medical transition (PMT) is very low. Nevertheless, the practice has continued to expand rapidly. The “very low” quality of evidence for benefits demands additional scrutiny of the potential harms in order to arrive at a proper understanding of the risk/benefit ratio.

It is well-established that SRs are better at detecting benefits than harms.[1] As Guyatt and colleagues remark, “Many, if not most, systematic reviews fail to address some key outcomes, particularly harms, associated with an intervention.”[2] Consequently, the absence of evidence of harms in published studies is not equivalent to evidence of absence of harms. In pediatric gender medicine (PGM), inadequate harm detection is amplified by the following factors:

- Insufficient time has elapsed since the widespread adoption of PMT;
- Short-term before-and-after observational studies that comprise the bulk of the evidence often have high ‘loss to follow up’ rates and do not systematically look for, track, or completely report harms;
- Publication bias impedes the recognition of harms.

The first three sections of this chapter (6.1–6.3) consider how these factors affect the ability of SRs to detect harms, with a summary in Section 6.4.

A comprehensive examination of harms associated with PMT is necessary to inform clinical practice. Harms associated with surgeries that remove healthy body parts are easy to recognize, as are some of the adverse effects of hormonal interventions. The latter are noted both in the Food and Drug Administration (FDA) drug labels[3] and on informed consent or assent forms parents and children sign prior to initiating treatment.[4]

[1] Loke et al. (2007); Mayo-Wilson et al. (2023); Qureshi et al. (2022).
[2] Guyatt, Oxman, Kunz, Atkins et al. (2011, p. 397).
[3] Testosterone is one of the most widely used drugs in the field and is classified as a Schedule III controlled substance due to the risk of psychological dependence and abuse.
[4] E.g. Cornell Health (n.d); Fenway Health (2024a, 2024b, 2025).

Use of these drugs off-label in PGM may add additional risk. It is well-established in adults that for the same drug, off-label uses are associated with considerably higher rates of adverse effects, especially when strong scientific evidence is lacking.[5] Clinical trials have never been conducted for using puberty blockers (PBs) to stop normally-timed puberty; such use will have a different risk profile than the use of PBs to temporarily stop abnormally early (precocious) puberty.

Additional uncertainty arises from the fact that, in studies, PBs are followed by cross-sex hormones (CSH) over 90% of the time;[6] this de facto combination therapy introduces new and potentially serious risks (e.g., concerning fertility) and has never been subjected to any FDA-regulated clinical trial for any population. Further, research shows that when the evidence supporting a particular off-label use is of very low certainty—as is the case for PMT—the already elevated risk of adverse effects associated with off-label use is increased even further.[7]

6.1 Insufficient elapsed time

Although the Dutch Protocol was first published 20 years ago,[8] it was not until the late 2010s to early 2020s that there were sufficient numbers of patients to allow for studies that can estimate rates of harms and benefits.[9] In addition, because the emergence of harms may be delayed by a decade or longer, SRs conducted relatively early in the field's tenure are more likely to understate these outcomes.[10] The average patient is still quite young—typically in their teens or early twenties—at the time of follow-up. This compounds problems with risk detection, since the effect of hormones on health may be cumulative (e.g., effects of hormones on cardiometabolic disease or malignancies) and may not fully manifest until later in life.

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[5] Eguale et al. (2016).
[6] E.g., Brik et al. (2020); Carmichael et al. (2021); Karakılıç Özturan et al. (2023a); van der Loos, Klink et al. (2023); Wiepjes et al. (2018).
[7] Eguale et al. (2016).
[8] de Vries et al. (2006); Delemarre-van de Waal & Cohen-Kettenis (2006). See Chapter 3.
[9] Respaut & Terhune (2022).
[10] A study in gender medicine with longer-term follow up found "poorer outcome[s] … [which] might also be explained by longer follow-up period (median 10 years) compared to previous studies. In support of this notion, the survival curve (Figure 1) suggests increased mortality from 10 years after sex reassignment and onwards" (Dhejne et al., 2011).

6.2 Short-term observational studies

The Cass Review recognized continued reliance on poorly-designed observational studies as a "key limitation to identifying … safety of gender-affirming hormones for children and adolescents."[11] A key problem that disadvantages SRs in their detection of harms is the fact that the entire body of evidence in PGM is largely composed of short-term "before and after" observational studies that are particularly prone to bias. Such studies focus on demonstrating benefits while inconsistently reporting harms.[12] Unlike the intended benefits of an intervention, which are hypothesized before the study begins and investigated as primary outcomes,[13] harms are not always expected, surveilled, or reported. Therefore, SRs are limited by being able to identify only those outcomes reported by primary studies.[14]

An example of the difficulty in identifying harms pertains to whether PBs represent a harmless "pause button" providing "time to think"[15] or a powerful intervention that promotes iatrogenic persistence of GD and promotes continuation to CSH. At least five studies indicate >90% rate of progression from PBs to CSH.[16] As the Cass Review noted, "These data suggest that puberty blockers are not buying time to think, given that the vast majority of those who start puberty suppression continue to masculinizing/feminising hormones, particularly if they start earlier in puberty."[17] Because the high rate of persistence from PBs to CSH is often mentioned only in the text of a study (and not delineated in outcome tables or abstracts), SRs may overlook this information at the screening stage. Only one low risk of bias SR assessed the proportion of CSH use after PBs, identifying only two studies.[18]

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[11] Cass (2024a, p. 76).
[12] Loke et al. (2007); Mayo-Wilson et al. (2023); Qureshi et al. (2022).
[13] In the case of prospective studies.
[14] Researchers may want their intervention to lead to beneficial outcomes, and may be reluctant to look for or focus on harms.
[15] See Chapter 4 for discussion of the "time to think" rationale.
[16] Brik et al. (2020); Carmichael et al. (2021); Karakılıç Özturan et al. (2023a); van der Loos, Klink et al. (2023); Wiepjes et al. (2018). See also Section 4.3.2.2.
[17] Cass (2024a, p. 176).
[18] Miroshnychenko, Roldan et al. (2025) was the SR that identified Carmichael et al. (2021) and Karakılıç Özturan et al. (2023a).

There are other examples of inappropriate reporting of adverse effects.[19] Three notable ones are profiled below.

6.2.1 de Vries et al., 2011, 2014[20]

The pair of seminal Dutch studies that launched PMT worldwide can serve as an example of how harms can go unreported. The 2014 study's conclusion that treatment with PBs, CSH and surgery "leads to improved psychological functioning"[21] did not comment on the finding that at least four of the original 70 young patients experienced adverse effects during treatment. Three adolescents were diagnosed with obesity and diabetes, which disqualified them from continuing to surgery, and one patient died from complications following surgery after early pubertal suppression.[22] These serious adverse events were not reported as formal outcomes,[23] precluding any discussion of whether they were caused by the experimental intervention or occurred incidentally. More recently published evidence suggests that the postsurgical death was likely directly related to the practice of early pubertal suppression.[24] Further, because these adverse effects were noted only in the context of accounting for the reduced postsurgical sample size, the study may not have attempted to detect and report less severe adverse effects that were not disqualifying for further participation.

Inadequate reporting of harms in the Dutch study was compounded when SRs excluded this study due to its unreliable design (e.g. the study comingled the CSH and surgery phases, making it impossible to determine which outcomes were associated with which

[19] This is not atypical in medicine. Researchers who invent innovative treatments are likely to focus on the apparent benefits.
[20] de Vries et al. (2011); de Vries et al. (2014).
[21] de Vries et al. (2014, p. 703).
[22] See Chapter 4 for discussion of the weaknesses in the original Dutch Protocol research.
[23] These outcomes were only discussed in the "methods" section (de Vries et al., 2014).
[24] de Vries et al. (2014) had 15 missing cases from the original cohort of 70 participants. Of these 15 participants, three were disqualified from the study because they developed obesity and/or diabetes. One dropped out of treatment, and one died from a surgical complication that was a likely consequence of pubertal suppression (Biggs, 2023b; Negenborn et al., 2017). Several others failed to return postsurgical questionnaires for unknown reasons.

intervention).[25] Thus, the serious harms reported incidentally by the study authors were entirely omitted from the SRs due to the study's poor design.

6.2.2 Tordoff et al., 2022[26]

Inadequate reporting of harm is also evident in more recent research. A highly influential 2022 study from Seattle Children's Gender Clinic by Tordoff et al. focused exclusively on psychological outcomes, where benefits had been hypothesized. It did not study or report physical health outcomes, where harms would have been more likely to occur.

The study by Tordoff et al. reported mental health outcome data for adolescents and young adults aged 13-20 years who were treated with PBs or CSH for up to one year. The study claimed to provide "quantitative evidence" of mental health improvements; however, the rates of depression in youth who started PBs or CSH remained unchanged—about 6 in 10 youth were moderately-to-severely depressed both pre- and post-intervention.[27] These data were reported in a supplement which was available only online. The study finding of improved mental health was derived from the odds ratios: 60% lower odds of depression and 73% lower odds of suicidality in patients treated with PBs or CSH as compared to those who were not. However, major methodological issues, including potential selection bias and confounding,[28] inappropriate statistical

[25] de Vries et al. (2014) was excluded from the systematic review of CSH by the SR conducted by the U.K.'s National Institute for Health and Care Excellence (NICE). The stated reason for exclusion was: "Exclude on intervention – all participants had surgery after gender-affirming hormones. Unable to determine whether changes were due to hormones or surgery. Complete data only available for 40 patients. Details of gender-affirming hormones are poorly reported" (National Institute for Health and Care Excellence, 2020a, p. 72). This study was also excluded from the SR by Miroshnychenko, Ibrahim et al. (2025) on CSH. Though it was included in the SR by Taylor, Mitchell, Hall, Langton et al. (2024) on CSH, it was classified as a low-quality study and not included in the evidence synthesis.

[26] Tordoff et al. (2022). This research was conducted in the U.S. at Seattle Children's Hospital/Washington State University.

[27] Raw Patient Health Questionnaire (PHQ-9) and Generalized Anxiety Disorder-7 (GAD-7) data was not reported, even in the online-only supplement.

[28] Of 104 youth aged 13-20, 62 initiated treatment with PBs or CSH during the 12-month study, and 7 were already on treatment at baseline. Participants who initiated treatment during the study contributed to both "treated" and "untreated" groups at different times, complicating interpretation.

modeling,[29] missing participant data,[30] and selective reporting[31]—raise serious concerns about the reliability of the reported findings.

The impressive-sounding odds ratios were thus calculated by relying on progressively smaller denominators in the untreated "comparator" group. The supplementary online-only data revealed that only seven cases from the "comparator group" of patients not treated with PBs or CSH remained enrolled in the study by its end.[32] It was also unclear if or to what extent this "comparator" group could be considered representative of all untreated patients. It appears that the "untreated" group comprised youth whose mental health problems and GD issues resolved who dropped out from the gender clinic and the study (representing 80% of the total "untreated group"); the patients who were about to cross-over to the treated group after a short assessment; and the eight patients (seven of whom provided follow-up data) who continued to attend the gender clinic 12 months later, but for an unknown reason were not starting hormonal interventions.[33]

Two recent systematic reviews have assessed Tordoff et al. for risk of bias, using two different tools (the Newcastle Ottawa Scale and ROBINS-I).[34] While both analyses identified some methodological weaknesses (e.g., short follow-up, high attrition rate), the study's inclusion of untreated youth as a comparison group somewhat boosted its

[29] Rather than analyzing individual mental health trajectories before and after treatment, the study performed cross-sectional comparisons at various time points, leading to potential bias.
[30] At 12 months, data are missing for 17% of medicalized youth (12 of 69) and an astounding 80% of non-medicalized youth (28 of 35). It is likely that non-medicalized participants without mental health distress, including those whose gender distress resolved, would be least likely to return to the clinic
[31] The authors performed analyses following multiple strategies, reporting in the abstract only the version of the analysis that produced the most dramatic results (strongest aOR [adjusted odds ratio] and smallest p-values), raising concerns about data-dredging.
[32] Based on eTable 3 in the supplementary material, the estimated prevalence of depression in the control group was 59% at baseline, 76% at month 3, 58% at month 6, and 86% at month 12. The substantial fluctuation across time points indicates that the estimates for the control group were unstable and likely influenced by random error.
[33] There was incomplete data for 80% of patients in the untreated group. It is possible that patients whose GD resolved stopped attending appointments. Additionally, the 7 untreated patients with follow-up data at one year may not have been approved for medical transition because they did not have sufficient capacity for consent—the only scenario under which this pediatric gender clinic would not recommend medical transition if desired by the patient, according to the study's lead author ("In practice, the only instances when it would have been appropriate to delay initiation of PB/GAH is if there was a concern that a patient did not have the capacity to provide informed consent … which is exceedingly rare in adolescence" (Tordoff, 2022). Barriers to provision of informed consent can include active psychosis or mania and profound intellectual disability.
[34] Miroshnychenko, Ibrahim et al. (2025); Taylor, Mitchell, Hall, Langton et al. (2024). ROBIS: Risk of bias in non-randomized studies - of interventions.

quality ratings. Systematic reviews are not always able to capture serious problems with comparison groups of this type.

This study's misrepresentation of its own results, serious confounding, and the exceptionally high loss-to-follow-up for untreated youth have been highlighted by science journalists and discussed in peer-reviewed articles.[35] Despite these well-demonstrated problems, this study, published in the *Journal of the American Medical Association* (JAMA) Open Network, continues to be uncritically described, by authoritative sources, as evidence that PBs and CSH are beneficial to mental health, medically necessary, and lifesaving.[36]

6.2.3 Chen et al., 2023[37]

This study, published in the *New England Journal of Medicine* (NEJM), reported mental health outcome data for 315 adolescents and young adults aged 12-20 (65% female) who were treated with CSH for a period of 24 months. Following the study protocol, there was no control group. Chen et al. (2023) cast its results in a positive light: "our findings showed improvements in psychosocial functioning ... which supports the use of [CSH] as effective treatment for transgender and nonbinary youth."[38] The study's observational, uncontrolled methodology does not justify the authors' use of explicitly causal language when reporting their results (CSH "improved appearance congruence and psychosocial functioning"). The lack of a parallel control group is this study's biggest limitation.[39]

In contrast to the authors' positive description of the outcomes, two of the study subjects died by suicide within one year of initiating hormones, representing an annualized

[35] E.g., Abbruzzese et al. (2023); Biggs (2023b); Singal (2022a). The university that conducted the research was made aware of the study's problems but chose not to disrupt the very positive medical narrative that misrepresented the authors' findings (Singal, 2022b).
[36] E.g., American Psychiatric Association (2023); Boerner (2022); Stringer (2023); U.S. v. Skrmetti (No. 23-477), American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations, Amicus curiae brief (2024). To date, this study has been cited over 300 times in other peer-reviewed publications and viewed nearly half a million times.
[37] Chen et al. (2023). This was an NIH-funded multi-site study which recruited patients from four pediatric gender clinics: Benioff Children's Hospital, Boston Children's Hospital, Children's Hospital Los Angeles, and Lurie's Children's Hospital of Chicago. The original 2016 protocol and the final 2021 protocol can be found in the study's supplementary material.
[38] Chen et al. (2023, p. 249).
[39] Miroshnychenko, Ibrahim et al. (2025).

suicide rate of 317 per 100,000 patients. The suicide rate in Chen et al. was higher than rates that have been reported by PGM clinics in the U.K. and Finland (13 per 100,000 and 51 per 100,000).[40] One Belgian study[41] has also reported a comparatively high annual suicide rate (1,126 per 100,000); like in Chen et al., all patient suicides in that study were among patients taking CSH.[42]

Chen et al. reported only four out of more than 19 mental health outcomes described in the study's pre-registered protocol.[43,44] In particular, outcomes of GD, self-harm, and suicidality were not reported, and no explanation was provided for omitting these critical data. The only statistically significant improvement in both sexes was in "appearance congruence" as measured by the "transgender congruence scale," which has not been validated in minors.[45] The authors also reported that there were statistically significant improvements in depression, anxiety and life satisfaction.[46] However, these improvements were small[47] and of questionable clinical significance.[48] The statistically significant improvements were observed only in females, whereas males experienced

[40] Society for Evidence-Based Gender Medicine (2023a, 2024a).
[41] Van Cauwenberg et al. (2021).
[42] Society for Evidence-Based Gender Medicine (2024a). See also Section 4.3.4.
[43] The four reported outcomes were the Transgender Congruence Scale, the Revised Children's Manifest Anxiety Scale, the Beck Depression Inventory II, and the Life Satisfaction/Positive Affect scale from the NIH Toolbox Emotion Battery. A recent paper describing this same patient cohort published more information on the life satisfaction/positive affect results along with information on additional measures from the NIH Toolbox Emotion Battery (Olson-Kennedy et al., 2025), but it did not report the gender dysphoria, self-harm, or suicidality outcomes, nor did it reference the two patient suicides.
[44] See pp. 24–28 of the pre-registered final protocol (2021) for a description of all outcome measures.
[45] Strauss et al. (2024).
[46] In the case of positive affect, there was no statistically significant difference between the mean baseline measure and the endpoint at 24 months. See Table S5 (Corrected) of Chen et al. (2023). The authors chose instead to focus on the fact that the slope of the regression line for the data collected at all time points was statistically significant: "positive affect … increased significantly" (p. 243)."
[47] The mean Beck Depression Inventory score improved from 16.01 to 13.85 (63-point scale); the mean Revised Children's Manifest Anxiety Scale improved from 59.84 to 57.32 (T-score, where 50 is the population average and 10 is one standard deviation); and the mean life satisfaction score improved from 40.03 to 44.68 (T-score). For all these improvements, the reported Cohen's *d* effect sizes were small.
[48] For the Beck Depression Inventory, for example, researchers have suggested a 17.5% decrease from baseline score may represent a "minimal clinically important difference" (Button et al., 2015). The mean decrease of 2.16 points on this (63-point) scale in Chen et al. (2023) does not, according to this criterion, meet the threshold of clinical importance (McDeavitt, 2024). It is unclear whether improvements for females meet this threshold: see Figure S3 in the supplementary appendix to Chen et al. (2023).

no significant improvement in these measures. Additionally, follow-up data for these measures were unavailable for 31–34% of participants, introducing bias.[49]

According to the study's pre-registered protocol, the authors' original hypothesis was that after starting CSH, patients would exhibit "decreased symptoms of … gender dysphoria, self-injury, trauma symptoms, and suicidality" (among other changes) over time.[50] The hypothesis articulated in the published paper[51] instead focused on "appearance congruence," a phrase that did not appear in the original hypothesis. Chen et al. (2023) did not report important measures central to its protocol's hypothesis (e.g. GD, self-injury, trauma symptoms, suicidality), and these measures remain unreported even a decade after the research initiative was launched. As mentioned above, two young patients died by suicide within one year of initiating treatment, and the most frequently occurring adverse event during hormonal treatment was "suicidal ideation."[52] These latter findings, reported as adverse events, do not support the original hypothesis of reductions in self-injury and suicidality.

Although a recent systematic review was able to capture issues like study attrition in its risk of bias assessment for Chen et al.,[53] such reviews are unable to capture serious concerns that may be more related to research ethics than to methodology (e.g., the altering of hypotheses between the protocol and the published article raises the possibility of "HARKing"[54]). Peer-reviewed critiques addressing the issues with Chen et al. were eventually published in NEJM, but not until nearly a year after the article first appeared.[55]

[49] Out of the total number of patients (315), these two-year follow-up data were recorded from a little over 200 (208–217). See Table S5 (Corrected) in the supplementary appendix to Chen et al. (2023).
[50] See p. 36 of the study's final protocol (2021).
[51] "We hypothesized that appearance congruence, positive affect, and life satisfaction would increase and that depression and anxiety symptoms would decrease" (Chen et al., 2023, p. 241).
[52] Chen et al. (2023, p. 241). Chen et al. do not explain how "suicidal ideation" was measured.
[53] Miroshnychenko, Ibrahim et al. (2025).
[54] "Hypothesizing after the results are known" (Kerr, 1998).
[55] E.g., Biggs (2023a); Hare (2023); Jorgensen (2023c); Dutch PMT researchers also published a commentary on Chen et al., which acknowledged the study's many problems (de Vries & Hannema, 2023).

The study continues to be widely cited and uncritically described as providing evidence of benefit for hormonal transition of minors.[56]

6.3 Publication bias

It is a well-documented problem in biomedical research that positive findings confirming an original hypothesis are much more likely to be published or published expeditiously, as compared to studies with inconclusive or negative results. “Publication bias” is not unique to this field. The U.K.’s national PGM clinic, the Gender Identity Development Service (GIDS), tried to replicate the seminal 2011 Dutch study, launching its own “early intervention” study of PBs in 2011. Although the results were available in 2016-2017, they were only released in 2021 following a complaint to the U.K. Health Research Authority.[57] Once published, the study acknowledged that the outcomes reported by the Dutch were not replicated.[58] The study also found that puberty blockade was associated with impaired bone density accumulation. Subsequent reanalysis of the same data showed that up to one-third of participants experienced a deterioration in mental health while on PBs.[59]

A similar pattern may be unfolding in the United States. The lead investigator of a NIH-funded PB study acknowledged delaying the publication of results—apparently due to fear that the unimpressive findings would undermine the field.[60]

A similar reluctance to report on disappointing findings is evident in other places, too. According to court disclosures, the World Professional Association for Transgender Health (WPATH) suppressed publication of SRs on at least 10 of 13 topics relating to endocrine treatment of adolescents with GD.[61] The unpublished SRs evaluated harms, including the effects of PBs on “clinical outcomes and harms”; the effects of estrogen on the risk of pulmonary embolism, deep-vein thrombosis, stroke, and myocardial

[56] E.g., U.S. v. Skrmetti (No. 23-477*),* Expert Researchers and Physicians*,* Amicus curiae brief (2024).
[57] Biggs (2023b).
[58] Carmichael et al. (2021).
[59] McPherson & Freedman (2023).
[60] As reported in *The New York Times* (Ghorayshi, 2024c). Of note, the investigator, Johanna Olson-Kennedy, denied having said this in a later deposition (Deposition of J. Olson-Kennedy in LB v Premera Blue Cross NO. 2:23:Cv-00953-TSZ, 2024).
[61] See Chapter 10.

infarction; the effects of testosterone on uterine, ovarian, cervical, vaginal, and breast pathology; and the effects of hormone therapy on fertility and metabolic syndrome.[62]

There also are instances of SRs arriving at conclusions that contradict the underlying evidence. One SR commissioned by WPATH found only "low" and "insufficient"[63] strength of evidence regarding the effects of hormonal interventions on mental health. Nevertheless, the SR's authors came to the unsupported conclusion that this treatment pathway "is likely associated with improvements" in quality of life, depression, and anxiety. The authors also asserted that "[t]hese benefits make hormone therapy an essential component of care that promotes ... health and well-being." Notably, there was no attempt to evaluate hormone effects on physical health.[64] The content of this SR was influenced by WPATH leadership, including approving the conclusion as a condition for eventual publication. This may explain the discrepancy between the SR's optimistic conclusion and its more problematic findings. Section 10.3.2 discusses evidence suppression by WPATH in detail.

Another 2021 SR, conducted by Bustos et al., examined postsurgical regret rates.[65] This SR is often cited as evidence that the regret rate after transition-related surgery is very low, about 1%.[66] But of the 27 studies included in Bustos et al., 23 were rated as "poor" or "fair" in quality. The few higher-rated studies suffered from substantial loss to follow-up and the reported results included deaths from suicide and complications. One included study contributed nearly half the total participants but reported a 36% loss to follow-up. The study authors acknowledged that the short follow-up period was a key limitation. However, the authors failed to address the most serious criticism, namely that their central conclusion of "extremely low regret" was unsupported.[67]

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[62] Sharma et al. (2018). See also Society for Evidence-Based Gender Medicine (2024b).
[63] Baker et al. (2021, p. 13).
[64] Appendix 4 includes a ROBIS assessment of Baker et al. (2021).
[65] Bustos et al. (2021) reported regret rates of around 1%. This SR was not included in this Review's overview of SRs as most of the included studies did not focus on the adolescent population.
[66] See examples of such statements in Cohn (2023).
[67] For the criticism, see Expósito-Campos & D'Angelo (2021). The authors provided a reply to the critique (Escandón et al., 2021), which addressed some but not all of the key concerns. See also footnote 109 in Section 7.6.2.

6.4 Summary

The quality of SRs in the field of gender medicine varies widely, but even the highest quality SRs typically find only “low certainty” evidence for most harms. However, there are familiar and plausible explanations for why evidence of harms may not have been sought, detected or reported. Reflecting on the state of evidence in PGM, the Cass Review noted, “it has been evident that there has been a failure to reliably collect even the most basic data and information in a consistent and comprehensive manner; data have often not been shared or have been unavailable.”[68]

Unless SRs specifically search for harms (and with the provisos above), they are not well-suited to detect complications or adverse effects. This is due to the relatively recent debut and rapid growth of the field of PGM, the tendency of the predominantly short-term observational studies to focus on benefits and underreport harms, and publication bias. EBM emphasizes the role of best available evidence. To address SRs’ limited ability to detect harms, decision-makers must consider other sources of scientific information. That is the topic of the following chapter.

[68] Cass (2024a, p. 39).

Chapter 7 Evidence from Basic Science and Physiology

When clinical studies provide insufficient information about harms, and therefore systematic reviews (SRs) are unable to reliably collate information about harms, other types of evidence should be integrated. Trustworthy evidence from other sources, including basic sciences, should be considered to arrive at a more informed understanding of the plausible effects of interventions.[1] In the case of pediatric medical transition (PMT), this involves consideration of human physiology, development, and the well-established mechanisms of action of the drugs used. The consideration of such evidence aligns with the core requirement of evidence-based medicine (EBM): the judicious use of the "best available" evidence.

The following sections explain: normal pubertal development and the mechanisms of action of PMT interventions (Section 7.1); treatment of central precocious puberty with puberty blockers (PBs) (Section 7.2); biologically plausible implications of using PBs to arrest normally timed puberty and cross-sex hormones (CSH) (Sections 7.3 and 7.4); surgical implications, particularly when pubertal development has been arrested (Section 7.5); and psychological risks of undergoing PMT interventions given what is known about child and adolescent development (Section 7.6). Mortality is discussed in Section 7.7.

7.1 Puberty

This section overviews physiology and the implications of disrupting normally-timed puberty. Of note, there are three distinct waves of hypothalamic-pituitary-gonadal (HPG) axis activity over an individual's lifespan: in utero, during the first month after birth, and in late childhood-early adolescence.[2] Only the latter is referred to as "puberty."[3] Medications can be given to suppress the HPG axis.

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[1] Sackett et al. (1996).
[2] Rohayem et al. (2024).
[3] The discussion in this section focuses on normal pubertal development. Individuals with disorders (differences) of sex development (DSDs) are not a focus of this chapter because the vast majority of adolescents with gender dysphoria do not have a DSD. Among those with DSDs, approximately 5% experience identity changes (Kreukels et al., 2018). As noted in the Cass Review, "Studies of children with DSD suggest that a complex interplay between testosterone levels, external genitalia, sex of rearing and socio-cultural environment all play a part in eventual gender identity" (Cass, 2024a, p. 102).

7.1.1 Overview of normal pubertal development

In mammals, puberty is defined as the period of time during which immature juveniles reach adult sexual maturity and become capable of reproduction. It is a transitional phase between childhood and adulthood. In humans, pubertal onset typically occurs between ages eight and 13 in females and nine and 14 in males. It is driven by increasing levels of sex steroid hormones—primarily estrogen and progesterone in females, and testosterone in males.[4]

During puberty, sex steroid hormones promote skeletal growth, muscular development, and neurologic development. In females, estrogen initiates breast development, menarche, ovulation, and changes in body composition and skeletal morphology.[5] In males, the androgenic surge results in testicular enlargement, penile growth, spermatogenesis, deepening of the voice, and the emergence of secondary sexual characteristics such as facial and body hair. Spermatogenesis in males and ovulatory cycles in females mark the attainment of fertility.

7.1.2 Tanner Stages of puberty

Physicians use a system known as Tanner Staging to document the physical progression of puberty based on a physical examination.[6] This framework delineates five stages of maturation, from a prepubertal baseline (Stage 1) to full adult development (Stage 5). Intermediate stages capture transitional morphological and physiological characteristics.

In females, Tanner Stage 2 commences with the growth of breast tissue (thelarche), followed by hair growth (pubarche), and then the first period (menarche), typically by Tanner Stage 3 or 4. Menarche typically occurs one to two years after thelarche, at an average age of 12-13 years. The first egg release (ovulation) generally occurs within the first year following menarche, typically at Tanner Stage 4. Ovulatory function stabilizes approximately one year after menarche. Female pubertal development is accompanied by bone growth, body hair growth, widening of the hips, redistribution of fat to the hips

[4] Breehl & Caban (2025).
[5] Kuohung & Hornstein (2024).
[6] Tanner (1962).

and breasts, and enlargement of both internal reproductive organs (uterus, ovaries) and external genitalia (labia, clitoris).[7]

In males, the initiation of Tanner Stage 2 is typically identified by increased testicular volume, followed by growth of the penis, emergence of pubic and later facial hair, and a rapid increase in lean body mass and skeletal size driven by androgens. There are significant increases in bone and muscle mass and thickening and elongation of the vocal cords results in voice deepening. First ejaculations (spermarche) generally occur about one year after the onset of puberty, with full gamete maturation following approximately one year later.[8] Spermatogenesis generally occurs during Tanner Stage 4.[9]

7.1.3 Neuroendocrine regulation of puberty

Puberty is initiated and sustained by complex endocrine signaling. In the brain, the anterior pituitary, in response to pulsatile gonadotropin-releasing hormone (GnRH) release from the hypothalamus, secretes luteinizing hormone (LH) and follicle-stimulating hormone (FSH). Collectively termed gonadotropins, LH and FSH act on the gonads (ovaries and testes) to stimulate the synthesis of sex steroids and promote gametogenesis.[10]

7.2 Puberty blockers and central precocious puberty

In central precocious puberty (CPP)—a condition occurring in one out of 5,000 to one out of 10,000 children, more often in girls[11]—the pituitary gland is activated prematurely, sometimes even during infancy or early childhood.[12] This leads to early-onset, or precocious, pubertal development. CPP is associated with several potential negative

[7] Breehl & Caban (2025).
[8] Breehl & Caban (2025); Kota & Ejaz (2023).
[9] Emmanuel & Bokor (2022).
[10] In males, LH stimulates Leydig cells to produce testosterone while FSH targets Sertoli cells to facilitate spermatogenesis. In females, LH and FSH coordinate estrogen production and follicular development in the ovaries.
[11] Eugster (2019). Although there are some genetic causes of CPP, it is usually idiopathic, meaning the cause is unclear. Females are generally treated for CPP with PBs if puberty occurs at age six or younger, males are generally treated if puberty occurs at age eight or younger (Ergun-Longmire et al., 2023).
[12] E.g., Nienaber & Van Der Walt (1991); Yoon & Kim (2016).

health outcomes, including decreased adult height due to early presence of sex hormones causing premature epiphyseal fusion.

GnRHa (puberty blockers or PBs) have been approved by the Food and Drug Administration (FDA) for use in the treatment of CPP. The evidence to date comparing large populations of untreated patients to treated patients suggests that, at least for appropriately chosen female patients, treatment of CPP with PBs is associated with increased height attainment and lower body mass index (BMI).[13]

When PBs are used for CPP, the medication is discontinued when the child reaches a more typical age for pubertal onset, allowing normal puberty to resume. The goals include facilitating normal timing of puberty, so that the patient goes through puberty alongside peers (as opposed to significantly before). Although FDA-approved for this indication, PBs—like all medications—are associated with risks and side effects, even when used for CPP.

7.3 Puberty blockers and gender dysphoria

The use of PBs to arrest normally timed puberty is the central element and original contribution of the Dutch Protocol. PBs act directly on the pituitary gland to significantly reduce the release of LH and FSH. Continuous administration of these agents desensitizes GnRH receptors, suppressing LH and FSH secretion, and consequently arresting the production of endogenous sex steroid hormones. In females, this causes the cessation of normal menstrual function, if it has begun. In males, sperm production is halted or forestalled. PBs have not been approved by the FDA for the indication of gender dysphoria (GD); they are used “off-label” in pediatric gender medicine (PGM).[14] Unlike in CPP, use of PBs for PMT is not FDA-approved and safety data are lacking.

Using PBs to stop normally timed puberty effectively induces hypogonadotropic hypogonadism (HH), a condition characterized by the failure of the pituitary to

[13] Luo et al. (2021).
[14] GnRHas have been approved by the U.S. Food and Drug Administration (FDA) for various indications, with effects that can differ significantly depending on their application. For instance, the GnRHa leuprolide (commonly marketed as Lupron) is FDA-approved for androgen deprivation therapy in adult males with prostate cancer and for estrogen deprivation in adult females with endometriosis. It has also been FDA-approved to treat central precocious puberty (CPP).

appropriately release gonadotropins. As a result, the gonads are unable to produce the sex-specific hormones testosterone or estrogen. Pubertal development is disrupted, halting the progression of physical and reproductive maturity. Left untreated, clinical research shows HH is associated with a range of risks including infertility and decreased bone mineral density, elevating the risk of osteoporosis and fractures.[15]

Although PBs for GD are typically indicated for short-term use (about two years), this time range may be considerably longer for some patients.[16] The reasons for the apparent deviation from the original Dutch Protocol in regard to the length of PB use remain unstudied, but may include increasingly younger social transition ages which 'necessitate' pubertal blockade at increasingly younger ages to allow young patients to continue living in "stealth,"[17] as well as the medical treatment of youth who identify as nonbinary and wish to maintain a sex-ambiguous appearance for an extended period of time.[18]

7.3.1 Developmental risks of blocking normal puberty

One of the key rationales for using PBs in CPP is to allow the child to experience normative psychosocial development alongside same-age peers. By contrast, in PMT, patients are maintained in a prepubertal or early pubertal stage while their peers developmentally progress. This has potential sequelae for the adolescent's psychosocial development.[19]

7.3.2 Bone mineral density and skeletal development

Puberty is recognized as providing a critical window for the accrual of peak bone mass. Sex steroid hormones play an essential role in the mineralization of the skeleton.[20] Failure to reach peak bone density may lead to increased risk of osteopenia,

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[15] Zhu & Chan (2015).
[16] A Cambridge Health Alliance fact sheet, for example, discusses using puberty blockers for up to four years (Cambridge Health Alliance, n.d.).
[17] The Cass Review's qualitative research program found that for prepubertal children who underwent full social transition "living in stealth appears to increase a child's level of stress and anxiety with resultant behaviour and mental health problems. These included social withdrawal, with children becoming increasingly isolated, including resorting to home-schooling or tutoring and even rarely leaving their house" (Cass, 2024a, p.159).
[18] Notini et al. (2020).
[19] This is noted in Vrouenraets et al. (2022), for example.
[20] Elhakeem et al. (2019).

osteoporosis, and fractures later in life, including debilitating fractures of the spine and hip. In older adults, hip fractures are particularly concerning, as they significantly elevate the risks of morbidity and mortality.[21]

Because of the known physiological role of sex steroid hormones in skeletal development, the original Dutch research acknowledged the possibility of negative effect on bone mineralization. Researchers measured 'Z-scores,' a measure comparing individual bone density to age- and sex-matched population norms, and these scores decreased after PBs in the original Dutch cohort.[22] Since then, multiple longitudinal, observational studies on pediatric patients undergoing medical transition have consistently demonstrated decreases in Z-scores with PB use.[23] In addition to decreases in the *average* scores, a re-analysis of the United Kingdom (U.K.) data found that one third of the puberty-blocked patients had a Z-score of below -2 (indicating osteoporosis) for hip, and more than one quarter of patients had low Z-scores for spine.[24] Fracture rates have not been reported alongside Z-scores in this literature.[25]

When PBs are followed by CSH, as has occurred in studies over 90% of the time, bone mineralization will increase, but a critical developmental window for bone density accrual during adolescence may have been missed or foreshortened, as bone density accrual slows during the 20s and then begins to decline. These patients may never reach the peak bone density they otherwise would have achieved. Research on medium and long-term outcomes is limited.[26] Due to the novel nature of PMT, no studies have yet followed patients into middle age or late adulthood.

7.3.3 Neurocognitive and psychosocial development

The human brain undergoes substantial reorganization during adolescence, including synaptic pruning and myelination, processes that are influenced by sex steroid

[21] Bentler et al. (2009).
[22] Delemarre-van de Waal & Cohen-Kettenis (2006).
[23] E.g., Boogers et al. (2023); Carmichael et al. (2021); Ciancia et al. (2024); Delemarre-van de Waal & Cohen-Kettenis (2006); Joseph et al. (2019); Klink et al. (2015); Navabi et al. (2021); Schagen et al. (2020); Stoffers et al. (2019); Van der Loos, Vlot et al. (2023); Vlot et al. (2017).
[24] Biggs (2021).
[25] E.g., Roy et al. (2024).
[26] Two longer-term studies (Schagen et al., 2020; van der Loos, Vlot et al., 2023) found Z-scores returned to pre-treatment baseline after 3-11 years of subsequent CSH treatment in females, but not in males.

hormones. Research suggests that sex steroid hormones impact brain regions associated with executive function, emotion regulation, and social cognition.[27] The precise neurocognitive effects of puberty suppression remain understudied,[28] and researchers in this field have recognized the limitations of the evidence in this area.[29] A recent literature review concluded that the effect of PBs on neurocognitive development is unknown, but that "there is some evidence of a detrimental impact of pubertal suppression on IQ [intelligence quotient] in children."[30] However, a 2022 Dutch study found that in patients treated with PBs the associations between pretreatment IQ and eventual education achievement were similar to population norms (the study did not longitudinally measure IQ).[31] The Cass Review has raised concern over the potential harm and unknown effects of pubertal suppression on the developing brain,[32] noting that "[t]here is increasing evidence that the changes in brain maturation described above are driven by a combination of chronological age and sex hormones released through puberty."[33]

7.3.4 Reproductive maturation

By halting the development of sex characteristics, PBs interrupt the maturation of reproductive anatomy and function. Suppression of the HPG axis can impair gametogenesis, potentially resulting in permanent infertility if CSH are started thereafter, particularly when gonadal maturation is not completed prior to the interruption of normally-timed puberty.

In adult males initiating estrogen for medical transition, testicular atrophy results, leading to impaired fertility or infertility that may be irreversible (even if estrogen were to

[27] Cservenka et al. (2015); Gonnabathula & Yakubu (2023); Macoveanu et al. (2016); Pillerová et al. (2022).
[28] One cross-sectional study (which cannot methodologically suggest causation) found poor executive functioning in patients taking PBs >1 year, but their baseline functioning before PBs was unknown (Strang et al., 2022). Another cross-sectional study reported similar executive functioning between patients on PBs and patients not on PBs (Staphorsius et al., 2015). Arnoldussen et al. (2022), another study, is discussed in the text.
[29] Chen et al. (2020).
[30] Baxendale (2024).
[31] Arnoldussen et al. (2022).
[32] Cass (2024a, p. 115).
[33] Cass (2024b, p. 104).

be discontinued).[34] However, adult males may choose to cryopreserve sperm prior to initiation of estrogen. This is not the case with children or early adolescents.[35] Spermatogenesis generally occurs in Tanner Stage 4 of puberty.[36] In PMT, if PBs are started in Tanner Stage 2, prior to gamete maturation, and estrogen is started thereafter (as is likely), cryopreservation of sperm cannot be completed beforehand.[37] Additionally, fertility may be affected in females initiated on PBs who proceed to take testosterone.[38] Effect of testosterone on the reproductive tract makes the likelihood of conception, pregnancy, and birth uncertain.[39] Maternal and fetal outcomes under these circumstances are also poorly studied.

It is possible that CSH use after pubertal arrest could permanently damage the immature gonadal tissues, leading to sterilization.[40] If the gonads are arrested in an immature state due to prolonged use of PBs, and this is followed by administration of CSH, there is no proven physiological mechanism by which fertility can reliably be re-established. The likelihood of permanent infertility will be substantially increased.[41,42]

With respect to fertility preservation (FP), techniques can range from relatively simple to technically challenging to not currently viable, depending on the patient's sex and Tanner Stage of development. For example, males who have undergone spermarche can produce a semen sample for long-term storage. However, males who have puberty

[34] Cheng et al. (2019); Deutsch (2020a).
[35] Fertility preservation for natal males in early puberty remains a theoretical and experimental undertaking, with no clinically validated protocol currently available (Laidlaw et al., 2025).
[36] See above, Section 7.1.2.
[37] The original Dutch research acknowledged that infertility would result for males initiated on PBs in Tanner Stage 2 and on estrogen thereafter: "In early pubertal boys, the hypogonadotrophic state will block the development of fertility" (Delemarre van de Waal & Cohen-Kettenis, 2006, p. S134).
[38] Cheng et al. (2019). Although pregnancies can occur in adult females taking testosterone, less is known about pregnancy in females who underwent PMT in childhood/adolescence.
[39] Laidlaw et al. (2025).
[40] See the subsequent section for specific effects of CSH.
[41] It should be noted that PBs for CPP does not negatively impact fertility. In pediatric medical transition, because PBs are generally the first part of a continuum including CSH, infertility is a likely result of treatment (depending on sex and Tanner Stage of patient).
[42] There is controversy regarding minors' capacity to provide informed consent to potential loss of fertility with respect to PMT. E.g., "Can these minors make adequately autonomous decisions in the present that may impact their opportunities in the future? This is less a question of decision-making capacity…than a matter of sufficient life experience to know their future desires … How to maintain an "open future" for transgender youth is a common concern of parents and healthcare professionals" (Harris et al., 2020, p. 2459). See also Jorgensen & Masson (2024). In a study of patients in their early 30's who had begun hormonal interventions at age 15, 23% expressed regret about infertility (de Nie et al., 2024).

blocked at Tanner Stage 2 will have immature testicles; FP necessitates testicular tissue cryopreservation, which currently remains entirely experimental.[43] For the mature female patient, oocyte preservation involves an invasive procedure (and is costly). For females in early Tanner Stages, techniques such as ovarian tissue cryopreservation, although technically possible,[44] have yet to be shown to result in viable pregnancies in patients who have undergone PMT.

Most studies on fertility preservation in adolescents with GD undergoing PMT have shown very low rates of FP, between 0% and 4.7% of patients.[45] One study in which male patients were able to access fertility preservation via testicular biopsy reported that 10 out of 23 patients (43%) were able to have gametes cryopreserved prior to PB initiation (Tanner Stages were not reported).[46]

7.3.5 Risks of sexual dysfunction

Concerns have been raised about the potential consequences of PMT on sexual function, particularly with respect to development of the capacity for sexual desire, arousal, and orgasm (phases of the sexual response cycle). The Tanner Stage (see Section 7.1.2) in which PBs are initiated is an important consideration:

> ... the extent to which individuals have experienced endogenous puberty could influence later sexual functioning. [PBs] inhibit sex steroid exposure of genitalia, which are highly sensitive to androgens during the typical pubertal timeframe ... Interference through [PBs] affects genital growth and development during a possibly critical period, with potential effects on subsequent sexual function.[47]

In females undergoing PMT, suppression of sex hormones with PBs may impede growth of genitalia,[48] and may also result in decreased blood flow to the clitoris and decreased sensation (as occurs in post-menopausal women).[49] In males undergoing PMT, suppression of sex hormones with PBs arrests genital development. As most males

[43] Klipstein et al. (2020).
[44] Practice Committee of the American Society for Reproductive Medicine (2019).
[45] Chen et al. (2017); Chiniara et al. (2019); de Nie et al. (2024); Nahata et al. (2017).
[46] Pang, Peri et al. (2020).
[47] van der Meulen, Arnoldussen et al. (2025, p. 1494).
[48] van der Meulen, Arnoldussen et al. (2025).
[49] See Section 7.5.1.

proceed to estrogen after PBs, the ongoing androgen deprivation (which is expected to be lifelong) may have ramifications for development of sensation in the genitals, as well as for capacity to experience sexual desire and/or arousal.

In 2021, Marci Bowers—a leading vaginoplasty surgeon and then-president-elect of the World Professional Association for Transgender Health (WPATH)—voiced concerns that male patients who commenced PBs at Tanner Stage 2 and subsequently received CSH were physiologically anorgasmic, prior to and following vaginoplasty surgery.

Many of these patients reported no history of genital sexual sensation before undergoing vaginoplasty. After vaginoplasty, the constructed clitoris provided no meaningful tactile or erogenous response. Bowers suggested that this issue had not been adequately addressed in discussions of informed consent for youth undergoing puberty suppression.[50]

Despite these concerning clinical observations, there is a striking paucity of research on sexual function outcomes in this population.[51] The potential for anorgasmia and sensory

[50] Shrier (2021b). It has been questioned "whether even highly intelligent children who have not had sexual experiences can meaningfully comprehend the loss of future sexual function and reproductive abilities" (Levine et al., 2022a, p. 720).

[51] Two Dutch studies have published data from one small patient cohort: Bungener et al. (2020); van der Meulen, Bungener et al. (2025). Although the researchers found that for the males, sexual function outcomes after vaginoplasty were similar regardless of which Tanner Stage of puberty PBs had been started in, experts pointed out that the small study was methodologically limited due to sample size (therefore unable to reliably compare different subgroups) and that the patients frequently reported serious sexual difficulties/dysfunction (orgasm difficulties, pain, shame about genitalia) (Clayton et al., 2025). A subsequent article (van der Meulen, Arnoldussen et al., 2025) assessed an overlapping cohort from the Amsterdam clinic at an older age (around 29). Although the claimed findings were positive—the timing of puberty suppression did not affect sexual function—the sample included only 20 males, for whom the nonresponse rate was 68%. The study had many other methodological limitations (e.g. related to small sample size and lack of statistical power, absence of separate analysis of subgroup blocked at Tanner Stage 2, misleading comparisons to population-level sexual dysfunction rates) (Society for Evidence-Based Gender Medicine, 2025). These three studies of overlapping patient cohorts comprise the entirety of the peer-reviewed longitudinal clinical research on sexual function outcomes after PMT. Although van der Meulen, Arnoldussen et al. (2025) hypothesized, based on evidence from physiology of sexual development, that "[patients] treated with [PBs] in early puberty will report lower rates of sexual satisfaction and more sexual dysfunctions than those treated with [PBs later in puberty] or started [on CSH] in adulthood," the authors then *rejected* this hypothesis ("... in contrast to what is hypothesized ... suppressing endogenous puberty early does not seem to result in an increased risk of sexual dysfunctions") even though the study was underpowered and the between-group comparisons did not meet the threshold for statistical significance. Hypothesis rejection in this setting is inconsistent with research norms.

dysfunction merits serious consideration, especially given the irreversible nature of some interventions and the centrality of sexual health to overall quality of life.

There is also a lack of published research regarding sexual function outcomes in females who underwent PMT with PBs followed by CSH.[52]

7.4 Cross-sex hormones and gender dysphoria

Testosterone for females and estrogen for males are routinely used in PGM to induce changes in the secondary sex characteristics that resemble those typical of the opposite sex. In males, estrogen is frequently used alongside a testosterone blocker or PB to enhance estrogen's effects.

7.4.1 Physical effects of cross-sex hormones

As described above, puberty involves the maturation of primary sex characteristics—the male and female genitalia—and the entire reproductive system, enabling the production of mature gametes: sperm in males and ova in females. The ES guidelines for PMT describe titration of testosterone for females and estrogen for males as the "Induction of Puberty," a term that is misleading.[53] Under the influence of high doses of testosterone, females may develop facial and body hair, cystic acne, male pattern scalp hair distribution, clitoral growth, changes in musculature, thickening of vocal cords leading to voice deepening, and alterations in fat deposition. Similarly, males receiving high doses of estrogen may experience significant breast tissue growth (gynecomastia), reduced muscle mass, change in skin texture, and may develop a more typically female pattern of fat distribution. These physical changes reflect the body's response to unusually high levels of sex steroids, not actual opposite-sex pubertal development. In fact, development of reproductive capacity—definitionally, the purpose of puberty—may be hindered. The physiological end point of puberty—sexual maturation that makes possible reproduction—is not and cannot be obtained via PMT.

[52] Two of the above-cited methodologically limited studies (Bungener et al., 2020; van der Meulen, Arnoldussen et al., 2025) also reported outcomes for female patients.
[53] Hembree et al. (2017, p. 3884), for example. See also Coleman et al. (2022, p. S115), and Chapter 2.

7.4.2 Dosing of cross-sex hormones

In WPATH and ES guidelines, the principal goal of CSH administration is to induce physical characteristics typical of the opposite sex. When hormone levels rise beyond the typical reference range for a person's sex, they are considered supraphysiologic. ES guidelines suggest that the sex an individual identifies as—as opposed to their biological sex—should determine the target reference range for hormonal concentrations.[54] Critics have argued that perceived identity does not alter physiological processes and that such a belief can result in inappropriate and potentially dangerous hormone dosing.[55]

7.4.3 Hyperandrogenism in females

Hyperandrogenism refers to the condition of abnormally elevated androgen levels—most commonly testosterone—in the bloodstream. Among adult females, typical serum testosterone levels range between 10–55 ng/dL.[56] In certain pathological conditions, testosterone may rise well above this range.

ES guidelines for cross-sex hormone administration in females recommend testosterone between 320–1000 ng/dL, comparable to, or exceeding levels found in endocrine disorders.[57] These concentrations represent a six to 100-fold increase above physiologic norms for females, inducing hyperandrogenism. Hyperandrogenism is also associated with health risks, discussed below.

7.4.4 Hyperestrogenemia in males

Hyperestrogenemia is defined as elevated blood levels of estrogens, such as estradiol, above the normal physiological range. In males, a standard reference range for total estrogen is approximately 56–213 pg/mL.[58] Certain disease states are known to cause

[54] Rosenthal et al. (2019).
[55] Laidlaw et al. (2021).
[56] Labcorp (2025b). There is variability in laboratory reference ranges for testosterone (as well as for estrogen; see Section 7.4.4 below).
[57] Hembree et al. (2017).
[58] Labcorp (2024).

excess estrogen. For instance, some adrenal tumors can elevate estrogen levels by a factor of three to ten.[59]

In PMT, supraphysiologic estrogen levels are intentionally induced through the off-label use of high doses of estrogen. ES guidelines advise titration of estradiol to levels between three and 25 times higher than the typical male range to induce the development of female-typical secondary sex characteristics such as breast tissue.[60]

7.4.5 Effects of testosterone on the female reproductive system

Testosterone use causes histopathological changes in the female reproductive tract.[61] Given the potential—though not well-defined—risk of cancer in the female reproductive tract, ES guidelines recommend that "health care providers should determine the medical necessity of a laparoscopic total hysterectomy as part of a gender-affirming surgery to prevent reproductive tract cancer."[62] WPATH's clinical practice guideline[63] has not adopted the same recommendation, but there is limited reliable evidence regarding the long-term cancer risks associated with testosterone use in the female reproductive tract. Testosterone can cause reproductive organ atrophy, including thinning and atrophy of vaginal epithelium,[64] persistent pelvic pain and discomfort,[65] and pelvic floor dysfunction.[66]

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[59] Cavlan et al. (2010).
[60] Based on adult male estradiol reference range 8-35 pg/mL (Labcorp, 2025a). ES guidelines: Hembree et al. (2017).
[61] A review of 11 histopathologic studies of resected ovaries found that 34.9% exhibited polycystic-appearing ovaries, and 0.7% had benign ovarian neoplasms (Toland et al., 2023). In another study of females aged 18-56, 57% of 35 ovariectomy cases showed multiple bilateral cystic follicles, and 80% of 40 uterine resections displayed endometrial stromal fibrosis. Abnormal tissue growth was also noted in the vagina and cervix following hysterectomy and vaginectomy. The most common findings included transitional cell metaplasia and the development of prostatic-type glands (Lin et al., 2022). A separate study found that 100% of vaginectomy specimens contained abnormal prostatic tissue growth (Xu et al., 2022).
[62] Hembree et al. (2017).
[63] Coleman et al. (2022).
[64] In 2020, a whistleblower from Washington University in St. Louis clinic described a case in which a female minor taking testosterone called the clinic due to vaginal bleeding: "In less than an hour she had soaked through an extra heavy pad, her jeans, and a towel she had wrapped around her waist … We found out later this girl had had intercourse, and because testosterone thins the vaginal tissues, her vaginal canal had ripped open. She had to be sedated and given surgery to repair the damage" (Reed, 2023a). Reportedly, multiple patients at this clinic had problems with vaginal lacerations.
[65] Patients have sought hysterectomies due to these symptoms; e.g., Zwickl et al. (2023).
[66] Da Silva et al. (2024); Tordoff et al. (2023); Zwickl et al. (2023).

7.4.6 Effects of estrogen on the male reproductive system

Testicles have two primary functions: producing testosterone and generating sperm capable of fertilizing an ovum. The use of estrogen in accordance with the ES and WPATH guidelines results in impairment of normal testosterone production and significant abnormal histologic changes to the male reproductive system.[67] These findings point to widespread structural reconfiguration of testicular tissue in response to prolonged exposure to the high levels of estrogen used in medical transition.

7.4.7 Cardiovascular and metabolic risks

Among the most significant long-term risks associated with CSH is an increase in cardiovascular risk factors. A 2018 review found that patients taking CSH had an elevated risk of heart attack and CV mortality compared to controls.[68]

Several studies and reviews have found increased risk of CV events like heart attacks and strokes in females taking testosterone.[69] This is thought to result from testosterone's effects on underlying metabolic factors related to CV risk. In females, testosterone can cause elevated blood pressure, polycythemia, and atherogenic

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[67] In one study of 99 testicle specimens, Leydig cells (crucial for producing testosterone) were completely absent or extremely diminished in 80% of cases. There was a significant average decrease in the diameter of the seminiferous tubules (site of spermatogenesis) when compared with controls, with 82% showing peritubular fibrosis, which interferes with tubular function (Matoso et al., 2018). In another study, 74% of specimens had abnormal basement membrane thickening (Riva-Morales et al., 2025). This mimics findings seen in conditions like cryptorchidism (undescended testes), which are associated with infertility (Mittal et al., 2017). In one of the abovementioned studies, all 125 testicular specimens showed atrophic changes and decreased spermatogenesis, with 71.2% having no sperm production at all (Riva-Morales et al., 2025). In another study, 80% of testicular tissue samples from males on estrogen showed maturation arrest, meaning that although the early stages of the sperm development may have begun, maturation to fully functioning spermatozoan did not occur (Matoso et al., 2018). These findings point to widespread structural reconfiguration of testicular tissue in response to prolonged exposure to high levels of estrogen used in medical transition. Other structures affected by estrogen (and/or androgen deprivation) include the epididymis, rete testes, and prostate (Crowley et al., 2023; Matoso et al., 2018). A long-term analysis involving 86 patients who underwent orchiectomies after a median duration of 7.5 years on estrogen therapy found a clear correlation between the length of hormonal treatment and the degree of tissue abnormality (Marins et al., 2024). This study discussed "[c]ompromise in integrity of blood-testis-barrier with *increased vulnerability to cytotoxic and immune damage*; impaired adhesion with premature detachment of spermatids from Sertoli cells, causing altered shaping in spermatids; germ cells phagocitation" as theoretical mechanisms of impaired spermatogenesis (emphasis added).

[68] Irwig (2018).

[69] E.g., Nota et al. (2019), van Zijverden et al. (2025). A systematic review found moderate and high certainty evidence of some incidence of cardiovascular events in young females under 26 years old (Miroshnychenko, Ibrahim et al., 2025).

changes in the lipid profile.[70] Longitudinal studies of PMT have reported increases in BMI (and/or fat mass) after initiation of CSH[71] and PBs.[72] Atherogenic changes to the lipid profile have also been reported.[73]

With respect to polycythemia, elevated hematocrit levels are known to increase blood viscosity, raising the risk of thromboembolic and CV complications. Among females, even modest elevations in hematocrit levels have been independently associated with heightened risks of CV disease, coronary events, and CV-related mortality.[74]

In males taking estrogen, studies have shown increased risk of CV events like venous thromboembolism and stroke.[75] One recent study found that, after adjusting for socioeconomic status, there was a decreased risk of heart attacks, although the risk of venous thromboembolism remained elevated.[76]

7.4.8 Other risks associated with cross-sex hormones

In both sexes, CSH use may be associated with early mortality.[77] In females taking testosterone, breast tissue undergoes structural remodeling, often with increased fibrous connective tissue and decreased glandular volume.[78] There is also some concern about possible increased risk of breast and ovarian cancer.[79] In males, some studies suggest that estrogen may increase risk of developing multiple sclerosis[80] and

[70] Glintborg et al. (2024); Safer & Tangpricha (2019).
[71] Boogers et al. (2024); Jarin et al. (2017); Klaver et al. (2018, 2020).
[72] Carmichael et al. (2021); Ciancia et al. (2024); Delemarre-van de Waal & Cohen-Kettenis (2006); Fisher et al. (2024).
[73] Klaver et al. (2020); Olson-Kennedy, Okonta, et al. (2018). Millington et al. (2021) found atherogenic changes only in females, not in males.
[74] Gagnon et al. (1994). In a longitudinal cohort study of 1,073 adult females taking testosterone (Madsen et al., 2021), approximately 24% of participants developed hematocrit values ≥50%, a threshold commonly used to define severe erythrocytosis. While the study did not report prevalence in the intermediate range (hematocrit levels between 45% and 50%) it is reasonable to infer that a similar or greater proportion of individuals would fall within this bracket.
[75] Nota et al. (2019) reported a nearly five-fold (4.6x) elevation in risk of venous thromboembolism, and Getahun et al. (2018) reported a nearly ten-fold (9.9x) elevation in risk of stroke. van Zijverden et al. (2025) reported that after adjusting for socioeconomic status (estimated by education, employment, and income) there was a nearly two-fold (1.8x) elevation in risk of venous thromboembolism, but (in contrast to the other studies) no elevation in risk of stroke.
[76] van Zijverden et al. (2025) reported a two-fold decrease (1.5x) in risk of heart attacks after adjusting for socioeconomic status.
[77] C. J. de Blok et al. (2021).
[78] Grynberg et al. (2010).
[79] Hembree et al. (2017).
[80] Papkoor et al. (2016); White et al. (2022).

thyroid cancer,[81] and that it may lead to a decrease in brain volume.[82] However, research in these areas is still preliminary. While breast cancer is uncommon in natal males, data suggest that high-dose estrogen therapy increases this risk.[83] Other effects of estrogen may include diminished libido, erectile dysfunction, and loss of spontaneous erections.[84]

7.5 Surgery and gender dysphoria

WPATH provides an extensive list of surgeries it considers appropriate treatments for GD.[85] All surgeries carry risks,[86] some of which are amplified when surgery follows PBs and CSH. Further, surgeries to remove healthy and functioning organs introduce a unique set of iatrogenic harms not encountered in other areas of medicine. An example is mastectomy performed as part of PMT, which results in an inability to breastfeed and potential loss of nipple sensation.[87]

7.5.1 Surgical problems related to early pubertal blockade

Males who initiate PBs at Tanner Stage 2 and then proceed to estrogen have narrowed options for future genital surgery, should this be desired. PBs arrest development of male genitalia. If PBs are started in Tanner Stage 2 and estrogen is started some time thereafter, the male genitalia will never develop beyond the prepubertal or early-pubertal state. For patients who proceed with vaginoplasty later in life, this may foreclose the

[81] Derwahl & Nicula (2014).
[82] Pol et al. (2006); Seiger et al. (2016); Zubiaurre-Elorza et al. (2014).
[83] C. J. M. de Blok et al. (2019).
[84] Hembree et al. (2017). Of note, some or all of these effects on sexual function (diminished erections, for example) may be desired by certain patients.
[85] According to WPATH's SOC-8, even highly unusual surgeries such as non-binary mastectomies (where female breasts are reshaped to resemble gynecomastia in males), penis-preserving vaginoplasty, and vagina-preserving phalloplasty (to provide patients with both sets of genitals), and genital nullification procedures (involving genital removal) are considered medically-necessary procedures for some patients. Only phalloplasty for females has a minimum recommended age of 18 (Coleman et al., 2022). In 2024, a Canadian patient successfully sued a provincial health insurer, who had declined to cover "penile-preserving vaginoplasty" surgery, considering it experimental. Media coverage noted that "…the court decided that [this] procedure…[was] consistent with the World Professional Association for Transgender Health (WPATH) Standards of Care, the leading authority on gender-affirming medical and surgical care, especially as it recommends individualized treatment plans" (Arsenych, 2024).
[86] E.g., bleeding, infection, scarring, and risks related to anesthesia.
[87] A mastectomy removes the mammary glands together with the ducts that transfer milk from them to the nipple. Loss of nipple sensation is invariably mentioned by surgeons performing "top surgery" as a potential side effect, although there is very low certainty evidence about the magnitude of the risk in adolescents and young adults (Miroshnychenko et al., 2025).

surgical option of penile inversion vaginoplasty due to lack of sufficient genital tissue for this procedure. This issue was recognized in the original Dutch papers,[88] but over subsequent decades almost no research has been published on this topic. A single Dutch study found greatly increased odds of receiving intestinal vaginoplasty (compared to penile inversion) in male patients with history of pubertal blockade.[89] Intestinal vaginoplasty is a more technically complex and risky procedure.[90] One notable and tragic case involved a member of the original Dutch Protocol research cohort who died from necrotizing fasciitis at age 18 following an intestinal vaginoplasty conducted because of inadequate genital tissue.[91]

7.6 Other risks associated with hormonal interventions or surgeries

The use of endocrine interventions affects multiple organ systems beyond the reproductive tract. In addition, there are psychological risks associated with PMT.

7.6.1 Adverse psychiatric effects

The FDA-mandated labeling for testosterone cautions about abuse potential, noting: "Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication ... Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions."[92] These effects have been reported in males and females, including adolescents.

Research on anabolic steroid misuse has demonstrated associations with severe psychiatric problems, including mood instability, psychosis,[93] and dependence.[94] The most frequently observed symptoms include irritability, aggression, euphoria, inflated self-perception, impulsivity, and risk-taking behaviors. Additional manifestations may include acute psychotic episodes, worsening of tic disorders or depression, and

[88] Delemarre-van de Waal & Cohen-Kettenis (2006).
[89] van de Grift et al. (2020).
[90] Lee et al. (2023).
[91] Negenborn et al. (2017).
[92] Actavis Pharma, Inc. (2018).
[93] R. C. W. Hall et al. (2005).
[94] Skauen et al. (2023).

delirium-like states. One study assessing medium (300–1000 mg/week) and high (>1000 mg/week) anabolic steroid use in men found that 23% of users met diagnostic criteria for a major mood disorder, including mania, hypomania, or depression, while 3.4-12% developed psychotic features.[95]

In an analysis of the FDA's Event Reporting System (FAERS) database for people using CSH for medical transition, 88% of adverse drug reactions were classified as serious.[96] Without an idea of denominators, individual risks are not possible to quantify. Among the 83 reports regarding females using testosterone, 87.8% of the events were deemed serious, with two reported deaths (2.4%) and 25 hospitalizations (30.5%).[97] Reported psychological harms included anxiety, depression, mood swings, suicidal ideation and behavior, aggression, dissociation, and self-harm. More extreme symptoms, such as antisocial behavior and homicidal ideation, were also documented.[98] It is unknown whether these patients had testosterone levels between 320 to 1000 ng/dL (the range recommended by the Endocrine Society for females undergoing medical transition), or levels outside of this range. What is known is that the patients were female, were categorized as having a "transgender" related treatment indication, presented with psychiatric problems, and were on testosterone.[99] Although it is not possible to determine causation from FAERS data, this underscores the importance of considering adverse psychiatric events as a potential risk in female patients initiating testosterone for medical transition.

A separate study from Sweden found an elevated rate of criminal convictions in natal females who had taken testosterone and undergone gender-transition surgery, compared to age-matched controls. This study also found that adults who had undergone medical and surgical transition had 19 times the rate of suicide deaths and nearly three times the rate of all-cause mortality and inpatient psychiatric care compared to age and sex-matched controls.[100] Elevated suicide rates (compared to the

[95] R. C. W. Hall et al. (2005).
[96] Gomez-Lumbreras & Villa-Zapata (2024).
[97] Laidlaw & Jorgensen (2024).
[98] Laidlaw & Jorgensen (2024).
[99] See Gomez-Lumbreras & Villa-Zapata (2024), Table 2.
[100] Dhejne et al. (2011).

general population) have also been reported in other studies.[101] As with FAERS data, it is impossible to determine causation, in part due to presence of confounders such as co-occurring mental health conditions.

7.6.2 Detransition and regret

In males, estrogen causes breast growth and infertility that may be irreversible even with cessation of CSH.[102] In females, irreversible virilizing effects of testosterone include face and body hair growth, deepening of the voice, clitoral growth, and male-pattern baldness.[103] Patients of any age may experience regret regarding the permanent physical and physiologic effects of CSH, regardless of how they identify. For example, stably transgender-identified patients may regret loss of fertility. Developing baldness, or chafing/discomfort caused by clitoromegaly, may lead a patient who identifies as a transgender man to regret taking testosterone. Such a patient, or (especially) a detransitioned female, may regret having had a mastectomy with the consequent loss of the ability to breastfeed.

If patients do detransition,[104] they may experience regret,[105] but some patients may integrate the physical changes into their self-concept and not experience regret.[106] Even

[101] C. J. de Blok et al. (2021) found that the standardized mortality ratio for suicide among transgender adults was 3.1 compared to the general population of the Netherlands. In Van Cauwenberg et al. (2021), five out of 177 adolescent patients died by suicide. All suicide deaths were in patients who had been started on CSH (Society for Evidence-Based Gender Medicine, 2024a). Biggs (2022) reported that four out of 15,032 patients referred to the U.K.'s pediatric gender medicine (PGM) clinic died by suicide over a ten-year period. Two of the suicides were in waitlisted patients (so probably not taking CSH). A recent U.S. study reported a suicide rate of two out of 315 patients taking CSH over a two-year period (Chen et al. 2023). See Section 4.3.4.
[102] Cheng et al. (2019); Deutsch (2020a).
[103] Deutsch (2020b).
[104] Detransition refers to reverting back to living as one's sex after having medically and/or surgically transitioned. For discussion of detransition as a phenomenon see Butler & Hutchinson (2020); Irwig (2022); MacKinnon, Expósito-Campos et al. (2023). For research based on survey data from detransitioners or their parents, see Bailey & Diaz (2023); Littman (2018), (2021); Vandenbussche (2022).
[105] Some detransitioners have described adverse experiences with CSH as well as regret; e.g., in a recent court case (DH v. Snyder Case: 21-15668, 07/07/2021, ID: 12164749, DktEntry: 22, n.d.) one patient described that testosterone "exacerbated her anxiety and depression" in addition to prompting increased aggression, risk-taking, and suicidal ideation (p. 22); another patient experiencing depression after several months of euphoria, (p. 24) and another described ongoing regret and distress due to a permanently deepened voice from testosterone and numb scars and absent breasts from mastectomy surgery (p. 18).
[106] MacKinnon et al. (2022).

proponents of PMT acknowledge that regret is a risk (e.g., the phrase “Some adolescents may regret the steps they have taken” in WPATH’s guidelines).[107]

This serious issue has been minimized with the claim that detransition and regret rates are vanishingly low. In fact, the detransition rate is unknown.[108] The ubiquitous claim that the detransition and regret rates are vanishingly low is unsupported by the evidence.[109] A U.K. population-based study not focused on minors found that about one-fifth of patients discontinued hormonal interventions within five years, with more than half of them reporting experiences of detransition and/or regret.[110] Reasons for detransition are complex[111] and can be related to external[112] or internal[113] factors. With respect to clinical research studies of children and adolescents, one study reported a 7.1% regret rate,[114] two found low rates of CSH discontinuation or reidentification with birth sex (<5%),[115] and one found a higher rate of CSH discontinuation (25%).[116]

7.7 Mortality risk

Four population-based cohort studies have found that transgender individuals appear to have higher mortality risk when compared to members of the general population of

[107] Coleman et al. (2022, p. S47).
[108] Cohn (2023).
[109] The detransition rate after PBs and CSH has been described as very low, but this is backed by little evidence. A few sources are frequently cited. One is an SR of surgery studies with limited (if any) relevance to PMT, which reported a regret rate of around 1% (Bustos et al., 2021). This SR had methodological problems, calculation errors, and included mostly studies of poor or moderate quality, many with follow-up times that were inadequate for capturing regret (Cohn, 2023; Expósito-Campos & D’Angelo, 2021). Additionally, there were issues with the ways included studies defined regret; in Wiepjes et al. (2018), for example, patients needed to report regret to their clinician and ask to start natal sex hormones. Another study was based on survey research of individuals who identified as transgender *at the time of survey completion*. Some respondents had detransitioned in the past (usually due to factors like stigma or other external difficulty) before re-identifying as transgender (Turban et al., 2021).
A survey of surgeons found respondents had rarely been asked to perform reversals (Narayan et al., 2021); Cohn (2023) noted that these findings were hard to interpret because of “unclear follow-up time, loss to follow-up, and even measurement instrument (Were questions about regret routinely asked and was there a consistent definition of regret in use?)” (p. 1944). Another study of surgical regret partly quantified regret via request for surgical reversals (Jedrzejewski et al., 2023), which Cohn pointed out would have excluded patients who do not return to their surgeons.
[110] Boyd et al. (2022).
[111] MacKinnon, Gould et al. (2023).
[112] Turban et al. (2021).
[113] Littman (2021); Littman et al. (2024).
[114] Crabtree et al. (2024).
[115] Cavve et al. (2024); van der Loos et al. (2022).
[116] Roberts et al. (2022).

similar age and sex. In the U.S., private insurance data from 2011 to 2019 indicated that transgender persons were nearly twice as likely to die as age- and sex-matched controls.[117] A Dutch cohort study that included five decades of data found that compared to their natal sex peers, transgender people had an elevated standardized mortality ratio (higher risk of death).[118] A 2023 cohort study from the U.K. found that compared to their natal sex peers, transgender people had higher risk of mortality (34 % higher for females, 60% higher for males).[119] Finally, a Swedish study that included three decades of data found that the mortality risk for transgender persons was 2.8 times that of age and natal sex matched population controls.[120]

This Review does not assess the methodological quality of these epidemiological studies or quantitatively synthesize their findings. The magnitude of the mortality risk for maintaining a transgender identity remains uncertain, as do the underlying causal factors (causes of death found to be elevated among transgender persons included suicide, cardiovascular disease, and HIV[121]). Moreover, in light of ongoing epidemiological shifts (see Section 4.3.1.1), it is unclear whether these findings extend to children and adolescents with GD. These studies further support a cautionary stance toward PMT, however, especially insofar as the Dutch cohort study found that despite changes in care of the transgender population over five decades, the elevated mortality risk has persisted, not declined.[122]

[117] Hughes et al. (2022).
[118] de Blok et al. (2021).
[119] Jackson et al. (2023).
[120] Dhejne et al. (2011).
[121] See de Blok et al., 2021; Dhejne et al., 2011; Hughes et al., 2022; Jackson et al. 2023.
[122] de Blok et al. (2021).

Chapter 8 Summary and Implications of Evidence Review

Medical and surgical interventions for children and adolescents with gender dysphoria (GD) are widely promoted as essential and even lifesaving, yet the evidence base does not support strong conclusions about their effectiveness in improving mental health or reducing GD. Analysis of the biological plausibility of harms is necessary, and suggests that some short- and long-term harms are likely (in some cases expected) sequelae of treatment.

The Food and Drug Administration (FDA) also looks at risks in this manner when making a risk/benefit determination:

> Benefit-risk planning is most valuable in cases where a challenging benefit-risk assessment can be reasonably anticipated, either because the extent of benefit is expected to be modest or is highly uncertain, or when serious adverse events of the drug can be anticipated (e.g., based on a suspected class effect, understanding of the mechanism of action, and/or early-phase or non-clinical safety findings).[1]

The FDA states that with respect to risks, it is important to understand suspected class effects, meaning the types of predicted effects that are known to occur within the same class of medications. For example, the class of diuretics called thiazides are known to cause hypokalemia (low potassium), and so this potential adverse effect must be taken into account when making a risk/benefit determination regarding thiazides.

The FDA also emphasizes the importance of understanding the physiological mechanism of action, meaning the known way in which a drug affects the body. For example, medications called beta blockers affect the beta-adrenergic receptor and by their known mechanism of action cause effects such as slowed heart rate and decreased cardiac contractility. These physiological mechanisms—and the potential adverse effects of bradycardia (slow heart rate) and reduced cardiac output (amount of

[1] Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) (2023).

blood pumped by the heart)—must be taken into account when making a risk/benefit determination regarding beta blockers.

Similarly, risk/benefit determinations regarding PMT must take into account both class effects and known mechanism of action for these interventions. Moreover, as the FDA also emphasizes, when the risks of a treatment are serious, anticipated effects must be proportionate:

> In cases where serious risks are anticipated, it is important to consider whether the risk can be outweighed by a benefit of sufficient certainty, magnitude, and clinical relevance to patients.[2]

Some of the plausible harms of PMT are serious. The likelihood of infertility when puberty blockers (PBs) are provided at the early stage of puberty and followed by cross-sex hormones (CSH) does not have to be demonstrated in a clinical trial. This is because the mechanism is well-understood and conducting a trial would amount to an unethical "parachute test."[3]

Analysis of all available data described in this section of the Review suggests that the risk/benefit profile of medical and surgical interventions for children and adolescents with GD is unfavorable.

This has implications for decision-makers—ranging from individual clinical care to guideline development, health policy, and regulation.[4] The findings of this evidence review also underscore the importance of clearly distinguishing how values and preferences are incorporated at different levels of decision-making.

At the individual level, shared decision-making must be grounded in transparency. This means that patients and their families need to be fully informed—not just about available interventions, but also about their potential benefits, harms, alternative

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[2] Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) (2023). See Chapter 13 for discussion of ethical implications.
[3] Smith & Pell (2003). The paper highlights the limitations of "gold-standard" research designs such as randomized controlled trials (RCTs) by pointing out that no RCTs have been done on the effects of jumping from a plane without a parachute. Narrow (mis)application of EBM would conclude that there is "very low certainty evidence" of death, given the dearth of high quality studies.
[4] Zeng et al. (2023); Zhang et al. (2017).

options, and the certainty or uncertainty of the supporting evidence. When this information is missing or inaccurate, the values and preferences people express may be influenced by incomplete understandings.[5]

At the level of clinical practice guidelines and health policy, values and preferences should reflect those of a population well-informed about the strength of evidence. Weak or uncertain evidence for benefits requires greater caution and flexibility, not stronger recommendations.[6]

At the regulatory level, because decisions must prioritize public health and safety, the strength of the evidence is especially important. When evidence for benefit is lacking or of very low certainty, regulatory frameworks should focus on ongoing evaluation, risk mitigation, and the collection of more robust data before allowing broad implementation. At all levels, responsible decision-making requires a clear grasp of what is known, what remains uncertain, and how this understanding informs ethical obligations of clinicians. Several of the other chapters in this Review explore these issues in greater depth.

[5] Zhang, Alonso-Coello, et al. (2019); Zhang, Coello, et al. (2019).
[6] Guyatt et al. (2008).

PART 3

CLINICAL REALITIES

Chapter 9 Review of International Guidelines

Like in other areas of medicine, clinical care for gender dysphoric (GD) youth is typically guided by clinical practice guidelines (CPGs). The aim of such guidelines is to promote practices that are proven to improve patient outcomes and reduce unwarranted variation in care. Although guidelines are not mandates and clinicians must still exercise professional judgment, they serve as important reference points that influence treatment decisions, institutional protocols, insurance coverage policies, and broader standards of medical practice.

This chapter provides an overview of CPGs that address care for youth with GD. Section 9.1 is a primer on the purpose and characteristics of trustworthy evidence-based guidelines. Section 9.2 provides an overview of the quality of the existing guidelines in pediatric gender medicine as assessed by a systematic guideline appraisal. It also discusses the newest guidelines not included in this appraisal. Section 9.3 profiles the clinical recommendations set out in the only two guidelines rated as trustworthy (both from Nordic countries).

9.1 The role and process of clinical practice guidelines

Clinical practice guidelines are a set of clinical care recommendations intended to optimize patient care.[1] While used primarily by healthcare providers, CPGs also guide hospitals in standardizing care, informing insurance coverage decisions, shaping health policy, and supporting medical education. Researchers use them to identify knowledge gaps, and legal professionals may cite them in malpractice cases. Informed patients and caregivers may also rely on CPGs to participate in shared decision-making and advocate for appropriate care.

The field of evidence-based medicine (EBM) provides several sources describing the characteristics of a trustworthy guideline.[2] According to the National Academy of Medicine (NAM),[3] trustworthy CPGs:

[1] Brignardello-Petersen et al. (2021).
[2] Brignardello-Petersen et al. (2021); Brouwers et al. (2010); Lima, Mirza et al. (2023).
[3] Formerly the Institute of Medicine.

> should be *based on a systematic review of the existing evidence*; be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups; consider important patient subgroups and patient preferences, as appropriate; be based on an explicit and transparent process that *minimizes distortions, biases, and conflicts of interest*; provide a clear explanation of the logical relationships between *alternative care options* and health outcomes, *provide ratings of both the quality [certainty] of evidence and the strength of the recommendations*; and be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.[4]

Most guideline users will focus on two core elements of guidelines: the content of the recommendations, and their strength. One of the most widely accepted approaches to rating the strength of recommendations is the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. GRADE classifies recommendations according to their direction and strength into four categories: (1) strong recommendation for an intervention; (2) conditional or weak recommendation for an intervention; (3) conditional recommendation against an intervention; and (4) strong recommendation against an intervention.[5]

In addition, there is a GRADE recommendation known as "only in research."[6] It is used sparingly in situations in which an intervention may be promising but lacks sufficient evidence to support its general use. The "only-in-research" recommendation is appropriate when three conditions are met: (1) the available evidence is of low or very low certainty, making it unclear whether the intervention provides meaningful benefit; (2) further research has a large potential to reduce this uncertainty and produce more definitive evidence; and (3) conducting such research is deemed valuable given anticipated costs and risks. This recommendation may be accompanied by a second strong recommendation not to use the intervention outside the research context.[7]

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[4] Graham et al. (2011, p. 5, emphasis added).
[5] Andrews, Schünemann et al. (2013).
[6] Agarwal et al. (2020).
[7] Andrews, Guyatt et al. (2013, p. 724); Guyatt, Oxman, Kunz et al. (2008, p. 1051).

In addition to interpreting evidence of benefits and harms, guideline panels that develop CPGs also must "trade off the benefits and risks, burden, and costs associated with alternative management strategies and, in doing so, consider their patients' unique predicament and values and preferences" to make their final recommendations and GRADE them for strength.[8] Guideline development groups must be free from or carefully manage financial, intellectual, and personal conflicts of interest, and should represent diverse and balanced views.

The credibility of guidelines should be assessed before their recommendations are accepted as trustworthy. A guideline's trustworthiness and authority depend on how closely the development group adhered to best practices for guideline development.[9] The Appraisal of Guidelines for Research and Evaluation (AGREE II) instrument is one of the most well-established validated tools for assessing the quality and methodological rigor of CPGs. The AGREE II instrument evaluates guidelines across six domains: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence. Each domain is rated on a standardized 7-point scale, with higher scores indicating greater methodological quality and trustworthiness. AGREE II further provides two overall assessments, one summarizing the guideline's overall quality and another evaluating whether the guideline should be recommended for implementation in clinical practice. By promoting transparency and consistency in guideline appraisal, AGREE II helps healthcare providers, policymakers, and patients identify guidelines most likely to improve patient outcomes and quality of clinical decision-making. Other approaches for evaluating the trustworthiness of CPGs emphasize related but distinct dimensions.[10]

9.2 Summary of systematic appraisal of clinical guidelines and guidance documents

At least two systematic reviews (SRs) have evaluated the quality (trustworthiness) of CPGs addressing the care of patients with GD. One focused on guidelines applying to

[8] Guyatt et al. (2015).
[9] Graham et al. (2011).
[10] Brignardello-Petersen et al. (2021); Lima, Mirza et al. (2023).

all age groups,[11] and the other on guidelines devoted specifically to the care of youth.[12] Both relied on AGREE II.[13] This section focuses on the SR that assessed guidelines for pediatric GD, which was conducted by researchers at the University of York to inform the development of the Cass Review.[14]

The York analysis identified 23 and appraised 21 clinical guidelines and clinical guidance documents for their methodological rigor and quality. York's analysis revealed three main findings: (1) all the guidelines, with the exception of two (from Sweden and Finland), were found to be untrustworthy due to serious deviations from the methodological standards for trustworthy guideline development; (2) most international guidance documents have relied heavily on the World Professional Association for Transgender Health (WPATH) and Endocrine Society (ES) guidelines,[15] which were themselves closely linked through overlapping authors and with WPATH acting as a sponsor for the development of ES guidelines; and (3) none of the three guidance documents that have shaped the United States's approach to pediatric GD are trustworthy due to serious problems in their development methodology.[16]

9.2.1 Methodological quality of existing guidelines and guidance documents

All guidelines and guidance documents assessed by the York appraisal were evaluated across AGREE II's six domains. The researchers also provided two assessments, one on quality of the guideline overall, and the other on whether the guideline can be recommended for clinical implementation.

The reviewers noted that while generally most guidelines scored well in the domain of "clarity of scope and purpose," most scored poorly in the domains of "rigour of

[11] Dahlen et al. (2021).
[12] Taylor, Hall, Heathcote et al. (2024a, 2024b).
[13] Brouwers et al. (2010).
[14] Taylor, Hall, Heathcote et al. (2024a, 2024b). In this chapter, as in this two-part systematic review (SR), the word "guidelines" will be used to refer to the various documents that were appraised, some of which were not formal clinical practice guidelines (CPGs). The reviewers included "published articles or documents that [provided] at least one specific recommendation for the assessment and/or care of children and/or adolescents (age 0–18) experiencing gender dysphoria/incongruence, and which were developed by or for a professional, healthcare or government organisation or from a research study" (Taylor, Hall, Heathcote et al., 2024a, p. s66).
[15] Coleman et al. (2012); Hembree et al. (2009); Hembree et al. (2017).
[16] See Taylor, Hall, Heathcote et al. (2024a).

development," "editorial independence," and "applicability" (see Figure 9.1 below). These are the domains that tend to most strongly influence the overall rating and the recommendation for use in clinical practice.[17]

Only the Swedish and the Finnish guidelines were rated as "recommended for implementation" by all reviewers; they also received the highest overall quality score, with Sweden rated as six and Finland rated as five (out of seven) (see Figure 9.2 below). The Swedish and Finnish guidelines were the only guidelines that described how the evidence base was reviewed and that linked the evidence to clinical recommendations. All other guidelines and guidance documents scored between two and four and were not recommended for implementation by one or more reviewers.[18]

Overall, the researchers described existing guidance documents that recommend pediatric medical transition (PMT) as "[lacking] an independent and evidence-based approach," noting that it was difficult to detect what evidence had been reviewed and how this informed development of recommendations. Moreover, they reported that the links between specific recommendations and evidence were often unclear or missing. See Figure 9.2 below.

[17] Hoffmann-Eßer et al. (2018).
[18] Taylor, Hall, Heathcote et al. (2024a, p. s65).

Figure 9.1[19]

Table 1 Critical appraisal domain scores

Guideline ID	Scope and purpose	Stakeholder involvement	Rigour of development	Clarity of presentation	Applicability	Editorial independence
AACAP 2012	65	39	44	63	7	31
American Academy of Paediatrics 2018	70	26	12	30	6	69
American Psychological Association 2015	74	74	24	50	18	14
Council for Choices in Healthcare Finland 2020	91	69	51	72	56	0
de Vries 2006	63	31	10	74	17	6
Endocrine Society 2009	65	33	44	70	22	31
Endocrine Society 2017	63	33	42	72	21	92
European Society for Sexual Medicine 2020	63	52	39	70	7	58
Fisher 2014	65	20	12	35	17	44
Health Policy Project 2015	63	63	16	24	33	6
Norwegian Directorate of Health 2020	76	81	30	57	47	17
Oliphant 2018	44	39	12	33	21	0
Pan American Health Organisation 2014	52	44	13	31	21	0
Royal Children's Hospital Melbourne 2018	81	59	19	41	19	14
Society for Adolescent Health and Medicine 2020	41	24	17	41	7	0
South African HIV Clinicians Society 2021	59	59	21	43	24	69
Strang 2018	87	31	18	37	15	19
Swedish National Board of Health & Welfare 2022	91	87	71	83	25	36
UCSF 2016	70	41	23	37	26	0
WPATH 2012	85	61	26	56	17	17
WPATH 2022	83	63	35	56	24	39

≥70%, 31%–69%, ≤30%.
AACAP, American Academy of Child & Adolescent Psychiatry; UCSF, University of California, San Francisco; WPATH, World Professional Association for Transgender Health.

[19] Taylor, Hall, Heathcote et al. (2024a, Table 1).

Figure 9.2[20]

Guideline ID	OQA1	R1	OQA2	R2	OQA3	R3
AACAP 2012	3	No	3	No	4	Yes (mod)
American Academy of Paediatrics 2018	2	No	3	No	1	No
American Psychological Association 2015	3	No	2	No	3	No
Council for Choices in Healthcare Finland 2020	5	Yes (mod)	5	Yes	5	Yes (mod)
de Vries 2006	2	No	3	No	2	No
Endocrine Society 2009	3	No	4	No	4	Yes (mod)
Endocrine Society 2017	4	Yes (mod)	4	No	4	Yes (mod)
European Society for Sexual Medicine 2020	3	Yes (mod)	2	No	3	No
Fisher 2014	2	No	3	No	1	No
Health Policy Project 2015	2	No	1	No	2	No
Norwegian Directorate of Health 2020	3	No	3	Yes (mod)	4	Yes (mod)
Oliphant 2018	2	No	3	No	1	No
Pan American Health Organisation 2014	2	No	2	No	1	No
Royal Children's Hospital Melbourne 2018	3	No	3	No	2	No
Society for Adolescent Health and Medicine 2020	2	No	2	No	1	No
South African HIV Clinicians Society 2021	3	No	3	No	2	No
Strang 2018	3	Yes (mod)	2	No	2	No
Swedish National Board of Health & Welfare 2022	6	Yes (mod)	6	Yes	6	Yes
University California San Francisco 2016	3	No	2	No	3	No
WPATH 2012	3	Yes (mod)	3	No	2	No
WPATH 2022	3	Yes (mod)	3	No	3	No

OQA: Overall quality assessment - 1-7 where 1 is lowest possible score and 7 is the highest possible score

R: Recommend guideline for use - Possible responses are Yes, Yes with modifications (Yes (mod)), No

The numbers 1-3 refer to the three reviewers who appraised the guidelines

Abbreviations
AACAP – American Academy of Child & Adolescent Psychiatry
WPATH – World Professional Association for Transgender Health

9.2.2 Interdependence of the existing guidelines and guidance documents

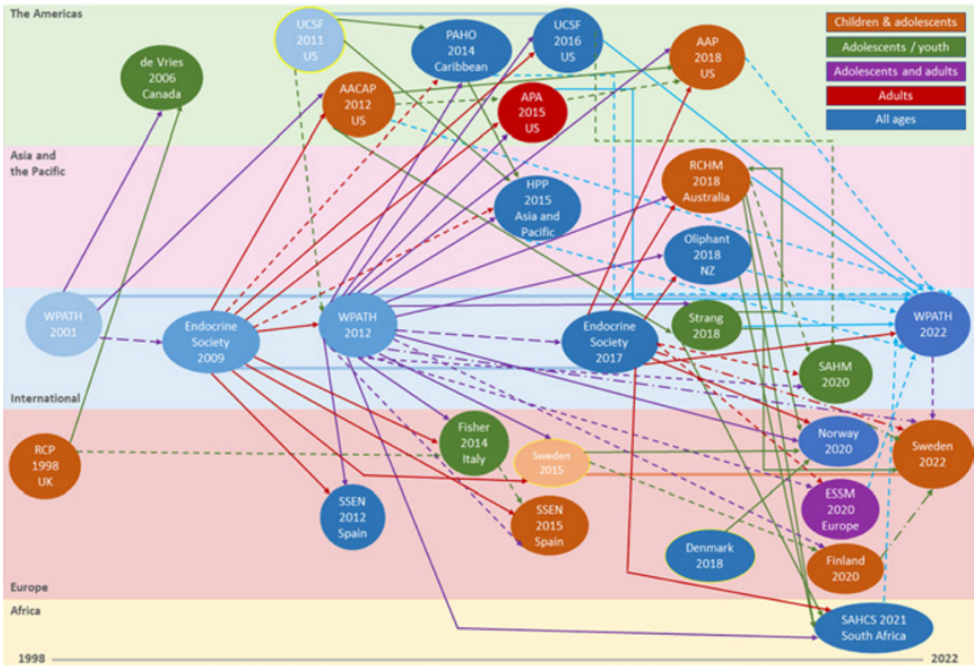
The guideline appraisal noted an unusual interdependence between much of the published guidance supporting the management of children and adolescents with GD (see Figure 9.3).[21] There was a marked pattern of "circular referencing and mutual endorsements"[22] between guidelines recommending PMT for routine care, with WPATH and the ES guidelines influencing all other guidelines and guidance documents.

The pattern of "links and influences between guidelines"[23] had been established early in the field's tenure with the ES 2009 and WPATH 2012 guideline versions.[24] The pattern persisted as both ES and WPATH updated their guidelines in 2017 and 2022

[20] Supplementary Table S3 in Taylor, Hall, Heathcote et al. (2024a).
[21] Taylor, Hall, Heathcote et al. (2024a, pp. s69–s70).
[22] Donkin et al. (2025, p. 3).
[23] Taylor, Hall, Heathcote et al. (2024a, p. s69).
[24] Coleman et al. (2012); Hembree et al. (2009).

respectively.[25] Moreover, the 2009 and 2017 ES guidelines state that WPATH was a guideline sponsor.[26] The University of York researchers noted that this represents problematic circularity, "with WPATH adopting Endocrine Society recommendations in its own guideline and acting as a cosponsor for and providing input on drafts of the Endocrine Society guideline."[27]

Figure 9.3[28]



The Cass Review emphasized the interdependence and circularity of the guidance documents:

> The circularity of this approach may explain why there has been an apparent consensus on key areas of practice despite the evidence being poor … the guideline appraisal raises serious questions about the reliability of current guidelines.[29]

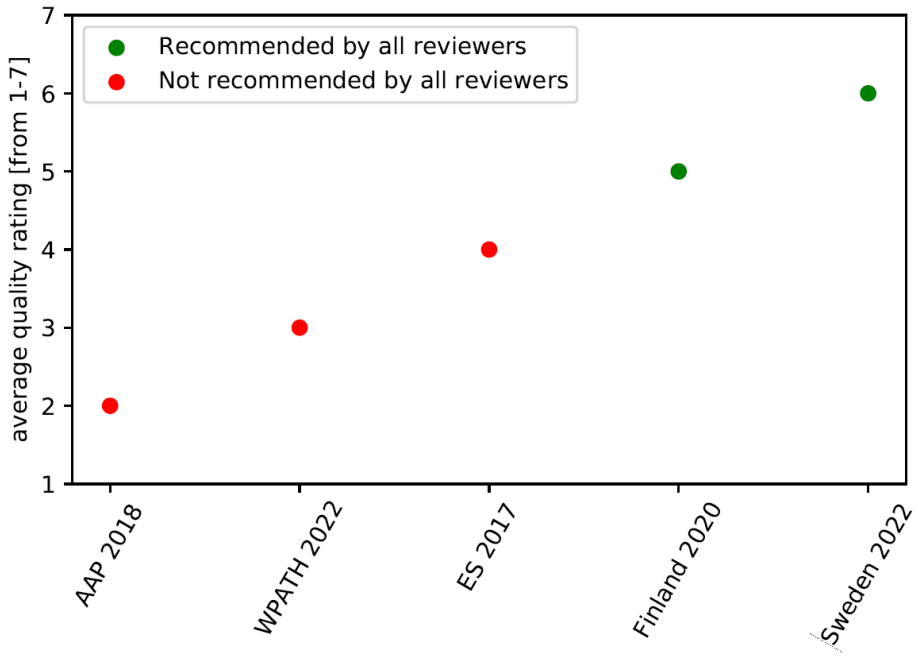
[25] Coleman et al. (2022); Hembree et al. (2017).
[26] Hembree et al. (2009); Hembree et al. (2017).
[27] Taylor, Hall, Heathcote et al. (2024a, p. s69).
[28] Taylor, Hall, Heathcote et al. (2024a, p. s69).
[29] Cass (2024a, pp. 129–130).

9.2.3 WPATH, Endocrine Society, and the American Academy of Pediatrics (AAP) guidelines and practice statements

The most influential sources of clinical guidance for treating pediatric GD in the U.S. are the WPATH and ES CPGs and the American Academy of Pediatrics' (AAP) guidance document.[30] The York appraisal assessed all three documents as very low quality and did not recommend them for implementation.

Figure 9.4 plots the overall rating of the quality of these three guidance documents relative to the only two guidelines that have been recommended for implementation by the York appraisal.[31]

Figure 9.4[32]



Legend**:** AAP: American Academy of Pediatrics; WPATH: World Professional Association for Transgender Health; ES: The Endocrine Society

[30] The American Academy of Pediatrics' (AAP) 2018 Policy Statement was reaffirmed in 2023 (Rafferty et al., 2018); the Endocrine Society's (ES) published in 2017 represents the most recent published version (Hembree et al., 2017); the World Professional Association for Transgender Health's (WPATH) most recent clinical practice guideline is *Standards of Care*, Version 8 (SOC-8) (Coleman et al., 2022).
[31] Taylor, Hall, Heathcote et al. (2024a).
[32] Figure 9.4 plots data from Supplementary Table S3 in Taylor, Hall, Heathcote et al. (2024a).

The York appraisal found that WPATH's guideline, *Standards of Care*, Version 8 (SOC-8) and the ES guidelines were both "[lacking] in developmental rigour." SOC-8 was given an overall score of three out of seven; the ES guideline scored four out of seven. The extensive problems in the SOC-8 development process, which included the failure to base recommendations on SRs and numerous other serious limitations in the process, ultimately led to this low rating and the status of "not recommended for implementation." These problems are discussed in more detail in Chapter 10.

The ES 2017 guideline, which used the GRADE framework, has been criticized for making strong recommendations for hormonal interventions in the setting of a weak evidence base.[33] Notably, none of the systematic reviews that supported the ES guidelines were based on outcomes for children or adolescents.[34] The ES recommendation to initiate puberty blockade using gonadotropin-releasing hormone agonists was derived by putting a higher value on achieving a "satisfactory physical appearance" while putting the lowest value on avoiding physical harms.[35] The ES recommendation for the initiation of cross-sex hormones no earlier than age 16 was justified by placing a higher value on adolescent's purported ability to meaningfully consent to cross-sex hormones (CSH) and placing a lower value on avoiding harm from potentially prolonged pubertal suppression.[36]

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[33] E.g. Block (2023c). If such recommendations are made, which the GRADE framework allows in specific circumstances, the reasoning for this must be clear. The ES guidelines did not do this.

[34] Maraka et al. (2017); Singh-Ospina et al. (2017); Of note, the only study of adolescents included in these systematic reviews, Klink et al. (2015), concluded that puberty blockers impede the development of bone mass density (BMD) and cross-sex hormones fail to bring up BMD to its pretreatment potential: "Between the start of GnRHa and age 22 years the lumbar areal BMD z score (for natal sex) in transwomen decreased significantly from 0.8 to 1.4 and in transmen there was a trend for decrease from 0.2 to 0.3. This suggests that the BMD was below their pretreatment potential and either attainment of peak bone mass has been delayed or peak bone mass itself is attenuated" (Klink et al., 2015, p. E270).

[35] Full quotation: "These recommendations place a high value on avoiding an unsatisfactory physical outcome when secondary sex characteristics have become manifest and irreversible, a higher value on psychological well-being, and a lower value on avoiding potential harm from early pubertal suppression" (Hembree et al., 2017, p. 13). Published gender-affirming care literature has also described a prioritization of aesthetic outcomes, e.g., a research paper noted gender-affirming care can be beneficial because (among other reasons) "The combination of pubertal suppression and cross-sex hormones] may … increase the concordance of youths' appearance with cisgender norms …" (McGregor et al., 2024, p. 5).

[36] Full quotation: ""The recommendation to initiate pubertal induction [cross-sex hormones] only when the individual has sufficient mental capacity (roughly age 16 years) to give informed consent for this partly irreversible treatment places a higher value on the ability of the adolescent to fully understand and oversee the partially irreversible consequences of sex hormone treatment and to give informed consent. It

"Panel stacking" refers to the practice of populating clinical practice guideline development groups with individuals who share a similar position regarding the treatment under consideration, often due to having financial or non-financial conflicts of interest. Because of its tendency to perpetuate groupthink, panel stacking represents a threat to the trustworthiness of any CPG, especially in the absence of systematic reviews of evidence.[37] Managing conflicts of interest is essential in CPG development because CPGs make recommendations factoring in not only the evidence, but a range of other considerations, such as "values and preferences" (see Section 10.3.1).

ES guidelines for this area of medicine have been heavily influenced by the Dutch clinician-researchers who pioneered the practice of PMT. Three of the eight authors of the 2009 ES guidelines, which first introduced PMT into clinical practice, were the founders of the Dutch protocol: Peggy Cohen-Kettenis, Henriette A. Delemarre-van de Waal, and Louis J. Gooren.[38] The group also included Norman Spack, who co-founded the first U.S. pediatric gender clinic. Most of the authors were also prominent WPATH members and leaders. The 2017 update to the ES guidelines continued to maintain a strong link with the Dutch clinical team and further cemented the relationship with WPATH through common authorship.

The intellectual commitments of ES guideline panel members find expression in the fact ES recommended PMT despite not having conducted SRs of evidence for benefits and most risks—a strong departure from norms governing how CPGs should be drafted—and the unusual "values and preference" statements mentioned above.

The AAP 2018 policy statement is not technically a CPG but has been widely cited in the U.S. as influential in establishing how pediatricians respond to children and adolescents with GD.[39] Because the document offers extensive clinical recommendations regarding every step of PMT—from social transition to PBs, CSH,

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places a lower value on the possible negative effects of delayed puberty. We may not currently have the means to weigh adequately the potential benefits of waiting until around age 16 years to initiate sex hormones vs the potential risks/ harm to BMD and the sense of social isolation from having the timing of puberty be so out of sync with peers" (Hembree et al., 2017, p. 3885).

[37] Kepp et al. (2024).

[38] Hembree et al. (2009).

[39] Rafferty et al. (2018).

and surgery—the York team assessed the trustworthiness of the AAP guidance using the same criteria they applied to CPGs. Using the AGREE II criteria, the AAP policy statement received the second-lowest average score among all international guidelines: 2 out of 7.

As noted in Chapter 2, the AAP's policy statement's use of "gender diverse" casts a very wide net regarding which patients the organization considers eligible for medical intervention. The statement has been heavily criticized in peer-reviewed articles, which have pointed out that it is rife with referencing errors and inaccurate citations.[40] Despite persistent advocacy among its members, who have petitioned the organization to release updated, evidence-based guidance for treating pediatric GD,[41] the organization chose to reaffirm their policy statement in 2023.[42]

9.2.4 More recent international guidelines

Since the publication of the York reviews, several new European guidelines have been issued in final or draft form, including those from the German AWMF, the French Society of Pediatric Endocrinology and Diabetology, the Polish Sexological Association, the European Society for Paediatric Endocrinology (ESPE), and the forthcoming final version of the French National Authority for Health (HAS) guidelines.[43] These reviews have been developed amid growing international awareness of the weaknesses of WPATH's SOC-8 and the outdated nature of the Endocrine Society's guidelines, reflecting the need to have defensible, localized, up-to-date guidelines that set the standards of care for youth with GD.

[40] E.g., Cantor (2020); McDeavitt (2025).
[41] See description of efforts led by pediatrician Julia Mason in Block (2023c).
[42] Block (2023c).
[43] The AWMF German guidelines (German Society for Child and Adolescent Psychiatry, Psychosomatics and Psychotherapy [DGKJP], 2025) are comprehensive; the guidelines by the French Society of Pediatric Endocrinology and Diabetology (SFEDP; Brezin et al., 2024) are limited to hormonal interventions and is currently available only as a preprint; the Polish guidelines, supported by the Polish Sexological Association, the Polish Psychiatric Association, and the Polish Society of Paediatric Endocrinology and Diabetology cover most aspects of PMT but are almost entirely derivative (Gawlik-Starzyk et al., 2025); the ESPE guidelines (Hannema et al., 2024) primarily focus on endocrine (medical/hormonal) interventions; the draft French national HAS guidelines became publicly available when a French newspaper published a draft in November 2024 (Sugy, 2024); the final version has not yet been released.

Unfortunately, these recently-published (or as yet to be finalized) guidelines suffer from the same or similar methodological weaknesses that have rendered the WPATH and the Endocrine Society's guidelines not trustworthy and not recommended for implementation. All suffer from non-evidence-based approaches to guideline development and exhibit one or more of the following problems: (1) guideline development groups are composed of individuals with unmanaged conflicts of interest relating to the provision of pediatric gender transition services; (2) the guideline takes an a priori WPATH-aligned position that medicalized pathway of hormones (and surgery) is the recommended treatment approach;[44] (3) the recommendations are not based on rigorously-conducted systematic reviews of evidence;[45] (4) individual studies that drive treatment recommendations are not appraised for quality, and their conclusions are accepted at face value; (5) the recommendations are not graded for strength, resulting in ambiguity in clinical decision-making.

While some guidelines, in response to criticism of the draft version, have added references to systematic reviews of evidence, it is apparent that SRs were not utilized to make treatment recommendations, with apparent and unreconciled contradictions between the findings of the SRs and the treatment recommendations.[46] Alternatives such as psychological support are in nearly all cases marginalized or even entirely absent. Ongoing reliance on the "consensus-based" non-evidence-based process underlines the trustworthiness of these guidelines, raising questions about the rigor of guideline development in pediatric gender medicine not just in the U.S., but worldwide.

[44] For example, the German AWMF guidelines state that the members of the guideline development group adhere to the WPATH positions (Society for Evidence-Based Gender Medicine, 2025).The Polish guideline explicitly bases itself on WPATH SOC-8, without independent review, stating, "This document is based on the Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (2022) [1] and an Endocrine Society Clinical Practice Guideline … The person conducting psychological or sexological assessment and care should be familiar with the content of the current standards of care of the World Professional Association for Transgender Health and comply with them" (Gawlik-Starzyk et al., 2025, pp. 4, 8).

[45] The German guidelines methodological report explicitly states that no evidence-based recommendations were developed (German Society for Child and Adolescent Psychiatry, Psychosomatics and Psychotherapy (DGKJP), 2025, p. 6).

[46] Society for Evidence-Based Gender Medicine (2025).

9.3 Overview of recommendations in the high-quality guidelines

Of the 23 guidelines that were appraised in the systematic evidence review, only two were recommended for practice by all three reviewers: the guidelines from Finland (which were scored five out of seven), and those from Sweden[47] (which were scored six out of seven). Both guidelines recommend that psychotherapy—not hormones or surgeries—should be the standard of care for youth with GD, and that any use of hormones should be limited to nationally overseen research or exceptional circumstances. As described in the systematic review, the two Scandinavian guidelines were the only ones that based their treatment recommendations on systematic evidence reviews, a key element of trustworthy clinical practice guidelines.

9.3.1 Finland

In 2020, Finland's Council for Choices in Health Care (PALKO/COHERE) issued national guidelines for treating gender dysphoria in minors, representing a major shift away from the model endorsed by WPATH's *Standards of Care* Version 7.[48] Finland's guidelines emphasize that the first-line treatment for adolescents experiencing gender distress should be psychosocial support and psychotherapy, not early medical intervention.[49]

Based on a commissioned SR, Finnish authorities concluded that the body of evidence supporting puberty blockers and cross-sex hormones for youth is inconclusive. Importantly, the guidelines explicitly state that "in light of available evidence, gender reassignment of minors is an experimental practice."[50] While medical transition remains possible, it is restricted to highly select cases—specifically, adolescents with persistent, childhood-onset gender dysphoria, no major psychiatric comorbidities, and stable identity development through adolescence.

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[47] In 2022, Sweden's healthcare authority, Socialstyrelsen, issued guidelines recommending that "Psychosocial support that helps adolescents deal with natal puberty without medication needs to be the first option when choosing care measures" (Socialstyrelsen, 2022b, p. 45).
[48] Council for Choices in Health Care Finland (2020a). There is an official English-language summary (Council for Choices in Health Care Finland, 2020c), as well as an unofficial English translation of the complete guideline document (Council for Choices in Healthcare Finland, 2020b).
[49] Council for Choices in Healthcare Finland (2020a).
[50] Council for Choices in Healthcare Finland (2020b, p. 8).

Surgery is not offered to minors in Finland. Furthermore, the guidelines stress that psychiatric conditions must be treated and stabilized before considering hormonal interventions. Special caution is placed on the use of puberty blockers, given emerging evidence about their potential impact on brain maturation and long-term decision-making capacity.

Adherence to this strict protocol is assured because Finland has only two centers that provide assessments and approve treatment indications for youth with GD, with highly coordinated clinical teams that adhere to the strict Finnish protocol.

Since the publication of the Finnish guidelines, two major register studies have provided additional support for their cautious approach. One explored psychiatric needs among gender clinic-referred patients, finding high rates of psychiatric comorbidities and suggesting that the rising number of referrals includes increasingly complex clinical cases.[51] The second examined suicide mortality among individuals under 23 and found that, after adjusting for psychiatric needs, there was no statistically significant difference in suicide rates between gender-referred youth and matched controls from the general population.[52]

Finland's cautious, evidence-focused guidelines stand in stark contrast to the WPATH model. Rather than expanding access amid uncertain outcomes, Finland has re-centered pediatric care around rigorous assessment, psychotherapeutic exploration, and prioritizing long-term health.

9.3.2 Sweden

In 2022, Sweden's National Board of Health and Welfare (Socialstyrelsen) issued an update to its national guidelines for the treatment of children and adolescents with gender dysphoria.[53] This update was motivated in part by shifts in epidemiology and uncertainty about the recent rise in cases, and limited data regarding rates of detransition or regret among young adults. Grounded in a systematic review of the

[51] Kaltiala et al. (2023).
[52] Ruuska et al. (2024).
[53] The official Swedish-language guidelines are Socialstyrelsen (2022c). Page numbers in this section refer to a certified, complete, unofficial translation that was submitted as evidence in a U.S. court case (Socialstyrelsen, 2022b). There is also an official English-language summary (Socialstyrelsen, 2022a).

evidence,[54] the new framework departs sharply from the SOC-8. Unlike WPATH's affirmation-based model, Sweden's guidelines conclude that the risks associated with puberty blockers and cross-sex hormones likely outweigh the expected benefits for young people. As with Finland, such interventions are now restricted to research settings, with exceptions permitted under strict clinical oversight.

The Swedish guidelines prioritize a comprehensive psychosocial evaluation and support. Clinicians are instructed to conduct thorough assessments of psychological, psychosocial, and psychiatric factors, utilizing validated instruments, investigative interviews, and detailed life histories from both the young person and their guardians.[55] Rather than presuming a fixed outcome, the guidelines emphasize the importance of supporting the open-ended exploration of gender identity.[56] Systematic screening for neurodevelopmental conditions, including autism spectrum disorder (ASD) and attention deficit hyperactivity disorder (ADHD), is required early in the evaluation process, with full neuropsychiatric assessments initiated when indicated.[57] Moreover, concurrent psychiatric conditions must be identified and addressed as early as possible, ensuring that psychosocial support and psychiatric interventions are available to bolster overall mental health throughout the evaluation.

Medical and surgical interventions are subject to equally rigorous restrictions. Treatment with puberty blockers is confined to the context of clinical research. Until such research protocols receive ethics board approval, puberty blockers may be administered only in exceptional cases under the updated guidelines.[58] Similarly, the use of cross-sex hormones is permitted solely within research studies, with narrowly defined exceptional cases allowed.[59] Only adolescents who meet stringent eligibility criteria may be considered for surgery, again under exceptional circumstances.[60] Across all

[54] Swedish Agency for Health Technology Assessment and Assessment of Social Services (2022).
[55] Socialstyrelsen (2022b, p. 63).
[56] Socialstyrelsen (2022b, p. 66).
[57] Socialstyrelsen (2022b, p. 69).
[58] Socialstyrelsen (2022b, p. 85).
[59] Socialstyrelsen (2022b, p. 90).
[60] Socialstyrelsen (2022b, p. 95).

interventions, the emphasis is on minimizing risk and ensuring that treatment decisions are based on the best available evidence.

Sweden's 2022 guidelines represent a marked shift away from the PMT model. Anchored in a systematic review of the literature, they embody a precautionary approach grounded in the principles of evidence-based medicine. Sweden's approach signals an important recalibration in gender medicine, reinforcing that interventions involving youth must be guided by systematic evidence appraisal, ethical responsibility, and a focus on long-term health trajectories.

9.3.3 United Kingdom

Currently, there is no finalized clinical practice guideline for pediatric gender medicine available from the National Institute for Health and Care Excellence (NICE) for England and Wales, or the Scottish Intercollegiate Guidelines Network (SIGN) for Scotland.[61]

NICE was commissioned by NHS (National Health Service) England[62] to perform a systematic evidence review evaluating treatments for gender dysphoria among children and adolescents. NICE's evidence reviews identified significant limitations in existing research, concluding that the available evidence was of very low quality (as assessed by the GRADE methodology) [63] and therefore insufficient to support the development of a formal clinical guideline.

These two SRs were cited as part of the Terms of Reference for an independent review that NHS England commissioned, led by Dr. Hilary Cass.[64] Released in 2024, the Cass Review aimed to thoroughly evaluate pediatric gender medicine services in the U.K. and provide clear recommendations on clinical practices and service delivery. Rather than providing explicit clinical guidelines, the Cass Review is a detailed, independent, investigative assessment based on multiple commissioned peer-reviewed systematic reviews.[65]

[61] Silver et al. (2025, p. 2).
[62] On March 13, 2025 it was announced that NHS England would be merged with the Department of Health and Social Care (DHSC).
[63] National Institute for Health and Care Excellence (2020b, 2020a).
[64] Cass (2024a, Appendix 1).
[65] Archives of Disease in Childhood (2024).

The Cass Review identified critical issues within the existing pediatric gender services, such as inadequate clinical assessments, insufficient long-term outcome data, and significant concerns over rapidly increasing referrals of young people with gender incongruence. Overall, it identified a significant gap between the available evidence and the clinical justifications for medical interventions for gender dysphoria in young people[66] and emphasized the necessity for comprehensive psychological support and thorough, individualized assessments.

In response to the Cass Review, NHS England introduced major policy changes. Puberty blockers are no longer routinely commissioned due to insufficient evidence regarding their long-term safety and effectiveness. Instead, they will only be accessible through structured clinical research trial, which is currently being designed. Additionally, cross-sex hormones are available to young people around the age of 16, contingent upon strict eligibility criteria and detailed assessment protocols by specialist multi-disciplinary teams and a new national Multi-Disciplinary Team (MDT) review process.[67] The NHS recently revealed that since the Cass Review was published, no minor has been found eligible to receive CSH according to the updated policy.[68]

Without a finalized clinical practice guideline, clinicians must follow the current policies directly informed by the Cass Review. These interim standards prioritize patient safety, rigorous clinical evaluation, ongoing research, and holistic care approaches, significantly revising the clinical pathways for young individuals experiencing gender incongruence.

9.4 Conclusion

The current landscape of CPGs for treating youth with GD underscores significant variability in methodological rigor and trustworthiness. A rigorous guideline appraisal demonstrates that only a select few guidelines, notably those from Finland and Sweden, meet high standards for evidence-based clinical decision-making. These Scandinavian

[66] Cass (2024a, pp. 22, 29, 32–35).
[67] National Health Service England (2024a); a review of adult services was also announced (National Health Service England, 2024b).
[68] Spencer (2025).

guidelines emphasize cautious approaches grounded firmly in systematic evidence reviews, advocating psychotherapy and psychosocial interventions as first-line treatments, and restricting medical interventions to carefully monitored research settings or exceptional circumstances.

In contrast, many internationally influential guidelines, including those from WPATH, the Endocrine Society, and the American Academy of Pediatrics, have been criticized for substantial methodological shortcomings and inadequately managed conflicts of interest, resulting in recommendations not reliably supported by rigorous evidence. This pattern of circular referencing and mutual endorsement among these guidelines further compromises their credibility and has likely perpetuated a perceived consensus in pediatric gender medicine that belies the actual paucity of high-quality evidence.

Given the ethical implications and lifelong consequences of medical interventions in youth, it is imperative that future guidelines in pediatric gender medicine adhere strictly to established standards of evidence-based medicine. Guideline developers must prioritize transparency, methodological rigor, independence from vested interests, and systematic evidence appraisal. Only through such disciplined approaches can clinical practice guidelines fulfill their intended role of safeguarding the health and well-being of youth with GD, promoting informed decision-making among clinicians, families, and policymakers alike.

Chapter 10 WPATH's *Standards of Care* 8

As shown in Chapter 9, the guidelines issued by the World Professional Association for Transgender Health (WPATH) have been rated among the lowest in quality and have not been recommended for implementation by systematic reviews (SRs) of guidelines. Despite their lack of trustworthiness, for more than a decade WPATH guidelines have served as the foundation of the healthcare infrastructure for gender dysphoric (GD) youth in the United States. The WPATH *Standards of Care* guidelines are embedded in nearly all aspects of healthcare including clinical education, delivery of care, and reimbursement decisions by private and public insurers.

This chapter focuses on the current Version 8 of the WPATH *Standards of Care* guidelines (SOC-8),[1] published in 2022.[2] Section 10.1 describes WPATH's central role in shaping the treatment of youth with GD in U.S. healthcare settings. Section 10.2 provides a brief overview of the rationale for the development of SOC-8, highlighting how it differs significantly from earlier guideline versions with particular emphasis on the new Adolescent chapter. Section 10.3 examines the development process of SOC-8, considering both internal dynamics and external pressures, and analyzes its multipurpose role as a clinical guideline, a tool to secure insurance coverage, and a legal instrument aimed at promoting broad access to pediatric medical transition (PMT). Section 10.4 highlights one critical downstream consequence of the guideline's flawed development process: the elimination of all minimum age requirements for endocrine and surgical interventions (except phalloplasty) in minors. Section 10.5 discusses the implications of continued reliance on WPATH.

10.1 Influence of WPATH in the United States

There is no accredited subspecialty in "gender medicine" in the U.S. Instead, the practice of PMT typically involves a series of handoffs among different providers: a pediatrician or an adolescent medicine specialist[3] first assesses whether PMT may be

[1] Coleman et al. (2022).
[2] Portions of this evaluation necessarily rely on internal WPATH communications made publicly available through subpoena. See Boe v. Marshall, No. 2:22-cv-00184, (M.D. Ala.). Some material from Boe v. Marshall was previously released in Voe v. Mansfield, No. 1:23-Cv-00864: 100-1 (M.D.N.C.).
[3] American Board of Pediatrics (2024).

warranted; mental health professionals diagnose GD or a related condition and recommend PMT; endocrinologists prescribe hormonal interventions (puberty blockers and cross-sex hormones); and various surgical specialties including plastic surgeons, urologists, and gynecologists perform a range of surgical procedures to alter the adolescent's sex-specific physical characteristics.

The multidisciplinary nature of PMT combined with the absence of a single medical specialty responsible for overseeing patient care has resulted in an oversight gap WPATH has filled. WPATH has successfully positioned itself as the leading authority in the field of gender medicine, including pediatric gender medicine. The first version of WPATH's Standards of Care was published in 1979. Subsequent updates followed in 1980, 1981, 1990, 1998, 2001, and 2012.[4] The most recent version, SOC-8, was published in 2022.[5] Chapter 3 provides a brief history of gender medicine and the role of WPATH, which was originally formed (under a different name, the "Harry Benjamin International Gender Dysphoria Association") to focus on the gender transition wishes of mature adults, but after pediatric transitions were pioneered in the Netherlands, increasingly shifted its attention to children and adolescents.

10.1.1 WPATH's role in clinical practice

Although some medical societies involved in providing PMT have issued guidance documents on specific aspects of care for youth with GD,[6] no professional society has published a comprehensive, up-to-date, evidence-based clinical guideline covering the full PMT pathway. Instead, medical societies have largely deferred to WPATH, adapting their own clinical positions to WPATH's most recent recommendations.[7] Unlike the U.K., Sweden, Finland, and other countries with centralized medical policymaking bodies that

[4] SOC-7 was released in 2011 and published in 2012.
[5] Coleman et al. (2022).
[6] The most notable documents are discussed in Chapter 9 and include the Endocrine Society's guidelines (Hembree et al., 2017) and the American Academy of Pediatrics position statement (Rafferty et al., 2018). Both are significantly outdated.
[7] In August 2024, WPATH was presented in a court case as "the leading association of medical professionals treating transgender individuals." It was further asserted that "[t]he Nation's leading medical and mental health organizations recognize [SOC-8] as reflecting the accepted standard of care for treating gender dysphoria." See U.S. v. Skrmetti (No. 23-477), Brief for the petitioner (2024, p. 3).

issue independent, authoritative clinical care guidelines,[8] in the United States, WPATH's influence has been outsized and largely uncontested—primarily due to the fragmented healthcare system and the complexity of the U.S. regulatory environment.[9] WPATH's influence on clinical protocols for the care of youth with GD is pervasive within U.S. medicine. Its *Standards of Care* have become the primary framework embedded in clinical protocols and hospital operating procedures for the diagnosis and treatment of youth with GD.[10]

10.1.2 WPATH's role in medical education and training

WPATH has become the dominant influence shaping the education and training of U.S. healthcare providers who treat youth with GD. Indeed, it is virtually coterminous with the field itself. Because there is no officially accredited medical subspecialty in gender medicine in the U.S., and no formal board certification process as exists in fields like adolescent medicine, endocrinology, or psychiatry, training in PMT remains informal, variable, and largely organized through WPATH-affiliated medical education efforts.

WPATH's Global Education Initiative (GEI) offers certified courses that serve as the core curriculum for clinical training in the U.S. and worldwide. WPATH GEI's official collaborators include pediatric gender clinics and hospitals, the American Medical Student Association, and the World Health Organization (WHO).[11] Major U.S. hospitals and medical schools have embedded WPATH-aligned standards into their residency, fellowship, and continuing medical education programs.[12] Gender clinics reference

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[8] When NHS England moved to remove puberty blockers for GD from clinical practice, it received complaints that the decision was "not consistent … with the WPATH standards of care for trans children." NHS England responded: "The policy proposition has been developed following a review of peer reviewed published evidence as per NHS England Policy Development Methods. NHS England does not commission based upon guidelines or treatment protocols e.g. WPATH 8.0 [SOC-8] or practices in other countries. The not for routine commissioning position has been concluded based on 'insufficient clinical benefit to the patient of which evidence of harm is one aspect'" (National Health Service England, 2023, p. 4).

[9] The U.S. lacks a centralized medical policy-making body, resulting in what has been described as a "bewildering regulatory maze" (Field, 2008, p. 607).

[10] For an example, see Seattle Children's Hospital (n.d.). Note: it appears some pediatric gender clinics have recently removed public references to WPATH and have also removed the backups of the websites, making them inaccessible to citation.

[11] See World Professional Association for Transgender Health (n.d.).

[12] For example, Mt. Sinai's transgender psychiatry fellowship: "Fellows are provided time and financial compensation to attend the U.S. Professional Association for Transgender Health or World Professional

WPATH's *Standards of Care* in clinical protocols and physician training.[13] WPATH-certified trainers further extend WPATH's reach into professional training at institutional and community levels.[14] WPATH certification not only is encouraged but also in some cases mandated.[15] This widespread integration has effectively established WPATH as the de facto authority for defining clinical competency, treatment eligibility criteria, and ethical frameworks across much of U.S. medicine.

10.1.3 WPATH's role in insurance reimbursement

Many U.S. public and private health insurers and regulatory bodies rely on SOC-8 when making coverage determinations. Requirements for credentialing, assessing medical necessity, and making coverage decisions almost universally reference WPATH's *Standards of Care*. Major U.S. private insurers, including Anthem,[16] Kaiser,[17] Aetna,[18] Cigna,[19] and UnitedHealthcare,[20] explicitly reference SOC-8 to define medical necessity, eligibility criteria, and coverage decisions.

Association for Transgender Health bi-annual conferences" (Icahn School of Medicine at Mt. Sinai, n.d.-b). Mt. Sinai's transgender surgery fellowship attending faculty includes Marci Bowers, the former president of WPATH (Icahn School of Medicine at Mt. Sinai, n.d.-a). Oregon Health and Sciences University's gender surgery fellowship program director is "the surgical lead for the World Professional Association for Transgender Health (WPATH) and the United States Professional Association for Transgender Health (USPATH) meetings" (OHSU School of Medicine Surgery, n.d.).

[13] For example, the Stanford Medicine Children's gender clinic website states, "the expert members of the Gender Clinic team consists [sic] of providers from pediatric endocrinology, adolescent medicine, pediatric urology and social services, supporting each child's or adolescent's gender identity. All our providers are members of the World Professional Association for Transgender Health (WPATH)" (Stanford Medicine Children's Health, n.d.). Fenway Health references WPATH as the authority in the field: "The World Professional Association of Transgender Health (WPATH) monitors current research and new knowledge about evidence-based medicine for transgender people. It publishes Standards of Care and Ethical Guidelines for health care providers, which 'articulate a professional consensus about the psychiatric, psychological, medical, and surgical management of gender dysphoria' to guide clinicians in providing quality care for transgender and gender diverse people, including children and adolescents" (Fenway Health, n.d.).

[14] See Harvard Medical School's continuing medical education (Harvard Medical School, n.d.), led by senior WPATH leaders involved in the production of SOC-8 (e.g., Sari Reisner, WPATH board member). Also see the following training initiatives: Gender Health Training Institute (n.d.); Silver Hill Hospital/World Professional Association for Transgender Health (n.d.).

[15] For example, the Washington State Department of Corrections mandates that physicians providing "gender-affirming care" must be WPATH-certified or obtain certification within two years (Washington State Department of Corrections, 2025). The Oregon Health Authority is another example (see following section).

[16] Anthem (2023). WPATH is referenced 35 times as the basis for all recommendations.

[17] Kaiser Permanente (2023). Transition and detransition policies require "WPATH letters."

[18] Aetna (2024). Adolescents are to meet "WPATH criteria" for hormonal interventions.

[19] Cigna (2025).

[20] Stroumsa & Kirkland (2020).

Government payers, such as Medicaid programs, also commonly rely on WPATH guidelines as the primary basis for developing their medical policies. In 2024, Oregon became the first state to officially adopt SOC-8 as its standard of care, committing the Oregon Health Authority to cover treatments based entirely on WPATH guidelines. Oregon additionally requires that if a patient is denied coverage for medical or surgical intervention related to gender transition, the clinicians reviewing the patient appeal must complete WPATH-aligned training:

> health care providers reviewing adverse benefit determinations denying or limiting access to gender-affirming treatment complete the "WPATH SOC-8 Health Plan Providers Training," which is specifically designed for providers responsible for such reviews, or an equivalent training.[21]

This is notable as WPATH SOC-8 lists a wide range of procedures that should be provided to patients wishing to receive them. These include, in addition to puberty blockers, cross-sex hormones, mastectomy, and male-to-female or female-to-male genital surgeries, procedures such as vaginoplasty with a "retention of penis and/or testicle" (also known as penis-preserving vaginoplasty), removal of genitals entirely to create a "flat front" appearance, and uterine transplantation for male patients. Procedures listed as potentially necessary also include body contouring, liposuction/lipofilling, facelift, blepharoplasty, various implants, hair transplantation, vocal cord surgery, and a wide range of other appearance-modifying surgical procedures.[22]

10.2 The development of SOC-8 and the Adolescent chapter

Unlike most professional medical associations, WPATH does not require its members to be medical professionals. Full professional membership with voting privileges is also available to professionals in such fields as law, family studies, anthropology, and other areas. Reflecting the diverse aims of its broad membership, WPATH treatment

[21] Oregon Department of Consumer and Business Services (2024a). This position was further strengthened in the final ruling in Oregon Department of Consumer and Business Services (2024b).
[22] Coleman et al. (2022, p. S136).

guidelines are designed to serve multiple purposes, ranging from clinical care to political advocacy.

Published in 2022, SOC-8 marked WPATH's first attempt to develop guidelines that were "evidence-based" and aimed to meet higher methodological standards through reliance on SRs.[23] The previous version, SOC-7, published in 2011 and described in Chapter 4, under which PMT began rapidly to accelerate, did not rely on SRs. Instead, its recommendations were based on "cultural shifts" and other factors.[24]

In pursuit of its goal to develop an evidence-based guideline, WPATH entered into a contractual agreement with the Evidence-Based Practice Center (EPC) at Johns Hopkins University (JHU), tasking JHU experts with conducting SRs and serving as methodological advisors to ensure a trustworthy guideline development process.[25] Given the sharp increase in the numbers of adolescents seeking PMT, and the rapid growth of pediatric gender clinics and PMT providers in the U.S., WPATH recognized the need to develop a robust adolescent section, acknowledging that "the Adolescent chapter is going to be one of the most scrutinized chapters in the entire standards of care."[26]

As the process of guideline development began, WPATH focused on two cornerstone issues for PMT: the evidence regarding the effectiveness of endocrine interventions in treating GD, and the evidence that adolescents have the capacity to consent to such treatments.

10.2.1 Hope for evidence of effectiveness

At the outset of its collaboration with JHU's EPC team, WPATH leadership expressed confidence that an SR would yield "evidence-based statements" supporting both the

[23] See Sinai (2022): "The World Professional Association for Transgender Health (WPATH) Standards of Care Version 7 (SOC7) are not evidence-based. The WPATH website clearly states that SOC8 is the first version being developed using an evidence-based approach."
[24] The prior version, SOC-7, stated that its recommendations were "based upon significant cultural shifts, advances in clinical knowledge, and appreciation of the many health care issues that can arise for transsexual, transgender, and gender nonconforming people beyond hormone therapy and surgery" (Coleman et al., 2012, p. 166).
[25] Coleman et al. (2022, pp. S248–S249); Karen Robinson is named as the EPC lead and listed as a member of the SOC-8 Guideline Steering Committee.
[26] Boe v. Marshall*,* No. 2:22-cv-00184: 560-18 (2024, p. 42).

benefits of PMT interventions and the capacity of adolescents to consent to them. SOC-8 Adolescent chapter co-chair Scott Leibowitz wrote:

> We are a unique chapter when it comes to the evidence based review because we do feel that there is a justification to do a literature review on what we postulate will be evidence based statements about the interventions (even though we expect the evidence to be graded low). Essentially the literature reviews on some of our statements—as we plan on submitting once I edit them to incorporate the feedback from our workgroup—are important for the following reasons:
>
> - Studies that demonstrate the psychological effectiveness of some of the interventions (blockers, hormones) in adolescence all included cohorts who went through a rather rigorous psychological assessment. We would like to talk this through as a group because it's a very important point.
> - There is also literature on adolescent decision making and capacity to make informed decisions that carry lifelong ramifications. Since our chapter is a new chapter for the standards of care, and it focuses in on a developmental age group/assessment, (as opposed to other chapters that are more intervention specific), we are going to want to justify certain statements with graded evidence in terms of looking at the literature on *decision making in the developmental cohort (adolescence)* in general.[27]

The JHU evidence evaluation team was presented with the expectation that their appraisal would support the "gender-affirming" medical approach WPATH had been advancing for over a decade. The original plan was for SOC-8 recommendations—asserting that treatment effects are beneficial and that adolescents possess sufficient capacity to consent to medical interventions—to be labeled "evidence-based," even if the quality of the evidence was low.[28] However, the evidence evaluation challenged

[27] Boe v. Marshall, No. 2:22-cv-00184: 560-18 (2024, pp. 43–44).
[28] From a WPATH internal email exchange related to SOC-8: "Adolescent medical decision making literature is something that the Johns Hopkins team is able to help out in terms of a literature review and grading" (Boe v. Marshall, No. 2:22-cv-00184: 560-18, 2024, p. 116); for discussion of grading recommendations, see Chapter 9.

WPATH's expectations on both fronts: adolescent capacity to consent, and the benefits of PMT overall.

10.2.2 Adolescent capacity to consent

In response to a request from JHU, Annelou de Vries, the leading Dutch developer of PMT and a co-chair of SOC-8's Adolescent chapter section, supplied the JHU team with publications she believed demonstrate adolescent competence to consent to PMT.[29] Upon reviewing these publications, however, the JHU team informed WPATH that they provided, at best, "limited indirect evidence" and were insufficient to support a statement asserting that adolescents possess the capacity to consent.[30]

Following the JHU team's findings, WPATH abandoned its original plan to base its claim about adolescent capacity to consent on evidence. Instead, the Adolescent chapter of SOC-8 features a section on consent that stresses the importance of careful assessment but cites the same studies that JHU had deemed insufficient to answer the question of competence. The section also features a discussion about the "unique situations in which an adolescent minor is consenting for their own treatment without parental permission."[31]

The section fails to acknowledge the dearth of reliable information about whether adolescents in a state of clinical distress can meaningfully consent to drastic interventions—with many known and some unknown risks—in the absence of demonstrable physical disease and without credible knowledge of their likely future identity trajectory.

The ethical challenges of obtaining informed consent from adolescents regarding the procedures that are expected to threaten their fertility is illustrated by a candid comment

[29] The primary investigator of the Dutch Protocol and WPATH Adolescent chapter co-lead (de Vries) provided the relevant literature on adolescent consent for JHU evaluation, writing: "some articles on decision making in teens; these are review articles, but show that there is some evidence. I think we need this sort of evidence base on decision making capacity in adolescents, regarding medical affirming treatment" (Boe v. Marshall, No. 2:22-cv-00184: 560-18, 2024, p. 106).
[30] The JHU response to WPATH regarding the literature on adolescent consent to PMT stated, "The articles forwarded provide limited indirect evidence for this question. Please let me know if I missed something" (Boe v. Marshall, No. 2:22-cv-00184: 560-18, 2024, p. 106).
[31] Coleman et al. (2022, pp. S61, Section 6.12.c).

from a WPATH physician, who observed, “it’s always a good theory that you talk about fertility preservation with a 14-year-old, but I know I’m talking to a blank wall,” adding, “they’d be like, ew, kids, babies, gross.”[32]

10.2.3 Treatment effects

In contrast to WPATH’s early abandonment of efforts to evaluate minors' capacity to consent, SRs assessing the treatment effects of puberty blockers (PBs), cross-sex hormones (CSH), and surgeries were completed by the JHU team. As the following sections in this chapter detail, WPATH perceived the JHU evidence appraisals as unfavorable to its goals of promoting broad access to these interventions for minors. In response, WPATH leadership moved to suppress the findings, barring the JHU evidence evaluation team from publishing its results.

The Adolescent chapter does not disclose that the SR regarding the effects of PMT had, in fact, been conducted. Instead, the chapter claims that SRs are not feasible:

> Despite the slowly growing body of evidence supporting the effectiveness of early medical intervention, the number of studies is still low, and there are few outcome studies that follow youth into adulthood. Therefore, a systematic review regarding outcomes of treatment in adolescents is not possible.[33]

Ultimately, SOC-8 recommended that adolescents wishing to undergo PMT be provided with PBs, CSH, and surgery. The recommendations are couched in cautious-sounding language, stating that GD should be “sustained over time,” particularly before administering CSH. However, no clear standard is set; the only guidance offered is the vague and clinically meaningless phrase “several years, leaving critical decisions open to broad and subjective interpretation”:

> Given potential shifts in gender-related experiences and needs during adolescence, it is important to establish the young person has experienced

[32] Hughes (2024, p. 12).
[33] Coleman et al. (2022, p. S46).

several years of persistent gender diversity/incongruence prior to initiating less reversible treatments such as gender-affirming hormones or surgeries.[34]

As the following sections describe, the recommendations were deliberately crafted to allow any "willing" medical provider to prescribe hormones or perform surgeries on minors, even those with significant co-occurring mental health conditions.

10.3 The process of creating SOC-8

The creation of trustworthy, evidence-based guidelines requires first assembling a guideline development group (GDG) that is free from conflicts of interest (COI) or, at minimum, where COIs are transparently disclosed and rigorously managed. Only after this foundation is established should SRs proceed, addressing pre-specified guideline questions. Finally, recommendations should be based on SRs of evidence and should consider additional factors, with the aim of improving healthcare quality for individual patients and improving public health and access to care.

Although WPATH originally embarked on an evidence-based guideline development process, internal documents reveal significant deviations from internationally recognized clinical guideline development standards established by organizations such as the National Academy of Medicine[35] (NAM) and the World Health Organization (WHO).[36] These serious deviations from established standards meant that the GDG could not fulfill its promise of producing credible, evidence-based guidelines.

10.3.1 Conflicts of interest management

Managing COIs—both financial[37] and intellectual[38]—is essential for producing trustworthy clinical practice guidelines. Intellectual conflicts may even surpass financial

[34] Coleman et al. (2022, p. S60).
[35] Graham et al. (2011), published under its previous name, Institute of Medicine (IOM).
[36] SOC-8's reference to WHO's International Classification of Diseases (ICD) appears to have intended to be WHO's *Handbook for Guideline Development*, 2nd Edition. See Boe v. Marshall, No. 2:22-cv-00184: 700-3 (2024, p. 204).
[37] The WHO defines financial COI as any "paid work, consulting income or honoraria and travel stipends; support for research, including direct monetary contributions or donations of equipment, laboratory space, etc.;" "that is related to, or could be affected by, the outcome" of the guideline development process (World Health Organization, 2014, p. 63).
[38] NAM and WHO define intellectual COIs relevant to clinical practice guideline development as "academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation" (Guyatt, 2010, p. 739).

ones in their influence,[39] especially when guidelines rely heavily on expert consensus. The selection of the GDG[40] chair plays a pivotal role in ensuring the integrity of clinical guideline development.[41] WHO recommends selecting a guideline chair who is free of significant conflicts and neutral between differing perspectives.[42] NAM advises using "unconflicted methodologists"[43] to lead recommendation development, working alongside clinical experts as advisors rather than panel members. Both NAM and WHO stress that conflicted members should constitute no more than a minority of any GDG, emphasizing ongoing COI management throughout the entire guideline development process.[44] In 2022, the Endocrine Society adopted NAM's recommendations, prioritizing reduced conflicts even if it limits expert involvement.[45]

When the principal investigator of the JHU EPC team became involved in the SOC-8 process, she observed that they "would expect many, if not most, SOC8 members to have competing interests."[46] SOC-8's final COI statement reads as follows:

> Conflict of interests [sic] were reviewed as part of the selection process for committee members and at the end of the process before publication. No conflicts of interest were deemed significant or consequential.[47]

Based in part on correspondence between WPATH and the EPC team during the development of SOC-8, there are serious questions regarding the accuracy of this statement.

SOC-8 GDG members, including Chair Eli Coleman, had unmanaged financial and/or non-financial COIs that were plausibly "significant or consequential." Coleman had both financial and non-financial interests in the topic. He was the lead author of SOC-7[48] and had coauthored academic publications in support of expanded access to medical

[39] Guyatt et al. (2015, p. 540).
[40] SOC-8's GDG comprised a guidelines steering committee with a chair and two co-chairs, who in turn appointed 26 chapter leads, 77 chapter members, and 16 stakeholders.
[41] Graham et al. (2011, p. 87).
[42] World Health Organization (2014, p. 61).
[43] Graham et al. (2011, pp. 81–82).
[44] World Health Organization (2014, p. 71); Graham et al. (2011, p. 7).
[45] McCartney et al. (2022).
[46] Boe v. Marshall*,* No. 2:22-cv-00184: 560-16 (2024, p. 2).
[47] Coleman et al. (2022, p. S177).
[48] Coleman et al. (2012).

transition.[49] Using WHO criteria, his professional activities and academic profile, which were closely aligned with advancing medical transition, likely constitute both intellectual and financial COIs.[50]

Additionally, Coleman's academic work was supported with funding from the Tawani Foundation, chaired by Jennifer Pritzker, a philanthropist and advocate for transgender issues.[51] The foundation funded a research center at the University of Minnesota, and Coleman played a significant role in its development. Public statements confirm that the Tawani Foundation also funded the majority of the out-of-pocket costs associated with SOC-8's development.[52]

With Coleman as chair of the GDG, the importance of managing COIs appears to have been consistently misunderstood or undervalued. Coleman admitted under deposition that disclosure statements were not presented until at least six months *after* members had already been selected.[53] In a December 21 (2018) email sent to the SOC-8 education committee, EPC's Karen Robinson stated, "Disclosure, and any necessary management of potential conflicts, should take place prior to the selection of guideline members. Unfortunately, this was not done here."[54]

For former WPATH president Marci Bowers, who played an influential role in shaping SOC-8, the idea of appointing an unconflicted professional to lead the project was outright nonsensical.[55] Another SOC-8 member wrote to the EPC to explain that "unlike other medical guidelines, trans health care is a socially and politically charged issue," and strongly recommended that the JHU team therefore rewrite their COI forms for this

[49] Eisenberg et al. (2020); Rider et al. (2018).
[50] "Financial and nonfinancial interests can overlap. For example, intellectual interests related to career advancement obviously have a monetary component. Examples of roles or positions that might interfere with the objective assessment of a body of evidence include: prior publication of a study or SR that is part of the evidence base under consideration in the guideline; prior public declaration of a firm opinion or position, as in public testimony during a regulatory or judicial process, or in an editorial in a journal; or professional or personal affiliation with an organization advocating for products or services related to the subject of the guideline" (World Health Organization, 2014, p. 63).
[51] Boe v. Marshall*,* No. 2:22-cv-00184: 700-3 (2024, p. 239).
[52] Boe v. Marshall*,* No. 2:22-cv-00184: 700-3 (2024, p. 239).
[53] Boe v. Marshall*,* No. 2:22-cv-00184: 700-3 (2024, pp. 219–222).
[54] Boe v. Marshall*,* No. 2:22-cv-00184: 560-16 (2024, p. 2).
[55] Boe v. Marshall*,* No. 2:22-cv-00184: 564-8 (2024, p. 121).

particular guideline.[56] Part of the justification for different treatment was that COIs were so prevalent within the GDG that it would be "impossible" for the group to be free of them.[57] One submitted COI form, on the question of non-financial interests, recorded that "everyone involved in the SOC process has a non-financial interest."[58]

Although WPATH later claimed that none of the SOC-8 members' COIs were significant or consequential, several members clearly met the internationally recognized definitions of COIs established by the NAM and WHO—the kind of conflicts known to bias clinical practice guidelines and erode their trustworthiness. For instance, SOC-8 chapter leaders Dan Karasic and Loren Schechter were paid expert witnesses in legal cases directly related to medical transition before and during the SOC-8 development process,[59] a role NAM explicitly identifies as a COI.[60] Schechter, co-chair of the surgery chapter and a plastic surgeon who derives part of his livelihood from performing gender transition surgeries, voiced concerns to fellow GDG members about openly acknowledging insufficient evidence, noting the potential impact this would have on two federal court cases in which he was serving as a paid expert witness.[61] Despite this clear overlap of financial interest and guideline content, SOC-8 chair Eli Coleman considered it "ethically justifiable" for members involved in active litigation to advocate for guideline changes that could strengthen their legal positions.[62]

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[56] Boe v. Marshall, No. 2:22-cv-00184: 560-16 (2024, p. 3).
[57] Boe v. Marshall, No. 2:22-cv-00184: 560-16 (2024, p. 3).
[58] Boe v. Marshall, No. 2:22-cv-00184: 560-24 (2024, p. 8).
[59] Schechter provided testimony for Dekker v. Weida, No. 4:22-cv-00325 (N.D. Fla. filed Sept. 7, 2022); Willis v. Flagg, No. 17-cv-02754 (N.D. Ill. filed Apr. 10, 2017); Bruce v. South Dakota, No. 3:17-cv-03023-RAL (D.S.D. filed Oct. 5, 2017); Boyden v. Conlin, No. 17-cv-00264-WMC (W.D. Wis. filed Apr. 6, 2017); Kadel v. Folwell, No. 1:19-cv-00272 (M.D.N.C. filed Mar. 11, 2019); Toomey v. State of Arizona, No. 4:19-cv-00035-RM-LAB (D. Ariz. filed Jan. 23, 2019); and Fain v. Crouch, No. 3:20-cv-00740 (S.D.W. Va. filed Nov. 12, 2020).

Karasic provided testimony for C.P. v. Blue Cross Blue Shield of Illinois, No. 3:20-cv-06145 (W.D. Wash. filed Nov. 24, 2020); Kadel v. Folwell, No. 1:19-cv-00272 (M.D.N.C. filed Mar. 11, 2019); Fain v. Crouch, No. 3:20-cv-00740 (S.D.W. Va. filed Nov. 12, 2020); Brandt v. Rutledge, No. 4:21-cv-00450 (E.D. Ark. filed May 25, 2021); K.C. v. Individual Members of the Indiana Medical Licensing Board, No. 1:23-cv-00595-JPH-KMB (S.D. Ind. filed Apr. 5, 2023); Dekker v. Weida, No. 4:22-cv-00325-RH-MAF (N.D. Fla. filed Sept. 7, 2022); and Doe v. Ladapo, No. 4:23-cv-00114-RH-MAF (N.D. Fla. filed Mar. 23, 2023).
[60] Graham et al. (2011, p. 79).
[61] Boe v. Marshall, No. 2:22-cv-00184: 700-13 (2024, p. 56).
[62] Boe v. Marshall, No. 2:22-cv-00184: 700-3 (2024, p. 158).

WPATH's process not only permitted significant financial and intellectual COIs among GDG members. It also allowed the creation of substantial panel composition bias—a phenomenon known as "panel stacking" (see Section 9.2.3). This occurs when GDGs predominantly consist of members sharing similar viewpoints or vested interests, thereby threatening the validity and trustworthiness of clinical guidelines. Experts in evidence-based medicine describe panel stacking as a major threat, emphasizing that it can profoundly reduce the credibility of recommendations, particularly when, as in pediatric gender medicine, the evidence is limited, contentious, or unsystematically reviewed.[63]

Kepp et al. note that "recruitment specifically because of expressed viewpoints and allegiance is a recognized major problem for guideline development." In their own example from an appraisal of a consensus statement on COVID-19 recommendations, the authors characterized a panel with a "35% (or more) prevalence" of advocates of COVID-19 elimination ("Zero-COVID") as "extreme."[64] For SOC-8, WPATH required that all members of the GDG be "WPATH Full Members in good standing."[65] Marci Bowers explicitly stated that it was important for participants to be "advocates" for WPATH's "gender-affirming" approach to be considered for the GDG,[66] further underscoring the GDG's bias.

Internal documents revealed that WPATH actively monitored SOC-8 members and disciplined those who publicly questioned WPATH's "gender-affirming" approach, creating an environment that discouraged critical dialogue. Psychologist Laura Edwards-Leeper, chair of WPATH's Child and Adolescent Committee and a member of both the child and adolescent SOC-8 committees, co-authored a *Washington Post* opinion piece with Erica Anderson,[67] a psychologist and then-president of WPATH's U.S. chapter, arguing that WPATH "largely seems to be a dangerous echo chamber"

[63] Kepp et al. (2024, p. 5).
[64] Kepp et al. (2024, p. 6).
[65] Coleman et al. (2022, p. 248).
[66] Boe v. Marshall, No. 2:22-cv-00184: 564-8 (2024, pp. 119–120). This response came after it was pointed out to Bowers that selecting GDG members based on their "advocacy" for medical treatment was in "tension" with selecting GDG members who could be "impartial arbiters" on the evidence for those treatments.
[67] Edwards-Leeper & Anderson (2021).

resistant to constructive criticism. Edwards-Leeper privately warned WPATH leaders that their intolerance for dissent and attempts to “muzzle clinicians” risked damaging the organization's credibility among professionals, patients, and educated parents.[68] Anderson faced a formal reprimand[69] after criticizing (with Bowers) the quality and consistency of care provided under the SOC framework.[70]

This combination of poorly managed COIs and restrictive membership practices significantly undermines the credibility and scientific integrity of SOC-8 as a clinical practice guideline. The GDG’s handling of the SRs of evidence WPATH commissioned for development of SOC-8 further highlights the serious threat to clinical integrity that plagued the guideline development process.

10.3.2 Suppression of evidence

NAM stipulates that trustworthy guidelines must be based on SRs of existing evidence. SOC-8 was promoted as the first to be “evidence-based,”[71] with its chair claiming it followed “the most rigorous protocol in the world to ensure these standards reflect scientific evidence.”[72] The Methodology section states that SOC-8 “incorporated the recommendations on clinical practice guideline development set forth by the National Academies of Medicine and the World Health Organization, which addressed transparency, conflict-of-interest policy, committee composition, and group process.”[73]

In 2018, as part of its development of a new clinical guideline, WPATH commissioned more than a dozen SRs from the EPC at JHU. SRs were completed and handed over to WPATH for its chapters on assessment, primary care, endocrinology, surgery, reproductive medicine, and voice therapy.[74]

These expert reviews had the potential to advance current understanding of the state of the evidence, but their usefulness cannot be evaluated because WPATH successfully

[68] Boe v. Marshall, No. 2:22-cv-00184: 560-26 (2024, p. 153).
[69] Boe v. Marshall, No. 2:22-cv-00184: 560-26 (2024, pp. 114–115).
[70] Shrier (2021b).
[71] “This version of the Standards of Care is the first to be developed using an evidence-based approach” (Radix, n.d., p. 13).
[72] Coleman (2023).
[73] Coleman et al. (2022, p. S247).
[74] Boe v. Marshall, No. 2:22-cv-00184: 560-17 (2024, p. 38).

suppressed them. In an email exchange from August 2020, a senior author from EPC, writing to the Agency for Healthcare Research and Quality (AHRQ),[75] stated that their SRs "found little to no evidence about children and adolescents" and that WPATH had been "trying to restrict our [JHU's] ability to publish."[76]

In a memo to all SOC-8 working group members, WPATH leadership reported that they "were caught on the wrong foot" when they learned that JHU wanted to publish reviews that would likely undermine WPATH's "gender-affirming" approach.[77] Despite their initial resistance, the JHU researchers ultimately capitulated to WPATH's new terms, allowing SOC-8's chair, co-chairs, a handpicked chapter member, and WPATH's Board of Directors to pre-approve manuscript content before any independent drafting could occur. Under WPATH's imposed process,[78] researchers were required to submit a proposal form outlining the planned results and conclusions before drafting even began—and again once the manuscript was ready for publication—ensuring that leadership could steer findings to align with predetermined agendas rather than allowing an independent, evidence-driven process.[79]

[75] A unit of the U.S. Department of Health and Human Services.
[76] Boe v. Marshall, No. 2:22-cv-00184: 560-23 (2024, p. 23) The AHRQ official acknowledged the message: "Knowing that there is little/no evidence about children and adolescents is helpful." Nevertheless, two years later HHS released a memo in which it asserted that "[r]esearch demonstrates that gender-affirming care improves the mental health and overall well-being of gender diverse children and adolescents" (OPA: Office of Population Affairs, n.d.).
[77] Boe v. Marshall, No. 2:22-cv-00184: 523-1 (2024, p. 14).
[78] See Figure 10.1.
[79] Boe v. Marshall, No. 2:22-cv-00184: 523-1 (2024, p. 8).

Figure 10.1: WPATH approval process for manuscripts

1. The lead author submits a proposal of the publication to WPATH with the following headings: Background; Aim(s); Method; Results;

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Approved by WPATH Board of Directors – August 2020

JHU_000003198

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Conclusion (Maximum 1 page and states which SOC8 chapter the publication is linked to);

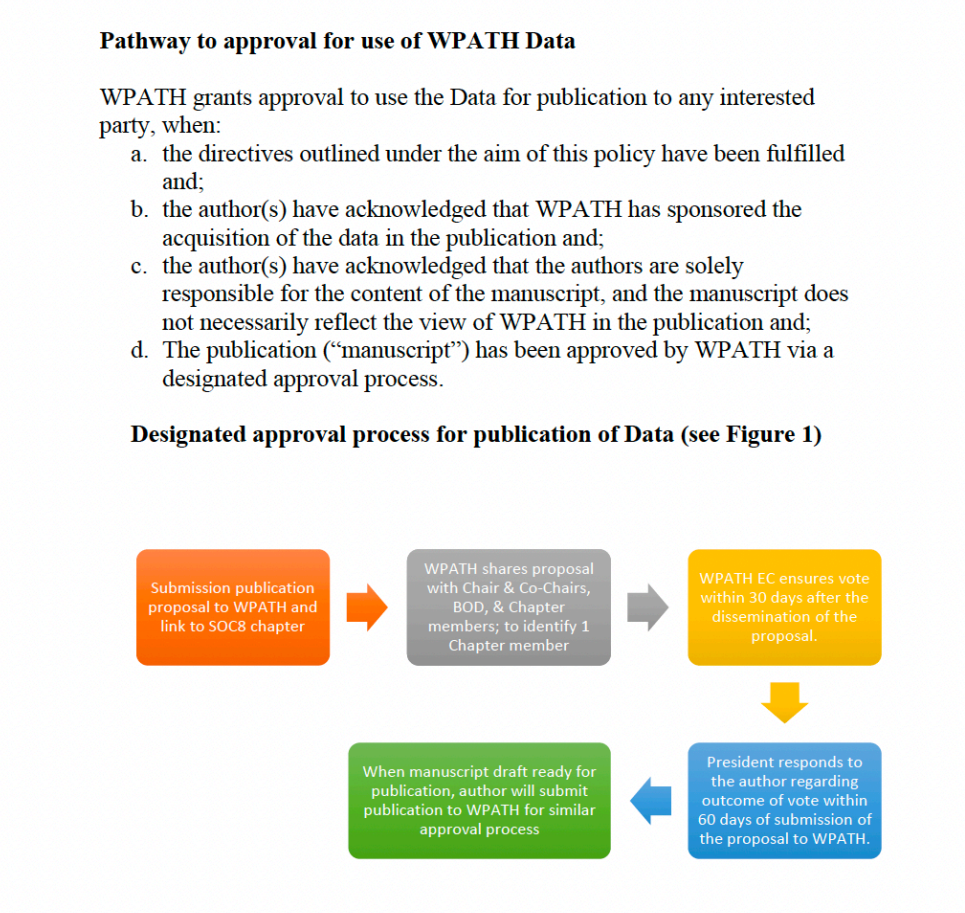
2. It is WPATH's responsibility that the proposal is shared with the Chair and Co-Chairs of the SOC8, the members of the WPATH Board of Directors and all members of the SOC8 chapter linked to the proposed publication within 14 days after receipt of the proposal. The aim will be to identify an individual (s) from the chapter (maximum 2 individuals if a publication concerns more than one chapter) who will work with the lead author(s) of the proposed publication (unless the lead author is already working with one or more Working Group members); it is the responsibility of the Working Group as a whole to identify and to nominate one of their members, either by vote or general consensus within the Working Group.
3. WPATH will keep a record of the possible proposals with deadlines for draft submissions - in order to avoid the development of multiple papers with the same aims using the same data;
4. It is WPATH Executive Committee's responsibility to ensure that a vote is held within 30 days after the dissemination of the proposal.
5. It will be a blind vote and approval to write the paper is granted to the author(s) by majority vote. In case of a tie, the WPATH President will have the deciding vote.
6. It is the President's responsibility to respond to the author(s) with approval or disapproval within fifty-six (56) days of submission of the proposal to WPATH.
7. Once the manuscript draft is ready for publication, the lead author will submit the publication to WPATH
8. It is WPATH Executive Committee's responsibility to ensure that the manuscript is disseminated to the Chair of the SOC8, the Co-Chairs of the SOC8, and the members of the WPATH Board of Directors within 7 days after receipt of the manuscript.
9. It is WPATH Executive Committee's responsibility to ensure that a vote is held within 14 days after the dissemination of the manuscript to the Chair and Co-Chairs of the SOC8 and Board members.
10. It will be a blind vote and approval is granted to author(s) for publication by majority vote. The Chair and Co-Chairs of the SOC8 and Board members all have one equal vote. In case of a tie, the WPATH President will have the deciding vote.

Among the terms required for gaining WPATH approval was ensuring that the SRs' findings supported, or at least did not undermine, WPATH's goal of promoting greater access to medical interventions. Additionally, the SOC-8 chapter's working group leader or an appointed representative or the SOC-8 chair/co-chairs and at least one person

who identified as transgender were required to oversee and approve the manuscript's design, drafting, and final content.[80]

Despite this close involvement and editorial control, all final documents were required to include a statement to the effect that "the authors are solely responsible for the content of the manuscript, and the manuscript does not necessarily reflect the view of WPATH."[81]

Figure 10.2: Pathway to manuscript approval



WPATH's stated goal was to "ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense."[82] Following this

[80] Boe v. Marshall, No. 2:22-cv-00184: 523-1 (2024, pp. 5–6).
[81] Boe v. Marshall, No. 2:22-cv-00184: 523-1 Exhibit 1 (n.d., p. 8). See Figure 10.2.
[82] Boe v. Marshall, No. 2:22-cv-00184: 560-17 (2024, p. 92).

renegotiation, only one SR, Baker et al. (2021), was published.[83] Internal WPATH documents reveal that Baker et al. complied with all the mandatory steps of WPATH's updated approval policy—from approving the conclusions before the manuscript was drafted to ensuring extensive WPATH engagement in the process and obtaining the final approvals. The Baker et al. SR was published with the mandatory disclaimer that "WPATH had no role in study design, data collection, analysis, interpretation, or drafting" of the SR. However, internally, WPATH actually recorded[84] its engagement in the design, drafting, and final approval of the article.[85]

[83] One other systematic review (Wilson et al., 2020) was published prior to the policy update.
[84] See checklist in Figure 10.3 below.
[85] Wilson et al. (2020) includes the same statement but was published prior to the new agreement, so it is not possible to determine the degree to which WPATH influenced its drafting and design.

Figure 10.3: Checklist for Baker et al.[86]

Checklist for JHU SOC8 systematic review papers

Title of Paper: Hormone Therapy, Mental Health, and Quality of Life among Transgender People: A Systematic Review

Supporting Chapter: initial question part of questions from Hormone Chapter

Proposed Authors: Kellan E. Baker, MPH, Lisa M. Wilson, ScM, Ritu Sharma, BSc, Vadim Dukhanin, MD, MHS, Kristen McArthur, BA, Karen A. Robinson, PhD

Acknowledged Authors: None

Yes or No	This paper provides data that advances the knowledge in the field of transgender health in a positive way
Yes or No	This paper will be published in a reputable, academic, peer-reviewed journal
	Journal proposed for first submission The Lancet Diabetes & Endocrinology
Yes or No	Involves the work group leader of the chapter or alternatively a designated representative of that specific SOC8 Chapter in the design, drafting of the article and final approval of the article
	Name of persons involved *chapter members provided original list of questions for reviews*
Yes or No	Involves at least one member of the transgender community in the design, drafting of the article and final approval of the article *chapter members provided original list of questions for reviews*
	Name of person if not open about trans status, if not open about trans status then enter N/A
Yes or No	Adheres to the WPATH language policy

WPATH's policy appears to have effectively blocked the planned[87] and completed[88] research—including critical evidence appraisals—from being developed into publishable manuscripts. As a result, important SRs addressing the safety of PBs, CSH, and surgery for adolescents were suppressed, keeping key findings out of the scientific record and shielding them from professional scrutiny.[89]

[86] Source: Boe v. Marshall, No. 2:22-cv-00184: 560-17 (2024, p. 41).
[87] Robinson, Sharma, Baker, et al. (2019); Robinson, Sharma, Wilson, et al. (2019); Sharma et al. (2018).
[88] In total, only 2 systematic reviews were published, and only one (Baker et al., 2021) followed the policy update.
[89] See Chapter 7 for a more extensive discussion.

As established in Section 10.3.1, members of the GDG were committed to PMT and believed their positions to be grounded in evidence. Indeed, a central goal for SOC-8 was to deliver an updated version explicitly supported by robust evidence. However, once the GDG began working with methodological experts and applying evidence-based medicine (EBM) standards, it quickly became clear that their understanding of what constituted "strong evidence" was fundamentally at odds with established scientific criteria. Evidence that the GDG previously regarded as strong or compelling was frequently downgraded under EBM standards to low or very low quality, revealing a troubling gap between WPATH members' beliefs about evidence and the actual rigor of the underlying research. This process is clearly articulated by SOC-8 Chair Eli Coleman under points six ("Expert Consultation in Guideline Development") and seven ("Research Agenda") of a 12-point draft following SOC-8's publication:

> As we faced challenges of developing and revising the methodology of SOC 8, we had to rely on Johns Hopkins, which while some degree helpful, was very constraining. We were able to consult with other experts and was [sic] able to learn that there were other ways of developing guidelines that were probably more appropriate for the state of our science. As a result, our methodology evolved and was improved—however, we were not able to be as systematic as we could have been … Now that we have reviewed the evidence, we are painfully aware of the gaps in the literature and the kinds of research that are needed to support our recommendations and strengthened [sic] the level of evidence in support of them.[90]

When confronted with SRs that did not adequately support its positions—particularly given their stated legal and advocacy concerns (see next section)—the GDG chose not to adjust its views but to find an alternative methodology to support its recommendations. As SOC-8 GDG Co-Chair Jon Arcelus explained in an email to other GDG members, "[t]here are many recommendations in the SOC that don't have direct

[90] Boe v. Marshall*,* No. 2:22-cv-00184: 700-18 (2024, pp. 8–9).

evidence (most of the direct evidence is in the hormone chapter) but they have background evidence. This is why we have Delphi."[91]

A consensus-building process, Delphi is not a substitute for evidence-based recommendations but rather a method for GDGs to reconcile disagreement in the interpretation of SRs, or in deciding how evidence should inform treatment recommendations.[92] Guidelines that are not based on SRs inadvertently risk promoting suboptimal or even harmful care. This is why guidelines that rely only on consensus are not considered trustworthy.[93]

10.3.3 Redefinition of medical necessity

SOC-8 makes a strong recommendation that PBs, CSH, and surgery be considered "medically necessary" for eligible adolescents:

> We recommend health care systems should provide medically necessary gender affirming psychological, medical and surgical treatments for trans and gender diverse children, adolescents, and adults."[94]

The development of the "medical necessity" statement in SOC-8 starkly illustrates how many WPATH contributors prioritized goals other than ensuring the highest-quality care for adolescents with GD. A good example is WPATH's rewording of patient "wishes" as patient "needs" with the intent to frame them as "medically necessary." At first, the statement described the desired interventions as "wishes":

> There is strong evidence demonstrating the benefits in quality of life and wellbeing of gender affirming treatments, including endocrine and surgical procedures, properly indicated and performed as outlined by the Standards of Care (Version 8), in TGD people *wishing these treatments.*[95]

However, the final SOC-8 statement reads:

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[91] Boe v. Marshall*,* No. 2:22-cv-00184: 560-37 (2024, p. 101). Delphi is a structured consensus-building method in which a GDG iteratively reviews and rates statements to achieve agreement; SOC-8 utilized a 75% threshold for consensus.
[92] Djulbegovic & Guyatt (2019).
[93] Lima, Tangamornsuksan et al. (2023).
[94] Boe v. Marshall*,* No. 2:22-cv-00184: 700-10 (2024, p. 32).
[95] Boe v. Marshall*,* No. 2:22-cv-00184: 700-10 (2024, p. 38).

> There is strong evidence demonstrating the benefits in quality of life and well-being of gender-affirming treatments, including endocrine and surgical procedures, properly indicated and performed as outlined by the Standards of Care (Version 8), in TGD people *in need of these treatments*.[96]

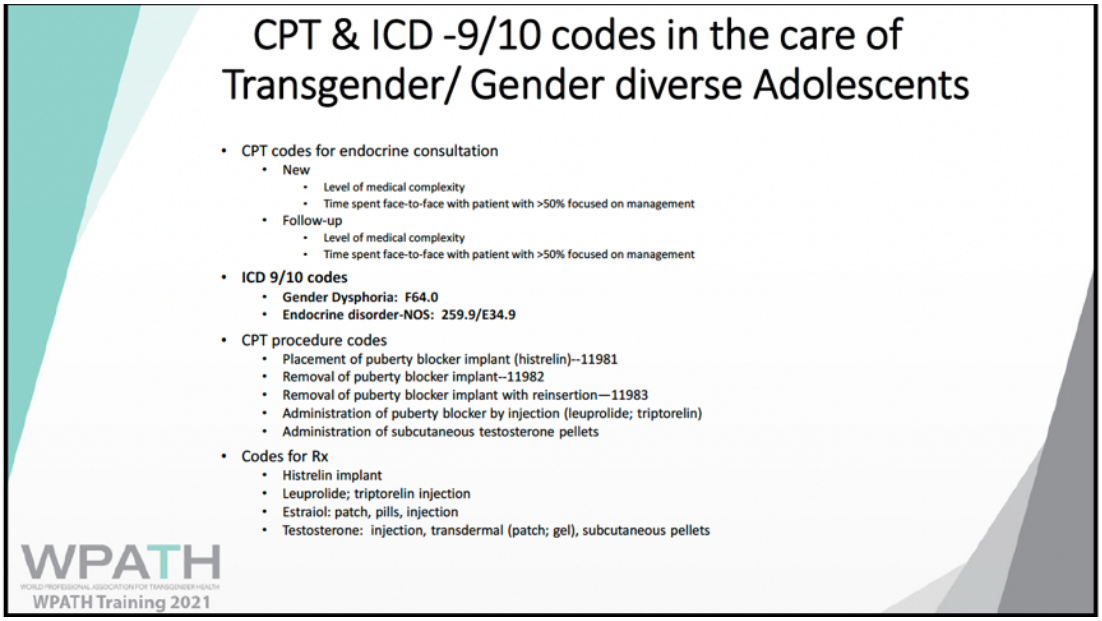
This consequential textual change was the result of WPATH members recognizing the implications of their word choice for insurance and legal contexts. The change was made based on the following request during the drafting phase:

> Thank you, I also very much like this statement and the supporting write-up. There is one word, though, in the middle (on the right side of the page) of the last paragraph on the first page of the document: “wishing.” This word gives me pause, and perhaps I am being too sensitive, but one of the biggest obstacles trans people experience in getting support for coverage of our care is that we are told “you can't always get what you want" and “wishing does not make it so." Wishing makes the needed care seem optional, and we are often told we are imagining that we are not who we are and we should just suck it up. Would it be possible or advisable or prudent to replace “wishing” with “in need of” here? Thanks for your consideration, and for your great work on this.[97]

This was accompanied by WPATH’s explicit instruction to providers to use the “Endocrine Disorder” diagnosis as an alternative for the mental health diagnosis of GD[98]:

[96] Coleman et al. (2022, p. 18, emphasis added).
[97] Boe v. Marshall, No. 2:22-cv-00184: 700-10 (2024, p. 28).
[98] Rosenthal (2021b, Slide 11). See Figure 10.4.

Figure 10.4: WPATH training instructs providers to use “Endocrine disorder” code



Together, these internal WPATH communications reveal that the "medical necessity" framing in SOC-8 was constructed to remove key safeguarding criteria and make patient desires central to treatment decisions. This was confirmed by another GDG member who candidly observed that the guidelines exist to allow any “goodwilling” clinician to meet patients’ wishes—however medically inappropriate they may be.

> I think it is clear as hell that the SOC8 refers to the necessity of treatment (in its broadest sense) of TGD people who pursue treatment (in its broadest sense) for their gender dysphoria (small "d": because it refers to the symptom of distress - which is a very broad category and one that any 'goodwilling' clinician can use for this purpose (or: in the unescapable medical lingo we, as physicians arc stuck with: those who fulfil a diagnosis of Gender Dysphoria and Gender Incongruence as per APA/WHO).[99]

The request to substitute “wish” for “need” and emphasize "medical necessity” was welcomed by WPATH leaders, who responded that the assertion of medical necessity

[99] Boe v. Marshall, No. 2:22-cv-00184: 700-10 (2024, p. 37).

would influence the “obtuse and unhealthy” U.S. healthcare system by compelling insurance coverage through the courts:

> Thank you for putting this together; you've done a great job with this. Indeed, it is important that such a statement is part of the actual SOC. And, indeed, the original Medical Necessity Statement was specific to the U.S. because this was where we were experiencing the problem with our obtuse and unhealthy system of healthcare "coverage" and we needed a tool for our attorneys to use in defending access to care here. I have long wanted this (and many of our other policy statements) to become part of the SOC because that gives them greater force.[100]

GDG Chair Eli Coleman stated that while WPATH had no definition of “medically necessary,” he understood this to be primarily a term used by insurance companies to determine which conditions or procedures to cover.[101] The SOC-8 legal and political goals are discussed in the next section.

10.3.4 Legal and political considerations

Internal documents reveal that SOC-8 authors manipulated guideline language with the explicit aim of shaping court rulings, legislative actions, and insurance coverage decisions, revealing a clear departure from the principles of unbiased, evidence-driven clinical guideline development. For example, contributors to the “Institutional Environments” chapter disclosed that “social justice lawyers” had advised them against rigorous evidence reviews, stating that such reviews might reveal limited or insufficient evidence, placing them “in an untenable position in terms of affecting policy or winning lawsuits.”[102] As discussed above, a key motivation for including a “medical necessity” statement in the guidelines was described as a strategic move to provide “a tool for our attorneys to use in defending access to care” within the U.S. legal context.[103]

[100] Boe v. Marshall, No. 2:22-cv-00184: 700-10 (2024, pp. 33–34)
[101] Boe v. Marshall, No. 2:22-cv-00184: 700-3 (2024, p. 166).
[102] Boe v. Marshall, No. 2:22-cv-00184: 560-24 (2024, p. 3).
[103] Boe v. Marshall, No. 2:22-cv-00184: 700-10 (2024, pp. 33–34).

Schechter also expressed concerns about language, cautioning colleagues that terms such as “insufficient evidence” and “limited data” could strengthen legal arguments claiming medical interventions are experimental, and noting his own role as an expert witness in related federal cases.[104] Karasic, chair of the SOC-8 Mental Health chapter, highlighted the critical legal implications of defining treatments for adolescents as “medically necessary,” stating that this determination affects court cases, policy decisions, and insurance coverage.[105] Elsewhere, Karasic emphasized the urgency of addressing this issue clearly in SOC-8 given multiple ongoing lawsuits—some potentially reaching the Supreme Court of the United States—concerning whether medical gender interventions are “medically necessary” or “experimental or cosmetic.”[106]

One internal communication explicitly advised against using specific numerical age guidelines for treatments, stating, “I would avoid absolute numbers [for ages] that can be taken out of context or used in court” because they would disadvantage the people “we are trying to advocate for.”[107] Elsewhere, editorial input was provided specifically to help “Chase” [presumably a reference to Chase Strangio, Deputy Director for Transgender Justice with the ACLU’s LGBT & HIV Project].[108] GDG Chair Coleman urged the group to adopt a stronger defensive stance, stating, “we need a more detailed defense that we can use ... in the many court cases that will be coming up … especially around adolescence.”[109] One contributor even acknowledged prioritizing political advocacy goals explicitly over scientific accuracy, stating that SOC-8 should “land in such a way as to have serious effect in the law and policy settings...even if the wording isn’t quite correct for people who have the background you and I have.”[110]

Further, the U.S. healthcare context was clearly a specific focus of the SOC-8 authors. Karasic (SOC-8 Mental Health chapter chair) wrote:

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[104] Boe v. Marshall, No. 2:22-cv-00184: 700-13 (2024, p. 56).
[105] Boe v. Marshall, No. 2:22-cv-00184: 560-24 (2024, p. 43).
[106] Boe v. Marshall, No. 2:22-cv-00184: 700-10 (2024, p. 44).
[107] Boe v. Marshall, No. 2:22-cv-00184: 560-34 (2024, p. 25).
[108] Boe v. Marshall, No. 2:22-cv-00184: 591-24 (2024, p. 9).
[109] Boe v. Marshall, No. 2:22-cv-00184: 700-8 (2024, p. 40).
[110] Boe v. Marshall, No. 2:22-cv-00184: 560-34 (2024, p. 25).

> But there are elements of the Medical Necessity statement that are critical to insurance reimbursement and access to care in the U.S., though not so in every country, and these should have a place somewhere in SOC 8. If WPATH SOC 8 fails to adequately support access to trans care in the U.S. by overgeneralizing wording, it may be globally applicable, but it is not globally useful, insofar as the U.S. is part of the globe. There should be room in SOC 8 to address concerns of national health systems, or other non-reimbursement focused systems without making SOC 8 less useful to U.S. trans care … Medical necessity is at the center of dozens of lawsuits in the U.S. right now over state actions to make trans care inaccessible, as well as being at the center of all reimbursement for trans care in the U.S. … it is critical that WPATH SOC 8 gets this right, which I think it does, currently."[111]

Incorporation of legal advocacy goals into guideline language, explicitly for purposes of influencing policy and litigation outcomes, conflicts sharply with accepted international standards emphasizing scientific rigor and impartiality.

Internal documents reveal that WPATH leadership was aware that the guidelines would be criticized due to the "continuing pressure in healthcare to provide evidence-based care." Coleman noted ongoing resistance from "academics and scientists who are naturally skeptical," "parents of youth who are caught in the middle of this controversy," and pressures arising from the "increasing number of regret cases and individuals who are vocal in their retransition process who are quick to blame clinicians for allowing themselves to transition despite an informed consent process."[112]

In response to anticipated criticism of SOC-8, Coleman drafted a "12-point strategic plan to advance gender-affirming care."[113] The plan acknowledged that all members of the GDG were "painfully aware that there are many gaps in research to back up our recommendations," and emphasized the importance of building consensus among

[111] Boe v. Marshall*,* No. 2:22-cv-00184: 700-10 (2024, p. 65).
[112] Boe v. Marshall*,* No. 2:22-cv-00184: 700-18 (2024, p. 5).
[113] Boe v. Marshall*,* No. 2:22-cv-00184: 700-18 (2024, p. 6).

medical groups in support of SOC-8. Coleman observed that the endorsement of medical organizations "has been an extremely powerful argument" in "legal battles":[114]

> As we are facing so many legal battles over trans health care and rights, the statement that the SOC has so many endorsements has been an extremely powerful argument. We need to be able to get the support of these important organizations and know how to indicate their support accurately or this argument in these court cases could be challenged.[115]

10.4 Elimination of age minimums

The handling of minimum age recommendations for clinical interventions for adolescents in SOC-8 exemplifies what happens when guideline development is compromised by ideological beliefs, COIs, and disregard for established evidence standards.

Initially, SOC-8 included age minimums for certain interventions: 14 years for cross-sex hormones; 15 years for mastectomy; 16 years for breast augmentation and facial surgery; 17 years for metoidioplasty, orchiectomy, vaginoplasty, hysterectomy, and fronto-orbital remodeling; and 18 years for phalloplasty. In July 2022, WPATH faced significant pressure from Admiral Rachel Levine, the U.S. assistant secretary for health, whose office communicated concern that listing specific, minor ages would trigger restrictive legislative actions. Internally, some SOC-8 members expressed discomfort about acceding to pressures from the federal government. "I don't know how I feel about allowing U.S. politics to dictate international professional clinical guidelines that went through Delphi," said one SOC-8 co-chair.[116] Another complained that it "is not appropriate to take any feedback from a nonmedical professional seriously."[117] Despite

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[114] Boe v. Marshall, No. 2:22-cv-00184: 560-40 (2024, pp. 6–8). Of note, although SOC-7 is now outdated, it was SOC-7 that was responsible for establishing the "gender-affirming" medical approach in the U.S. and internationally. The email from the lead author of both SOC-7 and SOC-8, Coleman, discloses that despite the widespread narrative that SOC-7 had been endorsed by all medical organizations, no such endorsements ever occurred. Coleman said he had "no idea how it was ever said that so many medical organizations … endorsed SOC 7" (Boe v. Marshall, No. 2:22-cv-00184: 700-3, 2024, pp. 262–264).
[115] Boe v. Marshall, No. 2:22-cv-00184: 560-40 (2024, p. 8).
[116] Boe v. Marshall, No. 2:22-cv-00184: 700-15 (2024, p. 33).
[117] Boe v. Marshall, No. 2:22-cv-00184: 700-15 (2024, p. 27).

these reservations, WPATH's apparent investment in securing endorsement from the Biden administration led it to agree to downgrade age guidelines from "recommendations" to "suggestions," thereby circumventing the original consensus process by making these changes without conducting a new round of validation.[118]

The issue of minimum ages resurfaced when the American Academy of Pediatrics (AAP) threatened to publicly oppose SOC-8 unless all age thresholds were eliminated—further exposing how political pressure, rather than scientific evidence or clinical judgment, dictated the final content of the guidelines.[119] Under pressure and facing open opposition from a key ally, WPATH leaders capitulated and agreed to eliminate minimum age criteria for all hormonal and surgical procedures (except phalloplasty). They did so despite acknowledging privately that the individuals within the AAP who were issuing the demand were very junior and lacked the authority or expertise to credibly dictate clinical standards.[120]

In the process of removing minimum ages, WPATH's president wrote that it was "disappointing that politics always trumps common sense and what is best for patients."[121] Another WPATH leader confided that the deletion of age minimums "is a balancing act between what I feel to be true and what we need to say."[122] SOC-8 Co-Chair Jon Arcelus said that removing ages would "make a joke of our methodology."[123]

The rushed, 11th-hour changes—made outside any formal or transparent guideline development process—resulted in SOC-8 initially being published with its original age recommendations still intact. Only after publication did WPATH scramble to issue a correction via an erratum in their official journal, the *International Journal of Transgender Health*, quietly removing age restrictions to align with political demands rather than

[118] Boe v. Marshall, No. 2:22-cv-00184: 700-3 (2024, pp. 292–295); Boe v. Marshall, No. 2:22-cv-00184: 700-15 (2024, p. 33). SOC-8's final round of Delphi processing was in January 2022 (Coleman et al., 2022, p. S251).
[119] Coleman explains that removing ages "led to them [i.e. AAP] formally not opposing the SOC. Yes this is highly confidential" (Boe v. Marshall, No. 2:22-cv-00184: 700-17, 2024, p. 153).
[120] Boe v. Marshall, No. 2:22-cv-00184: 700-16 (2024, p. 201).
[121] Boe v. Marshall, No. 2:22-cv-00184: 700-15 (2024, p. 26).
[122] Boe v. Marshall, No. 2:22-cv-00184: 700-6 (2024, p. 103).
[123] Boe v. Marshall, No. 2:22-cv-00184: 700-16 (2024, p. 110).

clinical evidence.[124] The current, published version of SOC-8 states that all recommendations went through the Delphi process. However, Coleman later acknowledged that removal of age minimums did not go through Delphi.[125]

10.5 Continued reliance on SOC-8

It remains concerning that SOC-8 continues to exert substantial influence over U.S. healthcare. WPATH's misconduct during the development of SOC-8 was covered by major news outlets including *The New York Times*,[126] *The Economist*,[127] *The Boston Globe*,[128] *Fox News,*[129] and *National Review,*[130] as well as by the *BMJ*, a leading medical journal.[131] Despite these reports, with the exception of the American Society of Plastic Surgeons,[132] major American medical associations have not issued public statements addressing the concerns detailed in this chapter.

In an amicus brief submitted to the Supreme Court of the United States for the upcoming case *U.S. v. Skrmetti*,[133] the AAP and 21 other medical organizations describe SOC-8 as an "established, evidence-based clinical guideline." The brief does not address any of the concerns or revelations regarding the guidelines' development outlined in this chapter. Similarly, a group of 11 prominent "adolescent medicine specialists, pediatricians, clinicians, methodologists, professors, and researchers"—including professionals affiliated with the medical schools of Harvard University, Stanford University, and the University of Pennsylvania—asserts in a separate brief that SOC-8 has "all" the National Academy of Medicine's "hallmarks of reliability."[134]

The U.S. Department of Justice (DOJ) intervened in 2022 to challenge Alabama's age limit law in *Boe v. Marshall*, thereby becoming familiar with the subpoenaed documents

[124] Correction (2022).
[125] Boe v. Marshall, No. 2:22-Cv-00184: 700-3 (2024, pp. 294–295).
[126] Ghorayshi (2024b).
[127] The Economist (2024).
[128] Selin Davis (2024b).
[129] Joseph (2024).
[130] Whelan (2024a).
[131] Block (2024a).
[132] Sapir (2024c).
[133] U.S. v. Skrmetti (No. 23-477), American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations, Amicus curiae brief (2024, p. 8).
[134] U.S. v. Skrmetti (No. 23-477), Clinical Practice Guideline Experts, Amicus curiae brief (2024, p. 22).

from WPATH. Nevertheless, in August 2024—two months after the documents were unsealed—the DOJ in a merits brief filed in *U.S. v. Skrmetti* described WPATH as "the leading association of medical professionals treating transgender individuals" and asserted that "[t]he Nation's leading medical and mental health organizations recognize [SOC-8] as reflecting the accepted standard of care for treating gender dysphoria."[135]

[135] U.S. v. Skrmetti (No. 23-477), Brief for the petitioner (2024, p. 3).

Chapter 11 Collapse of Medical Safeguarding

When children or adolescents develop feelings of severe discomfort with their sexed bodies, parents understandably worry and consult pediatricians or therapists for advice. These frontline clinicians in turn refer them to specialists, believing that this requires special expertise. Both parents and the clinicians they initially consult likely expect that those with expertise in "gender" will conduct a comprehensive evaluation to rule out other, perhaps more common causes of such feelings. They may further assume that puberty blockers (PBs), cross-sex hormones (CSH), and surgery are offered only in rare cases, when less invasive alternatives are ineffective, and after careful consideration of the patient's unique developmental needs as well as the profound uncertainties and risks of the treatments.

This chapter documents how the original Dutch Protocol that underpins pediatric medical transition (PMT) has undergone transformation in the U.S. to become a "child led" process in which the patient's personal "embodiment goals" form the basis for the determination of "medical necessity." Section 11.1 revisits the Dutch Protocol (critically assessed in earlier chapters) and explores how the original safeguards on the practice of pediatric medical transition (PMT) have been systematically dismantled in the U.S. Section 11.2 evaluates the frequent assertion that PMT is "rare," questioning whether this claimed infrequency genuinely indicates rigorous assessment standards. Section 11.3 discusses a deeper shift in PMT objectives, highlighting how the concept and role of "assessment" have fundamentally changed. Section 11.4 introduces whistleblowers with direct experience in PMT who, similarly to their counterparts in the U.K.,[1] have revealed practices they consider unsafe and inconsistent with established clinical standards, providing additional evidence of expedited pathways to medical interventions in leading pediatric gender clinics across the U.S.

11.1 The Dutch Protocol and the relaxation of its criteria in the U.S.

According to WPATH SOC-8, the Dutch studies associated with the Dutch Protocol provide "[t]he most robust longitudinal evidence supporting the benefits of gender-

[1] Barnes (2023).

affirming medical and surgical treatments in adolescence …"[2] In his testimony before the Florida Boards of Medicine and Osteopathic Medicine, Aron Janssen, vice chair of clinical affairs at Lurie's Pritzker Department of Child and Adolescent Psychiatry, who also serves as chair of the American Academy of Child and Adolescent Psychiatry's Sexual Orientation and Gender Identity Issues Committee, said that "the best longitudinal data we have on transgender youth comes primarily out of the Dutch clinic … The Dutch model of care [is] the prevailing model of care that most of the American clinics have based their care upon."[3] SOC-8 seems to acknowledge the guardrails recommended in the Dutch Protocol, contrasting the "detailed comprehensive diagnostic assessment process" of that Protocol with treatment based on "limited or no assessment." According to WPATH, the latter approach "has no empirical support and therefore carries the risk that the decision to start gender-affirming medical interventions may not be in the long-term best interest of the young person at that time."[4]

11.1.1 U.S. gender clinics' departure from the Dutch Protocol

In 2022, investigative reporters from Reuters interviewed "doctors and other staff at 18 gender clinics across the country" and found that "[n]one described anything like the months-long assessments [the Dutch clinicians] adopted in their research." Seven of the 18 clinics said they were comfortable prescribing hormones on an adolescent's first visit, provided clinicians saw no "red flags."[5]

The Dutch clinicians themselves recognized the divergence of the American model from their approach.[6] Noting the shift in age-of-onset, sex ratio, and mental health profile in the pediatric clinical population, Annelou de Vries wrote in 2020 that "[t]hese youth did not yet participate in the early evaluation studies. This raises the question of whether the positive outcomes of early medical interventions also apply to adolescents who more recently present in overwhelming large numbers for transgender care, including

[2] WPATH is referring to de Vries et al. (2011) and de Vries et al. (2014), discussed in several earlier chapters.
[3] Florida Boards of Medicine and Osteopathic Medicine Joint Rules/Legislative Committee (2022), 47:45–48:03.
[4] Coleman et al. (2022).
[5] Terhune et al. (2022).
[6] For a study on how different countries have responded to the Dutch Protocol see Kozlowska et al. (2024).

those that come at an older age, possibly without a childhood history of [gender incongruence]."[7] In 2021, Thomas Steensma complained that "the rest of the world is blindly adopting our research …"[8] Steensma reiterated this position in 2023, explicitly distancing his work from the child-led model prevalent in the United States, stating, "That's not our approach."

Of note, the Dutch Protocol did not recommend surgeries prior to legal adulthood, but according to WPATH guidelines, which are followed in the United States,[9] most surgeries, including most genital surgeries, may be deemed medically necessary for certain adolescents with GD.[10] Accordingly, adolescents with GD do undergo mastectomies[11] and (much less commonly) genital surgeries.[12] In the published research on mastectomies in adolescent females with GD,[13] some participants were as young as 12 years old.[14]

11.2 Is pediatric medical transition "rare"?

To bolster the perception that medical gatekeeping ensures patient safety, advocates of PMT frequently assert that medical interventions are "rarely prescribed" to minors. In 2022, for example, the president of the American Academy of Pediatrics (AAP) asserted in an opinion piece published in *The Wall Street Journal* that "for the vast majority of children," the "gender-affirming" approach recommends the "opposite" of medical interventions.[15] These claims are not supported by the data.

In 2025, a *JAMA Pediatrics* study utilizing insurance data reported that about 0.1% of American 17-year-olds, or one in 1,000, received CSH between 2018 and 2022. The authors concluded that hormonal interventions are therefore "rare" and decried the "politicization of gender-affirming care for transgender youth … driven by a narrative

[7] de Vries (2020).
[8] Tetelepta (2021a). There is an English translation available: Tetelepta (2021b).
[9] Coleman et al. (2022).
[10] E.g., "A key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical *and surgical treatments* (GAMSTs)" (Coleman et al., 2022, S45-S46, emphasis added).
[11] Wright et al. (2023); Ghorayshi (2022); Sapir (2024c).
[12] Milrod & Karasic (2017); Terhune et al. (2022).
[13] Ascha et al. (2022); Olson-Kennedy, Warus, et al. (2018); Tang et al. (2022).
[14] Tang et al. (2022).
[15] Szilagyi (2022a).

that millions of children are using hormones and that this type of care is too freely given."[16]

Such claims ignore a number of critical facts. First, no serious critic or skeptic of PMT has claimed that "millions of children are using hormones." Second, whether a prevalence of one in 1,000 is "rare" is subjective. For context, the prevalence of Type 2 diabetes in less than one in 1,000—a rate that medical authorities have described as "high" and even as "an awakening epidemic."[17] Third, even medical interventions that are objectively "rare" can raise profound ethical concerns. For example, "only" about 600 out of millions of African American men were recruited into the highly unethical Tuskegee syphilis study.

A central question in the debate over the frequency of medical interventions, and by extension whether they are "rare" or "freely given," concerns the appropriate choice of denominator. The authors of the *JAMA* study calculated prevalence using the total population of American adolescents as the denominator. However, in a press release accompanying the study, one of the authors noted that access to hormones was "surprisingly low, given that over 3% of high school youth identify as transgender"—implicitly invoking a different denominator.

Another denominator, which yields an even higher estimated frequency, is the number of adolescents diagnosed with GD and/or referred to a gender clinic, where they ostensibly undergo an "assessment" to determine whether medical interventions are indicated. Data on the rate of medicalization among adolescents diagnosed with GD and/or referred to a gender clinic are lacking.

Reports from individual clinics suggest that medicalization is the norm, rather than the exception. For example, pediatric endocrinologist Daniel Shumer of the Comprehensive Gender Services Program (CGSP) at University of Michigan Health estimated that "65 percent" of pediatric patients referred to his clinic end up receiving CSH.[18] According to data collected by Jamie Reed, a case worker at the Washington University School of

[16] Hughes et al. (2025).
[17] Lawrence et al. (2021); Kingsbury & Greene (2025) and the research articles cited therein.
[18] Doe v. Horne, No. 4:23-cv-00185-JGZ: 265 (2025, p. 52).

Medicine Pediatric Transgender Center at St. Louis Children's Hospital, 67 percent of the clinic's patients were prescribed endocrine interventions during her four-year tenure at the clinic.[19] Finally, WPATH has itself implied that medical interventions are appropriate for "most adolescents" who seek them. In its response to the release of the Cass Review in the U.K., WPATH issued a statement criticizing the Review as being "rooted in the false premise that non-medical alternatives to care will result in less adolescent distress for most adolescents…"[20]

11.3 Shift in objectives and the new meaning of "assessment"

The AAP and other American medical associations argue that transition-related medical decisions for minors are made in consultation with parents and only after a "robust diagnostic assessment."[21] Under the original Dutch Protocol, assessments were intended to predict lifelong transsexuality, with pubertal suppression conceptualized as part of the diagnostic process (buying "time to think"). By contrast, the "gender-affirming" model, as it has evolved in the United States, prioritizes the autonomy of children and adolescents, allowing their current "embodiment goals" to direct treatment decisions.[22]

A systematic review of recommendations for the management of GD in children and adolescents found an absence of "[d]etailed guidance" and "no consensus about the aim or clinical approach"[23] of assessment. Understanding the realities of clinical care for youth with GD in the U.S. requires appreciating the shift in the meaning of assessment, which reflects a deeper change in the goals of PMT. According to the Dutch approach, the goal was to predict lifelong "transsexualism." Mental health professionals were to ascertain whether a GD diagnosis was appropriate and if so, whether it was likely to persist through adulthood. Although advocates of this approach generally regard a

[19] Broyles & Trakas (n.d.).
[20] Block (2024c). The original statement from WPATH/USPATH (2024, April 12) was deleted from WPATH's website (404 Not Found | WPATH, n.d.). The April 12 WPATH/USPATH statement was covered by the NPR station WBUR (Scheimer et al., 2024). WPATH subsequently changed the statement, removing the referenced passage (see World Professional Association for Transgender Health & United States Professional Association for Transgender Health, 2024a; 2024b).
[21] U.S. v. Skrmetti (No. 23-477), American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations, Amicus curiae brief (2024).
[22] Block (2023d).
[23] Taylor, Hall, Heathcote et al. (2024b, s80).

diagnosis of GD as a necessary condition for medical interventions, there is considerable disagreement about whether it is sufficient.

More recently, advocates of early intervention have argued that "trans kids know who they are"[24] and that the goal of treatment is to help them achieve their personal "embodiment goals."[25] If an adolescent's self-conception or embodiment goals later change, this is not considered a failure of treatment but part of a "gender journey."[26] In 2023, Jason Rafferty, the lead author of the AAP's 2018 policy statement, "Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents," explained that PMT is about "affirming and validating the child's sense of identity from day one through to the end." If a child says, "I'm X, we operate under the assumption that what they're telling us is their truth, that the child's sense of reality and feeling of who they are is the navigational beacon to sort of orient treatment around." If patients later detransition, this does not mean that the treatments were inappropriate, even if the interventions' effects are partly or fully irreversible: "They're not treatment failures if that's what's affirming," Rafferty said.[27]

Of note, the more cautious approach, which seeks diagnostic and prognostic clarity and aims at improvements in mental health, has been found to be unsupported by evidence. No test can reliably predict the natural course of an adolescent's identity development. The U.K.'s Cass Review found that a gender dysphoria diagnosis "is not predictive that the individual will go on to have longstanding trans identity."[28] Clinicians who adopt the earlier diagnostic-oriented model might perceive their approach as more cautious relative to colleagues practicing the newer "affirming" model; however, research on outcomes from both approaches has been rated unreliable.

One indicator of the changing definition of "assessment" is that leading gender clinicians—who until recently characterized PBs as a "fully reversible" and temporary "pause button" intended to give patients "time to think"—now acknowledge that these

[24] See footnote 33 in Chapter 2.
[25] Ashley et al. (2023); Boskey et al. (2025, p. 2); Brennan et al. (2025, p. 5); Mosier-Mills et al. (2024).
[26] "Clinicians should see detransition as one of many possible steps in a person's gender journey" (Ashley et al., 2025, p. 7).
[27] Block (2023d).
[28] Cass (2024, p. 146).

drugs function as the first step in a broader medical transition protocol and must be considered in conjunction with cross-sex hormones. For example, in an amicus brief submitted to the Supreme Court of the United States, a leading advocate for PMT, Meredithe NcNamara of the Yale School of Medicine, and colleagues, fault the University of York systematic reviews, commissioned for the Cass Review, for failing to conceptualize PBs and CSH as a single "consistent, well-organized standard of care." According to McNamara et al., if, as research suggests, "the vast majority of adolescents with gender dysphoria who receive puberty blockers progress to cross-sex hormone therapy," that is not because PBs interfere with the natural process of GD resolution but "because [the adolescents] are indeed transgender and because their diagnosis of gender dysphoria is accurate."[29] This explanation for the observed high persistence of GD lacks empirical support due to the absence of controlled prospective studies and raises concerns about motivated reasoning. Many of the brief's authors are actively engaged in the practice of PMT and therefore have intellectual and financial conflicts of interest.[30]

11.3.1 Ambiguity in SOC-8

On the surface, WPATH SOC-8 might appear to recommend a cautious approach toward assessment. Mental health providers are to conduct a "comprehensive biopsychosocial assessment" prior to initiating medical interventions in order "to understand the adolescent's strengths, vulnerabilities, diagnostic profile, and unique needs to individualize their care."[31] At the same time, however, WPATH recommends that clinicians use the *International Classification of Diseases* (ICD-11) diagnosis of "Gender Incongruence of Adolescence and Adulthood," which, unlike the DSM-5 diagnosis of "Gender Dysphoria," requires only "marked and persistent incongruence between an individual's experienced gender and the assigned sex." Because SOC-8 defines transgender in a similar way ("people whose gender identities and/or gender

[29] U.S. v. Skrmetti (No. 23-477), Expert Researchers and Physicians, Amicus curiae brief (2024, pp. 16–17).
[30] The lead author, McNamara, has positioned herself in media and court appearances as a provider of PMT to minors. However, in a deposition McNamara revealed that she does not in fact administer PMT to minors with GD. See Sapir (2024b).
[31] Coleman et al. (2022, Chapter 6).

expressions are not what is typically expected for the sex to which they were assigned at birth") and provides no meaningful distinction between this meaning of transgender and gender non-conformity, SOC-8 effectively recognizes transgender identification as a medical condition justifying medical interventions.[32]

It is widely recognized that a fundamental tension exists between WPATH's desire to treat transgender identity (gender incongruence) as a normal and healthy variation of human development and its insistence that gender incongruence requires "medically necessary" treatment. This tension was explicitly acknowledged in medical literature supporting PMT contemporaneous with the preparation and publication of the fifth edition of the DSM. For example, in 2013, Jack Drescher, a prominent clinician-advocate of PMT, noted the significant difficulty in reconciling the "contradictory narratives" of "reducing stigma (which underlies the call for removal of the gender diagnoses [from the DSM]) and maintaining access to care (which requires the existence of a diagnosis in order to obtain needed medical treatment covered by third party payers)."[33]

In the lead-up to SOC-8's publication, *The New York Times* reported on disagreements among proponents of PMT concerning the proposed assessment recommendations for adolescents. One clinician told the *Times* it was "harmful and destructive and abusive and unethical and immoral" to require that a candidate for medical transition have longstanding GD since childhood—a key element of the Dutch Protocol. Another described the assessment recommendations as a "comprehensive inquisition of [an adolescent's] gender." The International Transgender Health Group criticized WPATH's draft chapter for its "harmful assertion of psychogatekeeping" and for "undermin[ing] patient autonomy." Asked whether it was appropriate to assess "the basis of a kid's gender identity," physician Colt St. Amand, a coauthor of SOC-8, told the *Times* that this "just reeks of some old kind of conversion-therapy-type things … People are who they say they are, and they may develop and change, and all are normal and OK." St. Amand was "less concerned with certainty around identity, and more concerned with

[32] See Chapter 13; The acronym "T/GNC" [transgender and gender-nonconforming] is commonly used in literature supportive of PMT.
[33] Drescher (2014, pp. 11–12).

hearing the person's embodiment goals. Do you want to have a deep voice? Do you want to have breasts? You know, what do you want for your body?"[34]

11.3.2 SOC-8 guardrails abandoned

Although WPATH's guidelines do not necessarily discourage mental healthcare, they likewise do not require it as a precondition for PMT. Some guideline authors opposed even minimal requirements for mental health support, arguing that such provisions were analogous to "conversion therapy."[35] SOC-8's only formal recommendation is for a "comprehensive biopsychosocial assessment," although WPATH emphasizes that its guideline is "flexible," thereby leaving room for considerable variation in clinical practice.[36]

In 2024, leaked discussions among WPATH members illustrated the extent to which the organization's own members' practice is not always consistent with SOC-8 recommendations. Some WPATH members candidly acknowledged foregoing even minimal psychological evaluations and moving quickly toward hormonal interventions. The candid nature of these exchanges suggests that non-adherence to the guidelines is not a source of professional shame, and not an isolated phenomenon.[37] The flexibility embedded in SOC-8 has facilitated significant gaps between the guidelines' theoretical standards and the practical reality in clinical settings.

Further, this flexibility has effectively provided leaders in the field of PMT with a basis to argue that assessment should not serve the purpose of differential diagnosis or medical "gatekeeping" but rather should function primarily to inform patients and their caregivers about the nature and effects of medical interventions. In 2020, a Canadian conference presentation reported that among pediatric gender clinics surveyed, half did not require any mental health assessment prior to initiation of hormonal interventions.[38] As one group of clinicians recently stated:

[34] Bazelon (2022b).
[35] Bazelon (2022a).
[36] Coleman et al. (2022, p. S6).
[37] Hughes (2024).
[38] Lawson et al. (2020).

> When a family comes to a mental health provider requesting a letter for a biopsychosocial assessment for pubertal suppression, work begins by explaining, in developmentally appropriate language, that this is not an assessment of whether they 'are actually transgender,' as many patients worry; rather this assessment is meant to help them understand the intricacies of pubertal suppression, so that they can make the best decision for themselves. The primary goal is to provide information, while identifying all potential avenues of support (social, educational, medical, and legal) related to gender.[39]

Jack Turban, the lead author of this statement and Director of the Gender Psychiatry Program at the University of California San Francisco, has said that differential diagnosis is pointless and may even be harmful. He disputes the notion that mental health assessment can reduce the risk of later regret, claiming that "there's not data [sic] that … any of these assessments make that [outcome] less likely."[40] According to Turban, children and adolescents "are just going to figure out the answers and then tell you what you want to hear. And you've set up this argumentative relationship with your patient or client."

Robert Garofalo of Lurie Children's Hospital in Chicago agrees that determining the causes of a child's feelings of alienation from their body through assessment is unnecessary.

> Sometimes parents will come in and be like, "I want to make sure that my young person, my child, is really trans … Can you help me with that?" And I'll turn to the child and be like, "yeah, so, you know, what gender identity do you have?" … You know, there's no form, there's no scale, there's no psychological battery of tests that needs to be done. Really, any young person can answer that question for themselves … Parents … think that they're going to come in and have this evaluation that is gonna help determine their child's gender identity, when really

[39] Turban et al. (2025, pp. 12–13).
[40] GenderGP (2021).

> … our work sometimes is just getting them to recognize that anyone's gender identity … is a normal variation …[41]

Amy Tishelman, formerly of the Gender Multispecialty Service at Boston Children's Hospital, expressed discontent with the new model of assessment in an interview with *The Boston Globe*. "I've never been happy with that way of characterizing it. I feel like an assessment should encompass more than just, 'Should a person get medical intervention, or shouldn't they?'"[42] In contrast, physician A.J. Eckert, former medical director at Anchor Health Initiative in Connecticut, avowed: "If you are trans, I believe you." For Eckert, minors "are best equipped to make decisions about [their] own body." Eckert further clarified that while medical interventions at Anchor Health are not provided before puberty, psychological therapy is not mandatory because "being trans is not a pathology."[43]

11.3.3 Collapse of assessment times

The erosion of medical safeguarding practices within American gender clinics is evident in the significant reductions in patient assessment durations at prominent institutions.

11.3.3.1 Boston Children's Hospital

GeMS at Boston Children's Hospital is the nation's first pediatric gender clinic and is highly regarded internationally. Whereas in 2013 GeMS allocated a minimum of 20 hours for mental health assessments per patient, court records indicate that by 2021 the clinic had reduced these evaluations to approximately two hours per patient.[44] Laura Edwards-Leeper, the clinic's founding psychologist, characterized this change as "shocking." Amy Tishelman, a former GeMS psychologist and SOC-8 developer, described it as "reckless."[45] Tishelman's tenure ended following disagreements with colleagues, culminating in litigation. Current co-director Kerry McGregor defended the reduction in assessment times, stating that two-hour assessments were initiated around

[41] Figliolia (2025).
[42] Damiano (2024b).
[43] Edwards-Leeper & Anderson (2021); the quote from Eckert is in Eckert (2020).
[44] Alder (2024).
[45] Ryan (2024a).

2017–2018 and are “appropriate” given the expanding patient load.[46] Endocrinologist and GeMS director Jeremi Carswell remarked in 2021 that puberty blockers were being prescribed “a lot like candy.”[47]

11.3.3.2 Children’s Hospital Los Angeles

Johanna Olson-Kennedy, medical director of the Center for Trans Youth Health and Development at Children’s Hospital Los Angeles, has acknowledged that she approves some of her minor patients for endocrine interventions after “a couple of hours” of assessment.[48] In December 2024, Olson-Kennedy and the hospital were named as defendants in a lawsuit filed by a former patient whom Olson-Kennedy allegedly approved for PBs at age 12 following a single consultation with no involvement of a mental health professional. The lawsuit further alleges that Olson-Kennedy told the parents of the patient that the patient faced suicide risk without medical interventions, despite no prior suicidal history. Subsequently, the patient was put on testosterone at 13, underwent a double mastectomy at 14, and was recommended for hysterectomy at 17.[49]

11.3.3.3 Lurie Children’s Hospital

In a webinar hosted by AMAZE, a producer of sex education content for students, Robert Garofalo of Lurie Children’s in Chicago explained how his clinic handles parents who have doubts about the safety of medical interventions.

> Most of the young people who come in are wanting to figure out how fast they can get on hormones and what is the safest process to do that … 80% of the young people who come are often really activist [sic] in their mindset and come dragging their parents to the medical visit … The counterweight to that is the parents who are often coming in with questions about how can this be done safely, is this really the right decision, and so it’s really a bit of a puzzle to put the pieces together to make sure that you are meeting the patient’s needs but also

[46] Damiano (2024a).
[47] Lindquist (2022).
[48] Deposition of J. Olson-Kennedy in LB v Premera Blue Cross NO. 2:23:Cv-00953-TSZ (2024, p. 63).
[49] Complaint, Breen v. Olson-Kennedy, No. 24STCV32096 (2024).

> moving the parents along … in a way that continues to get them educated so that they feel comfortable with the decisions they're about to make, because the truth is that these young people need their parents to be well and to do this well, and so it's our job as pediatricians to make sure that the entire family unit in some ways hopefully moves forward in an ideal situation in a way that feels supportive and nurturing. So, it's usually the young person who comes in knowing exactly what they want and us trying to navigate a process to ensure that's done safely and allaying parents' fears.

Garofalo went on to elaborate on his understanding of what shared decision-making means:

> If the medical provider thinks they have the answer [to whether medical interventions are appropriate] then they're the wrong medical provider. The answer lies within the young person and the family. Your job as a healthcare provider is to help them along that path, to find the answers and the solutions that feel authentic and healthy for them.[50]

11.3.3.4 Seattle Children's Hospital

In a response to Tordoff et al. (2022), a study conducted at Seattle Children's Gender Clinic,[51] one commentator pointed out that the control group, which received only psychotherapy, might have shown comparatively worse mental health due to selection bias: "patients with coexisting mental concerns may have been potentially discouraged from accepting the treatments until their coexisting conditions were addressed."[52] Lead author Diana Tordoff responded to the comment by pointing out that "youth who reported moderate to severe depression, anxiety, or suicidal thoughts were not precluded access to PB/GAH [puberty blockers and gender-affirming hormones], especially since initiating PB/GAH is known to improve or mitigate these symptoms."[53] Eighteen-year-olds "were provided care using an informed consent model and were not

[50] Figliolia (2025).
[51] Tordoff et al. (2022); see Section 6.2.2 for further discussion.
[52] Tordoff et al. (2022) [online comment; March 7, 2022].
[53] Tordoff et al. (2022) [online comment; March 13, 2022].

required to complete a mental health assessment." Tordoff also noted that Seattle Children's practices were consistent with the (then draft) SOC-8 guidelines.[54]

11.3.3.5 UCSF Benioff

In 2018, the organization Gender Spectrum hosted a panel with Ilana Sherer, a pediatrician and gender clinician, and Diane Ehrensaft, a clinical psychologist at UCSF Benioff and one of the principal architects of the "gender-affirming" approach in the United States. Sherer said that she sees "lots and lots of kids" who "don't have [gender] dysphoria, that really don't have mental health issues, and so to say to them 'you have to go get a letter from a mental health provider' feels challenging to me." But since a letter of support is required for medical interventions, Sherer went on to explain that "what we've started to do in our clinics is have someone like Diane [Ehrensaft] ... go in and do a brief assessment, and give their rubber—I know you [addressing Ehrensaft] said you don't rubber-stamp, but basically in my mind that's what it feels like—and so then we can move on and say 'OK, now we can talk about what you're actually here for.'"[55]

11.3.3.6 Planned Parenthood

Specialized gender clinics are not the only institutions prescribing hormonal interventions to adolescents. According to a 2024 investigative report published in *The Free Press*, Planned Parenthood is "the country's leading provider" of hormones for young people. Approximately 40% of the more than 40,000 patients for whom Planned Parenthood prescribed hormones in 2023 were between the ages of 18 and 22. Some branches, however, "offer hormones starting at age 16 with parental approval." In recent years, Planned Parenthood clinics have adopted an expedited access policy on an "informed consent" basis. Nicole Chaisson, medical director of Planned Parenthood North Central States, told *The Free Press* that "Gatekeeping is not necessary. People are the experts of their own body and of their own journey, and as long as they can

[54] Tordoff et al. (2022) [online comment; March 13, 2022].
[55] Sherer (2018).

make decisions, they should be the agent of their own healthcare." Chaisson said it was appropriate for teenagers to "leave the clinic with their prescription" after a single visit.[56]

Jamie Reed, the former case manager at the Washington University pediatric gender clinic in St. Louis, had previously worked at Planned Parenthood. Reed testified in a deposition that the St. Louis gender clinic would refer minor patients to Planned Parenthood "when we did not have consent from legal guardians" because Planned Parenthood would get "these kid's scripts [prescriptions] when they did not meet" diagnostic criteria. Although Planned Parenthood requires consent from an adult caregiver to prescribe hormones to minors, Reed said that Planned Parenthood "would not verify who the adult is that is bringing [the minor patient] to the building."[57]

11.4 The whistleblowers

In public statements, advocates and practitioners of PMT routinely imply that assessment functions as a form of medical gatekeeping, suggesting that PBs, CSH, and surgeries are offered cautiously and only to patients who genuinely require such interventions. Meredithe McNamara has argued that it is a "misconception" that "a child's disclosure of gender dysphoria leads to impulsive, irreversible decisions." Rather, "decisions on whether, when, and how to pursue medical interventions are slow-moving, rigorous, and individualized."[58] In his testimony before the Florida Boards of Medicine and Osteopathic Medicine in 2022, Aron Janssen, of Lurie Children's, said that treatments follow a "careful and thorough assessment of a patient's mental health including co-occurring conditions, history of trauma, substance use, among many other factors."[59]

In recent years, however, whistleblowers with firsthand experience working in gender clinic environments have come forward with compelling counterexamples. Their testimonies have often been dismissed, ignored, marginalized, or disparaged by colleagues. Several have also faced retaliation because of their disclosures.

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[56] Block (2024d).
[57] Noe v. Parson, No. 23AC-CC04530 (2024, p. 172).
[58] McNamara (2024).
[59] Florida Boards of Medicine and Osteopathic Medicine Joint Rules/Legislative Committee (2022), a 43:57.

11.4.1 Laura Edwards-Leeper and Erica Anderson

In 2021, Laura Edwards-Leeper, the founding psychologist of the first pediatric gender clinic in the United States, and Erica Anderson, a clinical psychologist and former president of the U.S. Professional Association for Transgender Health (USPATH), became the first prominent whistleblowers in the United States. In an opinion piece for *The Washington Post,* Edwards-Leeper and Anderson warned that adolescents were "being rushed into" medical interventions without sufficient psychological assessment or deliberation. "A flood of referrals to mental health providers and gender medical clinics, combined with a political climate that sees the treatment of each individual patient as a litmus test of social tolerance, is spurring many providers into sloppy, dangerous care,"[60] they wrote.

Following publication in *The Washington Post*, USPATH sought to impose a moratorium on Anderson's ability to speak to the press while WPATH was finalizing its SOC-8. Anderson resigned from the organization in protest.[61]

In an interview with journalist Abigail Shrier, Anderson cautioned that the current PMT approach involved "sloppy healthcare work," which could result in young people making decisions they would later regret. Marci Bowers, a gynecologist and surgeon who, like Anderson, identifies as transgender, echoed these concerns in the same interview. Bowers observed that although medical interventions initially seemed promising, in practice they had not yielded better—or even equivalent—outcomes compared to earlier approaches. Bowers specifically voiced concern about the long-term implications of these interventions on reproductive capacity, sexual health, and the ability of patients to experience intimacy.[62]

Despite criticizing the "gender-affirming" approach now dominant in their field, Anderson and Edwards-Leeper continue to believe that at least some children and adolescents benefit from medical transition. Bowers issued a detailed letter of apology to WPATH

[60] Edwards-Leeper & Anderson (2021).
[61] Selin Davis (2022).
[62] Shrier (2021b).

leadership[63] and remained with the organization, serving as its president from 2022 to 2024.

11.4.2 Jamie Reed

In 2022, Christopher Lewis and Sarah Garwood, then co-directors of the Washington University School of Medicine Pediatric Transgender Center at St. Louis Children's Hospital, testified before the Missouri House Judiciary Committee that "[m]edical interventions are done with a thorough and multidisciplinary team approach, which includes mental health assessment and requires consent from all custodial parents or caregivers."[64] Opening with the unfounded assertion that PMT is "literally lifesaving" (see Section 4.3.4 for discussion of suicide risk), Lewis, the Center's endocrinologist, emphasized that "[f]or pubertal transgender adolescents, medical services are started only after meeting strict eligibility criteria… [This] includes mental health professionals who have adequately documented and explored various aspects of gender and mental health exploration [sic], psychosocial medical concerns and conditions, and ability to understand their decisions and provide assent."[65]

These assertions were later disputed by Jamie Reed, who worked for four years at the Center as a case manager responsible for patient intake and oversight. In deposition testimony, Reed stated that Lewis had indicated at an early stage that he "[didn't] care" if patients met criteria for gender dysphoria. It was "not a requirement for [him] to prescribe hormones."[66] An investigation by *The New York Times* provided additional details about the clinic's practices and corroborated most aspects of Reed's testimony. According to the investigation, one patient, who subsequently detransitioned, received a prescription for testosterone following a single visit, without prior assessment by any mental health professional. When WPATH SOC-8 was published in September 2022, Lewis texted Karen Hamon, the Center's nurse, saying: "Right now I have no idea how to meet what would be the most intensive interpretations of the SOC."[67]

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[63] Boe v. Marshall, No. 2:22-cv-00184: 700-5 (2024, pp. 67–71).
[64] Lewis & Garwood (2022, 9:14:55).
[65] Lewis & Garwood (2022, 9:16:40).
[66] Noe v. Parson, No. 23AC-CC04530 (2024, p. 244).
[67] Ghorayshi (2023b).

According to Reed, the Center responded to a five-fold increase in its patient caseload by offering mental health providers a letter-of-support template for them to sign, in the hope that this would speed up the process of approval for endocrine treatments. It "was just copy paste," Reed testified in a deposition. Reed said that when she brought her concerns to Lewis, he "didn't care and was going to pass it [the letter] anyway".[68]

Concerned that the Center was not tracking patient outcomes, Reed and Hamon created a "red flag list," a private Excel spreadsheet in which they documented cases of patients with complex mental health presentations. As reported by the *Times*, the list included "a patient on testosterone [who] stopped taking schizophrenia medication without consulting a doctor and another [who] had visual and olfactory hallucinations. Another had been in an inpatient psychiatric unit for five months."[69] Reed also described an adolescent female from an "unstable family" who was in "an uncertain living situation and had a history of drug use" and was put on hormones at age 16, followed by a double mastectomy at 18. Three months later she regretted the surgery and informed the clinic, "I want my breasts back."[70] According to the *Times*, the patient contacted the surgeon at Washington University twice about her wish for breast reconstruction, but did not receive a response.[71]

Reed recalled a 17-year-old girl who was given testosterone and reported "bleeding from the vagina." The girl was advised to use a heavy pad to absorb the blood. "In less than an hour she had soaked through an extra heavy pad, her jeans, and a towel she had wrapped around her waist. The nurse at the center told her to go to the emergency room right away." The Center "found out later this girl had had intercourse, and because testosterone thins the vaginal tissues, her vaginal canal had ripped open. She had to be sedated and given surgery to repair the damage."[72]

Reed reported that when she raised concerns regarding inadequate mental health assessment and safeguarding with the Center's physicians, her objections were

[68] Noe v. Parson, No. 23AC-CC04530 (2024, p. 165).
[69] Ghorayshi (2023b).
[70] Reed (2023a).
[71] Ghorayshi (2023b).
[72] Reed (2023a).

repeatedly dismissed and she was advised to “Get on board, or get out.” Individuals who expressed doubts frequently faced “being called a transphobe.”[73] A similar phenomenon of intimidation was documented at the Tavistock’s Gender Identity Development Service in the U.K.[74]

Reed, who is lesbian, profoundly regrets her past involvement in PMT, and has since become a leading advocate for restrictions on practices she regards as harmful, especially for youth with emergent same-sex attraction who are overrepresented among patients.[75] The Center stopped providing PMT following the enactment of Missouri's Senate Bill 49 (SB 49).[76] Lewis, the Center’s endocrinologist, accepted a job in Colorado, where he currently practices PMT at Children's Hospital Colorado.[77]

11.4.3 Tamara Pietzke

In February 2024, Tamara Pietzke, a licensed clinical social worker and therapist at MultiCare Health System in Tacoma, Washington, disclosed harmful practices occurring in her clinical environment.[78] Pietzke described patients with significant comorbid mental health conditions and complicated life histories, who, despite these vulnerabilities, were approved for hormonal interventions.

One patient, a 13-year-old adolescent female, had diagnoses of depression, anxiety, post-traumatic stress disorder, and intermittent explosive disorder. She had experienced childhood abuse, neglect, and sexual violence, and, according to Pietzke, reported that “horror and porn movies … were the only ones available in her house.” The patient also told Pietzke that her mother practiced bestiality. She communicated in therapy sessions by displaying extremely sadistic and graphic pornographic videos to Pietzke on her phone. The patient also was reported to have autism spectrum disorder, a factor that may have contributed to her communication difficulties. Pietzke noted that the girl would “age-regress” by “watching *Teletubbies* and sucking on a pacifier.”[79] A restraining order

[73] Reed (2023a).
[74] Barnes (2023); Cass (2024).
[75] Reed (2023b).
[76] Washington University (2023).
[77] University of Colorado Anschutz Medical Campus (n.d.).
[78] Pietzke (2024a).
[79] Pietzke (2024a).

was also in place against the patient's mother, who had previously attempted to harm the girl's sister in her presence. The girls were being raised by their mother's former boyfriend.

In addition to these obvious red flags, Pietzke noted that her 13-year-old patient never asked for testosterone and failed to demonstrate an understanding of the hormone when the subject was raised. Nevertheless, the gender clinic at Mary Bridge Children's Hospital, part of MultiCare, approved the teenager for testosterone on her first visit. The clinic requested that Pietzke sign a letter of support clearing the patient of any mental health contraindications. Pietzke refused, and the case was referred to the hospital's risk management team. Instead of siding with Pietzke, however, the risk management team reassigned the adolescent to another therapist. Pietzke wrote to Amber Rolfe, MultiCare's in-house "gender-affirming care" expert, explaining her concerns and even citing Sections 6.3 and 6.12 from the Adolescent chapter of WPATH SOC-8 in support of her decision.

Rolfe disagreed with Pietzke's clinical judgment and citations from SOC-8, insisting that nothing in the patient's history, behavior, or concurrent diagnoses was a contraindication for hormone treatment.[80] "There is not valid, evidenced based, peer reviewed research that would indicate that gender dysphoria arises from anything other than gender (including trauma, autism, other mental health conditions, etc.)," Rolfe wrote to Pietzke.[81] "At it's [sic] core the diagnosis centers on an incongruence of gender identity and assigned gender at birth." Rolfe also suggested that Pietzke examine her biases and consider transferring the client "to someone who is comfortable with providing gender affirming care."[82] Pietzke resigned from MultiCare shortly thereafter and went public with her story.

11.4.4 Eithan Haim

Eithan Haim, a surgeon formerly affiliated with Texas Children's Hospital (TCH), became a whistleblower after discovering that TCH was performing medical transition

[80] Sapir (2024a).
[81] Rolfe (2023).
[82] Rolfe (2023).

procedures on minors despite publicly announcing a cessation of such procedures.[83] In 2022, prompted by a Texas Attorney General's opinion describing PMT as potentially abusive, TCH declared it would pause hormone interventions for transgender-identifying youth.[84] Despite this declaration, Haim became aware of ongoing practices that he asserted contradicted these claims; three days following the public statement, an 11-year-old patient received a puberty blocking implant, and similar interventions continued throughout the subsequent year involving dozens of other patients.[85] In May 2023, Haim anonymously provided de-identified hospital records and related documents to journalist Christopher Rufo, which resulted in a public exposé. The released data suggested that TCH had misled the public about halting its PMT program.[86]

Haim was charged with four felony counts under the Health Insurance Portability and Accountability Act (HIPAA). Prosecutors argued that Haim was not authorized to access patient data and that he did so with intent to maliciously harm the hospital.[87] The charges carried penalties of up to 10 years' imprisonment. Haim pleaded not guilty, denying his access to patient records was inappropriate, and asserting his disclosures were whistleblower actions aimed at safeguarding children rather than malicious acts.[88] The allegations were unusual, as HIPAA violations are typically addressed through civil rather than criminal procedure. The choice to pursue criminal charges raised suspicion that the federal government's actions were retaliatory in nature.[89]

The DOJ's indictment against Haim had to be amended multiple times after it was revealed that the government was mistaken about Haim's involvement with TCH. A second indictment had to be revised again because Haim was charged with actions as crimes that are not criminal under the law. The third indictment, which was shorn of most of the initial factual allegations, was for unauthorized access to patient records with intent to cause harm to doctors and the hospital, not patients. In January 2025,

[83] Haim (2024).
[84] Campion (2022).
[85] Haim (2024).
[86] Alder (2025).
[87] Trombly (2024).
[88] Alder (2025).
[89] Trombly (2024).

after months of legal contention and growing public criticism of the prosecution as "lawfare," federal prosecutors dismissed all charges against Haim with prejudice, effectively exonerating him.[90]

In November 2024, Haim's lawyers informed the DOJ that the lead prosecutor in the case, Tina Ansari, and her family, had "substantial financial and political ties" to Texas Children's Hospital and Baylor College of Medicine, resulting in a potential conflict of interest.[91] Shortly thereafter, Ansari withdrew from the case.[92]

[90] House Judiciary Committee (U.S. Congress) (2025).
[91] Patrick (2024).
[92] Whelan (2024b).

Chapter 12 Medical Association Response

This chapter examines how, despite growing recognition of its problems, the 8th version of the World Professional Association for Transgender Health (WPATH) *Standards of Care* (SOC-8) continues to have substantial influence on the medical field. This can be better understood by examining the critical role that major medical and mental health associations (MMHAs) play within the U.S. healthcare system (Section 12.1). Section 12.2 explores the reasons why MMHAs have not properly responded to updated evidence, nor to serious ethical concerns; Section 12.3 is a summary conclusion.

12.1 The role of major medical and mental health associations

Given the decentralized and fragmented nature of the U.S. healthcare system, MMHAs play a central role in shaping clinical practice guidelines, healthcare policy, and medical practices. They educate clinicians on emerging research, develop authoritative clinical practice guidelines, publish peer-reviewed journals, facilitate interdisciplinary collaboration, and engage in professional advocacy on behalf of their members. Typically, MMHAs limit full professional membership to practitioners actively engaged in clinical medicine or the mental health disciplines and enforce professional codes of conduct under which members may face sanctions or loss of privileges for noncompliance. MMHAs derive their authority in large part from their perceived adherence to rigorous professional standards and to science.

However, despite their scientific orientation, MMHAs are not immune to institutional biases, including groupthink and the disproportionate influence of vocal, specialized subcommittees. These specialized groups may receive broad deference from the larger organization, especially when their initiatives are framed in the language of civil or human rights. Consequently, MMHAs can inadvertently become echo chambers where dissent is suppressed, confirmation biases go unchecked, and professional deference is exploited. This dynamic of institutional capture is hardly unique to MMHAs: it occurs whenever support for a particular viewpoint is concentrated within a small, motivated subgroup, while opposing views are diffuse, less attentive, and less organized. As a result of this dynamic, the general public may inaccurately perceive the wider membership of individual MMHAs as uniformly aligned with the professed position of

their professional association. It is easy to overlook the fact that fundamentally, these organizations operate as trade associations, with a primary role of protecting their members' autonomy and professional interests. Although individual clinicians generally are motivated by altruism, it should not be assumed that the collective actions of an organization always reflect the values or intentions of its individual members.[1]

Historical examples demonstrate that despite their crucial role in safeguarding patients' interests, MMHAs have at times resisted necessary medical reforms, even when confronted with strong evidence of their urgency. For instance, the American Academy of Pediatrics (AAP) delayed rescinding its 2000 guidelines discouraging early peanut exposure for two years after evidence emerged linking the policy to increased rates of peanut allergies.[2] Similarly, professional organizations resisted evidence-based recommendations to limit arthroscopic knee surgeries, lobbying against healthcare reforms despite clear evidence of limited efficacy.[3] MMHAs may impede or even oppose evidence-based medicine when the professional or financial interests of their members are threatened by medical practice reversal.

The reliance of MMHAs on WPATH is exemplified by the Endocrine Society (ES) clinical practice guideline for the treatment of gender dysphoria (GD). As discussed in Chapter 9, the close alignment of these groups' guidelines suggests a lack of robust, independently derived frameworks for care, potentially limiting critical appraisal and alternative perspectives within the field. Notably, Joshua Safer, who is leading the 2024 revision of ES guidelines, is himself closely associated with WPATH and is a prominent advocate for pediatric medical transition (PMT).[4] His leadership role raises concerns about compliance with the National Academy of Medicine's standards for trustworthy guideline development, in particular with regard to conflict of interest management (see 10.3.1).[5]

[1] For a discussion of this phenomenon and its consequences for medical policy, see Patashnik et al. (2017).
[2] See Section 1.2.2.
[3] Patashnik et al. (2017, Chapter 2).
[4] Sapir (2024d).
[5] Graham et al. (2011, p. 87).

MMHAs have been reluctant to transparently address the weak evidence base underlying PMT. For example, the American Psychiatric Association's (APA) textbook *Gender-Affirming Psychiatric Care*[6] has faced internal criticism for failing to acknowledge the scientific debate and the policy shifts occurring internationally.[7] A petition with over 7,000 signatures, many from medical and mental health professionals, has called for the withdrawal or correction of the textbook,[8] yet APA leadership has not issued a substantive response.[9] Similarly, the American Academy of Child and Adolescent Psychiatry (AACAP) has rejected multiple proposals addressing important evidence and dissenting perspectives that were submitted to its conferences.[10] The AAP likewise has repeatedly declined to platform critical perspectives at its events.[11] This pattern of organizational defensiveness fosters environments in which clinicians feel compelled to self-censor.

The AAP has rejected multiple internal requests to conduct systematic reviews of the evidence underpinning PMT.[12] Although AAP leadership ultimately agreed in principle to a systematic review, it simultaneously reaffirmed the existing policy[13]—a move that evidence-based medicine experts have criticized as methodologically unsound and premature, as it presupposes the outcome of a review intended to impartially evaluate the evidence.[14] To date, there is no evidence the AAP has begun the review.

After the National Health Service (NHS)-commissioned Cass Review was published in April 2024, several affiliates of the American Psychological Association (APA) prohibited its very discussion on their professional listservs. When a San Francisco-area psychologist posted information about the Cass Review on a listserv of Division 39 of the APA, the listserv moderator blocked the post, citing a 2020 "Letter of Apology to

[6] Goetz & Keuroghlian (2023).
[7] Satel (2024).
[8] Foundation Against Intolerance & Racism (2024).
[9] Posner (2024).
[10] Sibarium (2023).
[11] Shrier (2021a).
[12] Block (2023c).
[13] Wyckoff (2023). AAP policy statements automatically expire after 5 years unless readopted, revised, or revoked.
[14] Ghorayshi (2023a).

LGBTQ+ Communities" that forbids "speech that is injurious to LGBTQ+ members."[15] The Pennsylvania Psychological Association (PPA), a state affiliate of the APA, sent an email to all its members informing them that the Cass Review was "no longer welcomed for discussion" on its professional listserv. The PPA explained that the Review "fail[s] to meet" the PPA's "professional standards," and that "LGBTQIA+" members and their "allies" might feel "targeted, harmed, and hurt by this literature being repeatedly shared."[16] A clinical psychologist who describes herself as "a liberal feminist" and who has "marched in Pride marches" told the *BMJ* that she was "reprimanded" by the Illinois Psychological Association after posting about the Cass Review on a therapist listserv.[17]

12.2 Factors contributing to neglect of evidence and open debate

Hilary Cass, past president of the Royal College of Paediatrics and Child Health and leader of the U.K.'s comprehensive review of pediatric gender medicine services, has stated that American physicians are "out of date" in their approach to pediatric gender medicine.[18] Several factors may help explain the reluctance of American MMHAs to engage fully with the shifting perspectives on evidence and ethics in this area of practice.

First, in managing unusual or complex conditions, primary care providers and generalist clinicians often rely on the expertise of specialists to inform their clinical decisions.[19] When the former also hold leadership positions in medical organizations and are tasked with shaping policies for the treatment of youth with GD, they often defer to specialized committees—such as committees devoted to LGBT issues—whose members they regard as the organization's content experts. These committees typically are composed of professionals whose careers are closely tied to supporting or delivering medical transition, limiting their ability to impartially evaluate the evidence due to significant intellectual and financial conflicts of interest. While reliance on specialist committees

[15] Selin Davis (2024a).
[16] Ryan (2024c).
[17] Block (2024b).
[18] Ghorayshi (2024a).
[19] Tzartzas et al. (2019).

poses fewer risks in well-established subspecialties with decades of robust research,[20] pediatric gender medicine remains a new, highly controversial field characterized by a limited and low-certainty evidence base.

Second, the framing of PMT as a civil rights matter[21] may have contributed to premature and uncritical support at both the individual and institutional levels. Most medical professionals are broadly supportive of civil rights.[22] U.S. specialty committees often frame PMT as a morally righteous or progressive cause, leading many professionals reflexively to adopt supportive positions. Given that transgender identification is relatively common among youth—estimated at 2–5%, though precise figures remain uncertain—many clinicians and policymakers also may have personal connections, such as friends or loved ones who identify as transgender. These personal ties, combined with a genuine desire to be compassionate and supportive, may understandably make it more difficult for professionals to critically and objectively evaluate the evidence base or ethical considerations underlying PMT.

Third, by the time the weak evidence and growing international retreat from the practice became difficult to ignore, several major U.S. MMHAs had been actively promoting PMT and denouncing its critics.[23] As a result, some organizations responded to international developments defensively rather than reflectively, viewing the shifts as a potential challenge to their institutional credibility.[24] The only notable exception to this pattern appears to be the American Society of Plastic Surgeons which, following the publication

[20] It should be noted, however, that with respect to developing reliable clinical practice guidelines the role of clinicians with intellectual conflicts of interest should be minimal: see Graham et al. (2011); McCartney et al. (2022).
[21] In 2016 psychologist Diane Ehrensaft, leading proponent of the "gender-affirming" approach, explicitly conceptualized her work as having “finally created a civil rights movement” (Ehrensaft, 2016, p. 355). Some medical guidelines in this field also call for specific political activism on the part of clinicians; e.g., the AAP policy statement (Rafferty et al., 2018). The editorial board of *The Washington Post*, recognizing the failure of pediatric gender specialists to self-regulate in the U.S., recently called for “new research of maximum possible rigor, overseen by scientists *who are not gender medicine practitioners*” (Washington Post Editorial Board, 2024, emphasis added).
[22] Levine & Abbruzzese (2023).
[23] Szilagyi (2022b).
[24] E.g. Endocrine Society (2024); Hoffman (2024).

of the Cass Review, publicly adopted a more cautious stance regarding the use of surgical interventions for treating pediatric GD.[25]

Experts within pediatric gender medicine hold sharply divergent views about best practices.[26] However, the absence of professional consensus is often obscured, as dissenting voices are seldom included on specialty committees responsible for policy development. Researchers who study detransition, investigate social influences underlying epidemiologic changes in GD presentations, express concerns about PMT, or advocate for a more cautious approach to pediatric GD frequently encounter hostility and a lack of support from major publishers, medical societies, and academic institutions.[27] Organizations advocating for higher evidentiary standards, journalists reporting on the controversies, and academics writing about issues related to sex and gender have also faced hostility and attempts at public shaming.[28] Activist organizations have contributed significantly to this dynamic, often targeting individuals and groups that question or critically examine prevailing practices in gender medicine.[29]

When MMHAs update their treatment guidelines and position statements, experts who question the evidence supporting PMT are excluded from guideline development

[25] American Society of Plastic Surgeons (2024).
[26] As the Cass Review found, "clinicians who have spent many years working in gender clinics have drawn very different conclusions from their clinical experience about the best way to support young people with gender-related distress. Some feel [they should] access a medical pathway at an early stage. Others feel that we are medicalising children and young people whose multiple other difficulties are manifesting through gender confusion and gender-related distress" (Cass, 2024a, p. 13). Examples of divergent clinical opinions can be found by comparing two papers on the role of mental health assessments: Levine (2024); Turban et al. (2025). Differing treatment approaches are also described in Levine et al. (2022a) and two follow-up articles: Drescher (2023); Levine et al. (2022b).
[27] For some examples, see Barnes (2023); Bazelon (2022a); Brown University (2019); Byrne & Gorin (2025); Edwards-Leeper & Anderson (2021); Gecsoyler (2024); Jenkins & Panozzo (2024); Keenan & Lovett (2025); LGBTQIA+ Coalition (2022); Pietzke (2024a, 2024b); Reed (2023a); Schenck (2022); Society for Evidence-Based Gender Medicine (2023d); Turley (2024).
[28] 100 signatories (2023); GLAAD (2023a, 2023b); Hansford (2024); Hooven (2023); Singal (2023a, 2023b); Weale (2025).
[29] In addition to the examples above, a recent article recounted therapists' experiences of attending a training workshop where the representative of the political activist group Southern Poverty Law Center (SPLC) spoke about efforts to "hunt" therapists who practice exploratory therapy, with the goal of leveling complaints leading to licensure revocations. Another therapist reported having been formally investigated by her graduate school for sharing information about new pediatric gender medicine evidence from Europe, an investigation which remains on her permanent record (Jenkins & Panozzo, 2024). SPLC also chose to wield the emotional power of the "hate group" label on several groups that have engaged in evidence-based evaluation of PMT or the development of alternative approaches.

committees.[30] Efforts to exclude dissenting perspectives from conferences and publications have been documented.[31] In addition, there is growing evidence of self-censorship among clinicians and researchers, driven by concerns about professional repercussions and reputational risks.[32] Some proponents of PMT explicitly endorse the use of silencing tactics and reputational attacks:

> The point of activism is sometimes 'silencing,' if by that one means destroying the credibility of professionals that activists deem dangerous.[33]

Medical professionals' years of training and social status leave them acutely aware of and sensitive to reputational risks. Fear of online attacks and social disapproval within professional medical societies may have contributed to widespread self-censorship among clinicians, mirroring similar trends observed across academia.[34] This dynamic is further reinforced when PMT is framed as a civil rights issue or a struggle against discrimination and oppression. Under this framing, critics—even those raising evidence-based concerns—are labeled "anti-trans" or intolerant by reputable, influential sources.[35] As Hilary Cass observed in the introduction to the Cass Review,

> There are few other areas of healthcare where professionals are so afraid to openly discuss their views, where people are vilified on social media, and where name-calling echoes the worst bullying behaviour. This must stop. Polarisation and stifling of debate do nothing to help the young people caught in the middle of a stormy social discourse, and in the long run will also hamper the research that is essential to finding the best way of supporting them to thrive.[36]

The American healthcare system relies heavily on MMHAs to create, organize, and disseminate knowledge and to referee scholarly dialogue through journals and

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[30] Marci Bowers, president of WPATH when its 2022 guidelines were published, acknowledged that it was "absolutely" important for someone to be an "advocate" of the "gender-affirming" approach to be considered for the committee. See Boe v. Marshall*,* No. 2:22-cv-00184: 564-8 (2024). Furthermore, most members of the guideline development committee had conflicts of interest, which were poorly managed.
[31] Curlin (2024); Kaliebe & Johnson (2024); Kaltiala (2023); Mason (2021); Sapir (2025).
[32] Clark et al. (2024); Pfaus (2023).
[33] Nichols (2008).
[34] Clark et al. (2024); Curlin (2024); Pfaus (2023).
[35] E.g., Endocrine Society (2024); Szilagyi (2022b).
[36] Cass (2024, p. 13).

conferences. Regardless of the underlying causes, major MMHAs have issued advocacy-driven recommendations prematurely, without adequate scientific support.[37] This contributed to a degradation of the norms of open inquiry and constructive disagreement—norms that are essential for the credibility of MMHAs and their capacity to issue trustworthy, evidence-based guidance.

12.3 Conclusion

The significant influence MMHAs exert over professional opinion, clinical practice, and healthcare policy extends broadly across the healthcare landscape. In the area of pediatric gender medicine, prominent MMHAs have aligned their clinical guidelines and policy statements with WPATH SOC-8. This reliance on WPATH guidelines effectively imported into MMHAs many of the methodological and ethical deficiencies documented in WPATH's guideline development process. Consequently, problems originating within WPATH have not remained isolated but have instead propagated through influential MMHAs, contributing to a broader erosion of clinical standards, scientific rigor, and open academic discourse.

Today, MMHAs wield considerable influence over both public and professional perceptions of medical practices through statements frequently cited in the media. These shape broader societal attitudes toward both the medical field generally and the practices within that field specifically. The implicit social contract underlying MMHAs' self-regulatory privileges rests on the expectation that these organizations will prioritize the best interests of patients and society. However, MMHAs' handling of issues related to PMT illustrates how institutional biases, reliance on external guidance from advocacy-oriented groups, and internal political dynamics can undermine their regulatory effectiveness and scientific credibility.

[37] See also Chapters 6-8.

PART 4

ETHICS REVIEW

Chapter 13 Ethical Considerations

This chapter discusses central ethical issues in pediatric medical transition (PMT), which involves the use of puberty blockers (PBs), cross-sex hormones (CSH), and surgery to suppress or alter the development of sex- and age-typical sex characteristics in physically healthy children or adolescents.[1] These interventions are used as treatment for the conditions of "Gender dysphoria" (GD) in the *Diagnostic and Statistical Manual* (DSM-5-TR) or "Gender incongruence of adolescence or adulthood" in the *International Classification of Diseases* (ICD-11).[2] In assessing the effects of PBs, CSH, and surgery, researchers typically focus on conventional psychiatric outcomes such as depression, anxiety, and suicidality; recently, some have added novel outcome measures such as "chest dysphoria," "appearance congruence," and "gender euphoria."[3]

However, some clinician-researchers have called into question what they call the "logic of improvement," according to which PMT is justified only if it enables "a progression from 'doing worse' to 'doing better,' ultimately leading to an overall improvement in the individual's functioning and well-being."[4] Acknowledging that the evidence that PMT has this effect is weak, these clinicians argue that conventional outcome measures should be supplemented with—if not replaced by—patient-determined outcomes.[5] In the same vein, other advocates of PMT claim that focusing on clinical improvement is "pathologizing" and question the need for any clinical indication beyond the adolescent's "embodiment goals"[6] or mere desire for the intervention.[7] The guiding question of this chapter is whether the provision of hormonal or surgical interventions for these shifting and sometimes contradictory purposes is consistent with well-established principles of

[1] Patients may reach Tanner Stage 2 of puberty by age 8 or 9. An 8- or 9-year-old person is uncontroversially a child. However, for the sake of brevity the remainder of this chapter will use "adolescents" rather than "children and adolescents" in most cases to refer to this patient population.
[2] American Psychiatric Association (2022); World Health Organization (2022b).
[3] See, respectively, Olson-Kennedy, Warus et al. (2018); Chen et al. (2023); Blacklock et al. (2025).
[4] Oosthoek et al. (2024, p. 10).
[5] Oosthoek et al. (2024, p. 17).
[6] Ashley (2019, pp. 480–482).
[7] Chu (2024).

medical ethics. Despite the high stakes—medical, social, political, and legal—this urgent question has received relatively little critical attention from bioethicists.

After a brief note on consent (Section 13.1), Section 13.2 summarizes how the medical profession's shift away from medical paternalism toward shared decision-making has strengthened patient protections against unwanted medical interventions via the mechanism of informed consent. This move toward greater respect for patient autonomy, however, does not negate clinicians' professional and ethical obligation to protect and promote their patients' health.

Section 13.2.3 turns to the pediatric context, where the latter obligation is especially strict due to the distinctive vulnerability of children and adolescents as well as their underdeveloped decision-making capacity. The best available evidence indicates an unfavorable risk/benefit profile for the prescription of hormonal and surgical interventions for adolescents with GD. The prescription of these interventions also raises justice-related concerns for members of this medically and socially vulnerable population.

Section 13.3 examines an alternative justification for PMT, one grounded in a purported right to access the medical resources needed to satisfy the patient's preferences for body modification. The shift to this alternative justification, which follows researchers' decades-long inability to demonstrate clear medical benefit, suggests that advocates of PMT have significantly altered the criteria for success.[8] The chapter then turns to a brief discussion of patient regret in Section 13.4 before concluding with some remarks on research ethics in Section 13.5.

13.1 Consent

Some disagreements in this field center on the question of whether adolescents have medical decision-making competence (MDC)—that is, whether they can provide

[8] "Clinicians remarked that there is no agreed fixed point of reference on which to judge the success of an intervention, let alone a societal consensus on the appropriate response" (Cass, 2024a, Appendix 3, p. 9).

informed consent or assent to transition-related medical interventions.[9] Some proponents of these interventions believe they can.[10] In support of this position, some point to research showing that many adolescent patients have MDC as assessed using a quantitative semi-structured interview tool.[11] They also note that there are other invasive, life-shaping interventions to which adolescents and their guardians commonly and unproblematically assent or consent. For example, an adolescent may assent to treatment of leukemia, even when the treatment may cause future infertility. An adolescent also may assent to amputation of a limb that is diseased or damaged beyond repair. There are many similar situations in which assent by the adolescent, and legal consent by the parents, is given to an intervention necessary to preserve the adolescent's overall health but which also causes foreseen serious adverse side effects.

Some critics of PMT, on the other hand, maintain that patients—some of whom are only eight or nine years old when they reach Tanner Stage 2 of puberty and thereby become candidates for PBs[12]—are too immature[13] to adequately understand the full range of consequences of medical transition. These young people cannot deliberate about the relevant considerations in a manner that is appropriately attentive to the seriousness and complexity of the decision. Critics point out that even proponents of PMT recognize that children and adolescents lack the cognitive and social maturity to deliberate well about their future fertility.[14]

Moreover, critics assert—reasonably[15]—that providers of PMT often fail properly to inform patients and their guardians about the uncertainty of the clinical evidence for medical benefit and that they overstate the probability and magnitude of the harms of

[9] "Consent" and "assent" here are technical terms. In the U.S. minors cannot provide *legal consent* for medical treatment (there are limited exceptions, e.g. for emancipated minors or for a narrow range of interventions such as treatment for sexually transmitted infections). Guardians provide legal consent while minors provide *assent*, or agreement to the intervention.
[10] Giordano et al. (2021); Mosier-Mills et al. (2024).
[11] Vrouenraets et al. (2021); See also Marino et al. (2024).
[12] See Chapter 7.
[13] Diekema (2020).
[14] Vrouenraets et al. (2022).
[15] See Chapter 11.

non-medicalization.[16] Finally, as noted in Chapter 2, clinicians providing PMT routinely employ euphemistic and morally loaded language, which can mislead or unduly influence patients and their guardians. The concern, then, is that this combination of high pressure, low information, and reflexive "affirmation" undermines the possibility of genuinely informed consent or assent.

Informed consent is critically important, but before it is even a consideration, the intervention must be otherwise ethically permissible. For example, before asking whether patients can consent to any proposed intervention, from antibiotics to lobotomy, a clinician must determine whether the intervention has a favorable risk/benefit profile as a treatment for the patient's condition. Thus, while informed consent plays a central role in medical ethics and clinical practice and informs discussions about the distinctive challenges that attend decision-making in pediatrics, this Review's ethical analysis of PMT focuses primarily on the necessarily prior step. Namely: do these interventions have favorable risk/benefit profiles?

13.2 From paternalism to shared decision-making and patient-centered care

Over the course of the 20th century, advances in the biomedical sciences, expansion of healthcare delivery systems, increasing professionalization in medicine, and a series of medical scandals and seminal legal cases led to greater sensitivity among clinicians and researchers to the rights of patients and participants in medical research. Judges, regulators, lawmakers, and ethicists introduced constraints on the power of clinicians to impose their values, preferences, and perspectives on patients.[17] The "paternalistic model" in medicine, according to which "doctor knows best," gave way to a more egalitarian model of "shared decision-making" that emphasizes respect for the autonomy and authority of competent patients and research participants. There is now universal consensus that respect for patient autonomy requires clinicians to provide patients with information relevant to their medical options and to act on competent

[16] Reluctant parents have reported being asked by their child's clinicians whether they (the parents) preferred having "a dead son or a living daughter." In an interview, Dr. Johanna Olson-Kennedy stated, "We often ask parents, Would you rather have a dead son than a live daughter?" (ABC News, 2011).
[17] Faden et al. (1986).

patients only with patients' consent. As the American Medical Association's *Code of Medical Ethics* puts it, patients have the right "[t]o make decisions about the care the physician recommends and to have those decisions respected. A patient who has decision-making capacity may accept or refuse any recommended medical intervention."[18] Patients are protected from unwanted medical interventions not only by professional and ethical norms but by the law. As Justice Cardozo famously wrote, "a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages."[19]

13.2.1 Respect for autonomy vs *caveat emptor*

Crucially, the shift from medical paternalism to shared decision-making does not absolve clinicians of their ethical and professional obligation to protect and promote the health and well-being of their patients. Beneficence "undergirds all medical and health care professions and their institutional settings."[20] As mentioned in Chapter 1, clinicians have ancient but enduring ethical duties to avoid harming their patients and to promote their health and welfare: "The health and well-being of my patient will be my first consideration."[21]

The principle of respect for patient autonomy does not justify subjecting patients to interventions that pose medically unnecessary risks of harm, or which are otherwise nonbeneficial, even when patients prefer, request, or demand those interventions. An ethical analysis of PMT published by Finnish health authorities provides a succinct explanation:

> In healthcare, self-determination primarily manifests as the right to refuse treatments within the available service spectrum. This principle must be balanced against the freedom of individuals to express their own gender identity. Nevertheless, autonomy in healthcare does not imply unrestricted freedom to select treatments based purely on personal preference; rather, patient autonomy

[18] American Medical Association (2016).
[19] Schloendorff v. Society of New York Hospital (1914).
[20] Beauchamp & Childress (2019, p. 217)
[21] Parsa-Parsi (2017, p. 1971).

> involves the choice among treatments *that are medically justified* and included within the recognized service options.[22]

The well-established moral and legal right of competent patients to refuse any medical intervention does not entail a corollary right to receive nonbeneficial interventions. The Institute of Medicine's Committee on Quality of Health Care in America warns clinicians against providing interventions based on this illicit inference, stating, "When a patient seeks inappropriate health care services, the challenge for clinicians is to find ways of reducing this conflict … If a conflict cannot be resolved through counseling, the clinician should refuse to provide nonbeneficial services."[23]

In refusing requests for nonbeneficial interventions, clinicians do not force anything upon their patients. They do not threaten, deceive, or mislead them. Nor do they withhold relevant information about risks, benefits, and available alternatives. In other words, withholding nonbeneficial interventions does not entail acting on patients without their informed consent. Conflating the right of patients to refuse medical intervention or to choose among the beneficial options offered by their clinicians with the wholly separate "right" to determine which interventions must be offered transforms the ethos of beneficent respect in medicine to the crude, responsibility-abdicating ethos of medical consumerism: *caveat emptor.*

> Using patient autonomy to justify acquiescence to patients' requests for nonbeneficial services violates professional integrity. Professional integrity requires physicians to adhere to standards of intellectual and moral excellence. Physicians achieve intellectual excellence by submitting clinical judgment to disciplined, evidence-based reasoning. Physicians achieve moral excellence by protecting patients' health-related interests as a primary concern, keeping self-

[22] Saarni & Uusitalo (2020, p. 41, emphasis added). Original text: "Itsemääräämisoikeus terveydenhuollossa toteutuu ensisijaisesti oikeutena kieltäytyä palveluvalikoimaan kuuluvista hoitotoimista. Tämä on tasapainotettava sen näkökulman kanssa, että ihmiset saavat itse vapaasti ilmaista omaa sukupuolista identiteettiään. Autonomialla ei terveydenhuollossa kuitenkaan tarkoiteta vapaata oikeutta valita hoitoja omien preferenssien perusteella, vaan potilas voi valita palveluvalikoiman ja lääketieteellisesti perusteltujen hoitomuotojen sisällä."

[23] Committee on Quality of Health Care in America, Institute of Medicine (2001, p. 77). See also the "Physicians Charter" mentioned in Section 1.3.

> interests systematically secondary. Commitment to professional integrity requires that physicians challenge requests for nonbeneficial interventions.[24]

13.2.2 Nonmaleficence, beneficence, and autonomy in pediatrics

Uncontroversially, then, the norms of medicine require clinicians to protect and promote the health and well-being of their patients. This means they must abstain from providing nonbeneficial interventions even when such interventions are requested by competent patients. In the domain of pediatrics, these norms limit the authority not only of patients (who in any case lack full decision-making capacity) but of parents as well. The American Academy of Pediatrics' (AAP) Committee on Bioethics puts it as follows:

> Pediatric health care providers have legal and ethical duties to provide a standard of care that meets the pediatric patient's needs and not necessarily what the parents desire or request. Parental decision-making should primarily be understood as parents' responsibility to support the interests of their child and to preserve family relationships, rather than being focused on their rights to express their own autonomous choices. It is important to note that parental authority regarding medical decision-making for their minor child or young adult who lacks the capacity for medical decision-making is constrained compared with the more robust autonomy in medical decision-making enjoyed by competent adults making decisions regarding their own care.[25]

The "constraint" on patient and parental authority is grounded in the medical best interests of the child:

> In pediatrics, the duties to protect and promote health-related interests of the child and adolescent by the physician are also grounded in the fiduciary relationship (to act in the best interest of the patient and subordinating one's own interests) between the physician and patient, but these duties may conflict with the parent's or patient's wishes …[26]

[24] Brett & McCullough (2012, p. 149).
[25] Committee on Bioethics et al. (2016, p. e5). First published in 2016, this report was reaffirmed by the AAP in 2023.
[26] Committee on Bioethics et al. (2016, p. e2).

In its influential policy statement, "Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents," the AAP states that in navigating disagreements between parents and children clinicians should "maintain their primary responsibility to the welfare of the child."[27] Thus, while the statement recommends that "transgender and gender-diverse" youth have access to PMT, this recommendation is contingent not on the autonomy rights of patients or their guardians,[28] but rather on these interventions' purported contribution to patient health and well-being. [29] This affirms the longstanding, consensus view of medicine's fundamental aim as protecting and promoting the health and well-being of patients.

13.2.3 Risk/benefit in pediatric medical transition

To discharge their duties of nonmaleficence and beneficence, clinicians must ensure, insofar as reasonably possible, that any interventions they offer to patients have clinically favorable risk/benefit profiles relative to the set of available alternatives, which includes doing nothing.[30] As described in Chapter 5, systematic reviews (SRs) of the

[27] Rafferty et al. (2018, p. 8).
[28] Bester (2024).
[29] It is worth noting, however, that while the AAP and WPATH support PMT, they do not promote intervening over a patient's objections. Neither group holds that a patient with gender dysphoria/incongruence who refuses puberty blockers, cross-sex hormones, or surgery should be strongly encouraged or, if necessary, forced to receive them. This distinguishes medical transition from other interventions claimed to offer great, potentially lifesaving benefit. In gender medicine and perhaps nowhere else, whether transition-related medical interventions are deemed medically necessary seems to hinge largely on whether the patient desires them. See Chapter 11 for more on this issue.
[30] An intervention has a clinically favorable risk/benefit profile when the expected medical benefits outweigh the expected medical harms. Expected benefits and harms are determined by their probabilities and magnitudes. This is a standard method for guiding action and policy, including in medicine, though the precise manner in which it is carried out can vary and depends on many variables, including risk tolerance, the way "benefit" and "harm" are defined and measured, the way probabilities are assigned, and the way uncertainty/ignorance is accounted for. Of course, it would not be difficult to adopt expected utility theory, defining "benefit" and "harm" and assigning values to the relevant variables, in a way that would render a verdict markedly different from the negative one reached in this Review. That said, the claims made here about the probability and magnitude of harms and benefits are grounded in the best available evidence. Sometimes, the probabilities are known with a high degree of certainty. For example, the probability that mastectomy will lead to an inability to breastfeed is 1.0 or close to it. Puberty blockers and cross-sex hormones threaten sexual function, though the precise magnitude of the problem and its distribution in the treated patient population is unknown. Where precise or even rough values are not available due to the absence of quality research, the analysis in this Review assumes plausible, if rough, estimates. As for the nature of medical benefits and harms and their relative weights, the Review's working assumptions cohere with common moral intuition, standard medical judgment as revealed in medical diagnostic criteria, and the outcomes of interest to clinicians and researchers, as well as the law. For example, the analysis would conclude that a minor improvement in depressive symptoms does count

evidence for benefit of hormonal or surgical intervention in the treatment of GD in adolescents have concluded that this evidence is of low or very low certainty. This means that the true effects of the interventions may or are likely to be substantially different from the effects reported in the studies.[31] In other words, the best available evidence indicates that PBs, CSH, and surgery have not been shown to improve mental health outcomes.

At the same time, there is increasing recognition of the risks and harms associated with PMT, which are supported by clinical research or grounded in established biological theory.[32] While the value or disvalue of some outcomes, such as hirsutism in females, may be determined primarily by the preferences or tastes of patients, other possible outcomes, such as impaired cognitive function, greater susceptibility to hormone-sensitive cancers, cardiac disease, reduced bone density, sexual dysfunction, infection, and infertility[33] are objectively detrimental to health. Such medical harms, or plausible

as a benefit but that such a benefit, even if assured, does not outweigh moderate or even low but non-negligible risks of infertility or serious sexual dysfunction, loss of breastfeeding function, or lifelong medical dependency, which the Review considers harms.

[31] Balshem et al. (2011).

[32] See Chapter 5 and Chapter 7.

[33] It may be objected that infertility is not necessarily a harm. One version of this objection is that for some young patients, perhaps those who have very clearly expressed that they do not want and will never want genetically-related children, infertility is not a harm since it is consistent with their chosen life plan. The response to this objection is that the medical profession does not ordinarily permit voluntary permanent contraception (sterilization) in children or adolescents and always takes the risk of infertility seriously in assessing the risk/benefit profile of any intervention that plausibly may impact reproductive health. That is to say that as a matter of well-established sociological fact, infertility is recognized by the medical profession as a harm (Geis et al., 2024). The second version of the objection relies on the claim that some patients are willing to accept infertility as a consequence of medical transition, even if they do not intend infertility. These patients prefer to remain fertile, all else being equal, but because all else is not equal they accept interventions that will undermine their fertility. The response to this objection is that such preferences reveal that these patients view infertility as a harm. The real question in the latter case is whether there is good reason to believe that the benefits of medical intervention outweigh this harm, and the answer to this question will depend on the evidence regarding benefits. Finally, research suggests that many transgender-identified people do want children and that some who medically transition experience decisional regret over their infertility. This suggests they also view infertility as a harm even if they do not regret their transition. See Asseler et al. (2024); Stolk et al. (2023).

risks thereof,[34] should not be imposed on children or adolescents in the absence of a reasonable expectation of proportionate medical benefit.[35]

Although a favorable risk/benefit profile is necessary to justify an intervention, it is not sufficient.[36] The intervention must be favorable relative not only to doing nothing but also to other known alternatives. With respect to PMT, a relevant alternative is some combination of psychotherapeutic interventions.[37] Like the evidence for hormonal and surgical interventions, evidence regarding alternative approaches to GD is sparse and inconclusive,[38] though as Chapter 14 reveals there is good reason to believe that psychotherapy can be an effective intervention. Regarding the potential harms of psychotherapy for adolescents with GD, a systematic review of the evidence found no evidence of negative or adverse effects in any of the studies examined (although absence of evidence for harm does not imply evidence of no harm, psychotherapy does not carry the medical or surgical risks associated with PMT).[39]

One possible objection is that although the evidence supporting hormonal and surgical interventions is of low or very low certainty, this does not prove that the interventions are ineffective. For all we know, the interventions may be *more* effective than researchers have reported. The methodological weaknesses of the studies do not prove inefficacy—they tell us only that we cannot infer much of anything about beneficial effects. The same limitations apply to evidence on harms—after all, because there are no well-designed randomized controlled trials (RCTs) of PMT, it follows that there are no well-designed RCTs demonstrating sexual dysfunction, infertility, bone density loss, impaired cognitive function, susceptibility to hormone-sensitive cancers, and other potential

[34] Sweden's National Board of Health and Welfare concluded that "the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatments" (Socialstyrelsen, 2022a, p. 3).
[35] The "should not" here is a moral "should not." It does not entail any conclusions about what the law should permit or require. The relationship between ethics and the law is complex and is not taken up in this Review.
[36] If considerations not directly related to health are included in the risk/benefit analysis, there may be cases where an intervention that is marginally less effective in promoting health may be recommended (e.g. when the marginally more effective treatment is much more expensive). And of course, to say that the clinicians should offer the more favorable intervention is not to say that patients do not have the right (in most cases) to refuse it.
[37] See Chapter 14.
[38] Cass (2024a, pp. 153–154).
[39] Heathcote et al. (2024, pp. s19–s32, Suppl. 2).

harms. Some argue that in the face of uncertain evidence both for benefit and for harm, patients themselves (and their families), with expert clinicians providing relevant clinical information, should decide how to proceed.[40] Medical decisions under uncertainty, the reasoning goes, should be made by those with the greatest personal stake in the outcome. In pediatrics, this means children and adolescents, supported (usually) by their families.

This objection properly expresses concern for patient health and well-being as well as respect for the developing decision-making capacity of children and adolescents (and the greater capacity of their guardians). But it fails, for two reasons.

First, the objection understates the cumulative case for evidence of harm. We can be certain in the ordinary sense of "certain" that these interventions cause harm, even if we do not have "high certainty" evidence in the technical sense employed in evidence-based medicine (EBM).[41] We do not need results from RCTs to be certain that removing an adolescent's breasts will eliminate or substantially impair capacity for breastfeeding. Nor do we need RCTs to establish that PBs and CSH stunt growth of the penis, increasing the risks associated with future surgery.[42] And apart from any systematic reviews of published studies, basic human physiology indicates that blocking puberty at Tanner Stage 2 and following with CSH will negatively impact fertility. That advocates of PMT recommend fertility counselling before undergoing these interventions is evidence that they, too, anticipate the risk of infertility and regard it as a harm. Other forms of evidence, such as indirect evidence from research on adults, also contribute to the case that these interventions cause harm.[43] Finally, research on PMT has focused largely on potential benefits to mental health, with less attention given to potential physical harms, compounding the problem of publication bias.[44]

Second, even granting that the uncertainty of the evidence makes it impossible to assign precise values to the probabilities or magnitudes of various potential outcomes, it

[40] Antommaria (2024).
[41] Smith & Pell (2003)
[42] Terhune et al. (2022).
[43] See Chapter 7.
[44] See Chapter 6 for discussion of publication bias.

does not follow that clinicians are dependent on their patients to guide clinical decision-making.[45] Rather, the obligation to avoid serious harm justifies a precautionary approach, particularly in the absence of evidence for a proportionately serious threat to the patient's health without the intervention. In their seminal textbook on medical ethics, Beauchamp and Childress write:

> Depending on what is valued and what is at risk, it may be ethically justifiable and even obligatory to take steps, in the absence of conclusive scientific evidence, to avoid a hazard where the harm would be both serious and irreversible—that is, a catastrophe. Triggering conditions for these measures include plausible evidence of potential major harm where it is not possible to adequately characterize and quantify risk because of scientific uncertainty and ignorance. The process of developing precautionary norms should not be viewed as an alternative to risk analysis and scientific research. It should instead be viewed as a way to supplement risk appraisals when the available scientific evidence does not permit firm characterizations of the probability or magnitude of plausible risks.[46]

It seems clear that the triggering conditions for adopting a precautionary approach to the use of hormonal and surgical interventions for the treatment of pediatric GD have been met. When precautionary considerations are added to the cumulative case for harm, the ethical argument against PMT becomes compelling.

> The importance of avoiding harm is emphasized by the fact that many treatments (e.g., surgery, hormone therapy) can lead to relatively common and potentially serious long-term adverse effects. This necessitates particularly strong justification (i.e., clear evidence of benefits and the decision-maker's competence) before administering such treatments or accepting these risks. In practice, physically modifying healthy bodies is generally associated with potential harms or risks. Empirical evidence concerning the long-term benefit-to-

[45] One would hope this would come as a relief to clinicians and especially to pediatricians, though some seem happy to let children lead the way. See Chapter 11.
[46] Beauchamp & Childress (2019, p. 250)

> harm ratio of these interventions is often limited. In other words, avoiding harm prompts considerations similar to those raised by competence: when evidence of benefit is uncertain, but risks are probable, the ethical imperative to minimize harm is further underscored.[47]

The unfavorable risk/benefit profile distinguishes PMT from many other off-label uses of drugs and medical devices. Advocates for PMT point to the prevalence of off-label prescribing in pediatrics,[48] but the legitimacy of some off-label uses does not license the prescription of any pharmaceutical to any patient for any reason. The favorable risk/benefit threshold, or, more minimally, the precautionary threshold, must be met irrespective of whether the intervention is approved by FDA. Off-label use of an intervention is sometimes justifiable based on studies of the intervention in a different patient population or for a different indication. Such use may be warranted when there is a reasonable expectation of benefit, when there are no superior alternatives, and when the prognosis, absent medical intervention, is predicted to be worse for the patient than the negative effects of the off-label drug.

This is decidedly not the situation with PMT. The natural history of pediatric GD is poorly understood[49] and decades of research has shown that early-onset GD usually resolves without medical intervention.[50] There is no compelling evidence that the same will not prove true in the case of adolescent-onset symptoms, and limited evidence suggesting it will.[51] And in any case, it is widely acknowledged that clinicians are unable to

[47] Saarni & Uusitalo (2020, p. 41); our translation. Original text: “Haittojen välttämisen tärkeyttä korostaa se, että monista hoidoista voi seurata varsin yleisiä ja vakaviakin pitkän tähtäimen haittoja (esim. kirurgia, hormonihoidot), jolloin hoitojen antamiselle (eli näiden riskien ottamiselle) pitää olla erityisen hyvät perusteet (eli näyttö hyödyistä sekä päätöksentekijän kompetenssista). Käytännössä terveiden kehojen fyysiseen muokkaukseen voidaan katsoa useimmissa tapauksissa liittyvän haittoja tai riskejä. Empiirinen näyttö hoitojen pitkän tähtäimen hyöty/haitta-suhteesta on useissa tapauksissa vähäistä. Toisin sanoen haitan välttäminen johtaa siis samankaltaiseen pohdintaan kuin kompetenssikysymys: jos näyttö hyödyistä on epävarmaa mutta haitat todennäköisiä, haittojen minimoinnin tärkeys eettisenä periaatteena korostuu.”
[48] Meng et al. (2022).
[49] See Chapter 4.
[50] Ristori & Steensma (2016); Singh et al. (2021).
[51] Bachmann et al. (2024); Byrne (2024a); Rawee et al. (2024); Sun et al. (2023)

distinguish patients whose GD will persist from those whose GD will resolve.[52] Further, there are concerns about the role medicalization itself may play in contributing to the persistence of the conditions being treated,[53] and less invasive and less risky interventions are available.[54] Lastly, medical intervention has known and plausible harms,[55] and decades of research conducted by leading academic institutions have failed to produce reliable evidence of medical benefit.[56]

13.2.4 Justice

According to the Belmont Report, published in 1978 in the wake of the U.S. Public Health Service's Untreated Syphilis Study at Tuskegee, "An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly."[57] While the Belmont report set out ethical principles to guide human subjects research, the principle of justice applies also to clinical medicine. Advocates for PMT sometimes claim it is unjust to withhold PBs, CSH, or surgeries from youth with GD.[58] They cite research finding that this patient population has significant healthcare needs and also suffers from social marginalization and stigma.[59] These patients indeed are vulnerable along multiple axes, and it would be an injustice to deny them safe and effective medical care. It would also be unjust, however, to subject them to serious hormonal and surgical interventions that lack a favorable risk/benefit profile. In fact, it seems particularly unjust to subject youth struggling with complex psychiatric, neurodevelopmental, and psychosocial challenges to the harms associated with these interventions. The justice principle has been rightly invoked but wrongly applied.

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[52] "Although a diagnosis of gender dysphoria has been seen as necessary for initiating medical treatment, it is not reliably predictive of whether that young person will have longstanding gender incongruence in the future, or whether medical intervention will be the best option for them." (Cass, 2024a, p. 29). The recent German clinical guidelines note that its own review found no studies that could supply empirical criteria to determine whether GD or gender incongruence would persist into or beyond adolescence (German Society for Child and Adolescent Psychiatry, Psychosomatics and Psychotherapy (DGKJP), 2025, p. 188).
[53] Jorgensen (2023a).
[54] See Chapter 14.
[55] See Chapter 7.
[56] See Chapter 5.
[57] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (2010).
[58] Kimberly et al. (2018); Maung (2024).
[59] Hatzenbuehler & Pachankis (2016); Rider et al. (2018).

In both her Interim and Final Reports, Cass notes concerns brought to her by patients and families about "diagnostic overshadowing."[60] Diagnostic overshadowing is a form of bias that leads clinicians to misattribute symptoms of one condition to a different previously diagnosed condition. This can happen, for example, when clinicians mistakenly attribute patients' complaints of physical discomfort to the patient's previously diagnosed psychiatric condition, a mistake that may lead to misdiagnosis and inadequate treatment.[61] Diagnostic overshadowing is especially salient in mental health care contexts, where a patient with psychiatric problems, neurodevelopmental challenges, or cognitive disabilities may be treated one-dimensionally as a "case" of some psychiatric diagnosis rather than holistically as a person susceptible to a range of health problems unrelated to that diagnosis.

In the context of PMT, the concern is that the diagnosis of GD tends to obscure causes of distress and crowd out other mental health care needs, particularly when patients are referred to specialty gender clinics. The gender clinic model of care becomes Maslow's hammer to which every problem appears as a nail. The risk of diagnostic overshadowing increases insofar as (1) clinicians fail to provide comprehensive psychiatric evaluations;[62] (2) clinicians face pressure from colleagues, patients, and parents to "affirm" patients prematurely, that is, prior to providing them sufficient time to develop and mature;[63] and (3) co-occurring mental health challenges or problem behaviors are reflexively assumed to be minority stress-mediated sequelae of the patient's GD diagnosis.[64] To neglect the mental health care needs of members of an already vulnerable population of youth with complex psychiatric, neurodevelopmental, and psychosocial challenges is to deny them a benefit to which they are entitled, and to expose them to medically unnecessary risk of harm is to impose a burden unduly.

There are additional problems related to justice. Compared to their age-matched peers, same-sex attracted youth are significantly overrepresented among patients presenting

[60] Cass (2022a, p. 46; 2024b, p. 200).
[61] Hallyburton (2022); Jones et al. (2008); Reiss et al. (1982).
[62] Damiano (2024a).
[63] Edwards-Leeper & Anderson (2021).
[64] Papers claiming minority stress explains various health problems of transgender-identified adolescents include Delozier et al. (2020); Dolotina & Turban (2022); Hunter et al. (2021).

to gender clinics.[65] As noted in Chapter 3, this phenomenon has been observed from the beginning. Of the 70 patients recruited by de Vries and colleagues in the Netherlands from 2000 to 2008, 62 reported being exclusively same-sex attracted, six reported being bisexual, and one reported being exclusively opposite-sex attracted.[66] That is, the original Dutch Protocol patient cohort was comprised almost entirely of gay, lesbian, and bisexual patients[67]—one of whom died as a result of surgical complications from vaginoplasty following pubertal blockade and cross-sex hormones.[68] Reports of negative attitudes towards homosexuality, which may be internalized, are not uncommon in this field.[69] One of the earliest clinical reports on adolescent transition describes a family concerned that their son's gender nonconformity was a sign of homosexuality.

> It is of interest to note that [the patient's family] were all reassured to discover that George was not a *homosexual*. The diagnosis of 'transexual' provided an explanation for his feminine behavior and was, especially for the parents, psychologically relieving.[70]

Given the medical profession's history of pathologizing and medicalizing same-sex attraction,[71] serious justice-related concerns are raised by the overrepresentation of gay, lesbian, and bisexual adolescents among patients receiving unproven interventions that adversely impact fertility and sexual function.

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[65] Drescher & Yarbrough (2024); Singh et al. (2021); Wood et al. (2013).
[66] de Vries et al. (2011, Table 1). The remaining one patient reported "don't know yet."
[67] Biggs (2023b).
[68] Biggs (2023b); de Vries et al. (2014); Negenborn et al. (2017) Bachmann et al. (2024); Sun et al. (2023).
[69] Barnes (2023); Sansfaçon et al. (2023); Littman (2021).
[70] Newman (1970). Given clinician reports of his self-reported sexual behavior and desires, it is almost certain that George was gay.
[71] Hodge (1950); Murphy (1992); Shidlo et al. (2001). From Hodge: "Male aged 37 years, who came voluntarily, being concerned by his definite homosexual bias which, though it had not since puberty found overt expression, was nevertheless a source of great worry and unhappiness … He appeared after close investigation to be a homosexual deviant of very long standing—an 'innate' pattern rather than one of traumatic 'level fixation'—and he failed to respond to psychotherapy. Treatment by oestrone has been followed by loss of sexual libido and he reports considerable 'mental relief.'" (p. 135) See also Chapter 3 for the influential case of George/Christine Jorgensen and the subsequent wave of lesbian and gay people who sought medical transition.

13.3 Alternative clinical rationales

Clinical research on pediatric medical transition has focused primarily on its effects on psychiatric morbidity and to a lesser extent on psychosocial function. The original Dutch Protocol required patients to have "Gender Identity Disorder" (GID), as GD was then called. The diagnostic criteria for GID and its DSM-5 successor GD include clinically significant distress and/or functional impairment.[72] While the diagnostic criteria for GD closely mirror the previous criteria for GID, the DSM-5 more explicitly emphasizes that cross-sex identity, by itself, does not constitute a pathology. The attendant distress, if present, is what is pathological. As such, medical interventions target the patient's distress or impairment, not the underlying identification.

That patients must have a mental health disorder to access medical resources has long troubled some patients and advocacy groups.[73,74] Some clinical protocols require patients to undergo assessment to determine if they meet (*inter alia*) the distress or impairment criterion—it is not enough that a patient attests to cross-sex identification or incongruence. These criteria thereby create an impediment[75] for people who do not suffer distress or impairment but who nevertheless wish to medically alter their bodies. To access the interventions they want, these patients may need to exaggerate or feign symptoms or else shop for clinicians willing to rubber stamp a diagnosis.[76]

One possible solution to this challenge is simply to eliminate any requirement for a medical diagnosis. Doing this would remove the obstacle of assessment from the path

[72] Because GID and GD are DSM diagnoses and the DSM is a manual of mental disorders, this is not surprising. However, it does constrain the options available to clinician-researchers insofar as reimbursement requires a DSM diagnosis, i.e. the categorization of the patient as suffering from a mental disorder.
[73] Drescher (2017).
[74] Objections to medical "gatekeeping" and tensions between patients and clinicians regarding the pathologization of cross-sex identification predate the Dutch Protocol and the medicalization of pediatric gender distress by decades. Adults, wishing for hormones and surgeries to satisfy their longing to modify their bodies and to be perceived as members of the other sex, have butted heads with psychiatrists, psychologists, endocrinologists, and surgeons since the early 20th century when the first "sex change" procedures took place. Disciplinary turf wars between experts, with each field vying for authority over diagnosis and treatment, contributed to the ongoing professional uncertainty over the fundamental aims of medical intervention and the appropriate balance of power between patients and clinicians. See Meyerowitz (2009); Shuster (2021).
[75] Jacobsen (2024).
[76] For accounts of patients feigning symptoms and manufacturing histories in order to convince clinicians of their medical need, see Ashley (2019); Pimenoff & Pfäfflin (2011); Shuster (2021).

of patients seeking medical interventions. The problem with this solution for the DSM and the ICD working groups was that removing the diagnoses altogether would make reimbursement for medical intervention difficult or impossible. The tension between ensuring reimbursement and thereby access, on the one hand, and satisfying the demands of patients and activist groups for depathologization, on the other, required compromises on the part of DSM and ICD developers.[77] The DSM developers depathologized incongruence and pathologized distress. The ICD-11 developers had more options because unlike the DSM, which is devoted exclusively to mental disorders, the ICD catalogues all diseases and health conditions. Having considered the various possibilities,[78] the ICD-11 working group decided to move the diagnosis out of the mental health chapter, where it was believed to contribute to stigma, and into a new chapter, "Conditions Related to Sexual Health," where it would be less stigmatizing but still useful for purposes of reimbursement.

Consequently, present DSM and ICD diagnoses comprise different frameworks shaped by historical contingencies—including, crucially, payment considerations.[79] According to the DSM-5, experiencing gender incongruence itself is not pathological, while associated distress or impairment are, rendering GD a mental disorder. Meanwhile, according to the ICD-11, gender incongruence (that is, being transgender according to contemporary understandings of what it is to be transgender) itself is pathological, but not a mental health disorder. ICD-11's diagnosis, Gender Incongruence of Adolescence or Adulthood, includes no requirement of distress or impairment for medicalization. Thus, DSM-5 and ICD-11 differ on whether hormonal and surgical interventions are treatments for a mental health problem or rather some other kind of pathology, on whether transgender identity itself is pathological, and on whether a patient must be distressed or impaired to receive reimbursable medical intervention. Despite these differences and inconsistencies, both diagnoses are employed to justify and reimburse the provision of hormonal and surgical interventions to adolescents.

[77] Drescher (2015).
[78] Drescher et al. (2012).
[79] See Drescher (2015); Drescher & Yarbrough (2024).

The more permissive approach to medicalization is defended by some clinicians,[80] bioethicists, and activists.[81] For example, bioethicist Florence Ashley argues that the provision of hormonal and surgical interventions to adolescents is justified by the interventions' capacity to satisfy patients' "gender embodiment goals":

> Adolescent medical transition aims at preventing or altering the development of sexual characteristics to achieve the individual's gender embodiment goals. Given its purpose, the effectiveness of adolescent medical transition is defined by its ability to achieve the sought physiological outcomes—a standard undisputedly met.[82]

While the Dutch Protocol was designed to alleviate adolescents' psychiatric distress and improve psychosocial functioning, Ashley's approach drops the requirement of clinical improvement—achieving the patient's embodiment goals is enough.[83] Elsewhere, Ashley explains that some people seek hormonal or surgical interventions not because they are suffering from a pathology but rather because these treatments can deliver certain desired experiences such as "gender euphoria" and "creative transfiguration." Gender euphoria is a "distinct enjoyment or satisfaction caused by the correspondence between the person's gender identity and gendered features associated with a gender other than the one assigned at birth."[84,85] Creative transfiguration, Ashley writes, "is more difficult to capture in words. Foregrounding creativity and aspirational aesthetics, creative transfiguration sees the body as a gendered art piece that can be made ours through transition-related interventions."[86]

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[80] See Chapter 11.
[81] Chu (2024).
[82] Ashley (2022a, p. 127).
[83] See Gorin (2024). It is notable that de Vries, the lead author of the two seminal papers (de Vries et al 2011 and 2014) that established the Dutch Protocol, has more recently questioned the "logic of improvement" that undergirds that original clinical rationale and has favorably cited the approach advocated by Ashley (Oosthoek et al., 2024).
[84] Ashley & Ells (2018, p. 24). The definition of gender euphoria offered by Ashley and Ellis entails that no one who does not experience incongruence can experience gender euphoria. According to other writers, however, gender euphoria is "quite common… among trans and cis folks alike." (Kukla, 2024, p. 288).
[85] Researchers recently have developed a scale intended to measure gender euphoria (Blacklock et al., 2025).
[86] Ashley (2019, p. 481).

Because contemporary gender medicine countenances a multiplicity of "genders," this newer emphasis on embodiment goals moves beyond the "sex change" framework of previous decades, in which male patients acquired female-typical characteristics to "live as women" and female patients acquired male-typical characteristics to "live as men" (see Chapter 3). Nothing in the newer "gender affirming" approach limits the number of bodily variations clinicians may be asked to create. Some girls or women want just a bit of stubble while others want full beards and flat chests; some boys or men want softer skin and breasts but wish to keep their penises intact. Expanding clinical offerings reflect these expanding embodiment goals. Surgeons provide penis-preserving vaginoplasty for patients who want both male and female genitals and offer "nullification" procedures for patients who identify as nonbinary and want no external genitals at all. There are at least as many physical combinations for patients to acquire as there are "gender identities"—indeed more, since presumably each gender identity can be embodied in different ways.[87]

While the ICD-11 does not mention "gender euphoria" or "gendered art pieces," the diagnostic criteria for Gender Incongruence of Adolescence or Adulthood implicitly formalize the "embodiment goals" approach to medical transition. The diagnosis is explained as follows:

> Gender Incongruence of Adolescence and Adulthood is characterized by a marked and persistent incongruence between an individual's experienced gender and the assigned sex, which often leads to a desire to 'transition', in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual's body align, as much as desired and to the extent possible, with the experienced gender. The diagnosis cannot be assigned prior the onset of puberty. Gender variant behavior and preferences alone are not a basis for assigning the diagnosis.[88]

[87] James et al. (2015).
[88] World Health Organization (2022b).

According to Jack Drescher, a member of the World Health Organization's (WHO) Working Group on the Classification of Sexual Disorders and Sexual Health, which was tasked with making recommendations for the ICD's eleventh edition, to qualify for the diagnosis of Gender Incongruence of Adolescence or Adulthood, a patient need satisfy only two of the following four criteria:

> 1. Strong dislike or disagreement with primary or secondary sexual characteristics due to incongruence with the experienced gender.
>
> 2. Strong desire to get rid of some of those sexual characteristics due to the incongruence with the experienced gender.
>
> 3. Strong desire to have the primary or secondary sexual characteristics of the experienced gender.
>
> 4. Strong desire to be treated and accepted as a person of the felt gender.[89]

It is hard to see how either of the first two criteria could be used to diagnose gender incongruence. ICD-11 says that gender incongruence is "characterized by a marked and persistent incongruence between an individual's experienced gender and the assigned sex …"[90] Criteria (1) and (2) themselves include incongruence and so the diagnosis, when met by the first two criteria, suggests that a person has gender incongruence because they have attitudes or desires due to incongruence.[91]

Setting problems of circularity aside, an adolescent can be diagnosed with gender incongruence by satisfying (3) and (4),[92] which amount to having certain strong embodiment goals. A male who strongly desires to have (some? all?) the sex characteristics of a female and to be treated or accepted as such, or a female who strongly desires to have (some? all?) the sex characteristics of a male and to be treated

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[89] Drescher & Yarbrough (2024, p. 2508).
[90] World Health Organization (2022a).
[91] The problem of circularity is also discussed in Chapter 2. It is also unclear what it could mean to be in a state of "disagreement" with one's sex characteristics. Perhaps the authors mean that one finds one's sex characteristics disagreeable, that is, unpleasant. This makes sense, as long as the unpleasantness does not rise to the level of distress, which would transform gender incongruence into something like gender dysphoria and thereby undermine the rationale for moving the gender incongruence diagnosis out of the mental disorder chapter of ICD-11.
[92] Whether the criteria must be met for a specific period of time is unclear. ICD-11 does not specify a time requirement; Drescher and Yarbrough say "several months" (Drescher & Yarbrough, 2024, p. 2508).

or accepted as such, qualifies for the diagnosis. According to the ICD-11, a patient with such desires has a "condition related to sexual health" and, therefore, clinicians have a rationale for providing, and being reimbursed for, hormonal or surgical interventions.

It is noteworthy that the ICD-11 employs identical diagnostic criteria for adolescents and adults, despite the clear physiological and psychological developmental differences between these populations and their respective capacities for decision-making and self-understanding. Neither DSM-5-TR nor ICD-11 provide any explanation for why children or adolescents might desire to modify their sex traits or to be treated or accepted as someone other than a member of their sex, and counseling approaches that might explore possible explanations with patients often are labeled "conversion therapy" by advocates of the "gender-affirming" approach.[93] As far as the DSM-5-TR and ICD-11 diagnoses are concerned, it makes no difference that a patient of 10 or 13 or 17 might wish to modify their body and be perceived and treated as someone other than a member of their sex for any number of reasons. These may include discomfort with one's homosexuality, a history of sexual trauma, pubertal distress, the rejection of perceived sex-based roles, and/or psychiatric comorbidities. For the ICD-11, desire alone is sufficient to justify a medical diagnosis and, within the "gender-affirming care" framework, set the adolescent on a course of PMT.

If using hormonal and surgical interventions to reduce psychiatric morbidity associated with gender dysphoria lacks a favorable risk/benefit profile, using these interventions merely to satisfy adolescents' embodiment goals veers from clinical error into clinical recklessness.

13.4 Regret

Patient regret has begun to receive significant attention in discussions of PMT. Proponents of PMT claim that regret is extremely rare.[94] Some also claim that since mental health assessments have not been shown to reduce regret rates, they should not be required prior to prescribing.[95] The tacit assumption is that absence of regret is

[93] Ashley (2023). See Chapter 14.
[94] Crabtree et al. (2024); Kidd & Sequeira (2024); McNamara et al. (2024); Turban et al. (2021).
[95] Ashley et al. (2023); Wu & Keuroghlian (2023). See also Chapter 11.

an indication of medical benefit or at least of absence of harm. Other researchers point out that research on regret, like most research in PMT, is severely lacking and that we do not know the true prevalence of regret.[96] Whether implicitly or explicitly, proponents and critics alike consider the question of regret as central to the ethics of PMT.

That some patients report profound regret after undergoing invasive, life-changing medical interventions is clearly of importance. However, regret alone (just like satisfaction alone) is not a valid indicator of whether an intervention is medically justified. Not only is regret a complex phenomenon itself,[97] but its relation to ethical considerations in medicine, and to benefit and harm in particular, is tenuous. Patients sometimes come to regret consenting to interventions that were in fact well-justified, that is, interventions that did offer a favorable risk/benefit profile at the time the intervention was proposed. Patients may come to regret such interventions because they suffer harmful complications that were unlikely to occur but did occur in their case. Or they may come to regret the interventions for other reasons. For example, a woman may undergo a spine surgery for which there is compelling evidence of net benefit to her health and yet come to regret the surgery because the modest relief of pain seems to her retrospectively to have not been worth the cost or hassle involved in recovering from the surgery. Or perhaps the improvement in her health allowed her to take some course of action that turned out to make her life worse, all things considered. That she comes to regret the surgery does not mean that it was clinically or ethically unjustified, nor that her clinician violated medical ethics.

Conversely, humans have a remarkable capacity to incorporate suffering and loss into their life stories. A man may be paralyzed as the result of a spine surgery that did not prospectively offer a favorable risk/benefit profile, and which should never have been attempted by the surgeon. Yet months or years later the man may report that he does not regret undergoing the surgery, because the injury and debility it caused led him to focus more attention on the love and care of his family and friends. Or perhaps, as able-bodied, he was isolated and lonely but now, due to his greater physical dependency, he

[96] Cohn (2023); Jorgensen (2023b); MacKinnon, Expósito-Campos et al. (2023).
[97] Landman (1987).

finds a supportive community within which he develops a new identity that imbues his life with structure and purpose. Or maybe as a result of his injury he simply comes to appreciate more deeply the gift of life in its fragility. That this man does not regret the surgery does not imply that his decision to consent to it was prudent, nor that the surgeon was justified in offering the surgery.

The implications for PMT are complex. The provision of hormonal or surgical interventions to physically healthy adolescents cannot be vindicated by purportedly low rates of regret. Some patients who have suffered objective medical harm and then detransitioned nevertheless do not regret having been medicalized.[98] Nor can the interventions be condemned based on the fact that some adolescents who have undergone them do report regret. The central question for PMT is not: "Do these medically transitioned patients have regret?" A more fundamental question is, "Does medical transition provide health benefits proportionate to its harms?" The best available evidence, along with a risk/benefit analysis and precautionary approach ethically appropriate to pediatrics, shows that the answer to the latter question is almost certainly "no."

13.5 Research Ethics

Multiple SRs, commissioned by leading international health authorities and conducted by independent academic researchers, have concluded that the evidence underpinning the expected benefits of PMT is of low or very low certainty.[99] A natural response among researchers to the absence of higher quality evidence is to conduct more and better research. Whether and how such research should be conducted, however, is a matter of significant ethical controversy.

One controversy concerns RCTs, the "gold standard" for clinical research.[100] Some proponents of PMT claim that RCTs on the effects of PBs or CSH would be infeasible and unethical.[101] With respect to feasibility, because the effects of PMT interventions are

[98] For some real examples, see Sansfaçon et al. (2023).
[99] See Chapter 5.
[100] Hariton et al. (2018).
[101] Ashley et al. (2024, 407-418).

so apparent, it is not possible to blind researchers and participants in an RCT for which the control group receives only psychotherapeutic support. Some worry that many adolescents would refuse to participate in a study that does not guarantee they receive hormonal interventions, or that they would drop out if randomized to the control group. These challenges may be harder to overcome in the current climate in which adolescents have been led to believe that hormonal and surgical interventions are well-supported by the evidence and even life-saving.[102] However, randomization does not require blinding, and until an RCT is attempted, speculation about how potential participants will respond is just that—speculation.

With respect to research ethics, one objection to conducting RCTs is that such research would violate the principle of equipoise. In their textbook, *Principles of Biomedical Ethics*, Beauchamp and Childress explain that "[t]he community of reasonable physicians is … in a state of 'clinical equipoise'" when "[n]o one knows, prior to conducting the research, whether it is more advantageous to be in the control group or in the experimental group … In this model, no patient, then, will receive something known to be less effective or to have a higher risk than an available alternative."[103]

Advocates for PMT allege that it would violate the principle of equipoise to conduct an RCT of PMT in which the control group receives only psychological counseling, "given the numerous studies associating adolescent gender-affirming interventions with improved mental health."[104] This allegation is unfounded, however, because it mischaracterizes the state of the science. Indeed, if equipoise were violated, it plausibly would be in the other direction, given the more certain evidence of harm. In the end, while their reasons differ, there may be a point of agreement between proponents of PMT and some of its critics concerning the impermissibility of conducting RCTs for hormonal or surgical interventions for pediatric GD.

It is not clear that hormonal or surgical interventions for GD can ethically be offered in a trial, irrespective of trial design. Currently, researchers in the U.K. are planning a PB

[102] Clayton, A. (2023).
[103] Beauchamp & Childress (2019), p. 365; See also Freedman (1987).
[104] Ashley et al. (2024, p. 408).

trial. At the time of this Review's writing, the trial has not yet received official ethics approval, and details regarding the trial's design, which outcomes will be studied, what the inclusion and exclusion criteria will be, and so on, have not been published. Some critics of PMT already are raising concerns about the proposed study. They worry about prescribing PBs even in research settings given the recognized inability of clinicians to distinguish between patients whose GD will persist into adulthood from those whose GD will resolve on its own,[105] and the high likelihood that any patient who begins PBs will go on to CSH and possibly surgery.[106] Since most adolescents who take PBs go on to CSH, and since it is CSH and surgery that provide the sought-after physical characteristics in PMT, it is unclear whether PBs are a stand-alone treatment and should be studied as such.

Other critics point out that safer types of research—for example, research into various psychotherapeutic approaches—have yet to be explored with this population of patients. They also point out that U.S. gender clinics have yet to collect longitudinal data on existing patients.

There are other important ethical problems to consider. The Nuremberg Code is a foundational and internationally accepted statement of norms guiding human subjects research and it includes the following:

> The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results justify the performance of the experiment.[107]

This suggests that, insofar as PMT poses risks that can be explored through animal studies, such studies should be conducted before these treatments are further tested on humans. Animal studies could help clarify how hormonal interventions affect fertility,

[105] Feinmann (2025).
[106] E.g. Brik et al. (2020); Carmichael et al. (2021); Karakılıç Özturan et al. (2023a); van der Loos, Klink et al. (2023); Wiepjes et al. (2018).
[107] BMJ (1996).

brain development,[108] bone development (including future risk of fracture), and cardiovascular outcomes. Such studies also could help clarify to what extent and under what conditions fertility can be recovered after suppression by hormonal interventions.

The World Medical Association's Declaration of Helsinki is another foundational and internationally accepted statement of guidance for human subjects research. It includes the following:

> All medical research involving human participants must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation. Measures to minimize the risks and burdens must be implemented. The risks and burdens must be continuously monitored, assessed, and documented by the researcher.
>
> Physicians and other researchers may not engage in research involving human participants unless they are confident that the risks and burdens have been adequately assessed and can be satisfactorily managed.[109]

It is not ethical to subject adolescents to hormonal and surgical interventions used in PMT, even in a research trial, until and unless the state of the evidence suggests a favorable risk/benefit profile for the studied intervention, *and* the researchers have well-grounded confidence that the foreseeable "risks and burdens have been adequately assessed and can be satisfactorily managed." As explained in this Review, the state of the science does not support a favorable risk/benefit profile, nor does it give researchers a basis for confidence that the risks of PMT can be satisfactorily managed.

Finally, the Belmont Report, authorized by the National Research Act of 1974 and published in 1979 by the United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, is a landmark statement of

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[108] Chen and colleagues, for example, write, "studies in rodents show ovarian hormones, acting during puberty, program cognitive flexibility by exerting long-lasting effects on excitatory-inhibitory balance in the pre-frontal cortex . . . [and] testosterone, acting during puberty, programs the ability to adapt behavior as a function of social experience" (Chen et al., 2020, Table 2).
[109] World Medical Association (2025).

ethical principles to guide human subjects research in the United States. The Belmont Report affirms that research on humans should not be conducted until and unless that research is "justified on the basis of a favorable risk/benefit assessment" arrived at through "systematic, nonarbitrary analysis of risks and benefits." It continues:

> Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible … It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies … [and] When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject …).[110]

As demonstrated throughout this Review, the presuppositions that guide PMT have not been shown to be valid; the nature, probability and magnitude of risks associated with PMT have not been distinguished with sufficient clarity; PMT proponents' estimates of the probability of harm and benefit have not been shown to be reasonable, as judged by known facts and available studies; and the risks of serious impairment that PMT involves have not been shown to be justified. For these reasons, administering PMT to adolescents, even in a research context, is in tension with well-established ethical norms for human subjects research.

[110] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (2010).

PART 5

PSYCHOTHERAPY

Chapter 14 Psychotherapy

This chapter reviews psychotherapy (talk therapy) for gender dysphoria (GD).[1] First, the chapter describes relevant trends in society at large and in the medical profession; specifically, trends in youth mental health (Section 14.1) and in diagnostic and social labels (Section 14.2). Section 14.3 discusses the role of mental health assessment in the care of youth with GD. Section 14.4 briefly recounts the re-emergence of psychotherapy as the primary treatment for this patient population in Europe, and Section 14.5 discusses psychotherapy and its specific application to GD.

14.1 Youth mental health

Puberty is the biological, developmental process during which a child becomes a sexually mature adult.[2] Puberty overlaps significantly with adolescence, the period between childhood and adulthood.[3] During puberty, hormonal fluctuations can affect mood and behavior.[4] The onset of puberty often coincides with heightened sensitivity to social dynamics and self-image along with increasing vulnerability to stress and anxiety. Emotional regulation can become challenging as adolescents navigate the complexities of identity formation and peer relationships. Cognitive development accelerates, allowing deeper abstract thinking and self-reflection, which can contribute to existential questioning and emotional instability.[5] Adolescence also involves learning to function independently, as part of identity formation and individuation from the family of origin. Rebellion and resistance to parents and other caregivers or authority figures frequently occur during this process. Adolescents often struggle with long-term planning and are more susceptible to risk taking, as drives for stimulation and affiliation increase but the prefrontal cortex, responsible for executive functions, is still maturing.[6]

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[1] Gender Dysphoria is a formal diagnosis in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5): see Appendix 2. In this chapter and throughout the Review the term “gender dysphoria” is used to refer to sex-related distress or discomfort, not the formal diagnosis (see Chapter 1, Note 1).
[2] See Chapter 7.
[3] According to the American Academy of Pediatrics (AAP), adolescence spans ages 12-21 (Hardin et al., 2017). See also National Academies of Sciences, Engineering, and Medicine (2019, pp. 22–23).
[4] Viner (2015).
[5] E.g., Reena (2015); Steinberg (2005).
[6] Steinberg (2009).

14.1.1 Trends in youth mental health

In 2021, the American Academy of Pediatrics (AAP), the American Academy of Child and Adolescent Psychiatry (AACAP), and the Children's Hospital Association declared a "National State of Emergency in Children's Mental Health."[7] In December of that year, U.S. Surgeon General Admiral Vivek Murthy issued an Advisory on Protecting Youth Mental Health, highlighting rising rates of depression, anxiety, hopelessness, and self-harm among youth—trends that worsened during the COVID-19 pandemic. The Lancet Psychiatry Commission on youth mental health noted a similar worldwide trend.[8]

In the U.S., there has been a significant increase in mental illness among teens and young adults since 2010.[9] Data reveal sharply increased rates of diagnosed depression and anxiety; some studies indicate that these rates have more than doubled.[10] Increases also have been documented in rates of suicidal ideation and behavior and self-harm,[11] emergency room visits and hospitalizations for self-harm,[12] and death by suicide.[13] Young people today experience weaker social connections and greater feelings of loneliness. Since 2010, adolescents have had fewer in-person social

[7] American Academy of Child and Adolescent Psychiatry et al. (2021).
[8] McGorry et al. (2024).
[9] Twenge (2020).
[10] Data from a large national database showed that rates of major depressive episodes among adolescents aged 12 to 17 increased by 52% from 2005 to 2017 (from 8.7% to 13.2%) and by 63% among young adults aged 18 to 25 from 2009 to 2017 (from 8.1% to 13.2%) (Twenge et al., 2019). The "Anxious Generation" website, using Centers for Disease Control and Prevention (CDC) data, shows that rates of major depressive disorder from 2010 to 2022 more than doubled for both boys and girls, with major depression in boys increasing by 161% and in girls by 145%. Mental illness for college students increased, with a 134% increase in anxiety and 106% increase in depression over that same period (Rausch & Haidt, 2023). A cohort study of approximately 1.7 million individuals aged 5 to 22 years in Southern California revealed that from 2017 to 2021 the overall incidence of depression increased by approximately 60%, and anxiety by 31% (Xiang et al., 2024). A survey of a Midwestern school district found from 2012 to 2018 there was a 29% increase in youth screening positive for past-month anxiety (Parodi et al., 2022). See also Goodwin et al. (2020); Keyes & Platt (2024).
[11] See CDC trends report, 2013-2023 (Centers for Disease Control and Prevention, 2023).
[12] See Gutiérrez-Sacristán et al. (2022) for information about increase in psychiatric hospitalizations during the COVID-19 pandemic, for example. See also McGorry et al. (2024).
[13] Suicide death rates for children and young adults aged 10 to 24 years increased 62% from 2007 (6.8 per 100,000 individuals) to 2021 (11.0 per 100,000 individuals) (Curtin et al., 2023). Youth suicides began to rise in the 2000s, with a sharper upward trend starting around 2012; see Farah et al. (2023); Miron et al. (2019); Twenge (2020).

interactions with peers compared to previous generations.[14] The deterioration in youth mental health has no one simple explanation. Researchers and theorists have identified several potential factors, including overprotective parenting,[15] the decline in free play,[16] and the ubiquity of smartphones and social media.[17] In 2023, the Surgeon General released an Advisory of Social Media and Youth Mental Health, which called attention to the potential risks associated with social media use for children and adolescents.[18]

14.2 Diagnostic and social labels

The rise in reported mental health problems may be partly attributable to overdiagnosis. Some argue that the rise in mental health awareness campaigns aimed at reducing stigma and increasing understanding may have led some young people to interpret normal behaviors and typical developmental challenges as a mental health disorder.[19] Being labeled with a mental health diagnosis can influence how young people see themselves, affect their belief in the possibility of change, and shape how others perceive them. The very act of classifying psychiatric conditions changes the behavior of patients and clinicians. Although diagnostic labels are important for research—where categorizing people or experiences is often necessary—they can oversimplify the

[14] Twenge et al. (2021); Twenge (2023). Based on CDC data, adolescents have, over time, reported increased feelings of meaninglessness, as well as less willingness to engage in risk-taking behaviors. This includes behavior such as drug and alcohol consumption, but also encompasses developmental experiences such as working or learning to drive a vehicle (Haidt, 2024).
[15] Wang et al. (2024); Winnicott (1965); Zhang & Ji (2024).
[16] According to the AAP: “Children need to develop a variety of skill sets to optimize their development and manage toxic stress. Research demonstrates that developmentally appropriate play with parents and peers is a singular opportunity to promote the social-emotional, cognitive, language, and self-regulation skills that build executive function and a prosocial brain” (Yogman et al., 2018).
[17]Increased use of technologies, including social media, caused a displacement of other activities, such in-person socializing, schoolwork, sleep, sports, reading, and other hobbies. Heavy use of smart phones and social media is ubiquitous among teenagers today (Rothwell, 2023; Twenge et al., 2022; Twenge & Campbell, 2019; Vogels et al., 2022), and common among pre-teens (Rideout et al., 2022). Social media in particular may result in worsening mood and negative self-image in adolescent girls (Choukas-Bradley, 2024; Rodgers & Rousseau, 2022; Scott et al., 2023), and in some cases may play an etiologic role in increasing presentations of specific psychiatric and neurologic issues (Giedinghagen, 2023; Haltigan et al., 2023; Hull & Parnes, 2021; Padín et al., 2021; Pringsheim et al., 2021; Weigle & Shafi, 2024). Social media has introduced a new sociomedical phenomenon in which individuals may find a sense of belonging online through identification with an illness or condition, which may place them at risk of inappropriate or unnecessary medical care (Corzine & Roy, 2024). For a meta-analysis that found reasons for skepticism about the evidence for the effects of social media on mental health, see Ferguson (2025).
[18] Office of the Surgeon General (2023).
[19] Foulkes & Andrews (2023).

richness and complexity of human experiences for the benefit of a standardized clinical language. To some extent, skillful clinicians can compensate for this reductionism,[20] but they cannot prevent diagnostic labels from escaping the clinic and being used in unintended ways in the wider culture.[21]

Overdiagnosis can lead to overtreatment; unnecessary tests, procedures or medical interventions may cause harm rather than helping. Loosening the diagnostic criteria for a condition will likely increase overdiagnosis and the risk of iatrogenic harm, so definitions should be formulated responsibly:

> … any changes [to diagnoses] should use a systematic, transparent approach where benefits and harms are explicit, especially when they lead to an increase in the prevalence of disease, and broadening of definitions should require evidence of clinical benefit.[22]

Although the term "gender identity" was used in the 1960s,[23] it did not appear in the *Diagnostic and Statistical Manual of Mental Disorders* until 1980 (third edition, DSM-III). "Gender Identity Disorders" was a subcategory of "Psychosexual Disorders," further divided into "Transsexualism" (for late adolescents and adults) and "Gender Identity Disorder of Childhood."[24] In the DSM-IV, published in 1994,[25] "Transsexualism" vanished, and "Gender Identity Disorder" (GID), covering both adults and children, appeared under "Sexual and Gender Identity Disorders." The DSM-5, published in 2013,[26] replaced "Gender Identity Disorder" with "Gender Dysphoria" and designated it as a separate category. This last change "focused the diagnosis on the gender identity-related distress that some transgender people experience (and for which they may seek

[20] Johnstone (2018).
[21] Hacking (1998); Shorter (1993). See also Brossard (2019); Elliott (2000); Haslam (2016); Lindholm & Wickström (2020); Smids & Vasterman (2025).
[22] Kale & Korenstein (2018, p. 8). The field of psychiatry is no stranger to the phenomenon of misdiagnosis, overdiagnosis and overtreatment; see, for example, Harris & Carey (2008), Havens et al. (2022), and Moreno et al. (2007) for discussion of controversies related to overdiagnosis of pediatric bipolar disorder.
[23] See Chapter 2.
[24] American Psychiatric Association (1980).
[25] American Psychiatric Association (1994).
[26] American Psychiatric Association (2013).

psychiatric, medical, and surgical treatments) rather than on transgender individuals or identities themselves."[27]

The intention of the DSM's linguistic evolution—from "Transsexualism," to "GID," to "GD"—was to reduce stigma. A parallel linguistic evolution in society at large has resulted in the increasing adoption of labels such as "nonbinary," "genderqueer," "queer," "gender-fluid," "two-spirit," and "transgender."[28] The individuals who identify with these labels—unlike historical or contemporary "transsexuals"[29]—are not a patient group of any kind. "Transgender," "nonbinary," and similar words are not medical terms: they apply to a diverse group of individuals, many of whom are neither dysphoric nor desire any medical or surgical interventions. If there is a common experience, it is "incongruence" between "experienced gender" or "gender identity" and "assigned sex." As the 2022 Text Revision of the DSM-5 explains, "not all individuals will experience distress from incongruence."[30]

As discussed in Chapter 4, social influences have plausibly contributed to the dramatic increase in adolescents presenting to pediatric gender medicine (PGM) clinics over the past decade.[31] Adolescents' need for belonging and acceptance[32] can be met by online communities and spaces centered around identity. The growing use of identity labels such as "transgender" and "nonbinary" among adolescents is an important topic for social science research. In the current U.S. healthcare environment, self-labeling of this kind increases the likelihood that a young person will seek input from a gender clinic,

[27] Drescher (2017). According to a systematic review of cross-sex hormones and mental health outcomes commissioned by the World Professional Association for Transgender Health (WPATH), "[the diagnostic changes] clarify that the target of gender-affirming medical interventions is not the person's gender identity itself but rather the clinically significant distress that can accompany a misalignment between gender identity and sex assigned at birth" (Baker et al., 2021, p. 2). For the diagnostic criteria, see Appendix 2.
[28] See James et al. (2015), and also Section 13.4 of the previous chapter, on "gendered art pieces."
[29] Some individuals who have medically and surgically transitioned still claim this label: e.g., "I do consider myself more as a Transsexual person, which to me is somebody who wanted to switch genders. I always wanted to be a man, I identify as a man, that's what I am, I don't identify as a Transperson at all" (LOTL staff, 2014). See also American Psychological Association (2023), and Chapter 3.
[30] American Psychiatric Association (2022). See also Chapters 2 and 11.
[31] See also the discussion of rapid-onset gender dysphoria (ROGD) in the same chapter.
[32] Especially in girls, e.g., Archer (2019); Prinstein et al. (2005); Rose & Rudolph (2006).

where medical transition may be recommended as early as the first appointment (see Chapter 12).[33]

14.3 Controversies regarding assessment and the role of the psychotherapist

In the Dutch research that underpins the contemporary pediatric medical transition (PMT) approach, the psychotherapist occupied an essential role. The original Dutch approach involved an intensive assessment process.[34] Adolescents who began medical transition were required by the protocol to continue to receive regular mental health care.[35]

When discussing contemporary applications of PMT in the U.S., providers often describe a similar approach: multidisciplinary, slow, careful, and methodical.[36] For healthcare providers, the term "multidisciplinary" may connote the lengthy, intensive deliberations that occur at "tumor boards"[37] or during organ transplantation assessments. In inpatient psychiatric units, it is considered preferable to have a multidisciplinary approach, for example involving nursing staff, psychologists, occupational therapists and social workers.[38]

However, in PGM, multidisciplinary teams (MDTs) often do not function like the collaborative model just described. They are more similar to the common healthcare scenario in which a patient sees a cardiologist for cardiac clearance before undergoing

[33] Discussion of labels is also salient to the treatment of the prepubertal patient cohort with GD. As discussed in Chapter 2, the relatively recent practice of calling gender dysphoric youth "transgender children" may increase the likelihood these patients will be placed on a medicalized pathway.
[34] As described in Delemarre-van de Waal & Cohen-Kettenis (2006), "[In] the first diagnostic phase, information must be obtained from both the adolescent and the parents on various aspects of general and psychosexual development of the adolescent, the adolescent's current functioning and functioning of the family. Standardized psychological assessment is a part of the procedure. The patient is always seen by two members of the gender team. If a child and adolescent psychologist makes the diagnosis, the child is also seen by a child and adolescent psychiatrist and vice versa" (p. S132).
[35] Delemarre-van de Waal & Cohen-Kettenis (2006). Mental health visits were required every 3 months.
[36] E.g., from ABC News: "[Kellan] Baker [the executive director of the Whitman-Walker Institute, an LGBTQ research organization and care provider] said the decision to pursue gender-affirming care is often a lengthy process that includes teams of medical care providers and mental health professionals who work with families to talk about their child's experience, their needs, their choices, and more…'We're talking months of appointments with a mental health specialist. We're talking lots of conversations between providers, parents, and kids,' Baker said" (Alfonseca & Geho, 2024).
[37] Okasako & Bernstein (2022).
[38] Russ (2021).

an orthopedic procedure. Under some models, the mental health professional (MHP) seeing the minor with GD writes a note or may just fill in a pre-written template; this is taken to an endocrinologist, who prescribes, or a surgeon, who operates.[39] Further, individuals who comprise the MDTs may all subscribe to the PMT model of care, which prioritizes administration of endocrine and surgical interventions to patients who desire them.[40] This is different from traditional MDTs where various specialties approach problem-solving from different perspectives, enhancing the accuracy of the diagnosis and identification of effective treatments.[41]

The MDT model in the context of PMT has created considerable uncertainty about whether the MHP or the physician providing the medical (and/or surgical) interventions bears the ultimate responsibility for the decision. This may have resulted in "diffusion of responsibility," a phenomenon in which "individuals can underperform in circumstances of shared accountability."[42] With respect to the U.K.'s National Health Service (NHS), the Cass Review's interim report provided some clarity by stipulating that the pediatric endocrinologist, as the physician providing the intervention, should be responsible for assessing the patient and formulating a full differential diagnosis. In other words, according to the interim report, receipt of a therapist's letter should not be sufficient for the prescription of hormonal intervention.[43]

In the U.S., no such clarity exists regarding which MDT professionals are ultimately responsible for medical interventions. Endocrinologists and surgeons may believe that the medical necessity of any intervention has been determined by the MHPs who made the diagnosis.[44] Whether the MHP "letter of approval" for hormones or surgery

[39] See description of the university-based multidisciplinary clinic in Reed (2023a). See description of two-hour long assessments at Boston Children's Hospital in Damiano (2024a).
[40] To further mitigate the potential biases of established MDT teams who subscribe to the PMT model, the National Health Service (NHS) in England issued a new clinical policy for cross-sex hormones in 2024. It calls for independent oversight, specifying that new national MDTs must include "clinicians *not directly involved* in the formation of the individual's care plan," who must agree "on the suitability of the individual receiving [CSH]" (National Health Service England, 2024c).
[41] Morabito et al. (2024).
[42] Marcotte et al. (2020, p. 802).
[43] Cass (2022a).
[44] See, for example, the role of endocrinologists as described in Karakılıç Özturan et al. (2023b). The field of pediatric gender medicine is unusual in this respect: "It [is] not the norm for doctors to prescribe powerful medication to people—especially children—they themselves [did] not diagnos[e]" (Barnes, 2023, p. 337).

constitutes a formal treatment indication will likely be determined by ongoing lawsuits brought by young people against the clinicians who treated them. In practice, these MHP approval letters may primarily serve to ease the ethical concerns of the physicians.[45]

Some prominent PMT advocates assert that children and adolescents should not receive *any* mental health assessment prior to initiation of hormonal interventions or surgeries.[46] As a principal investigator of NIH-funded research on PMT, Johanna Olson-Kennedy, a U.S. pediatrician and president-elect of the U.S. Professional Association for Transgender Healthcare (USPATH), likened the initiation of PMT to treating diabetes, asserting: "I don't send someone to a therapist when I'm going to start them on insulin."[47]

14.4 Psychotherapy for GD: Re-emergence in Europe

Three European countries—Sweden, Finland, and England—have conducted independent systematic reviews of evidence commissioned by their public health authorities.[48] All three concluded that the risks of medicalization may outweigh the benefits for children and adolescents with GD at the population level, and subsequently sharply restricted access to medical gender transition interventions for minors.[49] All three countries now suggest traditional mental health approaches and have begun efforts to de-exceptionalize GD. Psychotherapy is now the recommended first-line treatment, as it is for all psychological distress based on the conventions of "conservative management."[50]

Per England's National Health Service (NHS):

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[45] Levine (2024, p. 4).
[46] As described in McDeavitt (2025, p. 1298), "The argument for doing away with mental health assessments is often articulated alongside the opinion that the presence of a DSM-5 diagnosis of gender dysphoria (or indeed any type of psychological distress) should not have to be required in order for an adolescent to be initiated on PBs/GAH." See Mosier-Mills et al. (2024), for example, and similar arguments in Ashley (2022a, 2022b, 2023).
[47] Singal (2018).
[48] Ludvigsson et al. (2023); National Institute for Health and Care Excellence (2020b, 2020a); Pasternack et al. (2019); Taylor, Mitchell, Hall, Heathcote et al. (2024); Taylor, Mitchell, Hall, Langton et al. (2024).
[49] See Chapter 4.
[50] Adhiyaman & Ambalavanan (2021).

> The primary intervention for children and young people … is psychosocial (including psychoeducation) and psychological support and intervention; the main objective is to alleviate distress associated with gender dysphoria and promote the individual's global functioning and wellbeing.[51]

Per Finland's Council for Choices in Health Care in Finland (COHERE):

> The first-line treatment for gender dysphoria is psychosocial support and, as necessary, psychotherapy and treatment of possible comorbid psychiatric disorders.[52]

Per Sweden's National Guidelines:

> The psychosocial care of young people with gender dysphoria needs to be adapted to the needs of the individual adolescent. Psychosocial support that helps adolescents deal with natal puberty without medication needs to be the first option when choosing care measures. For those suffering from mental health problems, measures such as supportive counseling, psychotherapy, child psychiatric treatment, and suicide prevention need to be offered and adapted to the nature and severity of the mental health problem and the young person's overall situation.[53]

14.5 Psychotherapy and its application to gender dysphoria

Psychotherapy is the least invasive intervention for addressing psychological distress, regardless of its etiology, and it has been recognized as the international standard of care for a wide range of mental health diagnoses. However, the evidence for psychotherapy for GD is of very low certainty. As noted in Chapter 5, there are multiple reasons for the paucity of data, and "there has been a failure to systematically consider how psychosocial interventions should be used and to research their efficacy."[54]

[51] National Health Service England (2022, p. 2).
[52] Council for Choices in Healthcare Finland (2020b, p. 5).
[53] Socialstyrelsen (2022b, p. 45).
[54] Cass (2024a, p. 155).

14.5.1 Psychotherapy for conditions frequently co-occurring with gender dysphoria

The etiology of GD in youth remains understudied. However, patients presenting to PGM clinics today have a range of neurodevelopmental disorders and mental health conditions, including comorbid depression, anxiety, eating disorders, self-harm, and suicidality.[55] Some studies suggest that in more than 70% of cases, other DSM diagnoses appeared before the GD.[56] Etiologically, the relationship between the GD and the high rate of co-occurring mental health conditions in this population is unclear. [57] As explained by psychologist Kenneth Zucker,

> it may be that the gender dysphoria has emerged as secondary to another, more "primary" mental health diagnosis, such as autism spectrum disorder or borderline personality disorder, or as a result of a severe trauma (e.g., sexual abuse). Another explanation is that gender dysphoria is inherently distressing, i.e., the marked incongruence between one's felt gender and somatic sex—even within psychosocial milieus that are largely "affirming/supportive"—which leads to clinically significant symptoms such as anxiety or depression.[58]

Regardless of its etiology, psychotherapy as an effective intervention for depression, the most common mood disorder, has been studied extensively and is supported by high-quality evidence. For example, cognitive behavioral therapy (CBT), an (often) manualized therapy that helps patients recognize the reciprocal relationships between

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[55] See Section 4.3.

[56] Becerra-Culqui et al. (2018); Kaltiala-Heino et al. (2015); Kozlowska et al. (2021).

[57] Littman (2021), a study that analyzed online survey data from a convenience sample of detransitioners, found that 40.6% of females and 25.8% of males reported that their "feelings of being transgender actually were the result of a mental health condition." 44.9% of females and 16.1% of males reported that "feelings of being transgender actually were the result of trauma" (p. 3364). The Cass Review reported that "Clinicians have described … how in patients with [body dysmorphic disorder, or BDD], the intense focus on appearance is most commonly on facial features, but that some experience distress about genitalia or breasts. In this situation it can be difficult to determine whether the distress is due to BDD or gender dysphoria. However, at the end of a treatment package for BDD some young people say they no longer feel ill at ease with their birth-registered gender, while some may have less distress about their genitalia or breasts but still have marked gender incongruence and proceed to a social or medical gender transition" (Cass, 2024a, p. 92).

[58] Zucker (2019). In addition to these two possibilities, a third theory is that "co-occurring mental health issues are simply secondary to factors such as family rejection or social ostracism within the peer group vis-à-vis the gender dysphoria" (p. 3). This "minority stress model" is discussed later in the present chapter.

thoughts, feelings, physiology, and behaviors, has evidence for benefit across age groups.[59] Psychodynamic psychotherapy (PDT) focuses on relational interactions, the role of formative life events, and unconscious processes, with the aim of facilitating emotional expression and interpersonal effectiveness.[60] Research indicates that PDT is effective in adults with depression, and there is also evidence of benefit for younger populations.[61] Another approach for adolescent depression with evidence for benefit is family-based treatment (FBT).[62]

Anxiety disorders also are highly prevalent in children and adolescents. The AACAP clinical practice guidelines strongly recommend that children and adolescents (ages 6-18) be offered CBT to address social anxiety, generalized anxiety, separation anxiety, specific phobias, or panic disorder.[63] PDT is less-well studied for anxiety, but may also be effective.[64]

For suicidality and self-harm in adolescents, evidence suggests that dialectical behavioral therapy (DBT), an approach that combines CBT with mindfulness and

[59] "Manualized" therapeutic approaches follow specific, standardized guidelines. CBT is the most well-studied. A recent meta-analysis of CBT for depression, including more than 50,000 patients across all age groups and 409 randomized controlled trials (RCTs), found that "CBT is effective in the treatment of depression with a moderate to large effect size, and that its effect is still significant up to 12 months (Cuijpers et al., 2023, p. 114). Other forms of psychotherapy were also found to be significantly beneficial. With respect to studies specifically focused on children and adolescents, evidence suggests CBT had modest positive effects on depressive symptoms (Espada et al., 2023).

[60] Opland & Torrico (2025).

[61] A systematic review of PDT for adults, which used the GRADE framework for evidence assessment, found "high quality evidence for depressive disorders and somatic symptom disorders, and moderate quality evidence for anxiety and personality disorders, that PDT achieves clinically meaningful effects in target symptoms and functioning compared to controls and is associated with low risk of harms and reasonable costs" (Leichsenring et al., 2023, p. 286). Midgley et al. (2021) is a narrative review of studies on PDT for children and adolescents (including some RCTs), finding "evidence of effectiveness for psychodynamic therapy in treating a wide range of mental health difficulties in children and adolescents" (p. 1).

[62] For example, attachment-based family therapy is an evidence-based approach to treating adolescent mood disorders, including depression, using a combination of separate (adolescent-only and parents-only) and joint family sessions (Diamond et al., 2021).

[63] This recommendation was based on a commissioned Agency for Healthcare Research and Quality (AHRQ)/Mayo Clinic systematic review and meta-analysis that included 60 RCTs and almost 7,000 pediatric patients. It found moderate-strength evidence that CBT improves primary anxiety symptoms and global functioning (Walter et al., 2020).

[64] Leichsenring et al. (2015); Midgley et al. (2021).

interpersonal skills training,[65] is an effective treatment.[66] Guidance published by the Substance Abuse and Mental Health Services Administration (SAMHSA) in 2020 found strong evidence that DBT was associated with reductions in suicidality (ideation, non-suicidal self-injury, and suicide attempts).[67] Another evidence-supported intervention, attachment-based family therapy, supports adolescents and parents as they rebuild trust and safety within their relational patterns, gradually reducing the risk of self-harm and suicidality.[68]

Eating disorders also frequently co-occur with GD.[69] CBT has shown some effectiveness as treatment for eating disorders in adults,[70] and CBT, DBT, and family-based treatment or family therapy for eating disorders (FT-ED) have shown effectiveness in adolescents.[71] Such approaches initially target the presenting issue by helping parents and caregivers support their children more effectively, while issues related to identity development are addressed as the condition improves. These family-based treatments are considered first-line interventions for treating adolescent eating disorders, particularly anorexia nervosa and bulimia nervosa.

Body dissatisfaction, which is common in adolescence, is treated with specific evidence-informed protocols. A combination of CBT and selective serotonin reuptake inhibitors (SSRIs) is recommended by the National Institute of Health and Care Excellence (NICE) in the U.K. for body dysmorphic disorder. It also recommends that parents and caregivers actively participate in the treatment process.[72]

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[65] DBT originated as a treatment for adults with borderline personality disorder with chronic suicidality. Its focus is on helping patients achieve mindfulness, interpersonal effectiveness, emotional regulation, and distress tolerance (Substance Abuse and Mental Health Services Administration, 2020).
[66] This is in direct contrast to hormonal interventions, which have *not* been shown to reduce suicidality or suicide in minors with GD. See Section 4.3.4 and Chapter 5.
[67] This SAMHSA guidance considered evidence to be "strong" if positive impact was demonstrated by two or more RCTs (or other controlled trials). Nine studies (of varying methodologies) of DBT for suicidality in adolescents were included in this evidence review; two were RCTs (Substance Abuse and Mental Health Services Administration, 2020).
[68] Diamond et al. (2010).
[69] From a theoretical standpoint, eating disorders and GD both have been conceptualized as arising, in some cases, out of a subconscious desire to avoid the development of adult sex characteristics, perhaps in part due to maladaptive coping strategies or to avoid sexual objectification (Nadrowski, 2023).
[70] Öst et al. (2024).
[71] Datta et al. (2023); Lock et al. (2010); Vogel et al. (2021).
[72] National Institute for Health and Care Excellence (2005).

When discussing the broader issue of the high prevalence of GD in patients presenting with conditions like eating disorders, body dysmorphic disorder, and functional tic-like behaviors, the Cass Review noted:

> The distressing symptoms that occur in these 'body and mind' conditions are real, and like pain or discomfort that arises from other causes can be addressed and helped with psychological interventions. It is very important that gender-questioning young people are able to access these evidence-based treatments.[73]

The Cass Review also observed:

> Some therapies, which are well proven for associated mental health problems, already have a strong evidence base. Where it is clear that children/young people have such problems, they should receive the appropriate therapies in the same way as any other young person.[74]

14.5.2 Psychotherapy for gender dysphoria

The overview of systematic reviews (see Chapter 5 and Appendix 4) found a dearth of evidence for psychotherapeutic interventions for youth with GD. As summarized in the Cass Review,

> there is a lack of evidence about alternative approaches for managing gender-related distress, and it is difficult to obtain information about routine clinical practice or pathways of care for children and young people who do not receive medical interventions. An explicit clinical pathway must be developed for non-medical interventions, as well as a research strategy for evaluating their effectiveness.[75]

Although several studies suggest that psychotherapy for GD may effectively resolve the condition noninvasively,[76] the quality of the evidence is very low certainty.[77] At the same time, the overview identified two SRs deemed as trustworthy (at low risk of bias), and

[73] Cass (2024a, p. 93)
[74] Cass (2024a, p. 155).
[75] Cass (2024a, p. 157).
[76] Churcher Clarke & Spiliadis (2019); Cohen-Kettenis & Kuiper (1984); Costa et al. (2015); Smith et al. (2001); Spiliadis (2019).
[77] See Chapter 5.

noted that “neither systematic review suggested that there is indication of harm from psychotherapy.” One of the SRs concluded:

> Most analyses of mental health, psychological and/or psychosocial outcomes showed either benefit or no change, with none indicating any negative/ adverse effects of the interventions offered.[78]

Although there is no reliable evidence to suggest that psychotherapy for GD is harmful, some proponents of PMT have alleged that it is a form of “conversion therapy.” This allegation is addressed in the following section; the final section surveys psychotherapeutic approaches to GD.

14.5.2.1 The charge of “conversion therapy”

Although psychotherapy for GD is described by its practitioners as “neutral” and “unbiased,”[79] some advocates for PMT maintain that such “exploratory” approaches are equivalent to conversion practices.[80]

“Conversion therapy”—sometimes called “reparative therapy”—originally referred to efforts to change the sexual orientation of gay and lesbian people. In 1973, homosexuality was officially de-pathologized by the American Psychiatric Association (APA) when it was declassified as a mental disorder (via its removal from the DSM).[81] While proponents of PMT have characterized exploratory psychotherapeutic approaches for GD as a form of “conversion therapy,” others have claimed that PMT

[78] Heathcote et al. (2024, p. s19).
[79] D’Angelo et al. (2021, p. 12).
[80] E.g. Ashley (2022b, 2023); see also the quotation by Colt St. Amand conflating psychological assessments for minors seeking medical or surgical transition with conversion therapy in Bazelon (2022a). Turban, Beckwith et al. (2020), a widely-cited peer-reviewed analysis of data from the 2015 U.S. Transgender Survey (USTS) concluded that individuals who recalled having been exposed to “gender identity conversion efforts” in the past were more likely to have experienced recent psychological distress and lifetime history of suicidal thoughts, but D’Angelo et al. (2021, p. 12) pointed out that this analysis was based on a “simplistic ‘affirmation’ versus ‘conversion’ binary … The notion that all therapy interventions for GD can be categorically classified into this simplistic binary betrays a misunderstanding of the complexity of psychotherapy. At best, this blunt classification overlooks a wide range of ethical and essential forms of agenda-free psychotherapy that do not fit into such a binary; at worst, it effectively mis-categorizes ethical psychotherapies that do not fit the “affirmation” descriptor as conversion therapies” (p. 7). For methodological concerns about the USTS itself, see Chapter 4, Note 117.
[81] Drescher (2010, p. 434); McNally (2011, pp. 21–24). The first edition (1952) of the DSM classified same-sex attraction as a type of “sociopathic personality disturbance” (American Psychiatric Association, 1952, pp. 38–39).

itself deserves that label. This latter group contends that altering a person's body in response to distress rooted in internalized social disapproval is no more appropriate than attempting to change someone's sexual orientation for similar reasons.[82] Public and academic debates over what constitutes "conversion" in the context of youth with GD have been hindered by the politicization of the issue.[83]

Critics of exploratory psychotherapy for GD claim that therapists are trying to "promote gender identities that are aligned with the person's sex assigned at birth."[84,85] A less theoretically-laden description would be that some therapists are trying to help children and adolescents come to terms with their bodies.[86] Discomfort with the sexed body or with societal sex-based expectations is common during puberty and adolescence. For this and other reasons, characterizing as "conversion therapy" any approach focused on reducing a minor's distress about their body or social role is a problematic and potentially harmful rhetorical device.[87] There is evidence that the specter of being

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[82] See Bannerman (2019) and Hamedani (2014). A recent bioethics article argues that "a society that marginalizes youth who do not conform to gender norms must, as a matter of justice, change its ways. The burden of enacting this change is all of ours to bear. It should not be borne by the bodies of our youth" (Gorin, 2024, p. 43).

[83] Defenses of psychotherapy for GD have roundly rejected the label of "conversion therapy": e.g., "Psychotherapy resides outside the affirmation-conversion binary and aims to address the distress of gender-dysphoric youth rather than to correct a sense of misalignment. Psychotherapy does not attempt to force change or impose any predetermined notion … A core ethical principle of psychotherapy is that therapists must respect patient autonomy and self-determination and refrain from any attempt to influence the patient … A genuine psychotherapeutic process starts from a position of not knowing and seeks to open things up. Anything else is a misuse of psychotherapy" (D'Angelo, 2023, p. 3).

[84] The full quotation is: "Trans conversion practices refer to sustained efforts to promote gender identities that are aligned with the person's sex assigned at birth and/or to discourage behaviours associated with a gender other than the person's sex assigned at birth" (Ashley, 2022b, p. 26). This seems to more broadly characterize conversion therapy as an attempt to encourage conformity with sex stereotypes. However, as explained by D'Angelo, "Psychotherapy does not impose restrictive gender stereotypes, as is sometimes claimed, but critically examines them" (D'Angelo, 2023, p. 1). Such examination is necessary, because restrictive stereotypes could plausibly have contributed to the patient's GD.

[85] The 2020 United Nations (UN) Report on Conversion Therapy begins by explaining that "conversion therapy" refers to "interventions of a wide-ranging nature, all of which have in common the belief that a person's sexual orientation or gender identity (SOGI) can and should be changed. Such practices aim (or claim to aim) at changing people from gay, lesbian or bisexual to heterosexual and from trans or gender diverse to cisgender" (United Nations, 2020). See Lawford-Smith (2024) for discussion of recent legislation banning "conversion therapy" as the UN understands it.

[86] Once it is recognized that the operative notion of "gender identity" has not been properly explained (see Chapter 2), the charge of "conversion therapy" makes little sense. If gender identity is obscure, the goal of changing the patient's gender identity is equally obscure.

[87] E.g., D'Angelo (2023); D'Angelo et al. (2021); Edwards-Leeper & Anderson (2021); Jenkins & Panozzo (2024); McDeavitt (2025); Sinai & Sim (2024). Also, as noted in the Cass Review, "The role of

labeled a “conversion therapist”— a damaging accusation given the profession’s history with the mistreatment of gay people—has created a climate of anxiety among mental health professionals. Therapists worry that failing to affirm or recommend medical interventions for youth who meet the World Professional Association for Transgender Health’s (WPATH) eligibility criteria could jeopardize their careers and reputations.[88]

Equating “exploratory therapy” with “conversion therapy” is misguided for two additional key reasons. First, exploratory therapy was a fundamental and mandatory element of the original Dutch Protocol, which serves as the foundation for the current PMT model.[89] Second, quality psychotherapy is exploratory *by definition*: it is “a process of shared decision making in which the therapist … guides the patient in exploration of their material but does not input their own beliefs or ideas.”[90]

The conflation of psychotherapy with conversion therapy has been condemned not only by expert therapists who question the current emphasis on medical transition and surgical transition for youth, but also by practitioners and researchers in the PMT field itself.[91]

14.5.2.2 Psychotherapeutic approaches

The effectiveness of psychotherapy for a wide range of mental health problems, including those that often present with GD, suggests it may also be beneficial for GD specifically. The Cass Review’s emphasis on the de-exceptionalization of youth with GD underscored the observation that clinicians

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psychological therapies in supporting children and young people with gender incongruence or distress has been overshadowed by an unhelpfully polarised debate around conversion practices. Terms such as ‘affirmative’ and ‘exploratory’ approaches have been weaponised to the extent that it is difficult to find any neutral terminology” (Cass, 2024a, p. 150).

[88] Jenkins & Panozzo (2024). As summarized in McDeavitt (2025): “Some therapists who engage in exploratory talk therapy with [transgender and gender diverse] youth have faced licensure complaints related to accusations of “conversion therapy”—complaints made not by patients, but by activists and colleagues. One therapist reported having attended a workshop … in which activists described “hunting” for such therapists with the goal of bringing lawsuits and prompting licensure revocation.”

[89] Weaknesses of the original Dutch research are discussed in Chapter 4.

[90] Sinai & Sim (2024, p. 148); see also Churcher Clarke & Spiliadis (2019).

[91] For example, psychologist Laura Edwards Leeper has stated that “Conflating conversion therapy and identity exploration is perhaps the largest threat to both gender-distressed cisgender youth and transgender youth, alike. The rhetoric being used to conflate the two must stop immediately” (McDeavitt, 2025, p. 1298). See also Edwards-Leeper & Anderson (2021).

> just need the appropriate training, support and most importantly the confidence to do what [they] have been trained to do and treat this population as [they] would any other young person in distress.[92]

Unfortunately, efforts to research the influence of cultural and social factors, trauma, or co-occurring mental health conditions on GD have been denigrated as "harmful."[93] When combined with the highly charged accusation of "conversion therapy," therapists may be under significant pressure to assume—often without critical evaluation—that mental health issues co-occurring with GD are primarily the result of minority stress.[94] This pressure may cause clinicians to overlook the significant possibility that in some patients, GD has *arisen from* trauma, "primary" mental health concerns, or neurodevelopmental conditions (see Section 14.1 above). Publications by psychotherapists working with this population have noted that patients with GD may seek hormonal or surgical interventions in response to experiences of sexual violence, negative attitudes towards homosexuality, or bullying related to self-expression, interests, or behaviors that deviate from sex stereotypes.[95]

If these possibilities are ignored, medical and surgical interventions may be recommended as the obvious treatment.[96] The mischaracterization of psychotherapy for GD as "conversion therapy" or "doing nothing" may also contribute to a nocebo effect, disincentivizing therapists from providing care and patients from engaging in it.[97] In this way, the denigration of psychotherapy has "a chilling effect on the ethical

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[92] Cass (2024a, p. 15).
[93] E.g. Coalition for the Advancement and Application of Psychological Science (2021).
[94] Application of minority stress theory to mental health disparities in sexual minority adults was originally done in Meyer (2003). As defined in Chelliah et al. (2024), the "minority stress framework…has been used to conceptualize relationships between…mental health disparities and stressors associated with a minority identity or status." This framework, which (like all other conceptual frameworks) has its limitations (Bailey, 2020; Zucker et al., 2016), has over the past 5-10 years been widely-relied upon in the pediatric gender medicine literature (see examples in Chapter 13). Although it is important for therapists to elucidate patient experiences of bullying or hostility, it is not psychotherapeutically sound practice to make reflexive assumptions, especially when these assumptions could lead to inappropriate treatment recommendations.
[95] Churcher Clarke & Spiliadis (2019); D'Angelo et al. (2021); Lemma (2018); Sinai & Sim (2024); Spiliadis (2019).
[96] E.g. Tordoff (2022).
[97] Clayton (2023).

psychotherapists' willingness to take on complex GD patients, which will make it much harder for GD individuals to access quality mental health care."[98]

The practice of reflexive assumption contravenes fundamental principles of the psychotherapeutic approach, which emphasizes curiosity and consideration of *all* factors that may have contributed to the patient's problems.[99] It is also challenged by research on desistance and detransition.[100]

Stephen Levine, professor of psychiatry at Case Western Reserve University, has explained how the psychotherapeutic approach includes biological, psychological and social factors to formulate GD holistically:

> [If] the evaluator understands the focus of the [mental health assessment] to be on identifying the predisposing, precipitating, and maintaining forces on the patient's identity, a long list of influences will be explored. Problems such as autism, ADHD, difficulty making friends, crises of loneliness, depression, restrictive or excess eating, sexual abuse, and feedback from virtual friends will be investigated. The [therapist] will explore suicidality, self-harm, pre- and post-trans-identity psychiatric problems, and relationships with each parent. The parents will provide a developmental history beginning with pregnancy.[101]

Psychiatrist and psychoanalyst Roberto D'Angelo, a proponent of psychotherapy for GD, describes the role of psychotherapy for minors with GD as follows:

> Psychotherapy does not impose restrictive gender stereotypes, as is sometimes claimed, but critically examines them. It empowers young people to develop creative solutions to their difficulties and promotes agency and autonomy. Importantly, an exploratory psychotherapeutic process can help to clarify whether

[98] D'Angelo et al. (2021, p. 13).
[99] As the Cass Review noted, "a single focus on gender raises the issue of 'diagnostic overshadowing' … children [may have] more than one presenting issue, but different services … dealing with each issue in isolation, without considering how they might impact on each other" (Cass, 2024a, p. 200). See also discussion of diagnostic overshadowing in Section 13.2.4.
[100] E.g. Littman (2021).
[101] Levine (2024, p. 775).

gender dysphoria is a carrier for other psychological or social problems that may not be immediately apparent.[102]

Given that this population often presents with complex psychosocial histories and multiple mental health concerns, psychotherapy takes a holistic approach—addressing the full range of issues rather than focusing exclusively on GD. “Transdiagnostic psychotherapy”— that is, therapy that works across or with multiple diagnoses or problems—is already a convention.[103] While there is a clear need to develop and study therapeutic approaches tailored specifically for GD, effective therapy need not always center on a single issue. Psychotherapy for adolescents with GD is a well-suited intervention, as it is intended to help patients develop self-understanding, engage with emotional vulnerability, and build practical strategies for managing distress.

Human psychology is complex and the presence of one psychiatric diagnosis often increases the likelihood of others. A transdiagnostic psychotherapeutic approach—designed to address underlying patterns across multiple conditions—may be particularly effective in reducing distress among youth with GD, as it has been in other complex cases. The goals of psychotherapy remain the same regardless of a young person’s self-identification: to alleviate distress and improve interpersonal and social functioning.

Table 14.1 below presents a brief overview of psychotherapeutic modalities that are relevant for children and adolescents with GD.

[102] D’Angelo (2023, p. 1).
[103] Jeppesen et al. (2021).

Table 14.1

Type of psychotherapeutic modality	Definition of modality	Application to GD
Manualized approaches[104]	These approaches are performed according to manualized instructions that provide structure and standardization. The most-studied approach is cognitive behavioral therapy (CBT), which helps patients identify thoughts, feelings, and behaviors and the way they impact one another. Manualized therapies focus on development of coping skills and behavioral activation. Dialectical behavioral therapy, commonly used to address self-harm and suicidality, fosters distress-management techniques and interpersonal effectiveness. Manualized approaches typically involve several months of weekly individual or group sessions, and patients complete therapy-related assignments between sessions.	Manualized approaches are an evidence-based treatment for mental health problems that co-occur with GD, such as depression, anxiety, and eating disorders. For GD, manualized approaches can help patients identify thoughts and feelings related to sex-based distress, including cognitive distortions. Therapists can help patients develop healthy coping skills for managing this specific type of distress and can encourage behavioral activation. For example, engaging in physical activity, in-person social socialization, and/or mindfulness practices, can over time, decrease ruminations, including ruminations on sex-related discomfort.

[104] In Austin et al. (2018), mental health outcomes (including depression) improved with CBT in 8 adolescents who identified as transgender (subgroup of study population; unclear if hormonal interventions were used). Hollinsaid et al. (2020) re-analyzed data from four RCTs of standard manualized psychotherapeutic approaches, focusing on the cohort of 64 patients who had expressed desire to be the other sex (it is unclear how many would have met criteria for GD, however; additionally, there was no information about hormonal interventions). These patients' internalizing and externalizing symptoms improved, albeit more slowly than other patients. In Lucassen et al. (2021) the depression outcome measure did not change after online CBT in 14 patients who identified as transgender. In Silveri et al. (2021) mental health outcomes improved in 62 adolescents who self-identified as transgender/gender-expansive after CBT, DBT, and family therapy, integrated into a two-week long residential treatment program for psychiatric problems. In a study reporting longitudinal data on 26 adolescents (Bluth et al., 2023), mental health outcomes (including depression and suicidality) improved after eight sessions of mindfulness-based group therapy in transgender-identified patients who were not taking hormonal interventions.

Type of psychotherapeutic modality	Definition of modality	Application to GD
Psychodynamic approach[105]	This is a psychoanalytic approach that involves exploration of ego defenses and unconscious motivations. Through exploration of transference, patients come to better understand their interpersonal dynamics. Psychodynamic psychotherapy classically involves biweekly or weekly sessions and is not time-limited.	This approach is evidence-based for mental health conditions that co-occur with GD. Additionally, psychodynamic work around the theme of cross-sex identification or sex-related distress can facilitate exploration of patients' early childhood experiences, family of origin, beliefs/values system, and interpersonal patterns in familial and romantic relationships as well as in school/work environments. This approach can help patients gain deeper understanding of their personal identity, including any external factors that may contribute to their cross-sex identification and desire for medical/surgical interventions. Patients can gain clarity about their own wishes or desires for medical or surgical transition interventions.
Family therapy[106]	This approach identifies problems affecting the patient and the family unit and aims to strengthen familial bonds and improve communication skills, by supporting work around attachment ruptures, communication and understanding different family members' perspectives. It may involve parental education and development of strategies for improved interpersonal effectiveness within the family unit.	A child or adolescent exhibiting GD may occasionally lead to intense conflict and distress within the family unit. In family-based approaches a knowledgeable therapist can provide education about GD to parents and promote well-being of the family by bolstering effective communication and interpersonal skills. Family therapy is an evidence-based approach to treating adolescent eating disorders, where familial distress and embodied distress are heightened, as in GD. Family therapy is either the first-line intervention or the treatment of choice for many diagnoses in adolescence.

14.5.2.3 Evidence for benefit

As discussed earlier, the overview of systematic reviews conducted for this Review found that evidence for the effectiveness of psychotherapy for GD (or for co-occurring mental health problems in patients with GD) is of very low certainty. When direct evidence for the role of psychotherapy in children and adolescents with GD is lacking, the best available evidence can be obtained from the robust evidence supporting

[105] For case reports, vignettes, and case series describing the incorporation of dynamic aspects into exploratory work, see Churcher Clarke & Spiliadis (2019); D'Angelo (2020); Spiliadis (2019). For descriptions of dynamic approaches, see D'Angelo (2023); Sinai & Sim (2024).
[106] For a case report of family therapy for an adolescent with suicidality, see Russon et al. (2022). See also Silveri et al. (2021) and Churcher Clarke & Spiliadis (2019). For example of parent psychoeducation, see Levine (2024).

treatment effectiveness for children and adolescents with similar types of psychological distress. Psychotherapy is a noninvasive intervention that can be used transdiagnostically. It generally promotes improved mental health and psychosocial functioning and carries little risk.[107] As the Cass Review noted,

> the focus on the use of puberty blockers for managing gender-related distress has overshadowed the possibility that other evidence-based treatments may be more effective.[108]

[107] See also Baron & Dierckxsens (2022); Clayton (2023); Levine et al. (2022b).
[108] Cass, 2024a (p. 31).

Limitations, Strengths, and Conclusion

Limitations

The present Review has some limitations.[1]

1. This document is not intended to serve as a clinical practice guideline (CPG) and does not aim to issue treatment recommendations.[2] The Review was shaped by a distinct set of goals: namely, to clarify the evidentiary landscape; identify areas of uncertainty; and support the development of accountable care models. As such, it does not follow formal guideline development procedures, such as the use of Grading of Recommendations Assessment, Development, and Evaluation (GRADE) to inform clinical recommendations. The purview of this Review is limited to evidence and best practices for the care of minors.
2. This Review does not make any specific policy recommendations regarding the regulation of medicine. For instance, it does not make policy recommendations about the treatment of children and adolescents who have already begun puberty blockers or cross-sex hormones.

Strengths

This Review also has some strengths.

1. Although not a CPG, this document provides clinicians and other decision makers with essential pieces of knowledge regarding pediatric gender medicine (PGM).
    a. *Quality of evidence*: This Review describes the very low-quality evidence underpinning treatment approaches in pediatric gender medicine (Chapter 5).
    b. *Risk profile of hormones and surgeries*: This Review contains an extensive description of potential or plausible harms associated

[1] For strengths and limitations specific to the overview of systematic reviews (SRs), see Chapter 5.
[2] This is not technically a limitation (as this Review does not purport to be a CPG), but a clarification.

with certain treatment options (namely, hormonal interventions and surgeries), some of which are significant (Chapter 7).

c. *Ethics review*: This Review contains an ethical assessment of the use of hormonal interventions and surgeries for treatment of gender dysphoria (GD) in children and adolescents. It concludes that these interventions are inconsistent with widely endorsed principles of medical ethics (Chapter 13).

d. *Consideration of alternative treatments*: The role of psychotherapy, which has been sidelined in discussions of PGM, is one focus of this Review. This Review examines psychotherapy for GD in detail and concludes that its risk/benefit profile is favorable (Chapter 14).

2. The review of guidelines (Chapter 9) demonstrates that CPGs recommending psychotherapy for pediatric GD are higher-quality and are commensurate with evidence from PGM systematic reviews (SRs). In contrast, CPGs recommending an approach involving standard-of-care use of puberty blockers (PBs), cross-sex hormones (CSH), or surgery are lower-quality, with recommendations that are not commensurate with evidence from SRs. CPGs followed in the U.S., in particular WPATH's, are of the latter type and are inadequate to inform clinical practice for a vulnerable and distressed population of children and adolescents. High quality CPGs are urgently needed in this field.
3. This Review describes the enforced professional insularity of the field of pediatric gender medicine and the intense and hostile nature of the debates around PGM. Stakeholders should keep these in mind when presented with claims of medical consensus among U.S. medical organizations (Chapter 12).

Conclusion

The delegation of authority to the medical profession rests on an implicit social contract: Doctors as a profession receive the 'privilege of self-regulation' and

> financial awards on the expectation that they will serve the health needs of individual patients and society.[3]

A central theme of this Review is that many U.S. medical professionals and associations have fallen short of their duty to prioritize the health interests of young patients. First, there was a rapid expansion and implementation of a clinical protocol that lacked sufficient scientific and ethical justification. Second, when confronted with compelling evidence that this protocol did not deliver the health benefits it promised, and that other countries were changing their policies appropriately, U.S. medical professionals and associations failed to reconsider the "gender-affirming" approach. Third, conflicting evidence—evidence that challenged the foundational assumptions of the protocol and the professional standing of its advocates—was mischaracterized or insufficiently acknowledged. Finally, dissenting perspectives were marginalized, and those who voiced them were disparaged.

While no clinician or medical association intends to fail their patients—particularly those who are most vulnerable—the preceding chapters demonstrate that this is precisely what has occurred.

[3] Patashnik et al. (2017, p. 10).

APPENDICES

Appendix 1. Abbreviations

AACAP	American Academy of Child and Adolescent Psychiatry
AAP	American Academy of Pediatrics
AGREE	Appraisal of Guidelines for Research and Evaluation
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
AMSTAR	A MeaSurement Tool to Assess systematic Reviews
APA	American Psychological Association/American Psychiatric Association
ASD	Autism Spectrum Disorder; also ASC (Autism Spectrum Condition)
BDD	Body Dysmorphic Disorder
BMI	Body Mass Index
CBT	Cognitive Behavioral Therapy
CDC	Centers for Disease Control and prevention
CMS	Centers for Medicare and Medicaid
COHERE	Council for Choices in Health Care (Finland)
COI	Conflict of Interest
CPG	Clinical Practice Guideline
CPP	Central Precocious Puberty
CSH	Cross-Sex Hormones
DBT	Dialectical Behavioral Therapy
DSD	Disorder (Difference) of Sex Development
DSM	*Diagnostic and Statistical Manual of Mental Disorders*
DSM-5-TR	DSM, 5th edition, Text Revision (latest version, 2024)
DSM-5	DSM, 5th edition (2013)
DSM-IV	DSM, 4th edition (1994)
DSM-III	DSM, 3rd edition (1980)
EBM	Evidence-Based Medicine
EPC	Evidence-based Practice Center (at Johns Hopkins)
ES	Endocrine Society
FAERS	FDA's Event Reporting System

FBT	Family-Based Treatment
FDA	Food and Drug Administration
FM	Female-to-Male
FP	Fertility Preservation
FSH	Follicle-Stimulating Hormone
FT-ED	Family Therapy for Eating Disorders
GD	Gender Dysphoria (DSM-5; formerly Gender Identity Disorder (GID) in the DSM-IV)
GDG	Guideline Development Group
GeMS	Gender Multispeciality Service (at Boston Children's; formerly Gender Management Service)
GICE	Gender Identity Conversion Efforts
GIDS	Gender Identity Development Service (U.K.)
GnRHa	Gonadotropin Releasing Hormone Agonist
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HBIGDA	Harry Benjamin International Gender Dysphoria Association
HH	Hypogonadotropic Hypogonadism
HPG	Hypothalamic-Pituitary Gonadal axis
HRC	Human Rights Campaign
ICD-11	WHO's International Classification of Diseases, 11th edition (latest version, 2022)
IQ	Intelligence Quotient
ITJH	*International Journal of Transgender Health*
JAMA	*Journal of the American Medical Association*
JHU	Johns Hopkins University
LH	Luteinizing Hormone
MDC	Medical Decision-making Competence
MDT	MultiDisciplinary Teams
MF	Male-to-Female
MHP	Mental Health Professional
MMHA	Major Medical and mental Health Association

NAM	National Academy of Medicine
NEJM	*New England Journal of Medicine*
NGCF	Netherlands Gender Care Foundation
NHS	National Health Service (U.K.)
NICE	National Institute for Health and Care Excellence (U.K.)
NIH	National Institutes of Health
NLM	National Library of Medicine
NOS	Newcastle-Ottawa Scale
OCD	Obsessive Compulsive Disorder
PBs	Puberty Blockers
PCOS	Polycystic Ovary Syndrome
PDT	PsychoDynamic Therapy
PGM	Pediatric Gender Medicine
PICO	Population, Intervention, Comparator, Outcome
PMT	Pediatric Medical Transition
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
RCT	Randomized Controlled Trial
RoB 2	Cochrane Risk-of-Bias tool
ROBINS-I	Risk of Bias in Non-randomized Studies - of Interventions
ROBIS	Risk of Bias in Systematic reviews
ROGD	Rapid-Onset Gender Dysphoria
RSG	Review of Data, Statistics and Research on Sex and Gender (U.K., 2025)
SAMHSA	Substance Abuse and Mental Health Services Administration
SOC-8	*Standards of Care for the Health of Transgender and Gender Diverse People*, Version 8 (latest version, 2022)
SOC-7	*Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, Version 7 (2012)
SOC-6	*Standards of Care for Gender Identity Disorders*, Version 6 (2001)
SR	Systematic Review
SRS	Sex Reassignment Surgery
SSRI	Selective Serotonin Reuptake Inhibitor

TGD	Transgender and Gender Diverse
UCSF	University of California, San Francisco
USPATH	United States Professional Association for Transgender Health
USTS	US Transgender Survey
WHO	World Health Organization
WPATH	World Professional Association for Transgender Health

Appendix 2. Diagnostic Criteria

DSM-III (1980)[1]

Diagnostic criteria for Transsexualism

A. Sense of discomfort and inappropriateness about one's anatomic sex.

B. Wish to be rid of one's own genitals and to live as a member of the other sex.

C. The disturbance has been continuous (not limited to periods of stress) for at least two years.

D. Absence of physical intersex or genetic abnormality.

E. Not due to another mental disorder, such as Schizophrenia.

Diagnostic criteria for Gender Identity Disorder of Childhood

For females:

A. Strongly and persistently stated desire to be a boy, or insistence that she is a boy (not merely a desire for any perceived cultural advantages from being a boy).

B. Persistent repudiation of female anatomic structures, as manifested by at least one of the following repeated assertions:

(1) that she will grow up to become a man (not merely in role)

(2) that she is biologically unable to become pregnant

(3) that she will not develop breasts

(4) that she has no vagina

(5) that she has, or will grow, a penis

C. Onset of the disturbance before puberty.

For males:

[1] American Psychiatric Association (1980, pp. 261–266).

A. Strongly and persistently stated desire to be a girl, or insistence that he is a girl.

B. Either (1) or (2):

(1) persistent repudiation of male anatomic structures, as manifested by at least one of the following repeated assertions:

(a) that he will grow up to become a woman, (not merely in role)

(b) that his penis or testes are disgusting or will disappear

(c) that it would be better not to have a penis or testes

(2) preoccupation with female stereotypical activities as manifested by a preference for either cross-dressing or simulating female attire, or by a compelling desire to participate in the games and pastimes of girls

C. Onset of the disturbance before puberty.

DSM-IV (1994)[2]

Diagnostic criteria for Gender Identity Disorder

A. A strong and persistent cross-gender identification (not merely a desire for any perceived cultural advantages of being the other sex). In children, the disturbance is manifested by four (or more) of the following:

(1) repeatedly stated desire to be, or insistence that he or she is, the other sex

(2) in boys, preference for cross-dressing or simulating female attire; in girls, insistence on wearing only stereotypical masculine clothing

(3) strong and persistent preferences for cross-sex roles in make-believe play or persistent fantasies of being the other sex

[2] American Psychiatric Association (1994, pp. 537–538).

(4) intense desire to participate in the stereotypical games and pastimes of the other sex

(5) strong preference for playmates of the other sex

In adolescents and adults, the disturbance is manifested by symptoms such as a stated desire to be the other sex, frequent passing as the other sex, desire to live or be treated as the other sex, or the conviction that he or she has the typical feelings and reactions of the other sex.

B. Persistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex.

In children, the disturbance is manifested by any of the following: in boys, assertion that his penis or testes are disgusting or will disappear or assertion that it would be better not to have a penis, or aversion toward rough-and-tumble play and rejection of male stereotypical toys, games, and activities; in girls, rejection of urinating in a sitting position, assertion that she has or will grow a penis, or assertion that she does not want to grow breasts or menstruate, or marked aversion toward normative feminine clothing.

In adolescents and adults, the disturbance is manifested by symptoms such as preoccupation with getting rid of primary and secondary sex characteristics (e.g., request for hormones, surgery, or other procedures to physically alter sexual characteristics to simulate the other sex) or belief that he or she was born the wrong sex.

C. The disturbance is not concurrent with a physical intersex condition.

D. The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

DSM-5 (2013)[3]

Gender Dysphoria

[3] American Psychiatric Association (2013, pp. 452–453).

Diagnostic Criteria

Gender Dysphoria in Children

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be Criterion A1):

1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).

2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire: or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.

3. A strong preference for cross-gender roles in make-believe play or fantasy play.

4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.

5. A strong preference for playmates of the other gender.

6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.

7. A strong dislike of one's sexual anatomy.

8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.

B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.

Gender Dysphoria in Adolescents and Adults

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:

1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).

2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).

3. A strong desire for the primary and/or secondary sex characteristics of the other gender.

4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).

5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).

6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational or other important areas of functioning.

ICD-11 (2022)[4]

Gender incongruence of adolescence or adulthood

[4] World Health Organization (2022b).

Gender Incongruence of Adolescence and Adulthood is characterized by a marked and persistent incongruence between an individual's experienced gender and the assigned sex, which often leads to a desire to 'transition', in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual's body align, as much as desired and to the extent possible, with the experienced gender. The diagnosis cannot be assigned prior to the onset of puberty. Gender variant behavior and preferences alone are not a basis for assigning the diagnosis.

Gender incongruence of childhood

Gender incongruence of childhood is characterized by a marked incongruence between an individual's experienced/expressed gender and the assigned sex in pre-pubertal children. It includes a strong desire to be a different gender than the assigned sex; a strong dislike on the child's part of his or her sexual anatomy or anticipated secondary sex characteristics and/or a strong desire for the primary and/or anticipated secondary sex characteristics that match the experienced gender; and make-believe or fantasy play, toys, games, or activities and playmates that are typical of the experienced gender rather than the assigned sex. The incongruence must have persisted for about 2 years. Gender variant behavior and preferences alone are not a basis for assigning the diagnosis.

Appendix 3. Systematic Reviews and Evidence-Based Medicine

Imagine a courtroom where guilt or innocence is decided solely by the police, drawing on their extensive experience of investigating crime. Someone can be convicted of murder, say, on the verdict of these criminal experts, who have seen many murders before, and who have firm opinions about the sort of people most likely to commit them.

Such a courtroom would be better than nothing. The police have relevant knowledge and experience and are not simply guessing. But it would be far inferior to a real courtroom, where police testimony is just part of the evidence brought before judge and jury: the blood-stained knife, fingerprints, cellphone records, eyewitness testimony, and so on, are all included. Moreover, every piece of evidence is critically examined, weighed, and compared. The attitude is more scientific. Not all evidence is equal: eyewitness testimony can be unreliable, whereas properly collected DNA evidence is of high quality. Independent pieces of evidence (DNA, cellphone records) can point to the same conclusion, making the verdict more secure. Of course, the process is imperfect, but it's a vast improvement over simply relying on the opinions of police officers.

Medicine used to be more like the first (hypothetical) courtroom than the second:

> Clinical practice was historically viewed as the "art of medicine." Expert opinion, experience, and authoritarian judgment were the foundation for decision making. The use of scientific methodology, as in biomedical research, and statistical analysis, as in epidemiology, were rare in the world of medicine.[1]

Starting in the 1970s, evidence-based medicine (EBM) has attempted to move medicine from the first courtroom to the second, towards more empirical rigor.

EBM "is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."[2] The fundamental EBM principle is that clinical practice and practice guidelines should be based on the totality of evidence,

[1] Sur & Dahm (2011, p. 487).
[2] Sackett et al. (1996, p. 71).

assessed and synthesized in clear and reproducible ways from the medical literature. EBM contrasts with "eminence-based medicine," in which physicians make clinical decisions based on personal experience and expertise, and treatment guidelines themselves are created using a process humorously described as "GOBSAT" ("good old boys sitting around a table").[3]

It is important to emphasize that EBM does not say that evidence about treatments should be the *only* factor in medical decisions. Quite the opposite. According to the American Medical Association's (AMA) *User's Guides to Medical Literature: Essentials of Evidence-Based Clinical Practice*:

> [E]vidence alone is never sufficient to make a clinical decision. Decision makers must always trade off the benefits and risks, burden, and costs associated with alternative management strategies and, in doing so, consider their patients' unique predicament and values and preferences.[4]

Evidence is never sufficient to make health policy either, although policy makers have different priorities than clinicians. A clinician's primary concern is for the individual patient and their "unique predicament"; policy makers need to set general rules and standards with public health in mind. They may consider the cost-effectiveness of treatment, public values and preferences, the feasibility of widely offering the treatment, how its benefits can be distributed fairly, and so forth.

EBM uses a "hierarchy of evidence," often depicted as pyramid with colored layers, as in Figure A.1. Since the layers represent different types of study, the hierarchy is more strictly a hierarchy of *research methods* than a hierarchy of evidence. The pyramid in Figure A.1 should not be taken too seriously: many pyramids have been proposed, with varying numbers of layers and kinds of labels, not to mention colors.[5] In fact, the AMA's

[3] Lima, Tangamornsuksan et al. (2023, p. 1).
[4] Guyatt et al. (2015, p. 10, emphasis omitted). "Burden [of treatment]" means "the inconvenience of attending to the treatment's optimal use, of its monitoring, the limitations in lifestyle that it entails, and the possibility of interactions with other treatments" (p. 426). "Values and preferences" refer to "the collection of goals, expectations, predispositions, and beliefs that individuals have for certain decisions and their potential outcomes. The incorporation of patient values and preferences in decision making is central to evidence-based medicine" (p. 490).
[5] Blunt (2022). For another pyramid, see Cass (2024a, p. 55).

User's Guides to Medical Literature contains no such illustration.[6] But the basic point these pyramids make is sound: some ways of gathering evidence about the effects of a treatment are better than others. Systematic reviews (SRs, to be explained below) and meta-analyses are better than randomized controlled trials (RCTs), which are better than cohort studies and case reports,[7] with expert opinion coming in last. The medical consensus based on expert opinion or experience has been shown to be wrong many times before, after rigorous experimental studies were conducted. (See Section 1.2.2.)

EBM prioritizes findings from population-level research, such as RCTs and observational epidemiological studies. This can have drawbacks, sometimes resulting in insufficient consideration of biochemical or physiological evidence from laboratory, animal, or in vitro studies.[8]

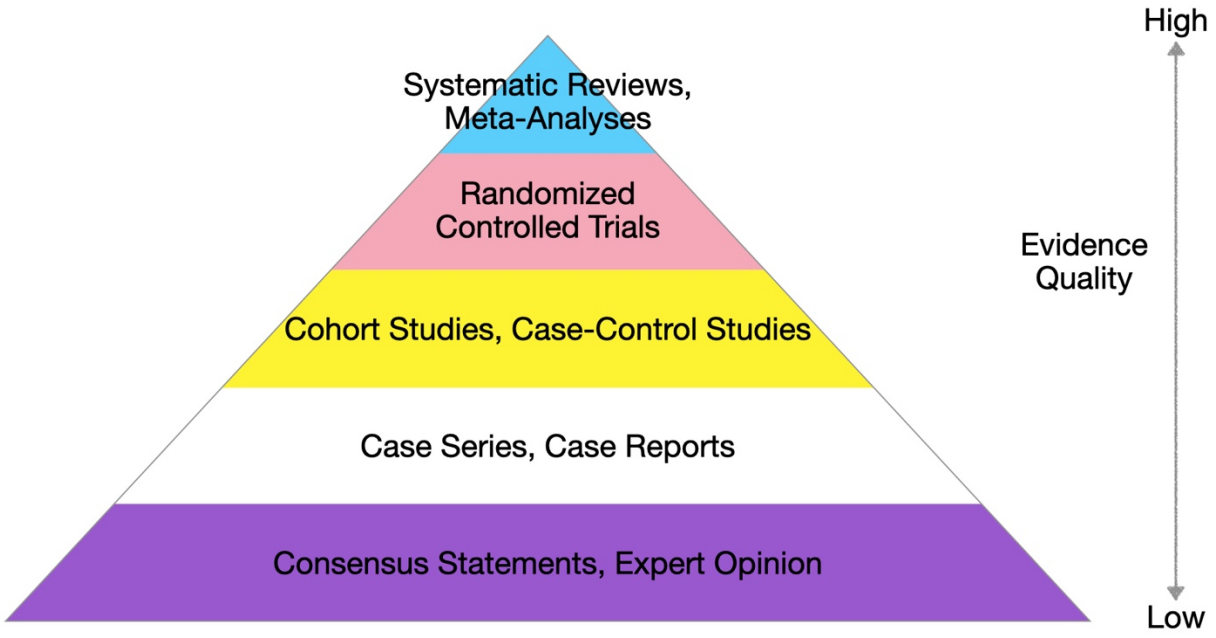
In the last few decades EBM has been refined and improved. This appendix includes a brief introduction to SRs, the methodology to systematically identify, synthesize, and assess the best available evidence, and to Grading of Recommendations Assessment, Development, and Evaluations (GRADE), the methodology to assess the quality of evidence and determine the strength of recommendations.

[6] See Guyatt et al. (2015, p. 48, Figure 4-1), which displays a simple three-level hierarchy of evidence in a blue box.

[7] A *meta-analysis* combines data from separate similar studies and statistically analyses the result. Two studies may investigate the same treatment in sufficiently different ways so that a meta-analysis of both is not possible. SRs may involve meta-analyses but need not. A *randomized controlled trial* (RCT) allocates treatment/non-treatment randomly to a group (*cohort*) of patients and follows them over time; the no-treatment group is the *control* group. Control groups may receive another kind of treatment, a *placebo* (an inert pill or procedure that superficially mimics the treatment), or no treatment at all. In a *double-blind* RCT neither the patients nor the attending medical staff know who is in the treatment group and who is in the control group. *Cohort studies* (or *longitudinal* studies) examine groups of patients over time, either *prospectively* (data collected as the study proceeds) or *retrospectively* (the data has already been collected, say in past medical records); there is no randomization to treatment/non-treatment as in an RCT. A *case-control* study starts with two groups, those who have the disease or condition of interest (the *cases*), and those who don't (the *controls*), and examines them retrospectively. The latter two kinds of study are called *observational*, to contrast them with RCTs. A *case report* describes a single patient's treatment and outcome; a *case series* is a collection of similar case reports.

[8] Clarke et al. (2014).

Figure A1.1 Example EBM Pyramid



1. Systematic reviews

SRs synthesize evidence from multiple studies in the medical literature and assess its quality, using a standard and reproducible methodology. The general steps are outlined below:[9]

Research questions and study eligibility criteria

SRs begin by asking four questions. What is the population being studied? What is the intervention or treatment? What groups are being compared to the group that received the treatment? What results or outcomes are of interest? This is the “PICO” framework: Population, Intervention, Comparator, Outcome. Study eligibility criteria are defined accordingly and documented.

Comprehensive search

Having defined the eligibility criteria for studies, the next step is to locate them. A properly conducted search requires expertise, and includes searching a variety of

[9] What follows is simplified; for more detail see Higgins et al. (2019).

medical databases, for instance Embase (produced by the publisher Elsevier) and Medline (produced by the U.S. National Library of Medicine (NLM)). The search could also cover registries of clinical trials and so-called grey literature (material outside academic publishing, such as reports and government documents).

Study selection

Reviewers then screen the search results, looking at a study's title and abstract, and then its full text to determine if the study is eligible to be included in the SR. This study selection process follows the pre-defined eligibility criteria. To minimize the risk of bias in the review process, independent duplicate screening may be applied in both the stage of title and abstract screening, and the stage of full text screening.

Data extraction and effect estimate computation

The reviewers extract all relevant data from the studies. The procedure is standardized, and the same kind of data is extracted from all studies. Most of this is in the methods and results sections of the study (and the supplementary material). Depending on the data, there are various ways of measuring the effect of an intervention; the extracted data may need to be converted to a consistent format so the treatment effect estimates reported across eligible studies can be combined as a pooled effect estimate.

Risk of bias assessment

Bias is "systematic error, or deviation from the truth, in results. Biases can lead to under-estimation or over-estimation of the true intervention effect and can vary in magnitude: some are small (and trivial compared with the observed effect) and some are substantial (so that an apparent finding may be due entirely to bias)."[10] Two or more independent reviewers assess the risk of bias of each study, using appropriate tools. One major consideration for choosing a risk of bias tool is the type of study design. For example, Version 2 of the Cochrane Risk-of-Bias tool for randomized trials (RoB 2) is the recommended tool to assess the risk of bias in randomized trials included in

[10] Higgins et al. (2019, pp. 177–178). Note that "biased" here does not mean *prejudiced*. Fair and impartial researchers may produce a "biased" study in the sense relevant to this Appendix.

Cochrane Reviews, while Risk Of Bias In Non-randomized Studies - of Interventions (ROBINS-I) is the recommended tool to assess the risk of bias in non-randomized studies.

Data synthesis and analysis

One key step for SRs is evidence synthesis, synthesizing or combining the results from the different studies. Meta-analyses of effect estimates (a quantitative synthesis strategy) may be performed, as well as sensitivity analyses (which examine whether the results would change if different statistical assumptions were made, if outcomes were defined slightly differently, and so on). If a meta-analysis is not feasible, other ways of synthesizing the results are available. A narrative that describes results study by study is not acceptable.[11]

Quality of evidence assessment

The quality of the evidence is now evaluated using, for instance, the methodological framework GRADE (explained in the following section).

Discussion and conclusion

The discussion section of the SR includes: “Summary of main results (benefits and harms); potential biases in the review process; overall completeness and applicability of evidence; certainty of the evidence; agreements and disagreements with other studies or reviews.”[12] The conclusions section considers the implications for clinical practice and for research.

High-quality SRs organize their PICO information, search strategy, methodologies, and findings according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement, which facilitates completeness, accuracy, transparency, and replicability.[13] Registering the protocol for a SR in a system such as PROSPERO increases transparency and trustworthiness of an SR.

[11] McKenzie & Brennan (2024).
[12] Higgins et al. (2019, p. 404, quotation marks and capitalization omitted).
[13] Page et al. (2021). See also Santesso et al. (2020).

2. GRADE

Grading of Recommendations Assessment, Development, and Evaluations is a widely adopted framework for assessing the quality (or "certainty") of the evidence and strength of recommendations.[14] GRADE uses four tiers to classify quality:

> *High*: We are very confident that the true effect lies close to that of the estimate of the effect.
>
> *Moderate*: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
>
> *Low*: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
>
> *Very low*: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.[15]

There is frequent confusion about the relationship between GRADE and tools that assess individual studies for risk of bias such as RoB 2 and ROBINS-I. When assessing risk of bias, the reviewers are assessing individual studies. When SR authors assess the quality or certainty of evidence with GRADE, they are assessing the total body of evidence. They ask: How confident should we be in the effect estimate (for instance, the estimate of average mortality, level of depression, degree of disease progression), given the evidence derived from all the included studies? GRADE does consider risk of bias in the individual studies that yielded the estimate, but that is just one of five factors that can downgrade the quality of the evidence. The other four are *inconsistency* (how consistent the results are across all the studies reporting on the same outcome); *indirectness* (how applicable the evidence is to the PICO in question); *imprecision* (whether the sample is too small or confidence intervals[16] surrounding the estimates too

[14] However, because GRADE "has become increasingly complex, such that new as well as existing users may find it unwieldy," a simplified and slightly revised version has recently been proposed, "Core GRADE" (Guyatt et al., 2025).
[15] Balshem et al. (2011, Table 2). See also M. Prasad (2024, p. 2).
[16] A confidence interval is a range of effect values and is used to quantify uncertainty about effect estimates.

wide), and *publication bias* (for instance, whether studies with negative results have not been published).[17] Evidence quality can be upgraded if there is a large effect size, a clear dose-response relationship, or if confounding factors would likely reduce the observed effect but did not.

GRADE not only provides guidance on assessing the quality of evidence, but guidance on recommending treatments. Key determinants for the strength of recommendations include the balance between benefits and harms of the alternative treatments, the certainty of evidence, values and preferences, and cost and resource allocation. Values and preferences of patients are a major consideration, especially when the certainty of evidence is low or very low.

In GRADE, there is an "explicit separation of the process for assessing the quality of a body of evidence from the process for making recommendations based in part on those assessments. Although higher quality evidence is more likely to be associated with strong recommendations than lower quality evidence, a particular level of quality does not imply a particular strength of recommendation. Sometimes, low or very low-quality evidence can lead to a strong recommendation."[18] For example, a low-cost safe treatment supported by low-quality evidence could lead to a strong recommendation if the potential benefits are large and there is no alternative. Conversely, a treatment might be supported by high quality evidence and yet not be strongly recommended, because it has side effects that some patients would not be willing to accept.

A treatment might be potentially promising but have harmful side effects with only weak evidence of benefit. In such cases a recommendation for "treatment-only-in-research" may be given under the following conditions:

> [T]here is insufficient evidence supporting an intervention for a panel to recommend its use; further research has a large potential for reducing uncertainty about the effects of the intervention; and further research is deemed good value for the anticipated costs.[19]

[17] Higgins et al. (2019, Table 2-1).
[18] Balshem et al. (2011, p. 402).
[19] J. Andrews et al. (2013, p. 724).

3. Overviews of reviews

Overviews of reviews, or “umbrella reviews,” such as the one performed to systematically assess the clinical evidence for this Review, use a similar methodology to SRs to evaluate SRs themselves. Overviews employ explicit and systematic methods to identify and analyze multiple systematic reviews that address related research questions within a common topic area, with the goal of synthesizing results across key outcomes.[20] This approach is particularly useful when multiple systematic reviews exist on overlapping or related research questions within the same topic area, or when stakeholders need a high-level synthesis to inform clinical, policy, or public health decision-making. Like SRs, overviews use GRADE or related tools and standardized reporting practices.

The process of an overview follows these steps:

1. Systematically search for all SRs addressing the relevant PICOs.

2. Identify and include the eligible SRs

3. Extract information about the estimated treatment effects, and assess each SR for risk of bias using a tool such as “Risk of Bias in Systematic reviews” (ROBIS)

4. Collect, analyze, and present the data from included systematic reviews, including characteristics of the SRs and their included primary studies; risk of bias of included primary studies; outcome data; and certainty of evidence for pre-defined, clinically important outcomes. Specifically, for each outcome of interest, reviewers summarize the information about treatment estimates from the SRs.

To assess the certainty of evidence, reviewers may opt to summarize and report the original GRADE ratings reported by the SRs in the included systematic reviews. However, reviewers may need to re-analyze outcome data from systematic reviews or conduct GRADE assessments themselves using the information reported in the SRs, for example, when the SRs do not include GRADE assessment, or when there is disagreement across included SRs.

[20] Pollock et al. (2024).

Performing a new SR is preferred when there is a lack of recent SRs or when existing SRs are limited in quality; but if the literature contains several recent high-quality SRs the overview is an approved option.[21]

4. Other types of reviews

Not every medical publication with "review" in its title is an SR or an overview of SRs. Such publications can be useful but are not systematic and reproducible syntheses of evidence. Other types of reviews include:

Narrative reviews

Also called *literature reviews*, a narrative review is "a review article (such as a typical book chapter) that is not conducted using methods to minimize bias (in contrast to a systematic review)."[22] For this reason, narrative reviews must be treated with caution, although they can be helpful as an introduction to a research topic.

Scoping reviews

The purpose of a scoping review is to survey the available research on a specific topic. Scoping reviews are systematic and reproducible like SRs but are usually not as rigorous. The aim of a scoping review is to survey existing research and suggest areas for future study, not to assess the evidence for a particular intervention.[23]

[21] Pollock et al. (2024).
[22] Guyatt et al. (2015, p. 461).
[23] Tricco et al. (2016).

Appendix 4. Overview of Systematic Reviews: Methodology, Evidence Synthesis, Tables

This Appendix is published separately.

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Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature

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Abstract

Purpose: This article reports on the findings of a meta-synthesis undertaken on published gray transgender suicidality literature, to determine the average rate of suicidal ideation and attempts in this population.

Methods: Studies included in this synthesis were restricted to the 42 that reported on 5 or more Canadian or U.S. adult participants, as published between 1997 and February 2016 in either gray or peer-reviewed health literature.

Results: Across these 42 studies an average of 55% of respondents ideated about and 29% attempted suicide in their lifetimes. Within the past year, these averages were, respectively, 51% and 11%, or 14 and 22 times that of the general public. Overall, suicidal ideation was higher among individuals of a male-to-female (MTF) than female-to-male (FTM) alignment, and lowest among those who were gender non-conforming (GNC). Conversely, attempts occurred most often among FTM individuals, then decreased for MTF individuals, followed by GNC individuals.

Conclusion: These findings may be useful in creating targeted interventions that take into account both the alarmingly high rate of suicidality in this population, and the relatively differential experience of FTM, MTF, and GNC individuals. Future research should examine minority stress theory and suicidality protection/resilience factors, particularly transition, on this population.

Keywords: transgender; suicide; marginalization

Introduction

In recent years, transgender individuals have rapidly gained visibility. Despite this, they continue to be at risk for negative life events that adversely affect their health and well-being, such as being rendered invisible, experiencing isolation, and being subjected to societal violence.[1] Perhaps as a result, current and past studies report appallingly high rates of suicidality (attempts and ideation) in this population. For instance, Scanlon et al.,[1] reported an attempt rate of 43% and an ideation rate of 77% among transgender Ontarians, compared to 0.5% and 3.7%, respectively, in the general population.[2,3] Unfortunately, the applicability of these findings in guiding policy and future research is impacted by wide variation in the findings of suicidality rates.[4,5] For example, Xavier et al.[6] report an attempt rate of 25% and an ideation rate of 65%, while Imbimbo et al.[7] record rates of 3% and 50%, respectively. The current meta-synthesis attempts to address these discrepancies by measuring the overall variation across and averaging the suicidality rates within these studies. This knowledge may encourage the creation of targeted and strategic mental health interventions and research.

Literature review

Historical trends. The field of transgender healthcare has been described by Bockting[8] as evolving from utilizing a disease-based lens of transgender health and behavior to an identity-based lens. Within this framework, and as confirmed by our literature review, the

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disease-based lens appears to have been prevalent from 1953, when the first report on transgender suicidality was published[9] until roughly 1997. This period was characterized by research that viewed transgender health and identity as fundamentally psychopathological, deviant, and manipulative.[10–13] Despite no empirical support, many healthcare professionals tended to view suicidality as a manipulative tactic to force surgery,[14] which would invariably lead to poor mental health outcomes, such as suicide and psychotic breakdown.[15] In fact, evidence existed that suggested the opposite: that improvement tended to be drastic following surgery.[16]

The utilization of an identity-based lens appears to have begun to overtake the disease-based lens in roughly 1997, with the publication of Devor's[17] seminal study on female-to-male (FTM) transsexuals. The identity-based lens is characterized by the assumption that transgender identity is part of a natural spectrum that includes identities beyond those that are male or female, feminine or masculine.[8] Proponents of this lens argue that physical and psychological stress, resultant from institutional and societal discrimination, are major contributors to suicidality in this population.[1,18,19]

While the disease-based lens continues to be used,[8] particularly outside of North America,[20] there is increasing disagreement as to whether the cause of transgender identity is mental, hormonal, biological, and/or genetic.[21] Similarly, suicidality in this population is variously attributed to psychopathology, neurobiology,[22] and/or antitransgender stigma.[19]

Meta-analyses and systematic reviews. Ten systematic reviews or meta-analyses have mentioned suicidality among transgender people; however, only Marshall et al.,[23] approached this as the primary question and was designed to include all articles on transgender suicidality. Nevertheless, although an important contribution to the literature and even accounting for the parameters of their review, Marshall et al.[23] appear to have missed several studies (numbers 2, 5–11, 16, 19–21, 23–26, 32–33, 35, and 42 in Table 1), and counted a single research project three times (37 in Table 1).

The remaining nine reviews and meta-analyses, while important, largely address transgender suicidality as a secondary question in relation to other issues, such as HIV or geographical location. As such, these articles do not encompass the breadth of transgender suicidality literature addressed in this meta-synthesis. For example Meads et al.[91] restricts itself to one region in England, while Herbst et al.[92] focuses primarily on HIV prevalence and risk factors which, though common in this field, is not reflective of all transgender individuals.[21] Finally, the articles by Pauly,[93–96] the Wessex Institute for Health Research and Development,[97] and Lundström et al.[98] address transgender suicidality vis-a-vis the impact of gender confirmation surgery, finding the persistently held notion that transgender individuals experience higher rates of suicidality after gender confirming surgery to be unfounded (indeed, suicidality has been recorded to be most common when requests for surgery are refused).[15]

Method

Eligibility criteria

All studies included in this meta-synthesis reported data from original participant research investigating transgender suicide attempts and/or ideation. Both gray and peer-reviewed academic literature were included, as the former allowed for a larger data pool and helped to reduce the impact of publication bias, where research with nonsignificant findings may be published in a thesis, but not a peer-reviewed journal. Studies were included if they were published in English-language North American (Canada and the United States) journals, between 1997 and February 1, 2016. These studies must also have reported quantitative data on suicidality among five or more transgender participants with a diagnosis of gender dysphoria and/or self-identification as transgender. Further, the majority (50% +1) of participants must have been 18 years or older at the time of participation.

Additionally, a word about the inclusion of cross-dressers (CDs). It is noted that there are many terms used by transgender individuals to define their experience of gender and gender identity.[65,99] The term CD, which identifies individuals "who dress in clothing or express their gender in ways that society deems inconsistent with the sex they were assigned at birth" is commonly used for this purpose.[99] In the case of this study, CDs are included because they answered research calls for transgender people and because in most cases this identity cannot be assumed to be exclusive of other transgender identities.

Studies were excluded if they reported only on completed suicides or nonsuicidal self-injury, single case reports, or included a transgender cohort as part of a larger population (e.g., LGB) without providing discrete transgender data. This includes reports that referenced, but did not provide data on investigations into transgender suicidality. Additionally, research that resulted in multiple publications was only counted

Table 1. Studies Included in the Meta-Synthesis

	Author/s	Population	Time measure	Ideation	Attempt	Description
1	Cole et al.[24]	318 MTF 117 FTM	Before/after treatment		Before treatment All: 15% MTF: 12% FTM: 21% After treatment All: 0%	Analyzed the incidence of Axis 1 and 2 diagnoses among patients at a Texas gender clinic from 1980 to ~1997. Patient charts included information garnered from a clinical interview and questionnaire administered on first contact. Psychometric inventories also utilized in some cases.
2	Devor[17,25]	45 FTM	Lifetime	FTM: 28.89%	FTM: 22.22%	Investigated the life experiences of FTMs via the first needs assessment conducted on the subject of transgender suicidality. Data collected from 1988 to 1992. Suicidality information was volunteered by all participants during the interview.
3	Rehman et al.[26]	28 MTF	After surgery	MTF: 7.14%		Investigated postsexual reassignment sex and surgery satisfaction in MTF patients of a NYC hospital from 1980 to 1994. Participants were asked whether they experienced suicidal ideation before and/or after surgery. Only postsurgical information is reported.
4	Mathy[27]	21 FAAB 49 MAAB 3 Intersex	Lifetime	All: 37%	TG: 23.30%	Examined suicidality among transgender respondents to two large surveys of human sexuality conducted on the MSNBC website over 1 month in 2000. First survey was a selected random sample and the second invited every thousandth visitor to participate. Transgender respondents were forced to select male, female, or transgender and represented 0.2% of each sample. Transgender participants were compared to 1083 heterosexual females, 1077 heterosexual males, 73 psychosocially matched cisfemales, 73 psychosocially matched cismales, 256 homosexual females, and 356 homosexual males.
5	Singer et al.[28]; Kenagy[29]; Kenagy[30]	23 FTM 38 MTF 25 GNC 17 CD	Lifetime		All: 38.83% MTF: 52.63% FTM: 43.48% TG: 28% CD: 17.65%	Employed a needs assessment to explore physical and mental health among Philadelphia-area transgender individuals from 1996 to 1997.
6	Kenagy and Bostwick[31]	33 FTM 78 MTF	Lifetime	All: 61.69%	All: 26.27%	Employed a needs assessment to explore the health and social service needs of transgender individual's in Chicago over 6 months (2000–2001) via snowball sampling and using trained transgender interviewers.
7	Bockting et al.[32,33]	141 MTF 34 FTM	In last 3 years	All: 52%		Sought to analyze the impact of an 8-week sexual health seminar (offered from 1997 to 2002) in Minnesota on health-risk factors, such as HIV risk behavior in a group of LGBT individuals. Transgender participants were compared to 480 "men who have sex with men" and 122 "women who have sex with women."
8	Kenagy[29,30,34]	49 MTF 32 FTM	Lifetime	All: 46.91% MTF: 59.18% FTM: 28.13%	All: 19.75% MTF: 28.57% FTM: 6.25%	Employed a needs assessment to investigate the health and social service needs of a Philadelphia-area transgender community over 6 months in 1997.
9	Risser et al.[35]	63 MTF 4 cismales	Attempts over lifetime Ideation over lifetime and in past 30 days	Lifetime All: 58.21% Past 30 days All: 16.42%	Lifetime All: 29.85%	Employed a needs assessment to investigate the social and sexual health status of a group of transgender women in Houston over 2 months (2002–2003).
10	Xavier[36]; Xavier and Simmons[37]; Xavier et al.[38]	7 FTM 12 MTF 183 GNC 4 intersex 23 ciswomen 23 cismen	Lifetime	All: 34.92%	All: 16.27%	Employed a needs assessment to investigate the health and social service needs of a transgender community in Washington, DC over 4 months (1999–2000). The number of respondents is amalgamated from the slightly different numbers published in the three articles.

(*continued*)

AR-001432

Table 1. (Continued)

	Author/s	Population	Time measure	Ideation	Attempt	Description
11	Clements-Nolle et al.[18]; Clements-Nolle et al.[39]	123 FTM 392 MTF	Lifetime		All: 32.23% MTF: 32.40% FTM: 31.71%	Examined HIV, risk behaviors, mental health and healthcare use of transgender individuals in San Francisco over 5 months in 1997.
12	Zians[40]	16 FTM 57 MTF 56 TG	Ideation past 12 months Attempts over lifetime	Past 12 months All: 31.62%	Lifetime All: 17.65%	Employed a needs assessment to investigate the healthcare and social service needs of transgender individuals in San Diego over 7 months in 2004. The manner of inquiry into suicidality was somewhat unclear.
13	Taylor[41,42]	21 FAAB 49 MAAB 3 intersex	Lifetime	All: 54%	All: 28%	Employed a needs assessment to investigate the health and social service needs of transgender and two-spirit individuals in Manitoba and Northwestern Ontario over 6 months in 2006. Contains an unusually high rate of Aboriginal participants (27.40%). Participants were given the option to complete either a long or short form questionnaire where the short form did not inquire into suicidality. Suicidality figures presumed to be for all 73 respondents, regardless as to whether they originate from the long or short survey.
14	Landers and Gilsanz[43]	52 TG	Last 12 months	All: 30.77%		Conducted for the Massachusetts Department of Public Health over 10 days in 2009, using the e-mail list of MassEquality, in part to determine the impact of Massachusetts' equal marriage law on LGBT health and security. The overall response rate was only 4.2% and transgender respondents were forced to select LGB or transgender. Transgender participants were compared to 450 heterosexual, 965 gay/lesbian, and 136 bisexual individuals.
15	McDuffie and Brown[44]	4 FTM 55 MTF 11 GNC	Lifetime	All: 60.71%	All: 10.71%	Analyzed chart data for U.S. Armed Forces Veterans examined for gender identity disturbances at a Tennessee Veterans Affairs office from 1987 to 2007. Likely overlap with Blosnich et al.[62] and Brown and Jones.[84]
16	Nuttbrock et al.[19]	571 MTF	Lifetime	MTF: 53.50%	MTF: 27.90%	Sought to determine the psychiatric impact of gender-related abuse across the life course of transwomen via a large-scale longitudinal study, conducted in New York City, from 2004 to 2009. Obtained responses for up to five distinct time periods (early adolescence, late adolescence, early adult, young adult, early middle age). Suicidality information elicited from respondents positive for either of the depression screens at any of these periods, with responses to suicidality questions scored as 1 (yes) or 0 (no) and the total for all three questions added to form a suicidality score.
17	Nemoto et al.[45]; Operario and Nemoto[46]; Nemoto et al.[47]	573 MTF	Lifetime	MTF: 54.97%	MTF: 33.33%	Undertaken over 8 months from 2000 to 2001 and again from 2004 to 2006. Recruited primarily San Franciscan transgender women of color (African American, Latina, Asian/Pacific Islander) with histories of sex work. Primarily sought to gauge the impact of HIV, but also investigated socioeconomic status, victimization, physical and mental health.
18	Maguen and Shipherd[48]; Shipherd et al.[49]	22 FTM 60 MTF 32 GNC 28 CD	Lifetime		All: 18.31% MTF: 20% FTM: 40.91% GNC: 9.38% CD: 7.14%	Examined suicidality among participants at a transgender conference in New England known to focus on CDs and may have under sampled FTM, MTF, and GNC individuals.

(*continued*)

AR-001433

Table 1. (Continued)

	Author/s	Population	Time measure	Ideation	Attempt	Description
19	Effrig et al.[50]; Hayes et al.[51]	97 TG	Lifetime	All: 53.61%	All: 27.84%	Discusses victimization and psychological distress among transgender college students via clinical (Fall 2008) and nonclinical (Spring 2010) samples. The clinical sample is comprised of college counseling center patients where, unlike the nonclinical sample, "other" was not a gender option. The nonclinical sample consisted of respondents to a survey conducted by colleges aligned with the counseling centers. Both used the same survey measure; however, institutions varied in their use of incentives and completion prompts. Effrig et al.[50] contains contradictory figures for both the number and suicidality of nonclinical and clinical participants, although it was possible to rationalize these figures, revealing a probable 65 nonclinical and 32 clinical participants. We have combined the nonclinical and clinical data because the articles don't provide enough raw data to determine each samples' individual attempt rates.
20	Meier et al.[52]	367 FTM	Lifetime		FTM: 43%	Investigated the effect of gender confirming hormonal treatment on FTM individuals over 3 months in 2008.
21	House et al.[53]	29 FAAB 135 MAAB	Lifetime		All: 34.8%	Explored the social and psychological experiences of sexual minorities via an internet survey of LGBT respondents conducted over 1 month in 2004. U.S. transgender respondents represented 14.6% of all participants, with their findings compared to the lesbian, gay, and bisexual respondents. Transgender participants were compared to 524 male-identified, and 438 female-identified individuals.
22	Fredriksen-Goldsen et al.[54]	46 FTM 105 MTF 23 GNC	Lifetime	All: 71.1%		Sought to investigate the health of older LGBT adults in the United States (50–90 years old) over 5 months in 2010. Transgender respondents represented 7% of all respondents, with their responses compared to LGB counterparts. Transgender participants were compared to 1462 gay men, 773 lesbians, and 127 bisexuals.
23	Xavier et al.[6]; Goldblum et al.[55]; Testa et al.[56]	121 FTM 229 MTF	Lifetime	All: 63.71% MTF: 58% FTM: 79%	All: 25.43% MTF: 41% FTM: 79%	Explored the health and service needs of transgender Virginians over 10 months (2005–2006).
24	Beemyn and Rankin[57]; Testa et al.[58]	653 FTM 2178 MTF 256 GNC	First felt transgender	All: 16.62% MTF: 16.80% FTM: 17.46% GNC: 12.89%		Explored the life experiences of transgender individuals over 3 months (2005–2006). Among other topics, it investigated whether suicidality was negatively correlated with having been exposed to positive representations of transgender individuals.
25	Heinz and MacFarlane[59]	23 FTM 21 MTF 10 GNC	Lifetime	All: 35.19% MTF: 47.62% FTM: 26.09% GNC: 30.00%	All: 27.78% MTF: 19.05% FTM: 39.13% GNC: 20%	Explored the health and social service needs of transgender respondents on Vancouver Island, British Columbia, from 2010 to 2011.
26	Brown et al.[60]	9 MTF	Before transition	MTF: 55.56%	MTF: 11.11%	Investigated the life experiences of transfeminine individuals in the Missouri-Kansas City area over an unspecified time period. All respondents spontaneously shared experiences of suicidality within the context of being pretransition.
27	Moody and Smith[61]	56 FTM 59 MTF 15 GNC 3 intersex	Attempts over lifetime Ideation over lifetime and in past year	Lifetime All: 65.41% Past year All: 74.44%	Lifetime All: 26.32%	Explored suicidality and resilience among transgender respondents in Canada, the majority of who were from Quebec and Ontario.

(*continued*)

AR-001434

Table 1. (Continued)

	Author/s	Population	Time measure	Ideation	Attempt	Description
28	Blosnich et al.[62]	1326 TG	2011	All: 5.13%		Tracked suicidality among transgender veterans through an analysis of the U.S. Department of Veterans Affairs' electronic health records of patients with a listed ICD-9 diagnosis of "gender identity disorder." The records searched stretch from 2000 to 2011, while records for suicidality (referred to as "suicide related-behaviors" or "events") were only available from 2009 to 2011. Quite a bit of potential overlap with McDuffie and Brown[44] and Brown and Jones[84]
29	Haas et al.[63]; Grant et al[64,65]	1776 FTM 3005 MTF 766 GNC 894 CD	Lifetime		All: 40.04% MTF: 41.63% FTM: 46.28% GNC: 35.64% CD: 25.84%	Examined the health and social service needs of the U.S. transgender population from 2008 to 2009 via a needs assessment. Data were partially collected from survey party, which may have increased the participation of particularly hard to find populations (e.g., homeless, or with a low literacy level).
30	Mereish et al.[66]	16 TG	Lifetime	All: 68.75%	All: 31.25%	Explored relationships between LGBT-based victimization, substance use problems, and suicidality among patients waiting for an appointment at a New England community health center from 2001 to 2003. Participants restricted to identifying their gender as either male, female, or transgender, with only 1.10% identifying as both "transgender" and a "sexual minority." Transgender participants were compared to 1130 sexual minority men and 305 sexual minority women.
31	Reisner et al.[67]	31 TG	Lifetime	All: 58.06%	All: 29.03%	Presented research into transgender health disparities among patients waiting for a medical appointment at a Massachusetts community health center (unrelated to Mereish et al.) over the span of one year (2001–2002). Respondents asked to indicate their gender identity as male, female, or transgender and the resulting 31 transgender respondents paired with cisgender controls, matched for age (within 3 years), ethnicity, education, and income. Transgender participants were compared to two cisfemales and two cismales each. Likely some crossover with Reisner et al.[85]
32	Reisner et al.[68]	23 FTM	Lifetime		FTM: 21.74%	Examined suicidality in a cohort of FTM patients screened for STDs from July to December 2007 at a Boston community health center. Data obtained via a retrospective chart review and past suicide attempts documented in the electronic medical record. Likely some crossover with Reisner et al.[85]
33	Wilson et al.[69]; Santos et al.[70]	314 MTF	Lifetime	MTF: 52.97%		Investigated access to transition-related healthcare, as well as other physical and mental health services among transgender women in San Francisco over 4 months in 2010.
34	Rosser et al.[71]; Perez-Brumer et al.[72]	532 FTM 697 MTF	Lifetime Past 12 months		Lifetime All: 28.89% MTF: 23.82% FTM: 35.53% Past 12 months All: 4.15%	Reported on the impact of individual and structural suicidality risk factors, specific to transgender individuals. Also investigated the social demographics of hidden sexual minorities as part a larger investigation into gender and HIV risk.
35	Scanlon et al.[1]; Rotondi et al.[73,74]; Bauer et al.[75,76]; Scheim and Bauer[77]; Bauer et al.[78]	227 FTM 205 MTF 7% GNC 9% CD	Lifetime Past 12 months	Lifetime All: 77% Past 12 months All: 36% MTF: 35% FTM: 38% GNC: 31%	Lifetime All: 43% Past 12 months All: 10% MTF: 10% FTM: 11% GNC: 6%	Investigated the health and social service needs of transgender people in Ontario from 2009 to 2010.

(*continued*)

AR-001435

Table 1. (Continued)

	Author/s	Population	Time measure	Ideation	Attempt	Description
36	Edelman et al.[79]	182 FTM 307 MTF 32 GNC	Attempts over lifetime and in past year Ideation over lifetime	Lifetime All: 60% MTF: 58% FTM: 66%	Lifetime All 34% MTF 36% FTM 31% Past 12 months All 10% MTF: 14% FTM: 4%	Washington, DC transgender needs assessment conducted from May 2012–2013. Update of a prior study (No. 10). It was not possible to determine the exact number of MTF and FTM (described as transfeminine and transmasculine) respondents that experienced suicidality. As a result the suicidality figures are recorded here as reported. Similarly, there was little suicidality data for the 32 respondents that did not identify as transmasculine or transfeminine and they are, therefore, excluded.
37	Mustanksi et al.[80]; Liu and Mustanski[81]; Mustanski and Liu[82]; Birkett et al.[83]	8 FTM 13 MTF	Attempts over lifetime and in last 12 months		Lifetime All: 52.4% Last 12 months All: 19.0%	Explored suicidality among Chicago LGBT youth from 2007 to 2008. Transgender participants were compared to 107 cismales, 119 cisfemales.
38	Brown and Jones[84]	1578 FAAB 3557 MAAB	Suicidality recorded in VA records (treated as lifetime)	All: 19.36%		Reports on mental and medical health disparities among transgender veterans receiving healthcare through the U.S. Veterans Administration from 1996 to 2013. Participants were identified by noting whether their sex marker had been changed since the time of VA enrolment. Suicidality determined from a diagnostic code in the patients file. Quite a bit of potential overlap with McDuffie and Brown[44] and Blosnich et al.[62] Transgender participants were compared to 15405 cisgender individuals.
39	Reisner et al.[85]	106 FTM 74 MTF	Lifetime	All: 31.11% MTF: 32.43% FTM: 30.19%	All: 17.22% MTF: 20.27% FTM: 15.09%	Assessed mental health information in electronic patient records of transgender youth at a Boston-area community health center from 2002 to 2011. Respondents were divided into FTM or MTF and matched to cisgender controls within 3 months of first being noted as transgender in their patient file and according to gender identity, age, and race/ethnicity (some partially matched for age and gender identity). Transgender participants were compared to 180 cisgender individuals. Likely some crossover with Reisner et al.[67] and Reisner et al.[68]
40	Olson et al.[86]; Olson[87]	49 FTM 47 MTF	Lifetime	All: 51.04% MTF: 42.55% FTM: 59.18%	All: 30.21% MTF: 27.66% FTM: 32.65%	Cohort study that investigated the physiological and psychological health of transgender youth between 12 and 24 years of age (mean 19.2) who presented for gender services at a children's hospital in Los Angeles. Psychosocial health assessed via a computer-assisted self-administered survey and a selection of psychometric items, while physiologic health assessed via patient files. Only patients that presented for care from February 2011 to June 2013 were eligible.
41	Kuper[88]	1562 FAAB 439 MAAB	Lifetime Past year	Lifetime All: 96.5% Past year All: 80.2%	Lifetime All: 32.30% Past year All: 10.4%	Reports on suicidality and gender development among a cross-sectional cohort of GNC youth and young adults from throughout the United States.
42	Irwin et al.[89]; Su et al.[90]	91 TG	Lifetime		All: 35.16%	Assessed factors leading to suicidal ideation and health disparities among LGBT Nebraskans in 2010. About 11.9% identified as transgender, where the options were male, female, and/or transgender. Transgender participants were compared to 676 cisgender LGB individuals.

CD, cross-dresser; FAAB, female assigned at birth; FTM, female-to-male; GNC, gender non-conforming; MAAB, male assigned at birth; MTF, male-to-female; TG, transgender.

AR-001436

once, while the most recently published report was of primary import, though all reports published on a single study were reviewed for pertinent information. Finally, all included studies were reported in a primarily written format, thus excluding posters and other visual presentations.

Data collection

Rates of transgender suicidality were collected from included studies. Data absent from the included articles were supplemented by interviews with the study authors. However, to ensure the confidentiality promised as a condition of these interviews and required by the original Research Ethics Board approval, obtained through Dalhousie University, we have not indicated where this supplementation occurred.

Literature. Transgender suicidality literature was primarily identified via the WorldCat database because it is one of the largest global digital catalogs of cross-referenced and multi-disciplinary material. This search was supplemented with and cross-checked against results from Google Scholar and Google Search and later by manually reviewing the reference lists of identified articles, which resulted in the identification of a small number of additional articles. University of Calgary suicidality research Richard Ramsay's collated list of transgender suicidality studies was also invaluable.[100] The following key terms were used when searching WorldCat, Google Scholar, and in Google Search; "transgender suicide"; "transsexual suicide"; "FTM suicide"; "MTF suicide"; "transsexual suicidality"; "transgender suicidality"; "transgender suicide attempt"; and "transsexual suicide attempt."

Of the 2016 records identified, 1005 duplicates were immediately eliminated. The titles and abstracts of the remaining articles were screened (Fig. 1). After excluding reference lists, non-English language publications, audiovisual reports, and those that did not mention transgender suicidality in either the title or the abstract, 311 articles remained. The full texts of these articles were reviewed. Those further eliminated include articles that reported no original data on transgender suicide attempts and/or ideation (105), meta-analyses/reviews of transgender suicidality (10), those with no/unclear quantitative data (42), articles published before 1997 (31), those not from the United States or Canada (43), those where the majority of participants were under 18 at the time of first data collection (5), and those with less than five participants (3). The remaining 72 articles, representing 42 distinct research studies (some published multiple times), were examined in the qualitative synthesis, while the 3 that reported suicidality as an amalgamate of ideation and attempts were excluded from the quantitative synthesis.[32–33,62,84]

Data analysis

The 42 studies on transgender suicidality are subjected here to a simple descriptive analysis, with the intention of summarizing the statistics on transgender suicidality included in the source research, and providing inroads to a more thorough examination in the future. To this end, individual studies' suicidality statistics (total number of participants, mean suicidality, range) were recalculated where possible using *all study participants* as a denominator. We considered but chose not to use *only participants that responded to a given suicidality question* because relatively few studies reported enough raw data to reliably and consistently calculate this figure. Similarly, we noted that the 42 studies differed in whether they reported ideation and attempts separately or in an amalgamate. We have compensated for this by separating these statistics where enough raw data are available to make this possible. Where this was not possible (three cases) we recorded the given figures as is and did not use them in subsequent calculations of cross-study suicidality averages. Note that, beyond these actions and the criteria set for inclusion on this meta-synthesis, no additional measures were taken to account for varying study designs.

After processing the individual studies as described, we combined their suicidality statistics and calculated the overall mean rate of suicidal ideation and attempts for the 39 that measured these as independent factors and excluding the 3 that combined these figures. Variation is operationalized in the current meta-synthesis as any difference between the calculated study ideation and attempt means and the overall ideation and attempt means for all studies included. After calculating these studies by comparing these means according to participants' gender identity and over time (*ever*, *past year*, and *before treatment/transition/when participants first felt transgender*). We also compared the range of suicidality figures reported by these studies. These calculations were conducted with the aid of Excel and SPSS v. 23.

Results

Methodologies and study design

Of the 42 studies analyzed here, 11.9% ($n=5$) were Canadian, with the remaining 88.1% ($n=37$) originating in the United States. Beginning with an average of 1 per

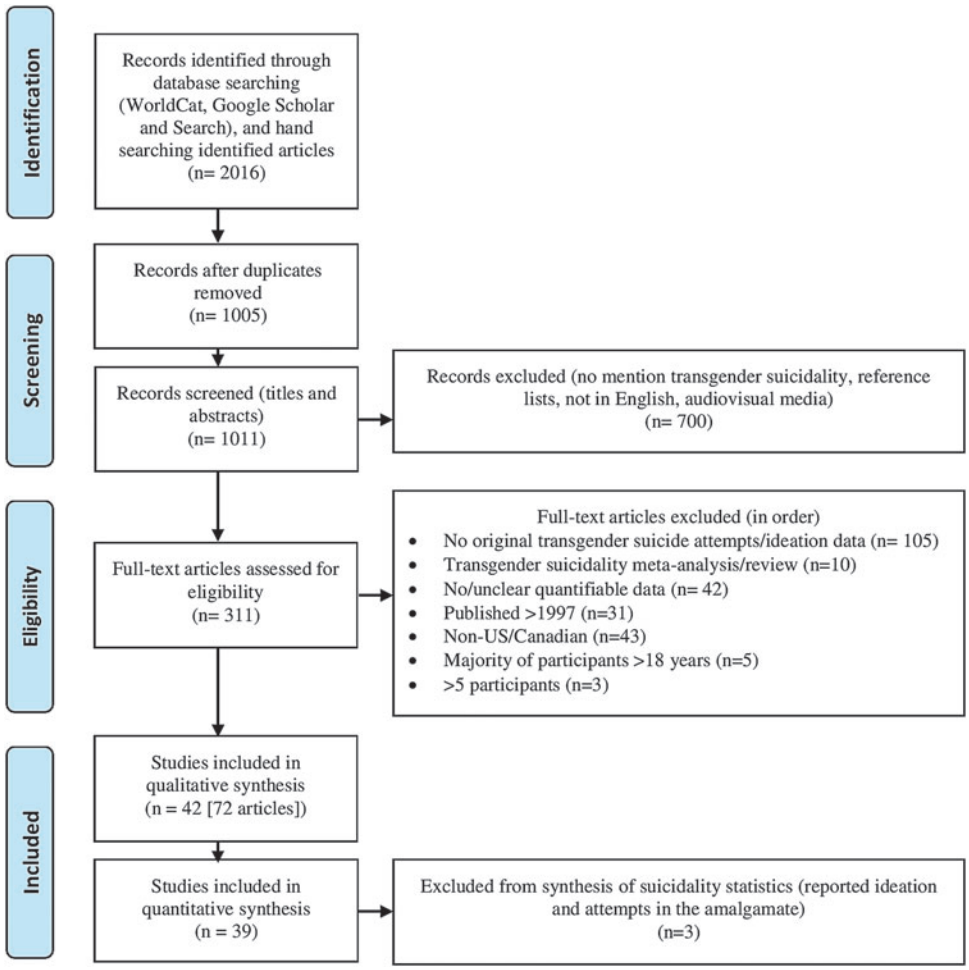

FIG. 1. A PRISMA[101] flow chart showing the literature reviewed for this assessment of transgender suicidality and the process of narrowing its scope to those North American studies that reported original transgender suicidality data, were published since 1997, and included five or more participants who were majority 18 years of age or older (50% +1).

year, there are now ~4 publications per year on this topic, with a high of 11 in 2011. Interestingly, despite the inclusion of gray literature, only six studies were solely published outside of a formal peer-reviewed format. Of these, one took the form of a thesis, while the remaining five were published in reports to communities, research granting agencies, governmental bodies, or as part of rigorous analyses by academic think tanks.

Eleven studies have included cisgender comparison or control groups, all of which were published since 2002, and 82% ($n=9$) since 2009. In comparing the research designs of all 42 studies, we see that 11.9% ($n=5$) used case series, 59.5% ($n=25$) used cross-sectional, 19% used case control ($n=8$), and 9.5% used cohort ($n=4$) designs, with a marked increase in the latter two since 2009 (83% of 12 total). Additionally, 73.8% ($n=31$) of these studies took place in a nonclinical setting, 23.8% ($n=10$) in a clinical setting, and 2.4% ($n=1$) in combined clinical and nonclinical settings. Finally, four different methods of data collection were employed, with 69% ($n=29$) using self-administered questionnaires, 31% ($n=13$) administered questionnaires, 14.3% ($n=6$) face-to-face interviews, and 16.7% ($n=7$) chart reviews.

Participant demographics

The individual studies that make up this meta-synthesis include from 9 to 6441 participants, for an

estimated total of 25,735 transgender individuals. Of these, ~4625 could be distinctly classified as FTM, 9698 as male-to-female (MTF), 1377 as gender non-conforming (GNC), and 939 as CDs. The majority of participants were male assigned at birth (MAAB; $n=15{,}074$ vs. female assigned at birth [FAAB]; $n=8697$). Additionally, though inconsistently recorded and difficult to track, four studies reported on a total of 13 intersex participants (Table 1).

The majority of studies excluded all participants under 18 years of age ($n=32$), though[36–38,40,80–83,88] reported a minority under this age (2.94–33.3%). In the remaining cases,[1,28–30,43,50,51,73–78,85–87] while it was apparent that the majority of the sample was over 18 years at the time of participation, insufficient information was provided to determine the exact number and proportion of those under this age.

Suicidality

Of the 42 studies analyzed, 83% ($n=35$) asked participants about lifetime ideation and/or attempts, while 36% ($n=15$) measured suicidality specific to a particular period either instead of, or in addition to this. (In one case, suicidality was recorded over a period of 17 years, which was treated as lifetime suicidality in the following calculations.) In addition to different studies assessing either ideation and attempts during different time frames (e.g., lifetime or part year), several studies assessed both ideation and attempts over different periods (e.g., lifetime ideation, attempts in past year) and/or for different gender identities and/or sexes assigned at birth.

Suicidal ideation and attempts were typically reported separately; for example, 67% ($n=28$) of the studies assessed ideation and 81% ($n=34$) assessed attempts. Additionally, three studies (7, 28, and 38 in Table 1) amalgamated ideation and attempts into a single figure, one of which investigated suicidality over the lifetime, one in the past 3 years, and one in 2011 alone. These three studies have therefore been excluded from the subsequent synthesis of suicidality statistics.

Lifetime suicidality. As seen in Figure 2, when suicidality statistics are averaged across all studies and analyzed by participants' gender identity, there is a tendency for MTF participants to ideate somewhat more often than FTM participants (51.7% vs. 45.4%), while attempts are virtually identical (31% vs. 32.3%). GNC individuals appear to ideate (30%) and attempt (25.6%) less than MTF and FTM individuals, while

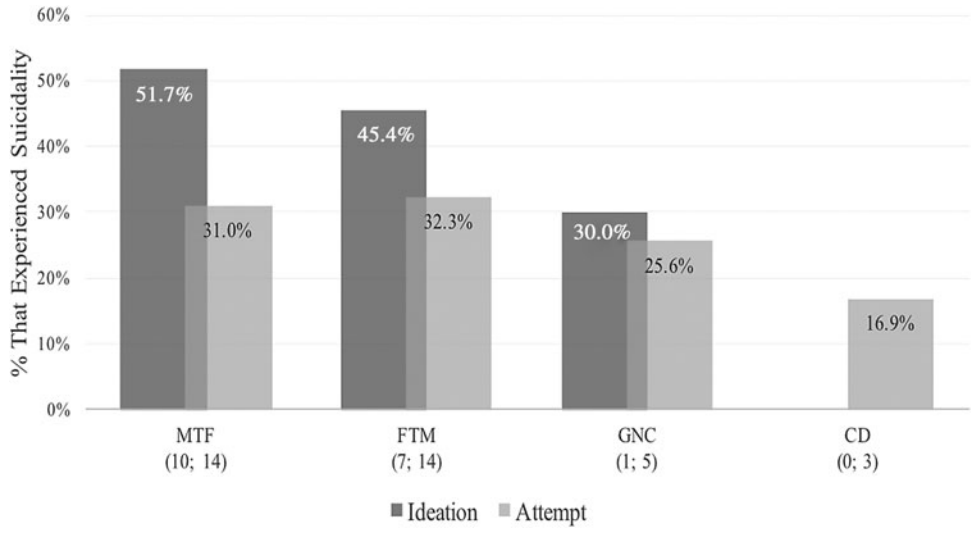

FIG. 2. Suicidality among transgender adults in studies that measured this across the lifetime, or "ever," as compared by gender identities. The numbers in brackets represent, first, the number of studies that recorded ideation statistics and second, the number that recorded attempt statistics. The label "All" indicates the figure for suicidality in studies that measured this among all participants, irregardless of gender identity. CD, cross-dresser; FTM, female-to-male; GNC, gender non-conforming; MTF, male-to-female.

CD individuals experience perhaps the least suicidality of the four groups (16.9% ideation).

Suicidality over a specific period. As seen in Figure 3, the most common time period used for measuring suicidality was over the *lifetime* ($n = 23$ for ideation; $n = 32$ for attempts), followed by the *past year* ($n = 5$ for ideation; $n = 5$ for attempts). Additionally, four studies measured suicidality surrounding transition (e.g., when participants *first felt transgender*, *before treatment*, *before transition*, and *after surgery*). Of this group, only the three ($n = 2$ for ideation; $n = 2$ for attempts) that investigated suicidality *before treatment*, *transition*, or when participants *first felt transgender* (representing a combined total of 3531 individuals) could reasonably be compared. Finally, one study measured ideation in the past 30 days.

The overall *lifetime* rate of suicidal ideation ($M = 55.5\%$; range = 28.9–96.5%) and attempts ($M = 28.9\%$; range = 10.7–52.4%) were calculated across the 23 and 32 studies for which these behaviors were, respectively, recorded. Similarly, we see the average and range of suicidality over the *past year* (ideation $M = 50.6\%$; range = 30.8–80.2%; attempt $M = 10.7\%$; range = 4.2–19%). Of equal import, this data set demonstrates the average and range of suicidality *before transition* (ideation $M = 36.1\%$; range = 16.6–55.6%; attempt $M = 13.1\%$; range = 11.1–15%).

Discussion

Findings

Methodologically speaking, much has changed within the period covered by this meta-synthesis. For example, there appears to have been an increase in methodological rigor, particularly in terms of study design and the use of comparison groups. Furthermore, the majority of transgender suicidality research now takes place in non-clinical environments, which is a marked contrast from the beginning of this period and the previous era. Demographically, these studies have included proportionately more MTF and MAAB participants than FTM/FAAB, GNC, or CD. Interestingly, CD appears to be something of a remnant of an older period in North American transgender culture, no longer in widespread use, at least as seen in recent academic publications.

In the studies examined in the current meta-synthesis, an average of 56% of participants experienced lifetime suicidal ideation and 29% had *ever* attempted suicide. Given the rate of suicidality in the general population, 0.5%[2] and 3.7%,[3] respectively, it

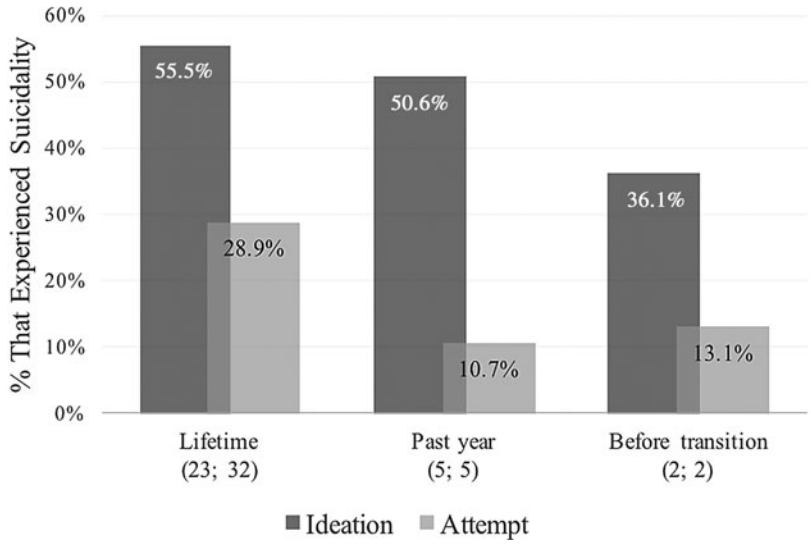

FIG. 3. Suicidality among transgender adults in studies that measured this in the past year, compared with those that measured this before transition. The numbers in brackets represent, first, the number of studies that recorded ideation statistics and second, the number that recorded attempt statistics. Studies that measured suicidality in "the past year" and "past 12 months" were combined. Little information was available for suicidality before transition (three studies total, two each for ideation and attempts) and the category is a combination of *before treatment*, *when participants first felt trans*, and *before transition*.

is clear that transgender individuals are disproportionately impacted by this phenomenon. Indeed, even over *the past year*, where 51% of participants ideated and 11% attempted, suicidality is approximately 14 and 22 times higher than in the general public. MTF participants also appear to experience more ideation and roughly equal attempts as their FTM counterparts, though both groups ideate and attempt more than participants identified as GNC, followed by those identified as CD. Finally, the vast majority of studies explored suicidality at any point in a participants' lifetime, either in addition to, or instead of time-specific measures (*past year*, *before transition*). Of those that did record time-specific measures, the majority did so for the past year.

We can also theorize on the impact of time and transition on suicidality, though only in an exploratory fashion. For example, as expected, when we compare *lifetime* to *past year* suicidality we find that ideation (55% vs. 51%) and especially attempts (29% vs. 11%) decrease. It seems counterintuitive, on the other hand, that suicide attempts are lower *before transition* (ideation 36.1%; attempt 13.1%) than over most other periods (past year attempts being the exception). However, we may expect to find higher rates of suicidality over the *lifetime* because this is a category that represents a non-transition specific and cumulative experience, in contrast to the single period represented by *before transition*. It may also be the case that individuals who do not desire transition represent a less dysphoric group and are therefore less suicidal.[64] By contrast, evidence is mounting that barriers to transition-related healthcare contribute to suicidality among those who desire such measures[63,78] and though it sometimes increases during transition,[78] it typically decreases once desired transitional goals are completed.[30,102] Indeed, a recent qualitative inquiry into suicide protective factors among trans adults identified several important protective factors among this population, one of which was socially and/or medically transitioning (for those who seek it).[103] Additionally, suicidality may be generally higher among transgender individuals than the general population throughout the life course, due to factors unrelated to transition, such as stigma and discrimination.[20,55,78]

Implications

The results of the current meta-synthesis can inform a number of potential transgender healthcare strategies. For example, as noted above, there is growing evidence for the role of both antitransgender discrimination and transitional services in suicidality among this population, with the former implicated in heightened suicidality and the provision of the latter in its reduction. Physical healthcare providers may, therefore, find it advisable to reduce barriers to transition, while mental healthcare providers should be prepared to support transgender clients in seeking out, preparing for, and obtaining these services. Nevertheless, given the continued vulnerability of this population, mental healthcare practitioners should also be prepared to develop and reinforce this populations' resiliency against antitransgender stigma and discrimination, as well as prepare them for the possible increase of stress during transition. This may also include supporting and participating in policy and legislative measures arguing for transgender healthcare and human rights protections and decrying attempts to discriminate against this population (e.g., The American Psychiatric Association's *Position Statement on Transgender and Gender Variant Individuals*,[104] The American Medical Associations' resolution on *Removing Financial Barriers to Care for Transgender Patients*,[105] and the American Academy of Pediatrics *Statement in Opposition of Legislation that Discriminates Against Transgender Children*).[106]

Limitations

The results of this meta-synthesis are very preliminary and there are a number of limitations inherent to a study of this kind, relying as it does on datasets that are methodologically varied. For example, relatively few studies reported on lifetime suicidality among individuals identified as GNC and CD, with the result that the analysis here is limited in generalizability. Similarly, relatively few studies measured suicidality either *before transition* or in the *past year* and it was, therefore, necessary to amalgamate several similar categories into the *before transition* group (*before treatment*, when *participants first felt trans*, and *before transition*). As noted, beyond the criteria set for an individual study's inclusion in this meta-synthesis and the actions taken to account for variation in their calculation of suicidality, no additional measures were taken to account for varying study designs and methodology.

Similarly, as is true within the broader field of transgender health, definitions of gender identity vary widely across these 42 studies. While documentation of nonbinary identities has increased in recent years[107] researchers continue to struggle to account

for the diversity among nonbinary individuals or respond to the rapid shifts in acceptable and preferred language within this community.[108]

The manner in which researchers inquired about suicidality is also concerning. For example, some researchers[63] note that yes/no questions, such as "have you ever attempted suicide?" tend to overestimate positive responses from those who have self-harmed, but not attempted to end their life. This might be corrected by questioning participants' intent to die through in-person interviews, which have been found to reduce attempt rates from 4.6% to 2.7% of an adult sample.[109,110] Unfortunately, only 14% of the 42 studies included here collected data primarily from face-to-face interviews.

Future research

There is a lack of research into transgender people's experiences of minority stress[111] and resiliency[61] particularly the impact of transition-related interventions on suicidality.[52] Researchers may also wish to include an additional measure reflecting current lived gender presentation which, owing to prejudice and/or other practical concerns, may differ from ones' core identity. It may also be the case that participants' gender identity evolves and shifts, and it is therefore difficult to capture this without asking participants to account for all previously held identities, rather than just that held in the moment of data collection.

Additionally, researchers might also explore the potential for bias in studies conducted in clinical environments, as participants may be dependent on the clinical environment for transition-related care. Consistent with social desirability bias, asking about suicidality in these environments, especially if not anonymously, may reinforce a *transitional narrative* where participants feel pressured to give a more positive picture of their mental health for fear of being denied, losing, or being forced to wait longer than necessary for life-saving transition-related services[112,113] Indeed, the practice of delaying transitional treatment due to comorbid symptomatology like depression and suicidality is widely practiced,[114] though evidence is mounting against the efficacy and ethics of this approach.[78] While set guidelines for transgender suicidality research would help to address this and other concerns, such a tool might not be help to address the expectation of bias created by the optics of the situation (e.g., that patients may not feel comfortable sharing their experiences of suicidality with those responsible for their care, where they are suspected to impact it).

Several decades of research have been conducted regarding suicidality experienced by transgender individuals. As summarized in the current meta-synthesis, rates of both ideation and attempts vary a great deal in subgroups of transgender individuals (FTM, MTF, GNC, CD), and based on several factors (e.g., type of questions asked, data collection method). The current meta-synthesis is the first of its kind to summarize 19 years of this important research and make sense of the 42 studies published in that time. It is our hope that the current article is a small but important addition to the body of knowledge regarding transgender suicidality and that the results may be used to inform future research and best practices.

Author Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

CD = cross-dressers
FAAB = female assigned at birth
FTM = female-to-male
GNC = gender non-conforming
MAAB = male assigned at birth
MTF = male-to-female

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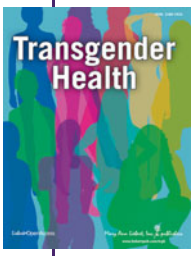

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HEALTH LAW: PEER-REVIEWED ARTICLE

Gender-Affirming Care, Incarceration, and the Eighth Amendment

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Abstract

As outlined in *Estelle v Gamble* (1976), the 8th Amendment to the US Constitution requires that states provide adequate care for people who are incarcerated—but what constitutes "acceptable" care under professional guidelines is frequently at odds with the standard of care used by clinicians outside of carceral facilities. Outright denial of standard care runs afoul of the Constitutional prohibition on cruel and unusual punishment. As the evidence base that undergirds standards of care in transgender health has evolved, people who are incarcerated have sued to expand access to mental health and general health care, including hormonal and surgical interventions. Carceral institutions must transition from lay administrative to licensed professional oversight of patient-centered, gender-affirming care.

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Transgender Care in Carceral Settings

Transgender people, especially those who are Black, Indigenous, and people of color, are disproportionately incarcerated, with 16% of all respondents in a 2011 national survey of transgender people reporting having a history of incarceration in jail or prison; the rate for Black respondents was 47% compared to a general population rate of 2.7%, although the latter figure is limited to state and federal prison systems.[1] It is estimated that there are nearly 5000 transgender people residing in US state prisons[2] and that another 1200 are incarcerated in the federal system.[3]

In the United States, no unified policy exists for the housing of and the delivery of health care to transgender and nonbinary prisoners in carceral settings. Variation can be found in state policies pertaining to where transgender and nonbinary prisoners are housed and with whom, what medical care they can access, and under which circumstances they are eligible for said care.[4] The policies governing jails and detention centers also vary by agency and county. Although policies vary, clinicians' ethical imperative to advocate for stronger protections for transgender people who are incarcerated and for best practices with respect to their care does not. In this paper, we seek to establish that, for transgender people who experience significant distress related to their inability

to access gender-affirming hormonal and surgical therapy while incarcerated, legal protection under the Eighth Amendment provides remedy. We also show that the United States regularly fails to meet the needs of transgender people who are incarcerated notwithstanding this legal standard and that remedy requires a lengthy judicial process to which few people who are incarcerated have access.

Standards

The state's responsibility to provide health care to people who are incarcerated rests largely on the Eighth Amendment prohibition on cruel and unusual punishment.[4,5] The judicial standard underpinning this claim was established in *Estelle v Gamble* (1976), which held that the state has a legal obligation to provide medical care for people who are incarcerated that is "reasonably commensurate with modern medical science" and guidelines and of "a quality acceptable within prudent professional standards."[6] Proof of violation of the Eighth Amendment under *Estelle* requires 2 criteria to be met: that the care be medically necessary and that failure to provide such care constitutes "deliberate indifference" by a prison administration that is aware of the suffering resulting from that lack of treatment.[4,5,7]

The World Professional Association for Transgender Health (WPATH) has published widely accepted standard of care guidelines for the medical treatment of gender minorities.[8] While it is recognized that not all transgender people experience gender dysphoria, or "the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender,"[9] many do suffer from such distress until they receive treatment. Access to gender-affirming care is associated with increased quality of life and decreased rates of self-harm, including 44% and 73% lower odds of suicidality in transgender adults[10] and youth,[11] respectively, compared to cohorts who do not receive gender-affirming-care. WPATH,[8] the American Medical Association,[12] and the American Academy of Family Physicians,[13] among other organizations, have recognized that gender-affirming mental health care, hormone therapy, and gender-affirming surgical procedures are medically necessary interventions that can relieve the distress of gender dysphoria. For some, gender-affirming surgery may be the only effective treatment.

Deliberate indifference, the second criterion that must be demonstrated in Eighth Amendment cases, requires awareness on the part of the prison officials that their conduct or lack of intervention will cause significant harm or risk of harm to a prisoner. While medical necessity of care is often fairly simple to prove, deliberate indifference is a subjective assessment that represents a much higher legal hurdle.

Why Gender Affirmation Doesn't Happen in Carceral Settings

There are many barriers to gender affirmation in carceral settings. The first is staff bias and a lack of training. Qualitative studies of both correctional and clinical staff[14] and transgender people with a history of incarceration[15] show that lack of staff competency regarding gender-affirming care presents a barrier to access, resulting in inadequate or complete denial of care. In particular, clinical staff report a lack of training and unfamiliarity with transgender care,[14] a finding replicated in other institutional settings such as the military.[16]

Housing is the second barrier to gender affirmation. Although under the federal Prison Rape Elimination Act (PREA), prisoners are legally entitled to be housed in a prison in accordance with their gender identity regardless of their anatomy,[17] in reality this

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practice is concerningly rare. A 2020 survey found that only 15 of 4890 transgender people were housed according to their gender identity in state prisons.[2] Many state prisons rely on a binary system of classification that rests largely on genital morphology, seeking to house only transgender prisoners who have had genital surgeries in accordance with their gender.[18,19,20] Yet data show that transgender women who are incarcerated in men's prisons have a vastly heightened risk for sexual assault than prisoners as a whole.[21] Conversely, transgender women housed in women's facilities have substantially lower rates of victimization than transgender women housed in men's facilities.[19] Prison administrators have responded to violence against transgender people by remanding them to "protective" custody (ie, solitary confinement), but this practice is notorious for exacerbating isolation, psychological distress, and exclusion from prison programming. This practice is not only legally precarious but also highlights an ethical failing of states that do not readily provide gender-affirming care. For if prisoners are only eligible for transfer to facilities in accordance with their gender upon achieving specific milestones in transition, and if housing in accordance with gender—not anatomy—is a predictor of violence against transgender people in prison, then the decision to provide or not provide gender-affirming care ultimately determines whether or not the state takes decisive action to mitigate some of the worst harms associated with incarceration for gender minority prisoners.

The third barrier to gender affirmation in prison settings is lack of medical and surgical intervention. *Estelle v Gamble* established that by neglecting essential medical care, prisons inflicted punishment beyond society's penological interests.[6] Prisoners, who must rely on the state for their medical needs, should receive adequate treatment. However, in *Maggert v Hanks* (1997), the prison psychiatrist disputed the very diagnosis of gender dysphoria, and the US Court of Appeals for the Seventh Circuit stated: "except in special circumstances that we do not at present foresee, the Eighth Amendment does not entitle a prison inmate to curative treatment for his gender dysphoria."[22] There was concern that if gender-affirming therapy became the norm in prisons, transgender people would purposely commit crimes in order to receive said treatment. Several legal challenges to carceral institutions' denial of gender-affirming hormone therapy have resulted in gender-affirming care being extended to people who are incarcerated. The decision of the US Court of Appeals for the Seventh Circuit in *Meriwether v Faulkner* (1987) recognized gender dysphoria as a serious medical condition constituting a valid Eighth Amendment claim as established in *Estelle* but emphasized that the plaintiff, a transgender woman denied estrogen, was entitled to "some" kind of medical intervention meeting minimal standards of adequacy though not necessarily the intervention she was requesting.[23] It was not until the landmark case of *Fields v Smith* (2011), in which the US Court of Appeals for the Seventh Circuit struck down a 2005 Wisconsin law barring all access to gender-affirming hormones or surgeries for people in the custody of the Department of Corrections as a violation of the prohibition of cruel and unusual punishment, that courts began to rule favorably for transgender plaintiffs.[24] In 2015, the Department of Justice's statement of interest in *Diamond v Owens* issued a directive to all state prisons to evaluate all persons seeking hormone therapy and to continue the hormone regimen they were on at the time of incarceration.[25]

In several other court cases, the Eighth Amendment argument has been extended to include gender-affirming surgeries.[26,27,28,29] As previously noted, some transgender people experience severe dysphoria even after counseling, nonmedical affirmation, and hormone therapy. Prisoner access to gender affirmation surgery remains extremely rare, although blanket bans on these procedures have been ruled unconstitutional under

Eighth Amendment claims.[30] The handful of successful petitioners have had their surgical requests fulfilled only after expressions of extreme self-harm and only after extensive litigation.[27,29,30,31] The plaintiff in *Kosilek v Spencer* filed her first claim in 1992, but the decision of the district court ordering the commissioner of the Massachusetts Department of Corrections to provide her with surgery didn't come until 2014.[26] This decision was immediately reversed by the First Circuit,[26] and the Supreme Court declined to hear her appeal.[32] She didn't receive surgery until 2021, after *Kosilek* was heavily scrutinized in the landmark case, *Edmo v Corizon* (2019),[29] a full 27 years after Kosilek initially sought remedy. Other people who are incarcerated who have sought gender affirmation surgery have lost their cases on a variety of grounds, including disagreement over WPATH guidelines representing standard of care,[28] safety considerations for other prisoners,[27]and prison-hired medical experts denying the necessity of the plaintiff's surgery.[33]

Removing Barriers

Despite legal advances, structural barriers to adequate gender-affirming care remain for transgender people who are incarcerated. Under *Estelle*, correctional institutions have an obligation to deliver gender-affirming care if "medically necessary" to transgender people who are incarcerated in accordance with "professional standards,"[6] such as the WPATH guidelines, which are widely accepted as representing the current medical and scientific consensus.[34] Even when this obligation is acknowledged, however, artificial administrative delays can prevent timely and adequate treatment,[35] effectively blocking access to appropriate care. Often, prisoners must meet a certain threshold (ie, a "serious" condition) to be eligible for medical intervention.[36] In order to gain access to gender-affirming care, prisoners have resorted to extreme measures to make their cases known, including self-surgery, such as autocastration.[5,7]

We hold that gender-affirming care for transgender and gender nonconforming people—which is required under the prevailing legal standard if it is medically necessary for alleviation of gender dysphoria—should be patient-centered. In light of the barriers noted above, patient-centered gender-affirming care within carceral institutions requires a multifaceted approach. Specifically, there are 3 foci that jails, prisons, and detention facilities must address to ensure a standard of care comparable to that available in the community: affirmation, custodial policy, and clinical competence.

Establishment of gender affirmation in jails, prisons, and detention centers should be formal and explicit, with medical and custodial staff receiving competency training. Custodial policy includes housing assignments, which, under PREA standards, shall be decided on a case-by-case basis with serious consideration given to the transgender person's views on their safety.[17] The use of solitary confinement for purported protection must end. This practice has always been a dangerous and inhumane solution, which can be avoided with adequate attention to the safety of transgender people. Other practices, including custodial staff conducting strip searches to determine genital status, should not be performed or should be performed in accordance with the person's gender, such as name and pronoun use and access to appropriate commissary items.[37] Carceral staff are often outwardly hostile to transgender people, exacerbating the distress they already experience from unjust housing assignments and lack of medical care.[38] Protocols must be established for managing staff who continue to violate the human rights of people who are incarcerated.

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Finally, clinical competence in gender-affirming care is as crucial as it would be for any other medical presentation. On-site staff should receive training to fill in gaps or correct practices that create barriers to care for transgender people.[39] In institutions with inadequate or unsuitable staff, outside care should be obtained, just as it would be for other forms of specialized medical care.[40] The use of nonclinical staff for "gender identity disorder review panels" must end, with external medical professionals, not prison officials, leading the process. Clinical guidelines produced by a professional entity, such as WPATH[8] or the University of California, San Franciso,[41] should be used to guide care. As these guidelines for medical and surgical interventions are widely used in community practice and are lifesaving and effective, their use should not be limited in carceral institutions.

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AAP News™



AAP speaks out against HHS report on gender dysphoria, infringement on physician-patient relationship

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Melissa Jenco, Senior News Editor

Article type: News

Topics: Advocacy, Diversity, equity and inclusion

AAP leaders say they are “deeply concerned” about a new government report on caring for transgender and gender-diverse youths. Medical society leaders also are defending the physician-patient relationship from political interference.

The report on pediatric gender dysphoria from the U.S. Department of Health and Human Services raises concerns about medical interventions for transgender youths and relies on a narrow set of data and perspectives.

AAP President Susan J. Kressly, M.D., FAAP, questioned the credibility of the report.

“This report misrepresents the current medical consensus and fails to reflect the realities of pediatric care,” Dr. Kressly said in a statement. “As we have seen with immunizations, bypassing medical expertise and scientific evidence has real consequences for the health of America's children. AAP was not consulted in the development of this report, yet our policy and intentions behind our recommendations were cited throughout in inaccurate and misleading ways. The report prioritizes opinions over dispassionate reviews of evidence.”

She urged policymakers to consider the “full breadth of peer-reviewed research” and said the AAP would continue to support pediatricians and the well-being of all children.

“Patients, their families, and their physicians—not politicians or government officials —should be the ones to make decisions together about what care is best for them based on evidence-based, age-appropriate care,”

she said. "… The AAP remains focused on supporting pediatricians in delivering the best possible care to every child, informed by science and the lived experiences of patients and families. We will continue to support the well-being of all children and access to high-quality care that meets their needs."

President Donald J. Trump called for the report in a Jan. 28 executive order on gender-affirming care, which he refers to as "chemical and surgical mutilation." An April 28 update on actions taken since the order was signed touts the elimination of $477 million in related research grant funding, making plans to remove gender-affirming care as a covered benefit for the children of federal employees and exploring ways to increase access to detransition care.

The update follows an April 22 memo from Attorney General Pam Bondi threatening physicians with felony charges for providing certain types of gender-affirming care.

The AAP joined five other medical organizations representing 600,000 physicians and medical students opposing infringements on the patient-physician relationship.

The groups said they "firmly believe the trusted relationship between a physician and their patient should never be jeopardized by the actions of policymakers, that physicians should not be criminalized or penalized for providing care and that medical standards of care and physician education training and education must remain evidence-based and free from political interference."

In addition to the AAP, the statement was signed by the American Academy of Family Physicians, American College of Obstetricians and Gynecologists, American College of Physicians, American Osteopathic Association and American Psychiatric Association.

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Gender Dysphoria

In this chapter, there is one overarching diagnosis of gender dysphoria, with separate developmentally appropriate criteria sets for children and for adolescents and adults. The area of sex and gender is highly controversial and has led to a proliferation of terms whose meanings vary over time and within and between disciplines. An additional source of confusion is that in English "sex" connotes both male/female and sexuality. This chapter employs constructs and terms as they are widely used by clinicians from various disciplines with specialization in treating gender dysphoria. In this chapter, *sex* and *sexual* refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and nonambiguous internal and external genitalia. Disorders of sex development or differences of sex development (DSDs) included the historical terms *hermaphroditism* and *pseudohermaphroditism*. DSDs include somatic intersex conditions such as congenital development of ambiguous genitalia (e.g., clitoromegaly, micropenis), congenital disjunction of internal and external sex anatomy (e.g., complete androgen insensitivity syndrome), incomplete development of sex anatomy (e.g., gonadal agenesis), sex chromosome anomalies (e.g., Turner syndrome; Klinefelter syndrome), or disorders of gonadal development (e.g., ovotestes).

Gender is used to denote the public, sociocultural (and usually legally recognized) lived role as boy or girl, man or woman, or other gender. Biological factors are seen as contributing, in interaction with social and psychological factors, to gender development. *Gender assignment* refers to the assignment as male or female. This occurs usually at birth based on phenotypic sex and, thereby, yields the *birth-assigned gender*, historically referred to as "biological sex" or, more recently, "natal gender." *Birth-assigned sex* is often used interchangeably with birth-assigned gender. The terms *assigned sex* and *assigned gender* encompass birth-assigned sex/gender but also include gender/sex assignments and reassignments made after birth but during infancy or early childhood, usually in the case of intersex conditions. *Gender-atypical* refers to somatic features or behaviors that are not typical (in a statistical sense) of individuals with the same assigned gender in a given society and historical era; *gender-nonconforming*, *gender variant*, and *gender diverse* are alternative nondiagnostic terms. *Gender reassignment* denotes an official (and sometimes legal) change of gender. *Gender-affirming treatments* are medical procedures (hormones or surgeries or both) that aim to align an individual's physical characteristics with their *experienced gender*. *Gender identity* is a category of social identity and refers to an individual's identification as male, female, some category in between (i.e., *gender fluid*), or a category other than male or female (i.e., *gender neutral*). There has been a proliferation of gender identities in recent years. *Gender dysphoria* as a general descriptive term refers to the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender. However, it is more specifically defined when used as a diagnostic category. It does not refer to distress related to stigma, a distinct although possibly co-occurring source of distress. *Transgender* refers to the broad spectrum of individuals whose gender identity is different from their birth-assigned gender. *Cisgender* describes individuals whose gender expression is congruent with their birth-assigned gender (also *nontransgender*). *Transsexual*, a historic term, denotes an individual who seeks, is undergoing,

or has undergone a social transition from male to female or female to male, which in many, but not all, cases also involves a somatic transition by gender-affirming hormone treatment and genital, breast, or other gender-affirming surgery (historically referred to as *sex reassignment surgery*).

Although not all individuals will experience distress from incongruence, many are distressed if the desired physical interventions using hormones and/or surgery are not available. The current term is more descriptive than the previous DSM-IV term *gender identity disorder* and focuses on dysphoria as the clinical problem, not identity per se.

Gender Dysphoria

Diagnostic Criteria

Gender Dysphoria in Children — F64.2

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be Criterion A1):

1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
3. A strong preference for cross-gender roles in make-believe play or fantasy play.
4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.
5. A strong preference for playmates of the other gender.
6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.
7. A strong dislike of one's sexual anatomy.
8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.

B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.

Specify if:

With a disorder/difference of sex development (e.g., a congenital adrenogenital disorder such as E25.0 congenital adrenal hyperplasia or E34.50 androgen insensitivity syndrome).

Coding note: Code the disorder/difference of sex development as well as gender dysphoria.

Gender Dysphoria in Adolescents and Adults — F64.0

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:

1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).

2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Specify if:

With a disorder/difference of sex development (e.g., a congenital adrenogenital disorder such as E25.0 congenital adrenal hyperplasia or E34.50 androgen insensitivity syndrome).

Coding note: Code the disorder/difference of sex development as well as gender dysphoria.

Specify if:

Posttransition: The individual has transitioned to full-time living in the experienced gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one gender-affirming medical procedure or treatment regimen—namely, regular gender-affirming hormone treatment or gender reassignment surgery confirming the experienced gender (e.g., breast augmentation surgery and/or vulvovaginoplasty in an individual assigned male at birth; transmasculine chest surgery and/or phalloplasty or metoidioplasty in an individual assigned female at birth).

Specifiers

The specifier "with a disorder/difference of sex development" should be used in the context of individuals who have a specific and codable disorder/difference of sex development documented in their medical record.

The "posttransition" specifier may be used in the context of continuing treatment procedures that serve to support the new gender assignment.

Diagnostic Features

Individuals with gender dysphoria have a marked incongruence between the gender to which they have been assigned (usually based on phenotypic sex at birth, referred to as *birth-assigned gender*) and their experienced/expressed gender. This discrepancy is the core component of the diagnosis. There must also be evidence of distress about this incongruence. Experienced gender may include alternative gender identities beyond binary stereotypes. Consequently, distress may involve not only the experience that the individual is a male or female gender other than the one assigned at birth but also an experience that the individual is an intermediate or alternative gender that differs from the individual's birth-assigned gender.

Gender dysphoria manifests itself differently in different age groups. The following examples may be less prominent in children raised in surroundings with fewer gender stereotypes.

Prepubertal individuals assigned female at birth with gender dysphoria may express a marked, persistent feeling or conviction that they are a boy, express aversion to the idea of

being a girl, or assert they will grow up to be a man. They often prefer boys' clothing and hairstyles, may be perceived by strangers as boys, and may ask to be called by a boy's name. Sometimes they display intense

negative reactions to parental attempts to have them wear dresses or other feminine attire. Some may refuse to attend school or social events where such clothes are required. These children may demonstrate marked gender nonconformity in role-playing, dreams, gender-typed play and toy preferences, styles, mannerisms, fantasies, and peer preferences. Contact sports, rough-and-tumble play, traditional boyhood games, and boys as playmates are most often preferred. They show little interest in stereotypically feminine toys (e.g., dolls) or activities (e.g., feminine dress-up or role-play). Occasionally, they refuse to urinate in a sitting position. Some may express a desire to have a penis or claim to have a penis or that they will grow one when older. They may also state that they do not want to develop breasts or menstruate.

Prepubertal individuals assigned male at birth with gender dysphoria may express a marked, persistent feeling or conviction that they are a girl or assert that they will grow up to be a woman. They may express aversion to the idea of being a boy. They often prefer dressing in girls' or women's clothes or may improvise clothing from available materials (e.g., using towels, aprons, and scarves for long hair or skirts). These children may demonstrate marked gender nonconformity in gender-typed play and toy preferences, styles, mannerisms, and peer preferences. They may role-play female figures (e.g., playing "mother") and may be intensely interested in female fantasy figures. Traditional feminine activities, stereotypical games, and pastimes (e.g., "playing house"; drawing feminine pictures; watching television or videos of favorite female characters) may be preferred. Stereotypical female-type dolls (e.g., Barbie) may be favorite toys, and girls are their preferred playmates. They avoid rough-and-tumble play and have little interest in stereotypically masculine toys (e.g., cars, trucks). They may state that they find their penis or testes disgusting, that they wish them removed, or that they have, or wish to have, a vagina.

Increasingly, parents are presenting to specialized clinics after their child with gender dysphoria has already socially transitioned.

As the onset of puberty for individuals assigned female at birth is somewhere between ages 9 and 13, and between 11 and 14 for individuals assigned male at birth, their symptoms and concerns may arise in a developmental phase somewhere between childhood and adolescence. As secondary sex characteristics of younger adolescents are not yet fully developed, these individuals may not state dislike of them, but they may be markedly distressed by imminent physical changes.

In adolescents and adults with gender dysphoria, the discrepancy between experienced gender and physical sex characteristics is often, but not always, accompanied by a desire to be rid of primary and/or secondary sex characteristics and/or a strong desire to acquire some primary and/or secondary sex characteristics of another gender. To varying degrees, older adolescents and adults with gender dysphoria may adopt the behavior, clothing, and mannerisms of their experienced gender. They feel uncomfortable being regarded by others, or functioning in society, as members of their assigned gender. Some adults and adolescents may have a strong desire to be of a different gender and treated as such, and they may have an inner certainty to feel and respond as their experienced gender without seeking medical treatment to alter body characteristics. They may find other ways to resolve the incongruence between experienced/expressed and assigned gender by partially living in the desired role or by adopting a gender role neither conventionally male nor conventionally female.

Associated Features

When visible signs of puberty develop, individuals assigned male at birth may shave their facial, body, and leg hair at the first signs of growth. They sometimes bind their genitals to make erections less visible. Individuals assigned female at birth may bind their breasts,

walk with a stoop, or use loose sweaters to make breasts less visible. Increasingly, adolescents request, or may obtain without medical prescription and supervision, drugs that suppress production of gonadal steroids (e.g., gonadotropin-releasing hormone [GnRH] agonists) or that block gonadal hormone actions (e.g., spironolactone). Clinically referred adolescents often want hormone treatment and many also wish for gender-affirming surgery. Adolescents living in an accepting environment may openly express the desire to

be and be treated as their experienced gender and dress partly or completely as their experienced gender, have a hairstyle typical of their experienced gender, preferentially seek friendships with peers of another gender, and/or adopt a new first name consistent with their experienced gender. Older adolescents, when sexually active, often do not show or allow partners to touch their sexual organs. For adults with an aversion toward their genitals, sexual activity is constrained by the preference that their genitals not be seen or touched by their partners. Not infrequently, adults may seek hormone treatment (sometimes without medical prescription and supervision) and gender-affirming surgery. Others are satisfied with either hormone treatment or surgery alone, or without any gender-affirming medical treatment.

In children, adolescents, and adults with gender dysphoria, an overrepresentation of autism spectrum traits has been observed. Also, individuals with autism spectrum disorder are more likely to exhibit gender diversity.

Adolescents and adults with gender dysphoria before gender-affirming treatment and legal gender change are at increased risk for mental health problems including suicidal ideation, suicide attempts, and suicides. After gender reassignment, adjustment may vary, and suicide risk and mental health problems may persist.

In prepubertal children, increasing age is associated with having more behavioral or emotional problems; this is related to the increasing nonacceptance of gender-nonconforming behavior by others. Children and adolescents who feel supported and accepted in their gender nonconformity may show less or even no psychological problems.

Prevalence

There are no large-scale population studies of gender dysphoria. Based on gender-affirming treatment–seeking populations, the prevalence for gender dysphoria diagnosis across populations has been assessed to be less than 1/1,000 (i.e., < 0.1%) for both individuals assigned male at birth and individuals assigned female at birth. Because many adults with gender dysphoria do not seek care at specialty treatment programs, prevalence rates are likely underestimates. Prevalence estimates based on surveys of self-reporting general population samples in the United States and Europe suggest higher numbers, although varied methods of assessment make comparisons difficult across studies. Self-identification as transgender ranges from 0.5% to 0.6%; experiencing oneself as having an incongruent gender identity ranges from 0.6% to 1.1%; feeling that one is a person of a different sex ranges from 2.1% to 2.6%; and the desire to undergo medical treatment ranges from 0.2% to 0.6%.

Development and Course

Because expression of gender dysphoria varies with age, there are separate criteria sets for children versus those for adolescents and adults. Criteria for children are defined in a more concrete, behavioral manner than those for adolescents and adults. Young children are less likely than older children, adolescents, and adults to express extreme and persistent anatomic dysphoria. In adolescents and adults, incongruence between experienced gender and assigned gender is a central feature of the diagnosis. Factors related to distress and impairment also vary with age. A very young child may show signs of distress (e.g., intense crying) only when parents tell the child that he or she is "really" not a member of another gender but only "desires" to be. Distress may not be manifest in social environments supportive of the child's gender nonconformity and may emerge only if there is parental/

social interference with the child's gender variance. In adolescents and adults, distress may manifest because of strong incongruence between experienced gender and birth-assigned gender. Such distress may, however, be mitigated by supportive environments and knowledge that biomedical treatments exist to reduce incongruence. Impairment (e.g., school refusal, development of depression, anxiety, peer and behavioral problems, and substance abuse) may be a correlate of gender dysphoria.

Gender dysphoria without a disorder of sex development. For clinic-referred children studied in Canada and the Netherlands, onset of gender-nonconforming behaviors is usually between ages 2 and 4 years. This corresponds to the developmental time period in which most children begin expressing gendered behaviors and interests. For some preschool-age children, both marked, persistent gender-atypical behaviors and the expressed desire to be another gender may be present, or labeling themselves as a member of another gender may occur. In other cases, the gender expression appears later, usually at entry into elementary school. Children may sometimes express discomfort with their sexual anatomy or will state the desire to have a sexual anatomy corresponding to their experienced gender ("anatomic dysphoria"). Expressions of anatomic dysphoria become more common as children with gender dysphoria approach and anticipate puberty.

No general population studies exist of adolescent or adult outcomes of childhood gender variance. Some prepubescent children expressing a desire to be another gender will not seek gender-affirming somatic treatments when they reach puberty. They frequently report nonheterosexual orientations and frequently marked gender-nonconforming behavior, although not necessarily a transgender identity in adolescence/young adulthood. Some children with gender dysphoria in childhood that remits in adolescence may experience a recurrence in adulthood.

In individuals assigned male at birth, studies from North America and the Netherlands found persistence ranged from 2% to 39%. In individuals assigned female at birth, persistence ranged from 12% to 50%. Persistence of gender dysphoria is modestly correlated with dimensional measures of severity ascertained at the time of a childhood baseline assessment. Early social transition may also be a factor in persistence of gender dysphoria in adolescence.

Studies have shown a high incidence of sexual attraction to those of the individual's birth-assigned gender, regardless of the trajectory of the prepubescent child's gender dysphoria. For individuals whose gender dysphoria continues into adolescence and beyond, most self-identify as heterosexual. In those who no longer have gender dysphoria by the time of adolescence, a majority self-identify as gay, lesbian, or bisexual.

Two broad trajectories have been described for development of gender dysphoria in individuals who identify as either male or female.

As opposed to gender-nonconforming children, individuals with prepubertal-onset gender dysphoria have symptoms that meet diagnostic criteria for gender dysphoria in childhood. The dysphoria can continue into adolescence and adulthood; alternatively, some individuals go through a period in which the gender dysphoria either desists or is denied. At such times, these individuals may self-identify as being gay or lesbian. Some may identify as heterosexual and cisgender. However, it is possible that some of these individuals may experience a recurrence of gender dysphoria later in life.

Regardless of whether the individual's gender dysphoria persists or desists at a later date, either the onset of puberty or the realization that puberty will begin with development of secondary sex characteristics can prompt distressing feelings of gender incongruence that can exacerbate the individual's gender dysphoria.

The early/prepubertal-onset group often present for clinical, gender-affirming care during childhood, during adolescence, or in young adulthood. This may reflect a more intense gender dysphoria compared with individuals with late/postpubertal-onset gender dysphoria, whose distress may be more variable and less intense.

Late-onset or pubertal/postpubertal-onset gender dysphoria occurs around puberty or even much later in life. Some of these individuals report having had a desire to be of another gender in childhood that was not expressed verbally to others or had gender-nonconforming behavior that did not meet full criteria for gender dysphoria in childhood. Others have no recollection of any signs of childhood gender dysphoria. Parents of individuals with gender dysphoria of pubertal/postpubertal-onset often report surprise, as they saw no signs of gender dysphoria during childhood.

Gender dysphoria in association with a disorder of sex development. Individuals with DSDs who require early medical intervention or decisions about gender assignment come to clinical attention at an early age. Depending on the condition, they may have been gonadectomized (often because of risk of future malignancy) before puberty so that administration of exogenous hormones is part of routine care to induce puberty. Infertility is common whether due to the condition itself or to gonadectomy, and genital surgery may have been done in infancy or childhood with the intent of affirming the assigned gender to both the affected individual and caregivers.

Affected individuals may exhibit gender-nonconforming behavior starting in early childhood in a manner that is predictable depending on the specific DSD syndrome and the gender assignment, and thresholds for supporting social and medical gender transition in minors have traditionally been much lower for those with compared to those without DSDs. As individuals with some DSD syndromes become aware of their condition and medical history, many experience uncertainty about their gender, as opposed to developing a firm conviction that they are of another gender. The proportion who develop gender dysphoria and progress to gender transition varies markedly depending on the particular syndrome and gender assignment.

Risk and Prognostic Factors

Temperamental. Gender-variant behavior among individuals with prepubertal-onset gender dysphoria can develop in early preschool age. Studies suggest that a greater intensity of gender nonconformity and an older age at presentation make persistence of gender dysphoria into adolescence and adulthood more likely. A predisposing factor under consideration, especially in individuals with postpubertal-onset gender dysphoria (adolescence, adulthood), includes history of transvestism that may develop into autogynephilia (i.e., sexual arousal associated with the thought or image of oneself as a woman).

Environmental. Individuals assigned male at birth with gender dysphoria without a DSD (in both childhood and adolescence) more commonly have older brothers when compared with cisgender males.

Genetic and physiological. For individuals with gender dysphoria without a DSD, some genetic contribution is suggested by evidence for (weak) familiality of gender dysphoria among nontwin siblings, increased concordance for gender dysphoria in monozygotic compared with dizygotic same-sex twins, and some degree of heritability of gender dysphoria. Research suggests that gender dysphoria has a polygenetic basis involving interactions of several genes and polymorphisms that may affect in utero sexual differentiation of the brain, contributing to gender dysphoria in individuals assigned male at birth.

As to endocrine findings in individuals with gender dysphoria, no endogenous systemic abnormalities in sex-hormone levels have been found in 46,XY individuals, whereas there appear to be increased androgen levels (in the range found in hirsute women but far below normal male levels) in 46,XX individuals. Overall, current evidence is insufficient to label gender dysphoria without a DSD as a form of intersexuality limited to the central nervous system.

In gender dysphoria associated with a DSD, the likelihood of later gender dysphoria is increased if prenatal production and utilization (via receptor sensitivity) of androgens are grossly variant relative to what is usually seen in individuals with the same assigned gender.

Examples include 46,XY individuals with a history of normal male prenatal hormone milieu but inborn nonhormonal genital defects (as in cloacal bladder exstrophy or penile agenesis) and who have been assigned to the female gender. The likelihood of gender dysphoria is further enhanced by additional, prolonged, highly gender-variant postnatal androgen exposure with somatic virilization as may occur in female-raised and noncastrated 46,XY individuals with 5-alpha reductase-2 deficiency or 17-beta-hydroxysteroid dehydrogenase-3 deficiency or in female-raised 46,XX individuals with classical congenital adrenal hyperplasia with prolonged periods of nonadherence to glucocorticoid replacement therapy.

However, the prenatal androgen milieu is more closely related to gendered behavior than to gender identity. Many individuals with DSDs and markedly gender-variant behavior do not develop gender dysphoria. Thus, gender-nonconforming behavior by itself should not be interpreted as an indicator of current or future gender dysphoria. There appears to be a higher rate of gender dysphoria and patient-initiated gender change from assigned female to male than from assigned male to female in individuals prenatally exposed to a full complement of masculinizing hormonal influences.

Culture-Related Diagnostic Issues

Individuals with gender dysphoria have been reported across many countries and cultural contexts around the world. The equivalent of gender dysphoria has also been reported in individuals living in cultural contexts with institutionalized gender identity categories other than men/boys or women/girls that sanction gender nonconforming development. These include India, Sri Lanka, Myanmar, Oman, Samoa, Thailand, and Indigenous Peoples of North America. It is unclear however, in such cultural contexts, whether the diagnostic criteria for gender dysphoria would be met with these individuals.

The prevalence of coexisting mental health problems differs among cultures; these differences may also be related to differences in attitudes toward gender nonconformity in children, adolescents, and adults. However, also in some non-Western cultures, anxiety has been found to be relatively common in individuals with gender dysphoria, even in cultures with accepting attitudes toward gender-variant behavior.

Sex- and Gender-Related Diagnostic Issues

Sex differences in rate of referrals to specialty clinics vary by age group. In children, sex ratios of individuals assigned male at birth to individuals assigned female at birth range from 1.25:1 to 4.3:1. Studies show increasing numbers of children and adolescents presenting to specialty clinics, presentation at younger ages, more frequent early social transition, and a shift to a greater number of individuals assigned female at birth in adolescents and young adults than individuals assigned male at birth. In adults, estimates generally suggest more individuals assigned male at birth seek gender-affirming treatment, with ratios ranging from 1:1 to 6.1:1 in most studies in the United States and Europe.

Association With Suicidal Thoughts or Behavior

Rates of suicidality and suicide attempts for transgender individuals are reported to range from 30% to 80%, with risk factors including past maltreatment, gender victimization, depression, substance abuse, and younger age. Transgender adolescents referred to gender clinics have substantially higher rates of suicidal thoughts and behaviors when compared with nonreferred adolescents. Prior to receiving gender-affirming treatment and legal gender reassignment, adolescents and adults with gender dysphoria are at increased risk for suicidal thoughts and suicide attempts. After gender-affirming treatment, adjustment varies, and while improvement in coexisting symptoms is often seen, some individuals continue to experience prominent anxiety and affective symptoms and remain at increased risk for suicide.

A study of 572 children referred for gender identity concerns in Canada and several comparison groups (siblings, other referred children, and nonreferred children) largely from other high-income countries found that gender-referred children were 8.6 times more likely to self-harm or attempt suicide than comparison children, even after adjustment for overall behavior and peer relationship problems, and particularly in the second half of childhood. Among adolescents, the highest rate of suicide attempt is among transgender young men, followed by those defining themselves as neither male nor female.

Functional Consequences of Gender Dysphoria

Gender nonconformity may appear at all ages after the first 2–3 years of childhood and may interfere with daily activities. In older children, gender nonconformity may affect peer relationships and may lead to

isolation from peer groups and to distress. Many children experience teasing and harassment or pressure to dress in attire associated with their birth-assigned sex, especially when growing up in a nonsupportive and nonaccepting environment. Also in adolescents and adults, the distress resulting from gender incongruence often interferes with daily activities. Relationship difficulties, including sexual relationship problems, are common, and functioning at school or at work may be impaired. Gender dysphoria is associated with high levels of stigmatization, discrimination, and victimization, leading to negative self-concept, increased rates of depression, suicidality, and other mental disorder co-occurrence, school dropout, and economic marginalization, including unemployment, with attendant social and mental health risks, especially in individuals who lack family or social support. In addition, these individuals' access to health services and mental health services may be impeded by structural barriers, such as institutional discomfort about, inexperience with, or hostility toward working with this patient population.

Differential Diagnosis

Nonconformity to gender roles. Gender dysphoria should be distinguished from simple nonconformity to stereotypical gender role behavior by the strong desire to be of another gender than the assigned one and by the extent and pervasiveness of gender-variant activities and interests. The diagnosis is not meant to merely describe nonconformity to stereotypical gender role behavior (e.g., "tomboyism" in girls, "girly-boy" behavior in boys, occasional cross-dressing in adult men). Given the increased openness of gender-diverse expressions by individuals across the entire range of the transgender spectrum, it is important that the clinical diagnosis be limited to those individuals whose distress and impairment meet the specified criteria.

Transvestic disorder. Transvestic disorder is diagnosed in heterosexual (or bisexual) adolescent and adult males (rarely in females) for whom women's clothing generates sexual excitement and causes distress and/or impairment without drawing their assigned gender into question. It is occasionally accompanied by gender dysphoria. An individual with transvestic disorder who also has clinically significant gender dysphoria can be given both diagnoses. In some cases of postpubertal-onset gender dysphoria in individuals assigned male at birth who are attracted to women, cross-dressing with sexual excitement is a precursor to the diagnosis of gender dysphoria.

Body dysmorphic disorder. An individual with body dysmorphic disorder focuses on the alteration or removal of a specific body part because it is perceived as abnormally formed, not because it represents a repudiated assigned gender. When an individual's presentation meets criteria for both gender dysphoria and body dysmorphic disorder, both diagnoses can be given. Individuals wishing to have a healthy limb amputated (termed by some *body integrity identity disorder*) because it makes them feel more "complete" usually do not wish to change gender, but rather desire to live as an amputee or a disabled person.

Autism spectrum disorder. In individuals with autism spectrum disorder, diagnosing gender dysphoria can be challenging. It can be difficult to differentiate potential co-occurring

gender dysphoria from an autistic preoccupation because of the concrete and rigid thinking around gender roles and/or poor understanding of social relationships characteristic of autism spectrum disorder.

Schizophrenia and other psychotic disorders. In schizophrenia, there may rarely be delusions of belonging to some other gender. In the absence of psychotic symptoms, insistence by an individual with gender dysphoria that he or she is another gender is not considered a delusion. Schizophrenia (or other psychotic disorders) and gender dysphoria may co-occur. Gender-themed delusions may occur in up to 20% of individuals with schizophrenia. They can usually be differentiated from gender dysphoria by their bizarre content and by waxing and waning with remissions and exacerbations of psychotic episodes.

Other clinical presentations. Some individuals with an emasculinization desire who develop an alternative, nonmale/nonfemale gender identity do have a presentation that meets criteria for gender

dysphoria. However, some males seek genital surgery for either aesthetic reasons or to remove psychological effects of androgens without changing male identity; in these cases, the criteria for gender dysphoria are not met.

Comorbidity

Clinically referred children with gender dysphoria show elevated levels of anxiety, disruptive, impulse-control, and depressive disorders. Autism spectrum disorder is more prevalent in clinically referred adolescents and adults with gender dysphoria than in the general population. Clinically referred adolescents and adults with gender dysphoria often have high rates of associated mental disorders, with anxiety and depressive disorders being the most common. Individuals who have experienced harassment and violence may also develop posttraumatic stress disorder.

Other Specified Gender Dysphoria

F64.8

This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The other specified gender dysphoria category is used in situations in which the clinician chooses to communicate the specific reason that the presentation does not meet the criteria for gender dysphoria. This is done by recording “other specified gender dysphoria” followed by the specific reason (e.g., “brief gender dysphoria,” in which symptoms meet full criteria for gender dysphoria but the duration is less than the required 6 months).

Unspecified Gender Dysphoria

F64.9

This category applies to presentations in which symptoms characteristic of gender dysphoria that cause clinically significant distress or impairment in social, occupational, or other important areas of functioning predominate but do not meet the full criteria for gender dysphoria. The unspecified gender dysphoria category is used in situations in which the clinician chooses *not* to specify the reason that the criteria are not met for gender dysphoria, and includes presentations in which there is insufficient information to make a more specific diagnosis.

Guidelines for Psychological Practice With Transgender and Gender Nonconforming People

American Psychological Association

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Transgender and gender nonconforming[1] (TGNC) people are those who have a gender identity that is not fully aligned with their sex assigned at birth. The existence of TGNC people has been documented in a range of historical cultures (Coleman, Colgan, & Gooren, 1992; Feinberg, 1996; Miller & Nichols, 2012; Schmidt, 2003). Current population estimates of TGNC people have ranged from 0.17 to 1,333 per 100,000 (Meier & Labuski, 2013). The Massachusetts Behavioral Risk Factor Surveillance Survey found 0.5% of the adult population aged 18 to 64 years identified as TGNC between 2009 and 2011 (Conron, Scott, Stowell, & Landers, 2012). However, population estimates likely underreport the true number of TGNC people, given difficulties in collecting comprehensive demographic information about this group (Meier & Labuski, 2013). Within the last two decades, there has been a significant increase in research about TGNC people. This increase in knowledge, informed by the TGNC community, has resulted in the development of progressively more trans-affirmative practice across the multiple health disciplines involved in the care of TGNC people (Bockting, Knudson, & Goldberg, 2006; Coleman et al., 2012). Research has documented the extensive experiences of stigma and discrimination reported by TGNC people (Grant et al., 2011) and the mental health consequences of these experiences across the life span (Bockting, Miner, Swinburne Romine, Hamilton, & Coleman, 2013), including increased rates of depression (Fredriksen-Goldsen et al., 2014) and suicidality (Clements-Nolle, Marx, & Katz, 2006). TGNC people's lack of access to trans-affirmative mental and physical health care is a common barrier (Fredriksen-Goldsen et al., 2014; Garofalo, Deleon, Osmer, Doll, & Harper, 2006; Grossman & D'Augelli, 2006), with TGNC people sometimes being denied care because of their gender identity (Xavier et al., 2012).

In 2009, the American Psychological Association (APA) Task Force on Gender Identity and Gender Variance (TFGIGV) survey found that less than 30% of psychologist and graduate student participants reported familiarity with issues that TGNC people experience (APA TFGIGV, 2009). Psychologists and other mental health professionals who have limited training and experience in TGNC-affirmative care may cause harm to TGNC people (Mikalson, Pardo, & Green, 2012; Xavier et al., 2012). The significant level of societal stigma and discrimination that TGNC people face, the associated mental health consequences, and psychologists' lack of familiarity with trans-affirmative care led the APA Task Force to recommend that psychological practice guidelines be developed to help psychologists maximize the effectiveness of services offered and avoid harm when working with TGNC people and their families.

Purpose

The purpose of the *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People* (hereafter *Guidelines*) is to assist psychologists in the provision of culturally competent, developmentally appropriate, and trans-affirmative psychological practice with TGNC people. Trans-affirmative practice is the provision

The American Psychological Association's (APA's) Task Force on Guidelines for Psychological Practice with Transgender and Gender Nonconforming People developed these guidelines. lore m. dickey, Louisiana Tech University, and Anneliese A. Singh, The University of Georgia, served as chairs of the Task Force. The members of the Task Force included Walter O. Bockting, Columbia University; Sand Chang, Independent Practice; Kelly Ducheny, Howard Brown Health Center; Laura Edwards-Leeper, Pacific University; Randall D. Ehrbar, Whitman Walker Health Center; Max Fuentes Fuhrmann, Independent Practice; Michael L. Hendricks, Washington Psychological Center, P.C.; and Ellen Magalhaes, Center for Psychological Studies at Nova Southeastern University and California School of Professional Psychology at Alliant International University.

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This document will expire as APA policy in 2022. After this date, users should contact the APA Public Interest Directorate to determine whether the guidelines in this document remain in effect as APA policy.

Correspondence concerning this article should be addressed to the Public Interest Directorate, American Psychological Association, 750 First Street, NE, Washington, DC 20002.

[1] For the purposes of these guidelines, we use the term *transgender and gender nonconforming* (TGNC). We intend for the term to be as broadly inclusive as possible, and recognize that some TGNC people do not ascribe to these terms. Readers are referred to Appendix A for a listing of terms that include various TGNC identity labels.

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of care that is respectful, aware, and supportive of the identities and life experiences of TGNC people (Korell & Lorah, 2007). The *Guidelines* are an introductory resource for psychologists who will encounter TGNC people in their practice, but can also be useful for psychologists with expertise in this area of practice to improve the care already offered to TGNC people. The *Guidelines* include a set of definitions for readers who may be less familiar with language used when discussing gender identity and TGNC populations (see Appendix A). Distinct from TGNC, the term "cisgender" is used to refer to people whose sex assigned at birth is aligned with their gender identity (E. R. Green, 2006; Serano, 2006).

Given the added complexity of working with TGNC and gender-questioning youth[2] and the limitations of the available research, the *Guidelines* focus primarily, though not exclusively, on TGNC adults. Future revisions of the *Guidelines* will deepen a focus on TGNC and gender-questioning children and adolescents. The *Guidelines* address the strengths of TGNC people, the challenges they face, ethical and legal issues, life span considerations, research, education, training, and health care. Because issues of gender identity are often conflated with issues of gender expression or sexual orientation, psychological practice with the TGNC population warrants the acquisition of specific knowledge about concerns unique to TGNC people that are not addressed by other practice guidelines (APA, 2012). It is important to note that these *Guidelines* are not intended to address some of the conflicts that cisgender people may experience due to societal expectations regarding gender roles (Butler, 1990), nor are they intended to address intersex people (Dreger, 1999; Preves, 2003).

Documentation of Need

In 2005, the APA Council of Representatives authorized the creation of the Task Force on Gender Identity and Gender Variance (TFGIGV), charging the Task Force to review APA policies related to TGNC people and to offer recommendations for APA to best meet the needs of TGNC people (APA TFGIGV, 2009). In 2009, the APA Council of Representatives adopted the Resolution on Transgender, Gender Identity, & Gender Expression Non-Discrimination, which calls upon psychologists in their professional roles to provide appropriate, nondiscriminatory treatment; encourages psychologists to take a leadership role in working against discrimination; supports the provision of adequate and necessary mental and medical health care; recognizes the efficacy, benefit, and medical necessity of gender transition; supports access to appropriate treatment in institutional settings; and supports the creation of educational resources for all psychologists (Anton, 2009). In 2009, in an extensive report on the current state of psychological practice with TGNC people, the TFGIGV determined that there was sufficient knowledge and expertise in the field to warrant the development of practice guidelines for TGNC populations (APA TFGIGV, 2009). The report identified that TGNC people constituted a population with unique needs and that the creation of practice guidelines would be a valuable resource for the field (APA TFGIGV, 2009). Psychologists' relative lack of knowledge about TGNC people and trans-affirmative care, the level of societal stigma and discrimination that TGNC people face, and the significant mental health consequences that TGNC people experience as a result offer a compelling need for psychological practice guidelines for this population.

Users

The intended audience for these *Guidelines* includes psychologists who provide clinical care, conduct research, or provide education or training. Given that gender identity issues can arise at any stage in a TGNC person's life (Lev, 2004), clinicians can encounter a TGNC person in practice or have a client's presenting problem evolve into an issue related to gender identity and gender expression. Researchers, educators, and trainers will benefit from use of these *Guidelines* to inform their work, even when not specifically focused on TGNC populations. Psychologists who focus on TGNC populations in their clinical practice, research, or educational and training activities will also benefit from the use of these *Guidelines*.

Distinction Between Standards and Guidelines

When using these *Guidelines*, psychologists should be aware that APA has made an important distinction between *standards* and *guidelines* (Reed, McLaughlin, & Newman, 2002). Standards are mandates to which all psychologists must adhere (e.g., the *Ethical Principles of Psychologists and Code of Conduct*; APA, 2010), whereas guidelines are aspirational. Psychologists are encouraged to use these *Guidelines* in tandem with the *Ethical Principles of Psychologists and Code of Conduct*, and should be aware that state and federal laws may override these *Guidelines* (APA, 2010).

In addition, these *Guidelines* refer to psychological practice (e.g., clinical work, consultation, education, research, and training) rather than treatment. Practice guidelines are practitioner-focused and provide guidance for professionals regarding "conduct and the issues to be considered in particular areas of clinical practice" (Reed et al., 2002, p. 1044). Treatment guidelines are client-focused and address intervention-specific recommendations for a clinical population or condition (Reed et al., 2002). The current *Guidelines* are intended to complement treatment guidelines for TGNC people seeking mental health services, such as those set forth by the World Professional Association for Transgender Health Standards of Care (Coleman et al., 2012) and the Endocrine Society (Hembree et al., 2009).

[2] For the purposes of these guidelines, "youth" refers to both children and adolescents under the age of 18.

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Compatibility

These *Guidelines* are consistent with the APA *Ethical Principles of Psychologists and Code of Conduct* (APA, 2010), the *Standards of Accreditation for Health Service Psychology* (APA, 2015), the APA TFGIGV (2009) report, and the APA Council of Representatives Resolution on Transgender, Gender Identity, & Gender Expression Non-Discrimination (Anton, 2009).

Practice Guidelines Development Process

To address one of the recommendations of the APA TFGIGV (2009), the APA Committee on Sexual Orientation and Gender Diversity (CSOGD; then the Committee on Lesbian, Gay, Bisexual, and Transgender Concerns) and Division 44 (the Society for the Psychological Study of Lesbian, Gay, Bisexual and Transgender Issues) initiated a joint Task Force on Psychological Practice Guidelines with Transgender and Gender Nonconforming People in 2011. Task Force members were selected through an application and review process conducted by the leadership of CSOGD and Division 44. The Task Force included 10 members who had substantial psychological practice expertise with TGNC people. Of the 10 task force members, five individuals identified as TGNC with a range of gender identities and five identified as cisgender. In terms of race/ethnicity, six of the task force members identified as White and four identified as people of color (one Indian American, one Chinese American, one Latina American, and one mixed race).

The Task Force conducted a comprehensive review of the extant scholarship, identified content most pertinent to the practice of psychology with TGNC people, and evaluated the level of evidence to support guidance within each guideline. To ensure the accuracy and comprehensiveness of these *Guidelines*, Task Force members met with TGNC community members and groups and consulted with subject matter experts within and outside of psychology. When the Task Force discovered a lack of professional consensus, every effort was made to include divergent opinions in the field relevant to that issue. When this occurred, the Task Force described the various approaches documented in the literature. Additionally, these *Guidelines* were informed by comments received at multiple presentations held at professional conferences and comments obtained through two cycles of open public comment on earlier *Guideline* drafts.

This document contains 16 guidelines for TGNC psychological practice. Each guideline includes a Rationale section, which reviews relevant scholarship supporting the need for the guideline, and an Application section, which describes how the particular guideline may be applied in psychological practice. The *Guidelines* are organized into five clusters: (a) foundational knowledge and awareness; (b) stigma, discrimination, and barriers to care; (c) life span development; (d) assessment, therapy, and intervention; and (e) research, education, and training.

Funding for this project was provided by Division 44 (Society for the Psychological Study of LGBT Issues); the APA Office on Lesbian, Gay, Bisexual, and Transgender (LGBT) Concerns; a grant from the Committee on Division/APA Relations (CODAPAR); and donations from Randall Ehrbar and Pamela St. Amand. Some members of the Task Force have received compensation through presentations (e.g., honoraria) or royalties (e.g., book contracts) based in part on information contained in these *Guidelines*.

Selection of Evidence

Although the number of publications on the topic of TGNC-affirmative practice has been increasing, this is still an emerging area of scholarly literature and research. When possible, the Task Force relied on peer-reviewed publications, but books, chapters, and reports that do not typically receive a high level of peer review have also been cited when appropriate. These sources are from a diverse range of fields addressing mental health, including psychology, counseling, social work, and psychiatry. Some studies of TGNC people utilize small sample sizes, which limits the generalizability of results. Few studies of TGNC people utilize probability samples or randomized control groups (e.g., Conron et al., 2012; Dhejne et al., 2011). As a result, the Task Force relied primarily on studies using convenience samples, which limits the generalizability of results to the population as a whole, but can be adequate for describing issues and situations that arise within the population.

Foundational Knowledge and Awareness

Guideline 1. Psychologists understand that gender is a nonbinary construct that allows for a range of gender identities and that a person's gender identity may not align with sex assigned at birth.

Rationale. Gender identity is defined as a person's deeply felt, inherent sense of being a girl, woman, or female; a boy, a man, or male; a blend of male or female; or an alternative gender (Bethea & McCollum, 2013; Institute of Medicine [IOM], 2011). In many cultures and religious traditions, gender has been perceived as a binary construct, with mutually exclusive categories of male or female, boy or girl, man or woman (Benjamin, 1966; Mollenkott, 2001; Tanis, 2003). These mutually exclusive categories include an assumption that gender identity is always in alignment with sex assigned at birth (Bethea & McCollum, 2013). For TGNC people, gender identity differs from sex assigned at birth to varying degrees, and may be experienced and expressed outside of the gender binary (Harrison, Grant, & Herman, 2012; Kuper, Nussbaum, & Mustanski, 2012).

Gender as a nonbinary construct has been described and studied for decades (Benjamin, 1966; Herdt, 1994; Kulick, 1998). There is historical evidence of recognition, societal acceptance, and sometimes reverence of diversity in gender identity and gender expression in several different cultures (Coleman et al., 1992; Feinberg, 1996; Miller

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& Nichols, 2012; Schmidt, 2003). Many cultures in which gender nonconforming persons and groups were visible were diminished by westernization, colonialism, and systemic inequity (Nanda, 1999). In the 20th century, TGNC expression became medicalized (Hirschfeld, 1910/1991), and medical interventions to treat discordance between a person's sex assigned at birth, secondary sex characteristics, and gender identity became available (Meyerowitz, 2002).

As early as the 1950s, research found variability in how an individual described their[3] gender, with some participants reporting a gender identity different from the culturally defined, mutually exclusive categories of "man" or "woman" (Benjamin, 1966). In several recent large online studies of the TGNC population in the United States, 30% to 40% of participants identified their gender identity as other than man or woman (Harrison et al., 2012; Kuper et al., 2012). Although some studies have cultivated a broader understanding of gender (Conron, Scout, & Austin, 2008), the majority of research has required a forced choice between man and woman, thus failing to represent or depict those with different gender identities (IOM, 2011). Research over the last two decades has demonstrated the existence of a wide spectrum of gender identity and gender expression (Bockting, 2008; Harrison et al., 2012; Kuper et al., 2012), which includes people who identify as either man or woman, neither man nor woman, a blend of man and woman, or a unique gender identity. A person's identification as TGNC can be healthy and self-affirming, and is not inherently pathological (Coleman et al., 2012). However, people may experience distress associated with discordance between their gender identity and their body or sex assigned at birth, as well as societal stigma and discrimination (Coleman et al., 2012).

Between the late 1960s and the early 1990s, health care to alleviate gender dysphoria largely reinforced a binary conceptualization of gender (APA TFGIGV, 2009; Bolin, 1994; Hastings, 1974). At that time, it was considered an ideal outcome for TGNC people to conform to an identity that aligned with either sex assigned at birth or, if not possible, with the "opposite" sex, with a heavy emphasis on blending into the cisgender population or "passing" (APA TFGIGV, 2009; Bolin, 1994; Hastings, 1974). Variance from these options could raise concern for health care providers about a TGNC person's ability to transition successfully. These concerns could act as a barrier to accessing surgery or hormone therapy because medical and mental health care provider endorsement was required before surgery or hormones could be accessed (Berger et al., 1979). Largely because of self-advocacy of TGNC individuals and communities in the 1990s, combined with advances in research and models of trans-affirmative care, there is greater recognition and acknowledgment of a spectrum of gender diversity and corresponding individualized, TGNC-specific health care (Bockting et al., 2006; Coleman et al., 2012).

Application. A nonbinary understanding of gender is fundamental to the provision of affirmative care for TGNC people. Psychologists are encouraged to adapt or modify their understanding of gender, broadening the range of variation viewed as healthy and normative. By understanding the spectrum of gender identities and gender expressions that exist, and that a person's gender identity may not be in full alignment with sex assigned at birth, psychologists can increase their capacity to assist TGNC people, their families, and their communities (Lev, 2004). Respecting and supporting TGNC people in authentically articulating their gender identity and gender expression, as well as their lived experience, can improve TGNC people's health, well-being, and quality of life (Witten, 2003).

Some TGNC people may have limited access to visible, positive TGNC role models. As a result, many TGNC people are isolated and must cope with the stigma of gender nonconformity without guidance or support, worsening the negative effect of stigma on mental health (Fredriksen-Goldsen et al., 2014; Singh, Hays, & Watson, 2011). Psychologists may assist TGNC people in challenging gender norms and stereotypes, and in exploring their unique gender identity and gender expression. TGNC people, partners, families, friends, and communities can benefit from education about the healthy variation of gender identity and gender expression, and the incorrect assumption that gender identity automatically aligns with sex assigned at birth.

Psychologists may model an acceptance of ambiguity as TGNC people develop and explore aspects of their gender, especially in childhood and adolescence. A nonjudgmental stance toward gender nonconformity can help to counteract the pervasive stigma faced by many TGNC people and provide a safe environment to explore gender identity and make informed decisions about gender expression.

Guideline 2. Psychologists understand that gender identity and sexual orientation are distinct but interrelated constructs.

Rationale. The constructs of gender identity and sexual orientation are theoretically and clinically distinct, even though professionals and nonprofessionals frequently conflate them. Although some research suggests a potential link in the development of gender identity and sexual orientation, the mechanisms of such a relationship are unknown (Adelson & American Academy of Child and Adolescent Psychiatry [AACAP] Committee on Quality Issues [CQI], 2012; APA TFGIGV, 2009; A. H. Devor, 2004; Drescher & Byne, 2013). *Sexual orientation* is defined as a person's sexual and/or emotional attraction to another person (Shively & De Cecco, 1977), compared with *gender identity*, which is defined by a person's felt, inherent sense of gender. For most people, gender identity develops earlier than sexual orientation. Gender identity is often established in young toddlerhood (Adelson & AACAP CQI, 2012; Kohlberg, 1966), compared with aware-

[3] The third person plural pronouns "they," "them," and "their" in some instances function in these guidelines as third-person singular pronouns to model a common technique used to avoid the use of gendered pronouns when speaking to or about TGNC people.

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ness of same-sex attraction, which often emerges in early adolescence (Adelson & AACAP CQI, 2012; D'Augelli & Hershberger, 1993; Herdt & Boxer, 1993; Ryan, 2009; Savin-Williams & Diamond, 2000). Although gender identity is usually established in childhood, individuals may become aware that their gender identity is not in full alignment with sex assigned at birth in childhood, adolescence, or adulthood. The developmental pathway of gender identity typically includes a progression through multiple stages of awareness, exploration, expression, and identity integration (Bockting & Coleman, 2007; A. H. Devor, 2004; Vanderburgh, 2007). Similarly, a person's sexual orientation may progress through multiple stages of awareness, exploration, and identity through adolescence and into adulthood (Bilodeau & Renn, 2005). Just as some people experience their sexual orientation as being fluid or variable (L. M. Diamond, 2013), some people also experience their gender identity as fluid (Lev, 2004).

The experience of questioning one's gender can create significant confusion for some TGNC people, especially for those who are unfamiliar with the range of gender identities that exist. To explain any discordance they may experience between their sex assigned at birth, related societal expectations, patterns of sexual and romantic attraction, and/or gender role nonconformity and gender identity, some TGNC people may assume that they must be gay, lesbian, bisexual, or queer (Bockting, Benner, & Coleman, 2009). Focusing solely on sexual orientation as the cause for discordance may obscure awareness of a TGNC identity. It can be very important to include sexual orientation and gender identity in the process of identity exploration as well as in the associated decisions about which options will work best for any particular person. In addition, many TGNC adults have disguised or rejected their experience of gender incongruence in childhood or adolescence to conform to societal expectations and minimize their fear of difference (Bockting & Coleman, 2007; Byne et al., 2012).

Because gender and patterns of attraction are used to identify a person's sexual orientation, the articulation of sexual orientation is made more complex when sex assigned at birth is not aligned with gender identity. A person's sexual orientation identity cannot be determined by simply examining external appearance or behavior, but must incorporate a person's identity and self-identification (Broido, 2000).

Application. Psychologists may assist people in differentiating gender identity and sexual orientation. As clients become aware of previously hidden or constrained aspects of their gender identity or sexuality, psychologists may provide acceptance, support, and understanding without making assumptions or imposing a specific sexual orientation or gender identity outcome (APA TFGIGV, 2009). Because of their roles in assessment, treatment, and prevention, psychologists are in a unique position to help TGNC people better understand and integrate the various aspects of their identities. Psychologists may assist TGNC people by introducing and normalizing differences in gender identity and expression. As a TGNC person finds a comfortable way to actualize and express their gender identity, psychologists may notice that previously incongruent aspects of their sexual orientation may become more salient, better integrated, or increasingly egosyntonic (Bockting et al., 2009; H. Devor, 1993; Schleifer, 2006). This process may allow TGNC people the comfort and opportunity to explore attractions or aspects of their sexual orientation that previously had been repressed, hidden, or in conflict with their identity. TGNC people may experience a renewed exploration of their sexual orientation, a widened spectrum of attraction, or a shift in how they identify their sexual orientation in the context of a developing TGNC identity (Coleman, Bockting, & Gooren, 1993; Meier, Pardo, Labuski, & Babcock, 2013; Samons, 2008).

Psychologists may need to provide TGNC people with information about TGNC identities, offering language to describe the discordance and confusion TGNC people may be experiencing. To facilitate TGNC people's learning, psychologists may introduce some of the narratives written by TGNC people that reflect a range of outcomes and developmental processes in exploring and affirming gender identity (e.g., Bornstein & Bergman, 2010; Boylan, 2013; J. Green, 2004; Krieger, 2011; Lawrence, 2014). These resources may potentially aid TGNC people in distinguishing between issues of sexual orientation and gender identity and in locating themselves on the gender spectrum. Psychologists may also educate families and broader community systems (e.g., schools, medical systems) to better understand how gender identity and sexual orientation are different but related; this may be particularly useful when working with youth (Singh & Burnes, 2009; Whitman, 2013). Because gender identity and sexual orientation are often conflated, even by professionals, psychologists are encouraged to carefully examine resources that claim to provide affirmative services for lesbian, gay, bisexual, transgender, and queer (LGBTQ) people, and to confirm which are knowledgeable about and inclusive of the needs of TGNC people before offering referrals or recommendations to TGNC people and their families.

Guideline 3. Psychologists seek to understand how gender identity intersects with the other cultural identities of TGNC people.

Rationale. Gender identity and gender expression may have profound intersections with other aspects of identity (Collins, 2000; Warner, 2008). These aspects may include, but are not limited to, race/ethnicity, age, education, socioeconomic status, immigration status, occupation, disability status, HIV status, sexual orientation, relational status, and religion and/or spiritual affiliation. Whereas some of these aspects of identity may afford privilege, others may create stigma and hinder empowerment (Burnes & Chen, 2012; K. M. de Vries, 2015). In addition, TGNC people who transition may not be prepared for changes in privilege or societal treatment based on gender identity and gender expression. To illustrate, an African American trans man may gain male privilege, but may face racism and

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societal stigma particular to African American men. An Asian American/Pacific Islander trans woman may experience the benefit of being perceived as a cisgender woman, but may also experience sexism, misogyny, and objectification particular to Asian American/Pacific Islander cisgender women.

The intersection of multiple identities within TGNC people's lives is complex and may obstruct or facilitate access to necessary support (A. Daley, Solomon, Newman, & Mishna, 2008). TGNC people with less privilege and/or multiple oppressed identities may experience greater stress and restricted access to resources. They may also develop resilience and strength in coping with disadvantages, or may locate community-based resources available to specific groups (e.g., for people living with HIV; Singh et al., 2011). Gender identity affirmation may conflict with religious beliefs or traditions (Bockting & Cesaretti, 2001). Finding an affirmative expression of their religious and spiritual beliefs and traditions, including positive relationships with religious leaders, can be an important resource for TGNC people (Glaser, 2008; Porter, Ronneberg, & Witten, 2013; Xavier, 2000).

Application. In practice, psychologists strive to recognize the salient multiple and intersecting identities of TGNC people that influence coping, discrimination, and resilience (Burnes & Chen, 2012). Improved rapport and therapeutic alliance are likely to develop when psychologists avoid overemphasizing gender identity and gender expression when not directly relevant to TGNC people's needs and concerns. Even when gender identity is the main focus of care, psychologists are encouraged to understand that a TGNC person's experience of gender may also be shaped by other important aspects of identity (e.g., age, race/ethnicity, sexual orientation), and that the salience of different aspects of identity may evolve as the person continues psychosocial development across the life span, regardless of whether they complete a social or medical transition.

At times, a TGNC person's intersection of identities may result in conflict, such as a person's struggle to integrate gender identity with religious and/or spiritual upbringing and beliefs (Kidd & Witten, 2008; Levy & Lo, 2013; Rodriguez & Follins, 2012). Psychologists may aid TGNC people in understanding and integrating identities that may be differently privileged within systems of power and systemic inequity (Burnes & Chen, 2012). Psychologists may also highlight and strengthen the development of TGNC people's competencies and resilience as they learn to manage the intersection of stigmatized identities (Singh, 2012).

Guideline 4. Psychologists are aware of how their attitudes about and knowledge of gender identity and gender expression may affect the quality of care they provide to TGNC people and their families.

Rationale. Psychologists, like other members of society, come to their personal understanding and acceptance of different aspects of human diversity through a process of socialization. Psychologists' cultural biases, as well as the cultural differences between psychologists and their clients, have a clinical impact (Israel, Gorcheva, Burnes, & Walther, 2008; Vasquez, 2007). The assumptions, biases, and attitudes psychologists hold regarding TGNC people and gender identity and/or gender expression can affect the quality of services psychologists provide and their ability to develop an effective therapeutic alliance (Bess & Stabb, 2009; Rachlin, 2002). In addition, a lack of knowledge or training in providing affirmative care to TGNC people can limit a psychologist's effectiveness and perpetuate barriers to care (Bess & Stabb, 2009; Rachlin, 2002). Psychologists experienced with lesbian, gay, or bisexual (LGB) people may not be familiar with the unique needs of TGNC people (Israel, 2005; Israel et al., 2008). In community surveys, TGNC people have reported that many mental health care providers lack basic knowledge and skills relevant to care of TGNC people (Bradford, Xavier, Hendricks, Rives, & Honnold, 2007; Xavier, Bobbin, Singer, & Budd, 2005) and receive little training to prepare them to work with TGNC people (APA TFGIGV, 2009; Lurie, 2005). The National Transgender Discrimination Survey (Grant et al., 2011) reported that 50% of TGNC respondents shared that they had to educate their health care providers about TGNC care, 28% postponed seeking medical care due to antitrans bias, and 19% were refused care due to discrimination.

The APA ethics code (APA, 2010) specifies that psychologists practice in areas only within the boundaries of their competence (Standard 2.01), participate in proactive and consistent ways to enhance their competence (Standard 2.03), and base their work upon established scientific and professional knowledge (Standard 2.04). Competence in working with TGNC people can be developed through a range of activities, such as education, training, supervised experience, consultation, study, or professional experience.

Application. Psychologists may engage in practice with TGNC people in various ways; therefore, the depth and level of knowledge and competence required by a psychologist depends on the type and complexity of service offered to TGNC people. Services that psychologists provide to TGNC people require a basic understanding of the population and its needs, as well as the ability to respectfully interact in a trans-affirmative manner (L. Carroll, 2010).

APA emphasizes the use of evidence-based practice (APA Presidential Task Force on Evidence-Based Practice, 2006). Given how easily assumptions or stereotypes could influence treatment, evidence-based practice may be especially relevant to psychological practice with TGNC people. Until evidence-based practices are developed specifically for TGNC people, psychologists are encouraged to utilize existing evidence-based practices in the care they provide. APA also promotes collaboration with clients concerning clinical decisions, including issues related to costs, potential benefits, and the existing options and resources related to treatment (APA Presidential Task Force on Evidence-Based Practice, 2006). TGNC people could benefit from such collaboration and active engagement in decision

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making, given the historical disenfranchisement and disempowerment of TGNC people in health care.

In an effort to develop competence in working with TGNC people, psychologists are encouraged to examine their personal beliefs regarding gender and sexuality, gender stereotypes, and TGNC identities, in addition to identifying gaps in their own knowledge, understanding, and acceptance (American Counseling Association [ACA], 2010). This examination may include exploring one's own gender identity and gendered experiences related to privilege, power, or marginalization, as well as seeking consultation and training with psychologists who have expertise in working with TGNC people and communities.

Psychologists are further encouraged to develop competence in working with TGNC people and their families by seeking up-to-date basic knowledge and understanding of gender identity and expression, and learning how to interact with TGNC people and their families respectfully and without judgment. Competence in working with TGNC people may be achieved and maintained in formal and informal ways, ranging from exposure in the curriculum of training programs for future psychologists and continuing education at professional conferences, to affirmative involvement as allies in the TGNC community. Beyond acquiring general competence, psychologists who choose to specialize in working with TGNC people presenting with gender-identity-related concerns are strongly encouraged to obtain advanced training, consultation, and professional experience (ACA, 2010; Coleman et al., 2012).

Psychologists may gain knowledge about the TGNC community and become more familiar with the complex social issues that affect the lives of TGNC people through first-hand experiences (e.g., attending community meetings and conferences, reading narratives written by TGNC people). If psychologists have not yet developed competence in working with TGNC people, it is recommended that they refer TGNC people to other psychologists or providers who are knowledgeable and able to provide trans-affirmative care.

Stigma, Discrimination, and Barriers to Care

Guideline 5. Psychologists recognize how stigma, prejudice, discrimination, and violence affect the health and well-being of TGNC people.

Rationale. Many TGNC people experience discrimination, ranging from subtle to severe, when accessing housing, health care, employment, education, public assistance, and other social services (Bazargan & Galvan, 2012; Bradford, Reisner, Honnold, & Xavier, 2013; Dispenza, Watson, Chung, & Brack, 2012; Grant et al., 2011). Discrimination can include assuming a person's assigned sex at birth is fully aligned with that person's gender identity, not using a person's preferred name or pronoun, asking TGNC people inappropriate questions about their bodies, or making the assumption that psychopathology exists given a specific gender identity or gender expression (Nadal, Rivera, & Corpus, 2010; Nadal, Skolnik, & Wong, 2012). Discrimination may also include refusing access to housing or employment or extreme acts of violence (e.g., sexual assault, murder). TGNC people who hold multiple marginalized identities are more vulnerable to discrimination and violence. TGNC women and people of color disproportionately experience severe forms of violence and discrimination, including police violence, and are less likely to receive help from law enforcement (Edelman, 2011; National Coalition of Anti-Violence Programs, 2011; Saffin, 2011).

TGNC people are at risk of experiencing antitrans prejudice and discrimination in educational settings. In a national representative sample of 7,898 LGBT youth in K-12 settings, 55.2% of participants reported verbal harassment, 22.7% reported physical harassment, and 11.4% reported physical assault based on their gender expression (Kosciw, Greytak, Palmer, & Boesen, 2014). In a national community survey of TGNC adults, 15% reported prematurely leaving educational settings ranging from kindergarten through college as a result of harassment (Grant et al., 2011). Many schools do not include gender identity and gender expression in their school nondiscrimination policies; this leaves TGNC youth without needed protections from bullying and aggression in schools (Singh & Jackson, 2012). TGNC youth in rural settings may be even more vulnerable to bullying and hostility in their school environments due to antitrans prejudice (Kosciw et al., 2014).

Inequities in educational settings and other forms of TGNC-related discrimination may contribute to the significant economic disparities TGNC people have reported. Grant and colleagues (2011) found that TGNC people were four times more likely to have a household income of less than $10,000 compared with cisgender people, and almost half of a sample of TGNC older adults reported a household income at or below 200% of poverty (Fredriksen-Goldsen et al., 2014). TGNC people often face workplace discrimination both when seeking and maintaining employment (Brewster, Velez, Mennicke, & Tebbe, 2014; Dispenza et al., 2012; Mizock & Mueser, 2014). In a nonrepresentative national study of TGNC people, 90% reported having "directly experienced harassment or mistreatment at work and felt forced to take protective actions that negatively impacted their careers or their well-being, such as hiding who they were to avoid workplace repercussions" (Grant et al., 2011, p. 56). In addition, 78% of respondents reported experiencing some kind of direct mistreatment or discrimination at work (Grant et al., 2011). Employment discrimination may be related to stigma based on a TGNC person's appearance, discrepancies in identity documentation, or being unable to provide job references linked to that person's pretransition name or gender presentation (Bender-Baird, 2011).

Issues of employment discrimination and workplace harassment are particularly salient for TGNC military personnel and veterans. Currently, TGNC people cannot serve openly in the U.S. military. Military regulations cite "transsexualism" as a medical exclusion from service (Department of Defense, 2011; Elders & Steinman, 2014). When

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enlisted, TGNC military personnel are faced with very difficult decisions related to coming out, transition, and seeking appropriate medical and mental health care, which may significantly impact or end their military careers. Not surprisingly, research documents very high rates of suicidal ideation and behavior among TGNC military and veteran populations (Blosnich et al., 2013; Matarazzo et al., 2014). Being open about their TGNC identity with health care providers can carry risk for TGNC military personnel (OutServe-Servicemembers Legal Defense Network, n.d.). Barriers to accessing health care noted by TGNC veterans include viewing the VA health care system as an extension of the military, perceiving the VA as an unwelcoming environment, and fearing providers' negative reactions to their identity (Sherman, Kauth, Shipherd, & Street, 2014; Shipherd, Mizock, Maguen, & Green, 2012). A recent study shows 28% of LGBT veterans perceived their VA as welcoming and one third as unwelcoming (Sherman et al., 2014). Multiple initiatives are underway throughout the VA system to improve the quality and sensitivity of services to LGBT veterans.

Given widespread workplace discrimination and possible dismissal following transition, TGNC people may engage in sex work or survival sex (e.g., trading sex for food), or sell drugs to generate income (Grant et al., 2011; Hwahng & Nuttbrock, 2007; Operario, Soma, & Underhill, 2008; Stanley, 2011). This increases the potential for negative interactions with the legal system, such as harassment by the police, bribery, extortion, and arrest (Edelman, 2011; Testa et al., 2012), as well as increased likelihood of mental health symptoms and greater health risks, such as higher incidence of sexually transmitted infections, including HIV (Nemoto, Operario, Keatley, & Villegas, 2004).

Incarcerated TGNC people report harassment, isolation, forced sex, and physical assault, both by prison personnel and other inmates (American Civil Liberties Union National Prison Project, 2005; Brotheim, 2013; C. Daley, 2005). In sex-segregated facilities, TGNC people may be subjected to involuntary solitary confinement (also called "administrative segregation"), which can lead to severe negative mental and physical health consequences and may block access to services (Gallagher, 2014; National Center for Transgender Equality, 2012). Another area of concern is for TGNC immigrants and refugees. TGNC people in detention centers may not be granted access to necessary care and experience significant rates of assault and violence in these facilities (Gruberg, 2013). TGNC people may seek asylum in the United States to escape danger as a direct result of lack of protections in their country of origin (APA Presidential Task Force on Immigration, 2012; Cerezo, Morales, Quintero, & Rothman, 2014; Morales, 2013).

TGNC people have difficulty accessing necessary health care (Fredriksen-Goldsen et al., 2014; Lambda Legal, 2012) and often feel unsafe sharing their gender identity or their experiences of antitrans prejudice and discrimination due to historical and current discrimination from health care providers (Grant et al., 2011; Lurie, 2005; Singh & McKleroy, 2011). Even when TGNC people have health insurance, plans may explicitly exclude coverage related to gender transition (e.g., hormone therapy, surgery). TGNC people may also have difficulty accessing trans-affirmative primary health care if coverage for procedures is denied based on gender. For example, trans men may be excluded from necessary gynecological care based on the assumption that men do not need these services. These barriers often lead to a lack of preventive health care for TGNC people (Fredriksen-Goldsen et al., 2014; Lambda Legal, 2012). Although the landscape is beginning to change with the recent revision of Medicare policy (National Center for Transgender Equality, 2014) and changes to state laws (Transgender Law Center, n.d.), many TGNC people are still likely to have little to no access to TGNC-related health care as a result of the exclusions in their insurance.

Application. Awareness of and sensitivity to the effects of antitrans prejudice and discrimination can assist psychologists in assessing, treating, and advocating for their TGNC clients. When a TGNC person faces discrimination based on gender identity or gender expression, psychologists may facilitate emotional processing of these experiences and work with the person to identify supportive resources and possible courses of action. Specific needs of TGNC people might vary from developing self-advocacy strategies, to navigating public spaces, to seeking legal recourse for harassment and discrimination in social services and other systems. Additionally, TGNC people who have been traumatized by physical or emotional violence may need therapeutic support.

Psychologists may be able to assist TGNC people in accessing relevant social service systems. For example, psychologists may be able to assist in identifying health care providers and housing resources that are affirming and affordable, or locating affirming religious and spiritual communities (Glaser, 2008; Porter et al., 2013). Psychologists may also assist in furnishing documentation or official correspondence that affirms gender identity for the purpose of accessing appropriate public accommodations, such as bathroom use or housing (Lev, 2009; W. J. Meyer, 2009).

Additionally, psychologists may identify appropriate resources, information, and services to help TGNC people in addressing workplace discrimination, including strategies during a social and/or medical transition for identity disclosure at work. For those who are seeking employment, psychologists may help strategize about how and whether to share information about gender history. Psychologists may also work with employers to develop supportive policies for workplace gender transition or to develop training to help employees adjust to the transition of a coworker.

For TGNC military and veteran populations, psychologists may help to address the emotional impact of navigating TGNC identity development in the military system. Psychologists are encouraged to be aware that issues of confidentiality may be particularly sensitive with active duty or reserve status service members, as the consequences of being identified as TGNC may prevent the client's disclosure of gender identity in treatment.

In educational settings, psychologists may advocate for TGNC youth on a number of levels (APA & National

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Association of School Psychologists, 2014; Boulder Valley School District, 2012). Psychologists may consult with administrators, teachers, and school counselors to provide resources and trainings on antitrans prejudice and developing safer school environments for TGNC students (Singh & Burnes, 2009). Peer support from other TGNC people has been shown to buffer the negative effect of stigma on mental health (Bockting et al., 2013). As such, psychologists may consider and develop peer-based interventions to facilitate greater understanding and respectful treatment of TGNC youth by cisgender peers (Case & Meier, 2014). Psychologists may work with TGNC youth and their families to identify relevant resources, such as school policies that protect gender identity and gender expression (APA & National Association of School Psychologists, 2014; Gonzalez & McNulty, 2010), referrals to TGNC-affirmative organizations, and online resources, which may be especially helpful for TGNC youth in rural settings.

Guideline 6. Psychologists strive to recognize the influence of institutional barriers on the lives of TGNC people and to assist in developing TGNC-affirmative environments.

Rationale. Antitrans prejudice and the adherence of mainstream society to the gender binary adversely affect TGNC people within their families, schools, health care, legal systems, workplaces, religious traditions, and communities (American Civil Liberties Union National Prison Project, 2005; Bradford et al., 2013; Brewster et al., 2014; Levy & Lo, 2013; McGuire, Anderson, & Toomey, 2010). TGNC people face challenges accessing gender-inclusive restrooms, which may result in discomfort when being forced to use a men's or women's restroom (Transgender Law Center, 2005). In addition to the emotional distress the forced binary choice that public restrooms may create for some, TGNC people are frequently concerned with others' reactions to their presence in public restrooms, including potential discrimination, harassment, and violence (Herman, 2013).

Many TGNC people may be distrustful of care providers due to previous experiences of being pathologized (Benson, 2013). Experiences of discrimination and prejudice with health care providers may be complicated by power differentials within the therapeutic relationship that may greatly affect or complicate the care that TGNC people experience. TGNC people have routinely been asked to obtain an endorsement letter from a psychologist attesting to the stability of their gender identity as a prerequisite to access an endocrinologist, surgeon, or legal institution (e.g., driver's license bureau; Lev, 2009). The need for such required documentation from a psychologist may influence rapport, resulting in TGNC people fearing prejudicial treatment in which this documentation is withheld or delayed by the treating provider (Bouman et al., 2014). Whether a TGNC person has personally experienced interactions with providers as disempowering or has learned from community members to expect such a dynamic, psychologists are encouraged to be prepared for TGNC people to be very cautious when entering into a therapeutic relationship. When TGNC people feel validated and empowered within the environment in which a psychologist practices, the therapeutic relationship will benefit and the person may be more willing to explore their authentic selves and share uncertainties and ambiguities that are a common part of TGNC identity development.

Application. Because many TGNC people experience antitrans prejudice or discrimination, psychologists are encouraged to ensure that their work settings are welcoming and respectful of TGNC people, and to be mindful of what TGNC people may perceive as unwelcoming. To do so, psychologists may educate themselves about the many ways that cisgender privilege and antitrans prejudice may be expressed. Psychologists may also have specific conversations with TGNC people about their experiences of the mental health system and implement feedback to foster TGNC-affirmative environments. As a result, when TGNC people access various treatment settings and public spaces, they may experience less harm, disempowerment, or pathologization, and thus will be more likely to avail themselves of resources and support.

Psychologists are encouraged to be proactive in considering how overt or subtle cues in their workplaces and other environments may affect the comfort and safety of TGNC people. To increase the comfort of TGNC people, psychologists are encouraged to display TGNC-affirmative resources in waiting areas and to avoid the display of items that reflect antitrans attitudes (Lev, 2009). Psychologists are encouraged to examine how their language (e.g., use of incorrect pronouns and names) may reinforce the gender binary in overt or subtle and unintentional ways (Smith, Shin, & Officer, 2012). It may be helpful for psychologists to provide training for support staff on how to respectfully interact with TGNC people. A psychologist may consider making changes to paperwork, forms, or outreach materials to ensure that these materials are more inclusive of TGNC people (Spade, 2011b). For example, demographic questionnaires can communicate respect through the use of inclusive language and the inclusion of a range of gender identities. In addition, psychologists may also work within their institutions to advocate for restrooms that are inclusive and accessible for people of all gender identities and/or gender expressions.

When working with TGNC people in a variety of care and institutional settings (e.g., inpatient medical and psychiatric hospitals, substance abuse treatment settings, nursing homes, foster care, religious communities, military and VA health care settings, and prisons), psychologists may become liaisons and advocates for TGNC people's mental health needs and for respectful treatment that addresses their gender identity in an affirming manner. In playing this role, psychologists may find guidance and best practices that have been published for particular institutional contexts to be helpful (e.g., Department of Veterans Affairs, Veterans' Health Administration, 2013; Glezer, McNiel, & Binder, 2013; Merksamer, 2011).

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Guideline 7: Psychologists understand the need to promote social change that reduces the negative effects of stigma on the health and well-being of TGNC people.

Rationale. The lack of public policy that addresses the needs of TGNC people creates significant hardships for them (Taylor, 2007). Although there have been major advances in legal protections for TGNC people in recent years (Buzuvis, 2013; Harvard Law Review Association, 2013), many TGNC people are still not afforded protections from discrimination on the basis of gender identity or expression (National LGBTQ Task Force, 2013; Taylor, 2007). For instance, in many states, TGNC people do not have employment or housing protections and may be fired or lose their housing based on their gender identity. Many policies that protect the rights of cisgender people, including LGB people, do not protect the rights of TGNC people (Currah, & Minter, 2000; Spade, 2011a).

TGNC people can experience challenges obtaining gender-affirming identity documentation (e.g., birth certificate, passport, social security card, driver's license). For TGNC people experiencing poverty or economic hardship, requirements for obtaining this documentation may be impossible to meet, in part due to the difficulty of securing employment without identity documentation that aligns with their gender identity and gender expression (Sheridan, 2009). Additionally, systemic barriers related to binary gender identification systems prevent some TGNC people from changing their documents, including those who are incarcerated, undocumented immigrants, and people who live in jurisdictions that explicitly forbid such changes (Spade, 2006). Documentation requirements can also assume a universal TGNC experience that marginalizes some TGNC people, especially those who do not undergo a medical transition. This may affect a TGNC person's social and psychological well-being and interfere with accessing employment, education, housing and shelter, health care, public benefits, and basic life management resources (e.g., opening a bank account).

Application. Psychologists are encouraged to inform public policy to reduce negative systemic impact on TGNC people and to promote positive social change. Psychologists are encouraged to identify and improve systems that permit violence; educational, employment, and housing discrimination; lack of access to health care; unequal access to other vital resources; and other instances of systemic inequity that TGNC people experience (ACA, 2010). Many TGNC people experience stressors from constant barriers, inequitable treatment, and forced release of sensitive and private information about their bodies and their lives (Hendricks & Testa, 2012). To obtain proper identity documentation, TGNC people may be required to provide court orders, proof of having had surgery, and documentation of psychotherapy or a psychiatric diagnosis. Psychologists may assist TGNC people by normalizing their reactions of fatigue and traumatization while interacting with legal systems and requirements; TGNC people may also benefit from guidance about alternate avenues of recourse, self-advocacy, or appeal. When TGNC people feel that it is unsafe to advocate for themselves, psychologists may work with their clients to access appropriate resources in the community.

Psychologists are encouraged to be sensitive to the challenges of attaining gender-affirming identity documentation and how the receipt or denial of such documentation may affect social and psychological well-being, the person's ability to obtain education and employment, find safe housing, access public benefits, obtain student loans, and access health insurance. It may be of significant assistance for psychologists to understand and offer information about the process of a legal name change, gender marker change on identification, or the process for accessing other gender-affirming documents. Psychologists may consult the National Center for Transgender Equality, the Sylvia Rivera Law Project, or the Transgender Law Center for additional information on identity documentation for TGNC people.

Psychologists may choose to become involved with an organization that seeks to revise law and public policy to better protect the rights and dignities of TGNC people. Psychologists may participate at the local, state, or national level to support TGNC-affirmative health care accessibility, human rights in sex-segregated facilities, or policy change regarding gender-affirming identity documentation. Psychologists working in institutional settings may also expand their roles to work as collaborative advocates for TGNC people (Gonzalez & McNulty, 2010). Psychologists are encouraged to provide written affirmations supporting TGNC people and their gender identity so that they may access necessary services (e.g., hormone therapy).

Life Span Development

Guideline 8. Psychologists working with gender-questioning [4] and TGNC youth understand the different developmental needs of children and adolescents, and that not all youth will persist in a TGNC identity into adulthood.

Rationale. Many children develop stability (constancy across time) in their gender identity between Ages 3 to 4 (Kohlberg, 1966), although gender consistency (recognition that gender remains the same across situations) often does not occur until Ages 4 to 7 (Siegal & Robinson, 1987). Children who demonstrate gender nonconformity in preschool and early elementary years may not follow this trajectory (Zucker & Bradley, 1995). Existing research suggests that between 12% and 50% of children diagnosed with gender dysphoria may persist in their identification with a gender different than sex assigned at birth into late adolescence and young adulthood (Drummond, Bradley,

[4] Gender-questioning youth are differentiated from TGNC youth in this section of the guidelines. Gender-questioning youth may be questioning or exploring their gender identity but have not yet developed a TGNC identity. As such, they may not be eligible for some services that would be offered to TGNC youth. Gender-questioning youth are included here because gender questioning may lead to a TGNC identity.

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Peterson-Badaali, & Zucker, 2008; Steensma, McGuire, Kreukels, Beekman, & Cohen-Kettenis, 2013; Wallien & Cohen-Kettenis, 2008). However, several research studies categorized 30% to 62% of youth who did not return to the clinic for medical intervention after initial assessment, and whose gender identity may be unknown, as "desisters" who no longer identified with a gender different than sex assigned at birth (Steensma et al., 2013; Wallien & Cohen-Kettenis, 2008; Zucker, 2008a). As a result, this research runs a strong risk of inflating estimates of the number of youth who do not persist with a TGNC identity. Research has suggested that children who identify more intensely with a gender different than sex assigned at birth are more likely to persist in this gender identification into adolescence (Steensma et al., 2013), and that when gender dysphoria persists through childhood and intensifies into adolescence, the likelihood of long-term TGNC identification increases (A. L. de Vries, Steensma, Doreleijers, & Cohen-Kettenis, 2011; Steensma et al., 2013; Wallien & Cohen-Kettenis, 2008; Zucker, 2008b). Gender-questioning children who do not persist may be more likely to later identify as gay or lesbian than non-gender-questioning children (Bailey & Zucker, 1995; Drescher, 2014; Wallien & Cohen-Kettenis, 2008).

A clear distinction between care of TGNC and gender-questioning children and adolescents exists in the literature. Due to the evidence that not all children persist in a TGNC identity into adolescence or adulthood, and because no approach to working with TGNC children has been adequately, empirically validated, consensus does not exist regarding best practice with prepubertal children. Lack of consensus about the preferred approach to treatment may be due in part to divergent ideas regarding what constitutes optimal treatment outcomes for TGNC and gender-questioning youth (Hembree et al., 2009). Two distinct approaches exist to address gender identity concerns in children (Hill, Menvielle, Sica, & Johnson, 2010; Wallace & Russell, 2013), with some authors subdividing one of the approaches to suggest three (Byne et al., 2012; Drescher, 2014; Stein, 2012).

One approach encourages an affirmation and acceptance of children's expressed gender identity. This may include assisting children to socially transition and to begin medical transition when their bodies have physically developed, or allowing a child's gender identity to unfold without expectation of a specific outcome (A. L. de Vries & Cohen-Kettenis, 2012; Edwards-Leeper & Spack, 2012; Ehrensaft, 2012; Hidalgo et al., 2013; Tishelman et al., 2015). Clinicians using this approach believe that an open exploration and affirmation will assist children to develop coping strategies and emotional tools to integrate a positive TGNC identity should gender questioning persist (Edwards-Leeper & Spack, 2012).

In the second approach, children are encouraged to embrace their given bodies and to align with their assigned gender roles. This includes endorsing and supporting behaviors and attitudes that align with the child's sex assigned at birth prior to the onset of puberty (Zucker, 2008a; Zucker, Wood, Singh, & Bradley, 2012). Clinicians using this approach believe that undergoing multiple medical interventions and living as a TGNC person in a world that stigmatizes gender nonconformity is a less desirable outcome than one in which children may be assisted to happily align with their sex assigned at birth (Zucker et al., 2012). Consensus does not exist regarding whether this approach may provide benefit (Zucker, 2008a; Zucker et al., 2012) or may cause harm or lead to psychosocial adversities (Hill et al., 2010; Pyne, 2014; Travers et al., 2012; Wallace & Russell, 2013). When addressing psychological interventions for children and adolescents, the World Professional Association for Transgender Health Standards of Care identify interventions "aimed at trying to change gender identity and expression to become more congruent with sex assigned at birth" as unethical (Coleman et al., 2012, p. 175). It is hoped that future research will offer improved guidance in this area of practice (Adelson & AACAP CQI, 2012; Malpas, 2011).

Much greater consensus exists regarding practice with adolescents. Adolescents presenting with gender identity concerns bring their own set of unique challenges. This may include having a late-onset (i.e., postpubertal) presentation of gender nonconforming identification, with no history of gender role nonconformity or gender questioning in childhood (Edwards-Leeper & Spack, 2012). Complicating their clinical presentation, many gender-questioning adolescents also present with co-occurring psychological concerns, such as suicidal ideation, self-injurious behaviors (Liu & Mustanski, 2012; Mustanski, Garofalo, & Emerson, 2010), drug and alcohol use (Garofalo et al., 2006), and autism spectrum disorders (A. L. de Vries, Noens, Cohen-Kettenis, van Berckelaer-Onnes, & Doreleijers, 2010; Jones et al., 2012). Additionally, adolescents can become intensely focused on their immediate desires, resulting in outward displays of frustration and resentment when faced with any delay in receiving the medical treatment from which they feel they would benefit and to which they feel entitled (Angello, 2013; Edwards-Leeper & Spack, 2012). This intense focus on immediate needs may create challenges in assuring that adolescents are cognitively and emotionally able to make life-altering decisions to change their name or gender marker, begin hormone therapy (which may affect fertility), or pursue surgery.

Nonetheless, there is greater consensus that treatment approaches for adolescents affirm an adolescents' gender identity (Coleman et al., 2012). Treatment options for adolescents extend beyond social approaches to include medical approaches. One particular medical intervention involves the use of puberty-suppressing medication or "blockers" (GnRH analogue), which is a reversible medical intervention used to delay puberty for appropriately screened adolescents with gender dysphoria (Coleman et al., 2012; A. L. C. de Vries et al., 2014; Edwards-Leeper, & Spack, 2012). Because of their age, other medical interventions may also become available to adolescents, and psychologists are frequently consulted to provide an assessment of whether such procedures would be advisable (Coleman et al., 2012).

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Application. Psychologists working with TGNC and gender-questioning youth are encouraged to regularly review the most current literature in this area, recognizing the limited available research regarding the potential benefits and risks of different treatment approaches for children and for adolescents. Psychologists are encouraged to offer parents and guardians clear information about available treatment approaches, regardless of the specific approach chosen by the psychologist. Psychologists are encouraged to provide psychological service to TGNC and gender-questioning children and adolescents that draws from empirically validated literature when available, recognizing the influence psychologists' values and beliefs may have on the treatment approaches they select (Ehrbar & Gorton, 2010). Psychologists are also encouraged to remain aware that what one youth and/or parent may be seeking in a therapeutic relationship may not coincide with a clinician's approach (Brill & Pepper, 2008). In cases in which a youth and/or parent identify different preferred treatment outcomes than a clinician, it may not be clinically appropriate for the clinician to continue working with the youth and family, and alternative options, including referral, might be considered. Psychologists may also find themselves navigating family systems in which youth and their caregivers are seeking different treatment outcomes (Edwards-Leeper & Spack, 2012). Psychologists are encouraged to carefully reflect on their personal values and beliefs about gender identity development in conjunction with the available research, and to keep the best interest of the child or adolescent at the forefront of their clinical decisions at all times.

Because gender nonconformity may be transient for younger children in particular, the psychologist's role may be to help support children and their families through the process of exploration and self-identification (Ehrensaft, 2012). Additionally, psychologists may provide parents with information about possible long-term trajectories children may take in regard to their gender identity, along with the available medical interventions for adolescents whose TGNC identification persists (Edwards-Leeper & Spack, 2012).

When working with adolescents, psychologists are encouraged to recognize that some TGNC adolescents will not have a strong history of childhood gender role nonconformity or gender dysphoria either by self-report or family observation (Edwards-Leeper & Spack, 2012). Some of these adolescents may have withheld their feelings of gender nonconformity out of a fear of rejection, confusion, conflating gender identity and sexual orientation, or a lack of awareness of the option to identify as TGNC. Parents of these adolescents may need additional assistance in understanding and supporting their youth, given that late-onset gender dysphoria and TGNC identification may come as a significant surprise. Moving more slowly and cautiously in these cases is often advisable (Edwards-Leeper & Spack, 2012). Given the possibility of adolescents' intense focus on immediate desires and strong reactions to perceived delays or barriers, psychologists are encouraged to validate these concerns and the desire to move through the process quickly while also remaining thoughtful and deliberate in treatment. Adolescents and their families may need support in tolerating ambiguity and uncertainty with regard to gender identity and its development (Brill & Pepper, 2008). It is encouraged that care should be taken not to foreclose this process.

For adolescents who exhibit a long history of gender nonconformity, psychologists may inform parents that the adolescent's self-affirmed gender identity is most likely stable (A. L. de Vries et al., 2011). The clinical needs of these adolescents may be different than those who are in the initial phases of exploring or questioning their gender identity. Psychologists are encouraged to complete a comprehensive evaluation and ensure the adolescent's and family's readiness to progress while also avoiding unnecessary delay for those who are ready to move forward.

Psychologists working with TGNC and gender-questioning youth are encouraged to become familiar with medical treatment options for adolescents (e.g., puberty-suppressing medication, hormone therapy) and work collaboratively with medical providers to provide appropriate care to clients. Because the ongoing involvement of a knowledgeable mental health provider is encouraged due to the psychosocial implications, and is often also a required part of the medical treatment regimen that may be offered to TGNC adolescents (Coleman et al., 2012; Hembree et al., 2009), psychologists often play an essential role in assisting in this process.

Psychologists may encourage parents and caregivers to involve youth in developmentally appropriate decision making about their education, health care, and peer networks, as these relate to children's and adolescents' gender identity and gender expression (Ryan, Russell, Huebner, Diaz, & Sanchez, 2010). Psychologists are also encouraged to educate themselves about the advantages and disadvantages of social transition during childhood and adolescence, and to discuss these factors with both their young clients and clients' parents. Emphasizing to parents the importance of allowing their child the freedom to return to a gender identity that aligns with sex assigned at birth or another gender identity at any point cannot be overstated, particularly given the research that suggests that not all young gender nonconforming children will ultimately express a gender identity different from that assigned at birth (Wallien, & Cohen-Kettenis, 2008; Zucker & Bradley, 1995). Psychologists are encouraged to acknowledge and explore the fear and burden of responsibility that parents and caregivers may feel as they make decisions about the health of their child or adolescent (Grossman, D'Augelli, Howell, & Hubbard, 2006). Parents and caregivers may benefit from a supportive environment to discuss feelings of isolation, explore loss and grief they may experience, vent anger and frustration at systems that disrespect or discriminate against them and their youth, and learn how to communicate with others about their child's or adolescent's gender identity or gender expression (Brill & Pepper, 2008).

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Guideline 9. Psychologists strive to understand both the particular challenges that TGNC elders experience and the resilience they can develop.

Rationale. Little research has been conducted about TGNC elders, leaving much to be discovered about this life stage for TGNC people (Auldridge, Tamar-Mattis, Kennedy, Ames, & Tobin, 2012). Socialization into gender role behaviors and expectations based on sex assigned at birth, as well as the extent to which TGNC people adhere to these societal standards, is influenced by the chronological age at which a person self-identifies as TGNC, the age at which a person comes out or socially and/or medically transitions (Birren & Schaie, 2006; Bockting & Coleman, 2007; Cavanaugh & Blanchard-Fields, 2010; Nuttbrock et al., 2010; Wahl, Iwarsson, & Oswald, 2012), and a person's generational cohort (e.g., 1950 vs. 2010; Fredriksen-Goldsen et al., 2011).

Even decades after a medical or social transition, TGNC elders may still subscribe to the predominant gender role expectations that existed at the time of their transition (Knochel, Croghan, Moore, & Quam, 2011). Prior to the 1980s, TGNC people who transitioned were strongly encouraged by providers to pass in society as cisgender and heterosexual and to avoid associating with other TGNC people (Benjamin, 1966; R. Green & Money, 1969; Hastings, 1974; Hastings & Markland, 1978). Even TGNC elders who were comfortable telling others about their TGNC identity when they were younger may choose not to reveal their identity at a later stage of life (Ekins & King, 2005; Ippolito & Witten, 2014). Elders' unwillingness to disclose their TGNC identity can result from feelings of physical vulnerability or increased reliance on others who may discriminate against them or treat them poorly as a result of their gender identity (Bockting & Coleman, 2007), especially if the elder resides in an institutionalized setting (i.e., nursing home, assisted living facility) and relies on others for many daily needs (Auldridge et al., 2012). TGNC elders are also at a heightened risk for depression, suicidal ideation, and loneliness compared with LGB elders (Auldridge et al., 2012; Fredriksen-Goldsen et al., 2011).

A Transgender Law Center survey found that TGNC and LGB elders had less financial well-being than their younger cohorts, despite having a higher than average educational level for their age group compared with the general population (Hartzell, Frazer, Wertz, & Davis, 2009). Survey research has also revealed that TGNC elders experience underemployment and gaps in employment, often due to discrimination (Auldridge et al., 2012; Beemyn & Rankin, 2011; Factor & Rothblum, 2007). In the past, some TGNC people with established careers may have been encouraged by service providers to find new careers or jobs to avoid undergoing a gender transition at work or being identified as TGNC, potentially leading to a significant loss of income and occupational identity (Cook-Daniels, 2006). Obstacles to employment can increase economic disparities that result in increased needs for supportive housing and other social services (National Center for Transgender Equality, 2012; Services and Advocacy for GLBT Elders & National Center for Transgender Equality, 2012).

TGNC elders may face obstacles to seeking or accessing resources that support their physical, financial, or emotional well-being. For instance, they may be concerned about applying for social security benefits, fearing that their TGNC identity may become known (Hartzell et al., 2009). A TGNC elder may avoid medical care, increasing the likelihood of later needing a higher level of medical care (e.g., home-based care, assisted living, or nursing home) than their same-age cisgender peers (Hartzell et al., 2009; Ippolito & Witten, 2014; Mikalson et al., 2012). Nursing homes and assisted living facilities are rarely sensitive to the unique medical needs of TGNC elders (National Senior Citizens Law Center, 2011). Some TGNC individuals who enter congregate housing, assisted living, or long-term care settings may feel the need to reverse their transition to align with sex assigned at birth to avoid discrimination and persecution by other residents and staff (Ippolito & Witten, 2014).

Older age may both facilitate and complicate medical treatment related to gender transition. TGNC people who begin hormone therapy later in life may have a smoother transition due to waning hormone levels that are a natural part of aging (Witten & Eyler, 2012). Age may also influence the decisions TGNC elders make regarding sex-affirmation surgeries, especially if physical conditions exist that could significantly increase risks associated with surgery or recovery.

Much has been written about the resilience of elders who have endured trauma (Fuhrmann & Shevlowitz, 2006; Hardy, Concato, & Gill, 2004; Mlinac, Sheeran, Blissmer, Lees, & Martins, 2011; Rodin & Stewart, 2012). Although some TGNC elders have experienced significant psychological trauma related to their gender identity, some also have developed resilience and effective ways of coping with adversity (Fruhauf & Orel, 2015). Despite the limited availability of LGBTQ-affirmative religious organizations in many local communities, TGNC elders make greater use of these resources than their cisgender peers (Porter et al., 2013).

Application. Psychologists are encouraged to seek information about the biopsychosocial needs of TGNC elders to inform case conceptualization and treatment planning to address psychological, social, and medical concerns. Many TGNC elders are socially isolated. Isolation can occur as a result of a loss of social networks through death or through disclosure of a TGNC identity. Psychologists may assist TGNC elders in establishing new social networks that support and value their TGNC identity, while also working to strengthen existing family and friend networks after a TGNC identity has been disclosed. TGNC elders may find special value in relationships with others in their generational cohort or those who may have similar coming-out experiences. Psychologists may encourage TGNC elders to identify ways they can mentor and improve the resilience of younger TGNC generations, creating a sense of generativity (Erikson, 1968) and contribu-

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tion while building new supportive relationships. Psychologists working with TGNC elders may help them recognize the sources of their resilience and encourage them to connect with and be active in their communities (Fuhrmann & Craffey, 2014).

For TGNC elders who have chosen not to disclose their gender identity, psychologists may provide support to address shame, guilt, or internalized antitrans prejudice, and validate each person's freedom to choose their pattern of disclosure. Clinicians may also provide validation and empathy when TGNC elders have chosen a model of transition that avoids any disclosure of gender identity and is heavily focused on passing as cisgender.

TGNC elders who choose to undergo a medical or social transition in older adulthood may experience antitrans prejudice from people who question the value of transition at an older age or who believe that these elders are not truly invested in their transition or in a TGNC identity given the length of time they have waited (Auldridge et al., 2012). Some TGNC elders may also grieve lost time and missed opportunities. Psychologists may validate elders' choices to come out, transition, or evolve their gender identity or gender expression at any age, recognizing that such choices may have been much less accessible or viable at earlier stages of TGNC elders' lives.

Psychologists may assist congregate housing, assisted living, or long-term care settings to best meet TGNC elders' needs through respectful communication and affirmation of each person's gender identity and gender expression. Psychologists may work with TGNC people in hospice care systems to develop an end-of-life plan that respects the person's wishes about disclosure of gender identity during and after death.

Assessment, Therapy, and Intervention

Guideline 10. Psychologists strive to understand how mental health concerns may or may not be related to a TGNC person's gender identity and the psychological effects of minority stress.

Rationale. TGNC people may seek assistance from psychologists in addressing gender-related concerns, other mental health issues, or both. Mental health problems experienced by a TGNC person may or may not be related to that person's gender identity and/or may complicate assessment and intervention of gender-related concerns. In some cases, there may not be a relationship between a person's gender identity and a co-occurring condition (e.g., depression, PTSD, substance abuse). In other cases, having a TGNC identity may lead or contribute to a co-occurring mental health condition, either directly by way of gender dysphoria, or indirectly by way of minority stress and oppression (Hendricks & Testa, 2012; I. H. Meyer, 1995, 2003). In extremely rare cases, a co-occurring condition can mimic gender dysphoria (i.e., a psychotic process that distorts the perception of one's gender; Baltieri & De Andrade, 2009; Hepp, Kraemer, Schnyder, Miller, & Delsignore, 2004).

Regardless of the presence or absence of an etiological link, gender identity may affect how a TGNC person experiences a co-occurring mental health condition, and/or a co-occurring mental health condition may complicate the person's gender expression or gender identity. For example, an eating disorder may be influenced by a TGNC person's gender expression (e.g., rigid eating patterns used to manage body shape or menstruation may be related to gender identity or gender dysphoria; Ålgars, Alanko, Santtila, & Sandnabba, 2012; Murray, Boon, & Touyz, 2013). In addition, the presence of autism spectrum disorder may complicate a TGNC person's articulation and exploration of gender identity (Jones et al., 2012). In cases in which gender dysphoria is contributing to other mental health concerns, treatment of gender dysphoria may be helpful in alleviating those concerns as well (Keo-Meier et al., 2015).

A relationship also exists between mental health conditions and the psychological sequelae of minority stress that TGNC people can experience. Given that TGNC people experience physical and sexual violence (Clements-Nolle et al., 2006; Kenagy & Bostwick, 2005; Lombardi, Wilchins, Priesing, & Malouf, 2001; Xavier et al., 2005), general harassment and discrimination (Beemyn & Rankin, 2011; Factor & Rothblum, 2007), and employment and housing discrimination (Bradford et al., 2007), they are likely to experience significant levels of minority stress. Studies have demonstrated the disproportionately high levels of negative psychological sequelae related to minority stress, including suicidal ideation and suicide attempts (Center for Substance Abuse Treatment, 2012; Clements-Nolle et al., 2006; Cochran & Cauce, 2006; Nuttbrock et al., 2010; Xavier et al., 2005) and completed suicides (Dhejne et al., 2011; van Kesteren, Asscheman, Megens, & Gooren, 1997). Recent studies have begun to demonstrate an association between sources of external stress and psychological distress (Bockting et al., 2013; Nuttbrock et al., 2010), including suicidal ideation and attempts and self-injurious behavior (dickey, Reisner, & Juntunen, 2015; Goldblum et al., 2012; Testa et al., 2012).

The minority stress model accounts for both the negative mental health effects of stigma-related stress and the processes by which members of the minority group may develop resilience and resistance to the negative effects of stress (I. H. Meyer, 1995, 2003). Although the minority stress model was developed as a theory of the relationship between sexual orientation and mental disorders, the model has been adapted to TGNC populations (Hendricks & Testa, 2012).

Application. Because of the increased risk of stress-related mental health conditions, psychologists are encouraged to conduct a careful diagnostic assessment, including a differential diagnosis, when working with TGNC people (Coleman et al., 2012). Taking into account the intricate interplay between the effects of mental health symptoms and gender identity and gender expression, psychologists are encouraged to neither ignore mental health problems a TGNC person is experiencing, nor erroneously

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assume that those mental health problems are a result of the person's gender identity or gender expression. Psychologists are strongly encouraged to be cautious before determining that gender nonconformity or dysphoria is due to an underlying psychotic process, as this type of causal relationship is rare.

When TGNC people seek to access transition-related health care, a psychosocial assessment is often part of this process (Coleman et al., 2012). A comprehensive and balanced assessment typically includes not only information about a person's past experiences of antitrans prejudice or discrimination, internalized messages related to these experiences, and anticipation of future victimization or rejection (Coolhart, Provancher, Hager, & Wang, 2008), but also coping strategies and sources of resilience (Hendricks & Testa, 2012; Singh et al., 2011). Gathering information about negative life events directly related to a TGNC person's gender identity and gender expression may assist psychologists in understanding the sequelae of stress and discrimination, distinguishing them from concurrent and potentially unrelated mental health problems. Similarly, when a TGNC person has a primary presenting concern that is not gender focused, a comprehensive assessment takes into account that person's experience relative to gender identity and gender expression, including any discrimination, just as it would include assessing other potential trauma history, medical concerns, previous experience with helping professionals, important future goals, and important aspects of identity. Strategies a TGNC person uses to navigate antitrans discrimination could be sources of strength to deal with life challenges or sources of distress that increase challenges and barriers.

Psychologists are encouraged to help TGNC people understand the pervasive influence of minority stress and discrimination that may exist in their lives, potentially including internalized negative attitudes about themselves and their TGNC identity (Hendricks & Testa, 2012). With this support, clients can better understand the origins of their mental health symptoms and normalize their reactions when faced with TGNC-related inequities and discrimination. Minority stress models also identify potentially important sources of resilience. TGNC people can develop resilience when they connect with other TGNC people who provide information on how to navigate antitrans prejudice and increase access to necessary care and resources (Singh et al., 2011). TGNC people may need help developing social support systems to nurture their resilience and bolster their ability to cope with the adverse effects of antitrans prejudice and/or discrimination (Singh & McKleroy, 2011).

Feminizing or masculinizing hormone therapy can positively or negatively affect existing mood disorders (Coleman et al., 2012). Psychologists may also help TGNC people who are in the initial stages of hormone therapy adjust to normal changes in how they experience emotions. For example, trans women who begin estrogens and antiandrogens may experience a broader range of emotions than they are accustomed to, or trans men beginning testosterone might be faced with adjusting to a higher libido and feeling more emotionally reactive in stressful situations. These changes can be normalized as similar to the emotional adjustments that cisgender women and men experience during puberty. Some TGNC people will be able to adapt existing coping strategies, whereas others may need help developing additional skills (e.g., emotional regulation or assertiveness). Readers are encouraged to refer to the World Professional Association for Transgender Health Standards of Care for discussion of the possible effects of hormone therapy on a TGNC person's mood, affect, and behavior (Coleman et al., 2012).

Guideline 11. Psychologists recognize that TGNC people are more likely to experience positive life outcomes when they receive social support or trans-affirmative care.

Rationale. Research has primarily shown positive treatment outcomes when TGNC adults and adolescents receive TGNC-affirmative medical and psychological services (i.e., psychotherapy, hormones, surgery; Byne et al., 2012; R. Carroll, 1999; Cohen-Kettenis, Delemarre-van de Waal, & Gooren, 2008; Davis & Meier, 2014; De Cuypere et al., 2006; Gooren, Giltay, & Bunck, 2008; Kuhn et al., 2009), although sample sizes are frequently small with no population-based studies. In a meta-analysis of the hormone therapy treatment literature with TGNC adults and adolescents, researchers reported that 80% of participants receiving trans-affirmative care experienced an improved quality of life, decreased gender dysphoria, and a reduction in negative psychological symptoms (Murad et al., 2010).

In addition, TGNC people who receive social support about their gender identity and gender expression have improved outcomes and quality of life (Brill & Pepper, 2008; Pinto, Melendez, & Spector, 2008). Several studies indicate that family acceptance of TGNC adolescents and adults is associated with decreased rates of negative outcomes, such as depression, suicide, and HIV risk behaviors and infection (Bockting et al., 2013; Dhejne et al., 2011; Grant et al., 2011; Liu & Mustanski, 2012; Ryan, 2009). Family support is also a strong protective factor for TGNC adults and adolescents (Bockting et al., 2013; Moody & Smith, 2013; Ryan et al., 2010). TGNC people, however, frequently experience blatant or subtle antitrans prejudice, discrimination, and even violence within their families (Bradford et al., 2007). Such family rejection is associated with higher rates of HIV infection, suicide, incarceration, and homelessness for TGNC adults and adolescents (Grant et al., 2011; Liu & Mustanski, 2012). Family rejection and lower levels of social support are significantly correlated with depression (Clements-Nolle et al., 2006; Ryan, 2009). Many TGNC people seek support through peer relationships, chosen families, and communities in which they may be more likely to experience acceptance (Gonzalez & McNulty, 2010; Nuttbrock et al., 2009). Peer support from other TGNC people has been found to be a moderator between antitrans discrimination and mental health, with higher levels of peer support associated with better mental health (Bockting et al., 2013). For some TGNC people, support from religious and spiritual communities provides

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an important source of resilience (Glaser, 2008; Kidd & Witten, 2008; Porter et al., 2013).

Application. Given the strong evidence for the positive influence of affirmative care, psychologists are encouraged to facilitate access to and provide trans-affirmative care to TGNC people. Whether through the provision of assessment and psychotherapy, or through assisting clients to access hormone therapy or surgery, psychologists may play a critical role in empowering and validating TGNC adults' and adolescents' experiences and increasing TGNC people's positive life outcomes (Bess & Stabb, 2009; Rachlin, 2002).

Psychologists are also encouraged to be aware of the importance of affirmative social support and assist TGNC adults and adolescents in building social support networks in which their gender identity is accepted and affirmed. Psychologists may assist TGNC people in negotiating family dynamics that may arise in the course of exploring and establishing gender identity. Depending on the context of psychological practice, these issues might be addressed in individual work with TGNC clients, conjoint sessions including members of their support system, family therapy, or group therapy. Psychologists may help TGNC people decide how and when to reveal their gender identity at work or school, in religious communities, and to friends and contacts in other settings. TGNC people who decide not to come out in all aspects of their lives can still benefit from TGNC-affirmative in-person or online peer support groups.

Clients may ask psychologists to assist family members in exploring feelings about their loved one's gender identity and gender expression. Published models of family adjustment (Emerson & Rosenfeld, 1996) may be useful to help normalize family members' reactions upon learning that they have a TGNC family member, and to reduce feelings of isolation. When working with family members or significant others, it may be helpful to normalize feelings of loss or fear of what may happen to current relationships as TGNC people disclose their gender identity and expression to others. Psychologists may help significant others adjust to changing relationships and consider how to talk to extended family, friends, and other community members about TGNC loved ones. Providing significant others with referrals to TGNC-affirmative providers, educational resources, and support groups can have a profound impact on their understanding of gender identity and their communication with TGNC loved ones. Psychologists working with couples and families may also help TGNC people identify ways to include significant others in their social or medical transition.

Psychologists working with TGNC people in rural settings may provide clients with resources to connect with other TGNC people online or provide information about in-person support groups in which they can explore the unique challenges of being TGNC in these geographic areas (Walinsky & Whitcomb, 2010). Psychologists serving TGNC military and veteran populations are encouraged to be sensitive to the barriers these individuals face, especially for people who are on active duty in the U.S. military (OutServe-Servicemembers Legal Defense Network, n.d.). Psychologists may help TGNC military members and veterans establish specific systems of support that create a safe and affirming space to reduce isolation and to create a network of peers with a shared military experience. Psychologists who work with veterans are encouraged to educate themselves on recent changes to VA policy that support equal access to VA medical and mental health services (Department of Veterans Affairs, Veterans' Health Administration, 2013).

Guideline 12. Psychologists strive to understand the effects that changes in gender identity and gender expression have on the romantic and sexual relationships of TGNC people.

Rationale. Relationships involving TGNC people can be healthy and successful (Kins, Hoebeke, Heylens, Rubens, & De Cuyprere, 2008; Meier, Sharp, Michonski, Babcock, & Fitzgerald, 2013) as well as challenging (Brown, 2007; Iantaffi & Bockting, 2011). A study of successful relationships between TGNC men and cisgender women found that these couples attributed the success of their relationship to respect, honesty, trust, love, understanding, and open communication (Kins et al., 2008). Just as relationships between cisgender people can involve abuse, so can relationships between TGNC people and their partners (Brown, 2007), with some violent partners threatening to disclose a TGNC person's identity to exact control in the relationship (FORGE, n.d.).

In the early decades of medical and social transition for TGNC people, only those whose sexual orientations would be heterosexual posttransition (e.g., trans woman with a cisgender man) were deemed eligible for medical and social transition (Meyerowitz, 2002). This restriction prescribed only certain relationship partners (American Psychiatric Association, 1980; Benjamin, 1966; Chivers & Bailey, 2000), denied access to surgery for trans men identifying as gay or bisexual (Coleman & Bockting, 1988), or trans women identifying as lesbian or bisexual, and even required that TGNC people's existing legal marriages be dissolved before they could gain access to transition care (Lev, 2004).

Disclosure of a TGNC identity can have an important impact on the relationship between TGNC people and their partners. Disclosure of TGNC status earlier in the relationship tends to be associated with better relationship outcomes, whereas disclosure of TGNC status many years into an existing relationship may be perceived as a betrayal (Erhardt, 2007). When a TGNC person comes out in the context of an existing relationship, it can also be helpful if both partners are involved in decision making about the use of shared resources (i.e., how to balance the financial costs of transition with other family needs) and how to share this news with shared supports (i.e., friends and family). Sometimes relationship roles are renegotiated in the context of a TGNC person coming out to their partner (Samons, 2008). Assumptions about what it means to be a "husband" or a "wife" can shift if the gender identity of one's spouse shifts

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(Erhardt, 2007). Depending on when gender issues are disclosed and how much of a change this creates in the relationship, partners may grieve the loss of aspects of their partner and the way the relationship used to be (Lev, 2004).

Although increasing alignment between gender identity and gender expression, whether it be through dress, behavior, or through medical interventions (i.e., hormones, surgery), does not necessarily affect to whom a TGNC person is attracted (Coleman et al., 1993), TGNC people may become more open to exploring their sexual orientation, may redefine sexual orientation as they move through transition, or both (Daskalos, 1998; H. Devor, 1993; Schleifer, 2006). Through increased comfort with their body and gender identity, TGNC people may explore aspects of their sexual orientation that were previously hidden or that felt discordant with their sex assigned at birth. Following a medical and/or social transition, a TGNC person's sexual orientation may remain constant or shift, either temporarily or permanently (e.g., renewed exploration of sexual orientation in the context of TGNC identity, shift in attraction or choice of sexual partners, widened spectrum of attraction, shift in sexual orientation identity; Meier, Sharp et al., 2013; Samons, 2008). For example, a trans man previously identified as a lesbian may later be attracted to men (Coleman et al., 1993; dickey, Burnes, & Singh, 2012), and a trans woman attracted to women pretransition may remain attracted to women posttransition (Lev, 2004).

Some TGNC people and their partners may fear the loss of mutual sexual attraction and other potential effects of shifting gender identities in the relationship. Lesbian-identified partners of trans men may struggle with the idea that being in a relationship with a man may cause others to perceive them as a heterosexual couple (Califia, 1997). Similarly, women in heterosexual relationships who later learn that their partners are trans women may be unfamiliar with navigating stigma associated with sexual minority status when viewed as a lesbian couple (Erhardt, 2007). Additionally, partners may find they are not attracted to a partner after transition. As an example, a lesbian whose partner transitions to a male identity may find that she is no longer attracted to this person because she is not sexually attracted to men. Partners of TGNC people may also experience grief and loss as their partners engage in social and/or medical transitions.

Application. Psychologists may help foster resilience in relationships by addressing issues specific to partners of TGNC people. Psychologists may provide support to partners of TGNC people who are having difficulty with their partner's evolving gender identity or transition, or are experiencing others having difficulty with the partner's transition. Partner peer support groups may be especially helpful in navigating internalized antitrans prejudice, shame, resentment, and relationship concerns related to a partner's gender transition. Meeting or knowing other TGNC people, other partners of TGNC people, and couples who have successfully navigated transition may also help TGNC people and their partners and serve as a protective factor (Brown, 2007). When TGNC status is disclosed during an existing relationship, psychologists may help couples explore which relationship dynamics they want to preserve and which they might like to change.

In working with psychologists, TGNC people may explore a range of issues in their relationships and sexuality (dickey et al., 2012), including when and how to come out to current or potential romantic and sexual partners, communicating their sexual desires, renegotiating intimacy that may be lost during the TGNC partner's transition, adapting to bodily changes caused by hormone use or surgery, and exploring boundaries regarding touch, affection, and safer sex practices (Iantaffi & Bockting, 2011; Sevelius, 2009). TGNC people may experience increased sexual self-efficacy through transition. Although psychologists may aid partners in understanding a TGNC person's transition decisions, TGNC people may also benefit from help in cultivating awareness of the ways in which these decisions influence the lives of loved ones.

Guideline 13. Psychologists seek to understand how parenting and family formation among TGNC people take a variety of forms.

Rationale. Psychologists work with TGNC people across the life span to address parenting and family issues (Kenagy & Hsieh, 2005). There is evidence that many TGNC people have and want children (Wierckx et al., 2012). Some TGNC people conceive a child through sexual intercourse, whereas others may foster, adopt, pursue surrogacy, or employ assisted reproductive technologies, such as sperm or egg donation, to build or expand a family (De Sutter, Kira, Verschoor, & Hotimsky, 2002). Based on a small body of research to date, there is no indication that children of TGNC parents suffer long-term negative impacts directly related to parental gender change (R. Green, 1978, 1988; White & Ettner, 2004). TGNC people may find it both challenging to find medical providers who are willing to offer them reproductive treatment and to afford the cost (Coleman et al., 2012). Similarly, adoption can be quite costly, and some TGNC people may find it challenging to find foster care or adoption agencies that will work with them in a nondiscriminatory manner. Current or past use of hormone therapy may limit fertility and restrict a TGNC person's reproductive options (Darnery, 2008; Wierckx et al., 2012). Other TGNC people may have children or families before coming out as TGNC or beginning a gender transition.

TGNC people may present with a range of parenting and family-building concerns. Some will seek support to address issues within preexisting family systems, some will explore the creation or expansion of a family, and some will need to make decisions regarding potential fertility issues related to hormone therapy, pubertal suppression, or surgical transition. The medical and/or social transition of a TGNC parent may shift family dynamics, creating challenges and opportunities for partners, children, and other family members. One study of therapists' reflections on their experiences with TGNC clients suggested that family constellation and the parental relationship was more significant for children than the parent's social and/or medical

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transition itself (White & Ettner, 2004). Although research has not documented that the transitions of TGNC people have an effect on their parenting abilities, preexisting partnerships or marriages may not survive the disclosure of a TGNC identity or a subsequent transition (dickey et al., 2012). This may result in divorce or separation, which may affect the children in the family. A positive relationship between parents, regardless of marital status, has been suggested to be an important protective factor for children (Amato, 2001; White & Ettner, 2007). This seems to be the case especially when children are reminded of the parent's love and assured of the parent's continued presence in their life (White & Ettner, 2007). Based on a small body of literature available, it is generally the case that younger children are best able to incorporate the transition of a parent, followed by adult children, with adolescents generally having the most difficulty (White & Ettner, 2007). If separated or divorced from their partners or spouses, TGNC parents may be at risk for loss of custody or visitation rights because some courts presume that there is a nexus between their gender identity or gender expression and parental fitness (Flynn, 2006). This type of prejudice is especially common for TGNC people of color (Grant et al., 2011).

Application. Psychologists are encouraged to attend to the parenting and family-building concerns of TGNC people. When working with TGNC people who have previous parenting experience, psychologists may help TGNC people identify how being a parent may influence decisions to come out as TGNC or to begin a transition (Freeman, Tasker, & Di Ceglie, 2002; Grant et al., 2011; Wierckx et al., 2012). Some TGNC people may choose to delay disclosure until their children have grown and left home (Bethea & McCollum, 2013). Clinical guidelines jointly developed by a Vancouver, British Columbia, TGNC community organization and a health care provider organization encourage psychologists and other mental health providers working with TGNC people to plan for disclosure to a partner, previous partner, or children, and to pay particular attention to resources that assist TGNC people to discuss their identity with children of various ages in developmentally appropriate ways (Bockting et al., 2006). Lev (2004) uses a developmental stage framework for the process that family members are likely to go through in coming to terms with a TGNC family member's identity that some psychologists may find helpful. Awareness of peer support networks for spouses and children of TGNC people can also be helpful (e.g., PFLAG, TransYouth Family Allies). Psychologists may provide family counseling to assist a family in managing disclosure, improve family functioning, and maintain family involvement of the TGNC person, as well as aiding the TGNC person in attending to the ways that their transition process has affected their family members (Samons, 2008). Helping parents to continue to work together to focus on the needs of their children and to maintain family bonds is likely to lead to the best results for the children (White & Ettner, 2007).

For TGNC people with existing families, psychologists may support TGNC people in seeking legal counsel regarding parental rights in adoption or custody. Depending on the situation, this may be desirable even if the TGNC parent is biologically related to the child (Minter & Wald, 2012). Although being TGNC is not a legal impediment to adoption in the United States, there is the potential for overt and covert discrimination and barriers, given the widespread prejudice against TGNC people. The question of whether to disclose TGNC status on an adoption application is a personal one, and a prospective TGNC parent would benefit from consulting a lawyer for legal advice, including what the laws in their jurisdiction say about disclosure. Given the extensive background investigation frequently conducted, it may be difficult to avoid disclosure. Many lawyers favor disclosure to avoid any potential legal challenges during the adoption process (Minter & Wald, 2012).

In discussing family-building options with TGNC people, psychologists are encouraged to remain aware that some of these options require medical intervention and are not available everywhere, in addition to being quite costly (Coleman et al., 2012). Psychologists may work with clients to manage feelings of loss, grief, anger, and resentment that may arise if TGNC people are unable to access or afford the services they need for building a family (Bockting et al., 2006; De Sutter et al., 2002).

When TGNC people consider beginning hormone therapy, psychologists may engage them in a conversation about the possibly permanent effects on fertility to better prepare TGNC people to make a fully informed decision. This may be of special importance with TGNC adolescents and young adults who often feel that family planning or loss of fertility is not a significant concern in their current daily lives, and therefore disregard the long-term reproductive implications of hormone therapy or surgery (Coleman et al., 2012). Psychologists are encouraged to discuss contraception and safer sex practices with TGNC people, given that they may still have the ability to conceive even when undergoing hormone therapy (Bockting, Robinson, & Rosser, 1998). Psychologists may play a critical role in educating TGNC adolescents and young adults and their parents about the long-term effects of medical interventions on fertility and assist them in offering informed consent prior to pursuing such interventions. Although hormone therapy may limit fertility (Coleman et al., 2012), psychologists may encourage TGNC people to refrain from relying on hormone therapy as the sole means of birth control, even when a person has amenorrhea (Gorton & Grubb, 2014). Education on safer sex practices may also be important, as some segments of the TGNC community (e.g., trans women and people of color) are especially vulnerable to sexually transmitted infections and have been shown to have high prevalence and incidence rates of HIV infection (Kellogg, Clements-Nolle, Dilley, Katz, & McFarland, 2001; Nemoto, Operario, Keatley, Han, & Soma, 2004).

Depending on the timing and type of options selected, psychologists may explore the physical, social, and emotional implications should TGNC people choose to delay or

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stop hormone therapy, undergo fertility treatment, or become pregnant. Psychological effects of stopping hormone therapy may include depression, mood swings, and reactions to the loss of physical masculinization or feminization facilitated by hormone therapy (Coleman et al., 2012). TGNC people who choose to halt hormone therapy during attempts to conceive or during a pregnancy may need additional psychological support. For example, TGNC people and their families may need help in managing the additional antitrans prejudice and scrutiny that may result when a TGNC person with stereotypically masculine features becomes visibly pregnant. Psychologists may also assist TGNC people in addressing their loss when they cannot engage in reproductive activities that are consistent with their gender identity, or when they encounter barriers to conceiving, adopting, or fostering children not typically faced by other people (Vanderburgh, 2007). Psychologists are encouraged to assess the degree to which reproductive health services are TGNC-affirmative prior to referring TGNC people to them. Psychologists are also encouraged to provide TGNC-affirmative information to reproductive health service personnel when there is a lack of trans-affirmative knowledge.

Guideline 14. Psychologists recognize the potential benefits of an interdisciplinary approach when providing care to TGNC people and strive to work collaboratively with other providers.

Rationale. Collaboration across disciplines can be crucial when working with TGNC people because of the potential interplay of biological, psychological, and social factors in diagnosis and treatment (Hendricks & Testa, 2012). The challenges of living with a stigmatized identity and the need of many TGNC people to transition, socially and/or medically, may call for the involvement of health professionals from various disciplines, including psychologists, psychiatrists, social workers, primary health care providers, endocrinologists, nurses, pharmacists, surgeons, gynecologists, urologists, electrologists, speech therapists, physical therapists, pastoral counselors and chaplains, and career or educational counselors. Communication, cooperation, and collaboration will ensure optimal coordination and quality of care. Just as psychologists often refer TGNC people to medical providers for assessment and treatment of medical issues, medical providers may rely on psychologists to assess readiness and assist TGNC clients to prepare for the psychological and social aspects of transition before, during, and after medical interventions (Coleman et al., 2012; Hembree et al., 2009; Lev, 2009). Outcome research to date supports the value and effectiveness of an interdisciplinary, collaborative approach to TGNC-specific care (see Coleman et al., 2012 for a review).

Application. Psychologists' collaboration with colleagues in medical and associated health disciplines involved in TGNC clients' care (e.g., hormonal and surgical treatment, primary health care; Coleman et al., 2012; Lev, 2009) may take many forms and should occur in a timely manner that does not complicate access to needed services (e.g., considerations of wait time). For example, a psychologist working with a trans man who has a diagnosis of bipolar disorder may need to coordinate with his primary care provider and psychiatrist to adjust his hormone levels and psychiatric medications, given that testosterone can have an activating effect, in addition to treating gender dysphoria. At a basic level, collaboration may entail the creation of required documentation that TGNC people present to surgeons or medical providers to access gender-affirming medical interventions (e.g., surgery, hormone therapy; Coleman et al., 2012). Psychologists may offer support, information, and education to interdisciplinary colleagues who are unfamiliar with issues of gender identity and gender expression to assist TGNC people in obtaining TGNC-affirmative care (Holman & Goldberg, 2006; Lev, 2009). For example, a psychologist who is assisting a trans woman with obtaining gender-affirming surgery may, with her consent, contact her new gynecologist in preparation for her first medical visit. This contact could include sharing general information about her gender history and discussing how both providers could most affirmatively support appropriate health checks to ensure her best physical health (Holman & Goldberg, 2006).

Psychologists in interdisciplinary settings could also collaborate with medical professionals prescribing hormone therapy by educating TGNC people and ensuring TGNC people are able to make fully informed decisions prior to starting hormone treatment (Coleman et al., 2012; Deutsch, 2012; Lev, 2009). Psychologists working with children and adolescents play a particularly important role on the interdisciplinary team due to considerations of cognitive and social development, family dynamics, and degree of parental support. This role is especially crucial when providing psychological evaluation to determine the appropriateness and timeliness of a medical intervention. When psychologists are not part of an interdisciplinary setting, especially in isolated or rural communities, they can identify interdisciplinary colleagues with whom they may collaborate and/or refer (Walinsky & Whitcomb, 2010). For example, a rural psychologist could identify a trans-affirmative pediatrician in a surrounding area and collaborate with the pediatrician to work with parents raising concerns about their TGNC and questioning children and adolescents.

In addition to working collaboratively with other providers, psychologists who obtain additional training to specialize in work with TGNC people may also serve as consultants in the field (e.g., providing additional support to providers working with TGNC people or assisting school and workplaces with diversity training). Psychologists who have expertise in working with TGNC people may play a consultative role with providers in inpatient settings seeking to provide affirmative care to TGNC clients. Psychologists may also collaborate with social service colleagues to provide TGNC people with affirmative referrals related to housing, financial support, vocational/educational counseling and training, TGNC-affirming religious or spiritual communities, peer support, and other community resources (Gehi & Arkles, 2007). This collaboration might also in-

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clude assuring that TGNC people who are minors in the care of the state have access to culturally appropriate care.

Research, Education, and Training

Guideline 15. Psychologists respect the welfare and rights of TGNC participants in research and strive to represent results accurately and avoid misuse or misrepresentation of findings.

Rationale. Historically, in a set of demographic questions, psychological research has included one item on either sex or gender, with two response options—male and female. This approach wastes an opportunity to increase knowledge about TGNC people for whom neither option may fit their identity, and runs the risk of alienating TGNC research participants (IOM, 2011). For example, there is little knowledge about HIV prevalence, risks, and prevention needs of TGNC people because most of the research on HIV has not included demographic questions to identify TGNC participants within their samples. Instead, TGNC people have been historically subsumed within larger demographic categories (e.g., men who have sex with men, women of color), rendering the impact of the HIV epidemic on the TGNC population invisible (Herbst et al., 2008). Scholars have noted that this invisibility fails to draw attention to the needs of TGNC populations that experience the greatest health disparities, including TGNC people who are of color, immigrants, low income, homeless, veterans, incarcerated, live in rural areas, or have disabilities (Bauer et al., 2009; Hanssmann, Morrison, Russian, Shiu-Thornton, & Bowen, 2010; Shipherd et al., 2012; Walinsky & Whitcomb, 2010).

There is a great need for more research to inform practice, including affirmative treatment approaches with TGNC people. Although sufficient evidence exists to support current standards of care (Byne et al., 2012; Coleman et al., 2012), much is yet to be learned to optimize quality of care and outcome for TGNC clients, especially as it relates to the treatment of children (IOM, 2011; Mikalson et al., 2012). In addition, some research with TGNC populations has been misused and misinterpreted, negatively affecting TGNC people's access to health services to address issues of gender identity and gender expression (Namaste, 2000). This has resulted in justifiable skepticism and suspicion in the TGNC community when invited to participate in research initiatives. In accordance with the APA ethics code (APA, 2010), psychologists conduct research and distribute research findings with integrity and respect for their research participants. As TGNC research increases, some TGNC communities may experience being oversampled in particular geographic areas and/or TGNC people of color may not be well-represented in TGNC studies (Hwahng & Lin, 2009; Namaste, 2000).

Application. All psychologists conducting research, even when not specific to TGNC populations, are encouraged to provide a range of options for capturing demographic information about TGNC people so that TGNC people may be included and accurately represented (Conron et al., 2008; Deutsch et al., 2013). One group of experts has recommended that population research, and especially government-sponsored surveillance research, use a two-step method, first asking for sex assigned at birth, and then following with a question about gender identity (GenIUSS, 2013). For research focused on TGNC people, including questions that assess both sex assigned at birth and current gender identity allows the disaggregation of subgroups within the TGNC population and has the potential to increase knowledge of differences within the population. In addition, findings about one subgroup of TGNC people may not apply to other subgroups. For example, results from a study of trans women of color with a history of sex work who live in urban areas (Nemoto, Operario, Keatley, & Villegas, 2004) may not generalize to all TGNC women of color or to the larger TGNC population (Bauer, Travers, Scanlon, & Coleman, 2012; Operario et al., 2008).

In conducting research with TGNC people, psychologists will confront the challenges associated with studying a relatively small, geographically dispersed, diverse, stigmatized, hidden, and hard-to-reach population (IOM, 2011). Because TGNC individuals are often hard to reach (IOM, 2011) and TGNC research is rapidly evolving, it is important to consider the strengths and limitations of the methods that have been or may be used to study the TGNC population, and to interpret and represent findings accordingly. Some researchers have strongly recommended collaborative research models (e.g., participatory action research) in which TGNC community members are integrally involved in these research activities (Clements-Nolle & Bachrach, 2003; Singh, Richmond, & Burnes, 2013). Psychologists who seek to educate the public by communicating research findings in the popular media will also confront challenges, because most journalists have limited knowledge about the scientific method and there is potential for the media to misinterpret, exploit, or sensationalize findings (Garber, 1992; Namaste, 2000).

Guideline 16. Psychologists Seek to Prepare Trainees in Psychology to Work Competently With TGNC People.

Rationale. The *Ethical Principles of Psychologists and Code of Conduct* (APA, 2010) include gender identity as one factor for which psychologists may need to obtain training, experience, consultation, or supervision in order to ensure their competence (APA, 2010). In addition, when APA-accredited programs are required to demonstrate a commitment to cultural and individual diversity, gender identity is specifically included (APA, 2015). Yet surveys of TGNC people suggest that many mental health care providers lack even basic knowledge and skills required to offer trans-affirmative care (Bradford et al., 2007; O'Hara, Dispenza, Brack, & Blood, 2013; Xavier et al., 2005). The APA Task Force on Gender Identity and Gender Variance (2009) projected that many, if not most, psychologists and graduate psychology students will at some point encounter TGNC people among their clients, colleagues, and trainees. Yet professional education and training in psychology includes little or no preparation for

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working with TGNC people (Anton, 2009; APA TFGIGV, 2009), and continuing professional education available to practicing mental health clinicians is also scant (Lurie, 2005). Only 52% percent of psychologists and graduate students who responded to a survey conducted by an APA Task Force reported having had the opportunity to learn about TGNC issues in school; of those respondents, only 27% reported feeling adequately familiar with gender concerns (n = 294; APA TFGIGV, 2009).

Training on gender identity in professional psychology has frequently been subsumed under discussions of sexual orientation or in classes on human sexuality. Some scholars have suggested that psychologists and students may mistakenly believe that they have obtained adequate knowledge and awareness about TGNC people through training focused on LGB populations (Harper & Schneider, 2003). However, Israel and colleagues have found important differences between the therapeutic needs of TGNC people and those of LGB people in the perceptions of both clients and providers (Israel et al., 2008; Israel, Walther, Gorcheva, & Perry, 2011). Nadal and colleagues have suggested that the absence of distinct, accurate information about TGNC populations in psychology training not only perpetuates misunderstanding and marginalization of TGNC people by psychologists but also contributes to continued marginalization of TGNC people in society as a whole (Nadal et al., 2010, 2012).

Application. Psychologists strive to continue their education on issues of gender identity and gender expression with TGNC people as a foundational component of affirmative psychological practice. In addition to these guidelines, which educators may use as a resource in developing curricula and training experiences, ACA (2010) has also adopted a set of competencies that may be a helpful resource for educators. In addition to including TGNC people and their issues in foundational education in health service psychology (e.g., personality development, multiculturalism, research methods), some psychology programs may also provide coursework and training for students interested in developing more advanced expertise on issues of gender identity and gender expression.

Because of the high level of societal ignorance and stigma associated with TGNC people, ensuring that psychological education, training, and supervision is affirmative, and does not sensationalize (Namaste, 2000), exploit, or pathologize TGNC people (Lev, 2004), will require care on the part of educators. Students will benefit from support from their educators in developing a professional, nonjudgmental attitude toward people who may have a different experience of gender identity and gender expression from their own. A number of training resources have been published that may be helpful to psychologists in integrating information about TGNC people into the training they offer (e.g., Catalano, McCarthy, & Shlasko, 2007; Stryker, 2008; Wentling, Schilt, Windsor, & Lucal, 2008). Because most psychologists have had little or no training on TGNC populations and do not perceive themselves as having sufficient understanding of issues related to gender identity and gender expression (APA TFGIGV, 2009), psychologists with relevant expertise are encouraged to develop and distribute continuing education and training to help to address these gaps. Psychologists providing education can incorporate activities that increase awareness of cisgender privilege, antitrans prejudice and discrimination, host a panel of TGNC people to offer personal perspectives, or include narratives of TGNC people in course readings (ACA, 2010). When engaging these approaches, it is important to include a wide variety of TGNC experiences to reflect the inherent diversity within the TGNC community.

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Appendix A
Definitions

Terminology within the health care field and transgender and gender nonconforming (TGNC) communities is constantly evolving (Coleman et al., 2012). The evolution of terminology has been especially rapid in the last decade, as the profession's awareness of gender diversity has increased, as more literature and research in this area has been published, and as voices of the TGNC community have strengthened. Some terms or definitions are not universally accepted, and there is some disagreement among professionals and communities as to the "correct" words or definitions, depending on theoretical orientation, geographic region, generation, or culture, with some terms seen as affirming and others as outdated or demeaning. American Psychological Association (APA) Task Force for *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People* developed the definitions below by reviewing existing definitions put forward by professional organizations (e.g., APA Task Force on Gender Identity and Gender Variance, 2009; the Institute of Medicine, 2011; and the World Professional Association for Transgender Health [Coleman et al., 2012]), health care agencies serving TGNC clients (e.g., Fenway Health Center), TGNC community resources (Gender Equity Resource Center, National Center for Transgender Equality), and professional literature. Psychologists are encouraged to refresh their knowledge and familiarity with evolving terminology on a regular basis as changes emerge in the community and/or the professional literature. The definitions below include terms frequently used within the *Guidelines*, by the TGNC community, and within professional literature.

Ally: a cisgender person who supports and advocates for TGNC people and/or communities.

(*Appendices continue*)

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Antitrans prejudice (transprejudice, transnegativity, transphobia): prejudicial attitudes that may result in the devaluing, dislike, and hatred of people whose gender identity and/or gender expression do not conform to their sex assigned at birth. Antitrans prejudice may lead to discriminatory behaviors in such areas as employment and public accommodations, and may lead to harassment and violence. When TGNC people hold these negative attitudes about themselves and their gender identity, it is called *internalized transphobia* (a construct analogous to internalized homophobia). Transmisogyny describes a simultaneous experience of sexism and antitrans prejudice with particularly adverse effects on trans women.

Cisgender: an adjective used to describe a person whose gender identity and gender expression align with sex assigned at birth; a person who is not TGNC.

Cisgenderism: a systemic bias based on the ideology that gender expression and gender identities are determined by sex assigned at birth rather than self-identified gender identity. Cisgenderism may lead to prejudicial attitudes and discriminatory behaviors toward TGNC people or to forms of behavior or gender expression that lie outside of the traditional gender binary.

Coming out: a process by which individuals affirm and actualize a stigmatized identity. Coming out as TGNC can include disclosing a gender identity or gender history that does not align with sex assigned at birth or current gender expression. Coming out is an individual process and is partially influenced by one's age and other generational influences.

Cross dressing: wearing clothing, accessories, and/or make-up, and/or adopting a gender expression not associated with a person's assigned sex at birth according to cultural and environmental standards (Bullough & Bullough, 1993). Cross-dressing is not always reflective of gender identity or sexual orientation. People who cross-dress may or may not identify with the larger TGNC community.

Disorders of sex development (DSD, Intersex): term used to describe a variety of medical conditions associated with atypical development of an individual's physical sex characteristics (Hughes, Houk, Ahmed, & Lee, 2006). These conditions may involve differences of a person's internal and/or external reproductive organs, sex chromosomes, and/or sex-related hormones that may complicate sex assignment at birth. DSD conditions may be considered variations in biological diversity rather than disorders (M. Diamond, 2009); therefore some prefer the terms *intersex*, *intersexuality*, or *differences in sex development* rather than "disorders of sex development" (Coleman et al., 2012).

Drag: the act of adopting a gender expression, often as part of a performance. Drag may be enacted as a political comment on gender, as parody, or as entertainment, and is not necessarily reflective of gender identity.

Female-to-male (FTM): individuals assigned a female sex at birth who have changed, are changing, or wish to change their body and/or gender identity to a more masculine body or gender identity. FTM persons are also often referred to as *transgender men*, *transmen*, or *trans men*.

Gatekeeping: the role of psychologists and other mental health professionals of evaluating a TGNC person's eligibility and readiness for hormone therapy or surgery according to the Standards of Care set forth by the World Professional Association for Transgender Health (Coleman et al., 2012). In the past, this role has been perceived as limiting a TGNC adult's autonomy and contributing to mistrust between psychologists and TGNC clients. Current approaches are sensitive to this history and are more affirming of a TGNC adult's autonomy in making decisions with regard to medical transition (American Counseling Association, 2010; Coleman et al., 2012; Singh & Burnes, 2010).

Gender-affirming surgery (sex reassignment surgery or gender reassignment surgery): surgery to change primary and/or secondary sex characteristics to better align a person's physical appearance with their gender identity. Gender-affirming surgery can be an important part of medically necessary treatment to alleviate gender dysphoria and may include mastectomy, hysterectomy, metoidioplasty, phalloplasty, breast augmentation, orchiectomy, vaginoplasty, facial feminization surgery, and/or other surgical procedures.

Gender binary: the classification of gender into two discrete categories of boy/man and girl/woman.

Gender dysphoria: discomfort or distress related to incongruence between a person's gender identity, sex assigned at birth, gender identity, and/or primary and secondary sex characteristics (Knudson, De Cuypere, & Bockting, 2010). In 2013, the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM–5*; American Psychiatric Association, 2013) adopted the term *gender dysphoria* as a diagnosis characterized by "a marked incongruence between" a person's gender assigned at birth and gender identity (American Psychiatric Association, 2013, p. 453). Gender dysphoria replaced the diagnosis of gender identity disorder (GID) in the previous version of the *DSM* (American Psychiatric Association, 2000).

Gender expression: the presentation of an individual, including physical appearance, clothing choice and accessories, and behaviors that express aspects of gender identity or role. Gender expression may or may not conform to a person's gender identity.

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Gender identity: a person's deeply felt, inherent sense of being a boy, a man, or male; a girl, a woman, or female; or an alternative gender (e.g., genderqueer, gender nonconforming, gender neutral) that may or may not correspond to a person's sex assigned at birth or to a person's primary or secondary sex characteristics. Because gender identity is internal, a person's gender identity is not necessarily visible to others. "Affirmed gender identity" refers to a person's gender identity after coming out as TGNC or undergoing a social and/or medical transition process.

Gender marker: an indicator (M, F) of a person's sex or gender found on identification (e.g., driver's license, passport) and other legal documents (e.g., birth certificate, academic transcripts).

Gender nonconforming (GNC): an adjective used as an umbrella term to describe people whose gender expression or gender identity differs from gender norms associated with their assigned birth sex. Subpopulations of the TGNC community can develop specialized language to represent their experience and culture, such as the term "masculine of center" (MOC; Cole & Han, 2011) that is used in communities of color to describe one's GNC identity.

Gender questioning: an adjective to describe people who may be questioning or exploring their gender identity and whose gender identity may not align with their sex assigned at birth.

Genderqueer: a term to describe a person whose gender identity does not align with a binary understanding of gender (i.e., a person who does not identify fully as either a man or a woman). People who identify as genderqueer may redefine gender or decline to define themselves as gendered altogether. For example, people who identify as genderqueer may think of themselves as both man and woman (bigender, pangender, androgyne); neither man nor woman (genderless, gender neutral, neutrois, agender); moving between genders (genderfluid); or embodying a third gender.

Gender role: refers to a pattern of appearance, personality, and behavior that, in a given culture, is associated with being a boy/man/male or being a girl/woman/female. The appearance, personality, and behavior characteristics may or may not conform to what is expected based on a person's sex assigned at birth according to cultural and environmental standards. Gender role may also refer to the *social* role in which one is living (e.g., as a woman, a man, or another gender), with some role characteristics conforming and others not conforming to what is associated with girls/women or boys/men in a given culture and time.

Hormone therapy (gender-affirming hormone therapy, hormone replacement therapy): the use of hormones to masculinize or feminize a person's body to better align that person's physical characteristics with their gender identity. People wishing to feminize their body receive antiandrogens and/or estrogens; people wishing to masculinize their body receive testosterone. Hormone therapy may be an important part of medically necessary treatment to alleviate gender dysphoria.

Male-to-female (MTF): individuals whose assigned sex at birth was male and who have changed, are changing, or wish to change their body and/or gender role to a more feminized body or gender role. MTF persons are also often referred to as *transgender women*, *transwomen*, or *trans women*.

Passing: the ability to blend in with cisgender people without being recognized as transgender based on appearance or gender role and expression; being perceived as cisgender. Passing may or may not be a goal for all TGNC people.

Puberty suppression (puberty blocking, puberty delaying therapy): a treatment that can be used to temporarily suppress the development of secondary sex characteristics that occur during puberty in youth, typically using gonadotropin-releasing hormone (GnRH) analogues. Puberty suppression may be an important part of medically necessary treatment to alleviate gender dysphoria. Puberty suppression can provide adolescents time to determine whether they desire less reversible medical intervention and can serve as a diagnostic tool to determine if further medical intervention is warranted.

Sex (sex assigned at birth): sex is typically assigned at birth (or before during ultrasound) based on the appearance of external genitalia. When the external genitalia are ambiguous, other indicators (e.g., internal genitalia, chromosomal and hormonal sex) are considered to assign a sex, with the aim of assigning a sex that is most likely to be congruent with the child's gender identity (MacLaughlin & Donahoe, 2004). For most people, gender identity is congruent with sex assigned at birth (see *cisgender*); for TGNC individuals, gender identity differs in varying degrees from sex assigned at birth.

Sexual orientation: a component of identity that includes a person's sexual and emotional attraction to another person and the behavior and/or social affiliation that may result from this attraction. A person may be attracted to men, women, both, neither, or to people who are genderqueer, androgynous, or have other gender identities. Individuals may identify as lesbian, gay, heterosexual, bisexual, queer, pansexual, or asexual, among others.

Stealth (going stealth): a phrase used by some TGNC people across the life span (e.g., children, adolescents) who choose to make a transition in a new environment (e.g., school) in their affirmed gender without openly sharing their identity as a TGNC person.

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TGNC: an abbreviation used to refer to people who are transgender or gender nonconforming.

Trans: common short-hand for the terms transgender, transsexual, and/or gender nonconforming. Although the term "trans" is commonly accepted, not all transsexual or gender nonconforming people identify as trans.

Trans-affirmative: being respectful, aware and supportive of the needs of TGNC people.

Transgender: an adjective that is an umbrella term used to describe the full range of people whose gender identity and/or gender role do not conform to what is typically associated with their sex assigned at birth. Although the term "transgender" is commonly accepted, not all TGNC people self-identify as transgender.

Transgender man, trans man, or transman: a person whose sex assigned at birth was female, but who identifies as a man (see FTM).

Transgender woman, trans woman, or transwoman: a person whose sex assigned at birth was male, but who identifies as a woman (see MTF).

Transition: a process some TGNC people progress through when they shift toward a gender role that differs from the one associated with their sex assigned at birth. The length, scope, and process of transition are unique to each person's life situation. For many people, this involves developing a gender role and expression that is more aligned with their gender identity. A transition typically occurs over a period of time; TGNC people may proceed through a social transition (e.g., changes in gender expression, gender role, name, pronoun, and gender marker) and/or a medical transition (e.g., hormone therapy, surgery, and/or other interventions).

Transsexual: term to describe TGNC people who have changed or are changing their bodies through medical interventions (e.g., hormones, surgery) to better align their bodies with a gender identity that is different than their sex assigned at birth. Not all people who identify as transsexual consider themselves to be TGNC. For example, some transsexual individuals identify as female or male, without identifying as TGNC. Transsexualism is used as a medical diagnosis in the World Health Organization's (2015) International Classification of Diseases version 10.

Two-spirit: term used by some Native American cultures to describe people who identify with both male and female gender roles; this can include both gender identity and sexual orientation. Two-spirit people are often respected and carry unique spiritual roles for their community.

Appendix B
Guidelines for Psychological Practice With Transgender and Gender Nonconforming People

Foundational Knowledge and Awareness

Guideline 1. Psychologists understand that gender is a nonbinary construct that allows for a range of gender identities and that a person's gender identity may not align with sex assigned at birth.

Guideline 2. Psychologists understand that gender identity and sexual orientation are distinct but interrelated constructs.

Guideline 3. Psychologists seek to understand how gender identity intersects with the other cultural identities of TGNC people.

Guideline 4. Psychologists are aware of how their attitudes about and knowledge of gender identity and gender expression may affect the quality of care they provide to TGNC people and their families.

Stigma, Discrimination, and Barriers to Care

Guideline 5. Psychologists recognize how stigma, prejudice, discrimination, and violence affect the health and well-being of TGNC people.

Guideline 6. Psychologists strive to recognize the influence of institutional barriers on the lives of TGNC people and to assist in developing TGNC-affirmative environments.

Guideline 7. Psychologists understand the need to promote social change that reduces the negative effects of stigma on the health and well-being of TGNC people.

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Life Span Development

Guideline 8. Psychologists working with gender-questioning and TGNC youth understand the different developmental needs of children and adolescents and that not all youth will persist in a TGNC identity into adulthood.

Guideline 9. Psychologists strive to understand both the particular challenges that TGNC elders experience and the resilience they can develop.

Assessment, Therapy, and Intervention

Guideline 10. Psychologists strive to understand how mental health concerns may or may not be related to a TGNC person's gender identity and the psychological effects of minority stress.

Guideline 11. Psychologists recognize that TGNC people are more likely to experience positive life outcomes when they receive social support or trans-affirmative care.

Guideline 12. Psychologists strive to understand the effects that changes in gender identity and gender expression have on the romantic and sexual relationships of TGNC people.

Guideline 13. Psychologists seek to understand how parenting and family formation among TGNC people take a variety of forms.

Guideline 14. Psychologists recognize the potential benefits of an interdisciplinary approach when providing care to TGNC people and strive to work collaboratively with other providers.

Research, Education, and Training

Guideline 15. Psychologists respect the welfare and rights of TGNC participants in research and strive to represent results accurately and avoid misuse or misrepresentation of findings.

Guideline 16. Psychologists Seek to Prepare Trainees in Psychology to Work Competently With TGNC People.

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Ethical Principles of Psychologists and Code of Conduct

Including 2010 and 2016 Amendments

Effective date June 1, 2003 with amendments effective June 1, 2010 and January 1, 2017.
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Introduction and Applicability

The American Psychological Association's (APA) Ethical Principles of Psychologists and Code of Conduct (hereinafter referred to as the Ethics Code) consists of an Introduction, a Preamble (?item=2) , five General Principles (?item=3) (A-E) and specific Ethical Standards (?item=4) . The Introduction discusses the intent, organization, procedural considerations, and scope of application of the Ethics Code. The Preamble and General Principles are aspirational goals to guide psychologists toward the highest ideals of psychology. Although the Preamble and General Principles are not themselves enforceable rules, they should be considered by psychologists in arriving at an ethical course of action. The Ethical Standards set forth enforceable rules for conduct as psychologists. Most of the Ethical Standards are written broadly, in order to apply to psychologists in varied roles, although the application of an Ethical Standard may vary depending on the context. The Ethical Standards are not exhaustive. The fact that a given conduct is not specifically addressed by an Ethical Standard does not mean that it is necessarily either ethical or unethical.

This Ethics Code applies only to psychologists' activities that are part of their scientific, educational, or professional roles as psychologists. Areas covered include but are not limited to the clinical, counseling, and school practice of psychology; research; teaching; supervision of trainees; public service; policy development; social intervention; development of assessment instruments; conducting assessments; educational counseling; organizational consulting; forensic activities; program design and evaluation; and administration. This Ethics Code applies to these activities across a variety of contexts, such as in person, postal, telephone, Internet, and other electronic transmissions. These activities shall be distinguished from the purely private conduct of psychologists, which is not within the purview of the Ethics Code.

Membership in the APA commits members and student affiliates to comply with the standards of the APA Ethics Code and to the rules and procedures used to enforce them. Lack of awareness or misunderstanding of an Ethical Standard is not itself a defense to a charge of unethical conduct.

The procedures for filing, investigating, and resolving complaints of unethical conduct are described in the current Rules and Procedures of the APA Ethics Committee (/ethics/code/committee) . APA may impose sanctions on its members for violations of the standards of the Ethics Code, including termination of APA membership, and may notify other bodies and individuals of its actions. Actions that violate the standards of the Ethics Code may also lead to the imposition of sanctions on psychologists or students whether or not they are APA members by bodies other than APA, including state psychological associations, other professional groups, psychology boards, other state or federal agencies, and payors for health services. In addition, APA may take action against a member after his or her conviction of a felony, expulsion or suspension from an affiliated state psychological association, or suspension or loss of licensure. When the sanction to be imposed by APA is less than expulsion, the 2001 Rules and Procedures do not guarantee an opportunity for an in-

person hearing, but generally provide that complaints will be resolved only on the basis of a submitted record.

The Ethics Code is intended to provide guidance for psychologists and standards of professional conduct that can be applied by the APA and by other bodies that choose to adopt them. The Ethics Code is not intended to be a basis of civil liability. Whether a psychologist has violated the Ethics Code standards does not by itself determine whether the psychologist is legally liable in a court action, whether a contract is enforceable, or whether other legal consequences occur.

The modifiers used in some of the standards of this Ethics Code (e.g., reasonably, appropriate, potentially) are included in the standards when they would (1) allow professional judgment on the part of psychologists, (2) eliminate injustice or inequality that would occur without the modifier, (3) ensure applicability across the broad range of activities conducted by psychologists, or (4) guard against a set of rigid rules that might be quickly outdated. As used in this Ethics Code, the term reasonable means the prevailing professional judgment of psychologists engaged in similar activities in similar circumstances, given the knowledge the psychologist had or should have had at the time.

In the process of making decisions regarding their professional behavior, psychologists must consider this Ethics Code in addition to applicable laws and psychology board regulations. In applying the Ethics Code to their professional work, psychologists may consider other materials and guidelines that have been adopted or endorsed by scientific and professional psychological organizations and the dictates of their own conscience, as well as consult with others within the field. If this Ethics Code establishes a higher standard of conduct than is required by law, psychologists must meet the higher ethical standard. If psychologists' ethical responsibilities conflict with law, regulations, or other governing legal authority, psychologists make known their commitment to this

Ethics Code and take steps to resolve the conflict in a responsible manner in keeping with basic principles of human rights.

Preamble

Psychologists are committed to increasing scientific and professional knowledge of behavior and people's understanding of themselves and others and to the use of such knowledge to improve the condition of individuals, organizations, and society. Psychologists respect and protect civil and human rights and the central importance of freedom of inquiry and expression in research, teaching, and publication. They strive to help the public in developing informed judgments and choices concerning human behavior. In doing so, they perform many roles, such as researcher, educator, diagnostician, therapist, supervisor, consultant, administrator, social interventionist, and expert witness. This Ethics Code provides a common set of principles and standards upon which psychologists build their professional and scientific work.

This Ethics Code is intended to provide specific standards to cover most situations encountered by psychologists. It has as its goals the welfare and protection of the individuals and groups with whom psychologists work and the education of members, students, and the public regarding ethical standards of the discipline.

The development of a dynamic set of ethical standards for psychologists' work-related conduct requires a personal commitment and lifelong effort to act ethically; to encourage ethical behavior by students, supervisees, employees, and colleagues; and to consult with others concerning ethical problems.

General Principles

This section consists of General Principles. General Principles, as opposed to Ethical Standards, are aspirational in nature. Their intent is to guide and inspire psychologists toward the very highest ethical ideals of the profession. General Principles, in contrast to Ethical Standards, do not represent obligations and should not form the basis for imposing sanctions. Relying upon General Principles for either of these reasons distorts both their meaning and purpose.

Principle A: Beneficence and Nonmaleficence

Psychologists strive to benefit those with whom they work and take care to do no harm. In their professional actions, psychologists seek to safeguard the welfare and rights of those with whom they interact professionally and other affected persons, and the welfare of animal subjects of research. When conflicts occur among psychologists' obligations or concerns, they attempt to resolve these conflicts in a responsible fashion that avoids or minimizes harm. Because psychologists' scientific and professional judgments and actions may affect the lives of others, they are alert to and guard against personal, financial, social, organizational, or political factors that might lead to misuse of their influence. Psychologists strive to be aware of the possible effect of their own physical and mental health on their ability to help those with whom they work.

Principle B: Fidelity and Responsibility

Psychologists establish relationships of trust with those with whom they work. They are aware of their professional and scientific responsibilities to society and to the specific communities in which they work. Psychologists uphold professional standards of conduct, clarify their professional roles and obligations, accept appropriate responsibility for their behavior, and seek to manage conflicts of interest that could lead to exploitation or harm. Psychologists consult with, refer to, or cooperate with other professionals and institutions to the extent needed to serve the best interests of those with whom they work. They are concerned about the ethical compliance of their colleagues' scientific and professional

conduct. Psychologists strive to contribute a portion of their professional time for little or no compensation or personal advantage.

Principle C: Integrity

Psychologists seek to promote accuracy, honesty, and truthfulness in the science, teaching, and practice of psychology. In these activities psychologists do not steal, cheat or engage in fraud, subterfuge, or intentional misrepresentation of fact. Psychologists strive to keep their promises and to avoid unwise or unclear commitments. In situations in which deception may be ethically justifiable to maximize benefits and minimize harm, psychologists have a serious obligation to consider the need for, the possible consequences of, and their responsibility to correct any resulting mistrust or other harmful effects that arise from the use of such techniques.

Principle D: Justice

Psychologists recognize that fairness and justice entitle all persons to access to and benefit from the contributions of psychology and to equal quality in the processes, procedures, and services being conducted by psychologists. Psychologists exercise reasonable judgment and take precautions to ensure that their potential biases, the boundaries of their competence, and the limitations of their expertise do not lead to or condone unjust practices.

Principle E: Respect for People's Rights and Dignity

Psychologists respect the dignity and worth of all people, and the rights of individuals to privacy, confidentiality, and self-determination. Psychologists are aware that special safeguards may be necessary to protect the rights and welfare of persons or communities whose vulnerabilities impair autonomous decision making. Psychologists are aware of and respect cultural, individual, and role differences, including those based on age, gender, gender identity, race, ethnicity, culture, national origin, religion, sexual orientation, disability, language, and socioeconomic status, and consider these factors when working with members of such groups. Psychologists try to eliminate the effect on their

work of biases based on those factors, and they do not knowingly participate in or condone activities of others based upon such prejudices.

Section 1: Resolving Ethical Issues

1.01 Misuse of Psychologists' Work

If psychologists learn of misuse or misrepresentation of their work, they take reasonable steps to correct or minimize the misuse or misrepresentation.

1.02 Conflicts Between Ethics and Law, Regulations, or Other Governing Legal Authority

If psychologists' ethical responsibilities conflict with law, regulations, or other governing legal authority, psychologists clarify the nature of the conflict, make known their commitment to the Ethics Code, and take reasonable steps to resolve the conflict consistent with the General Principles and Ethical Standards of the Ethics Code. Under no circumstances may this standard be used to justify or defend violating human rights.

1.03 Conflicts Between Ethics and Organizational Demands

If the demands of an organization with which psychologists are affiliated or for whom they are working are in conflict with this Ethics Code, psychologists clarify the nature of the conflict, make known their commitment to the Ethics Code, and take reasonable steps to resolve the conflict consistent with the General Principles and Ethical Standards of the Ethics Code. Under no circumstances may this standard be used to justify or defend violating human rights.

1.04 Informal Resolution of Ethical Violations

When psychologists believe that there may have been an ethical violation by another psychologist, they attempt to resolve the issue by bringing it to the attention of that individual, if an informal resolution appears appropriate and the intervention does not violate any confidentiality

rights that may be involved. (See also Standards 1.02, Conflicts Between Ethics and Law, Regulations, or Other Governing Legal Authority (#102), and 1.03, Conflicts Between Ethics and Organizational Demands (#103).)

1.05 Reporting Ethical Violations

If an apparent ethical violation has substantially harmed or is likely to substantially harm a person or organization and is not appropriate for informal resolution under Standard 1.04, Informal Resolution of Ethical Violations (#104), or is not resolved properly in that fashion, psychologists take further action appropriate to the situation. Such action might include referral to state or national committees on professional ethics, to state licensing boards, or to the appropriate institutional authorities. This standard does not apply when an intervention would violate confidentiality rights or when psychologists have been retained to review the work of another psychologist whose professional conduct is in question. (See also Standard 1.02, Conflicts Between Ethics and Law, Regulations, or Other Governing Legal Authority (#102).)

1.06 Cooperating with Ethics Committees

Psychologists cooperate in ethics investigations, proceedings, and resulting requirements of the APA or any affiliated state psychological association to which they belong. In doing so, they address any confidentiality issues. Failure to cooperate is itself an ethics violation. However, making a request for deferment of adjudication of an ethics complaint pending the outcome of litigation does not alone constitute noncooperation.

1.07 Improper Complaints

Psychologists do not file or encourage the filing of ethics complaints that are made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

1.08 Unfair Discrimination Against Complainants and Respondents

Psychologists do not deny persons employment, advancement, admissions to academic or other programs, tenure, or promotion, based

solely upon their having made or their being the subject of an ethics complaint. This does not preclude taking action based upon the outcome of such proceedings or considering other appropriate information.

Section 2: Competence

2.01 Boundaries of Competence

(a) Psychologists provide services, teach, and conduct research with populations and in areas only within the boundaries of their competence, based on their education, training, supervised experience, consultation, study, or professional experience.

(b) Where scientific or professional knowledge in the discipline of psychology establishes that an understanding of factors associated with age, gender, gender identity, race, ethnicity, culture, national origin, religion, sexual orientation, disability, language, or socioeconomic status is essential for effective implementation of their services or research, psychologists have or obtain the training, experience, consultation, or supervision necessary to ensure the competence of their services, or they make appropriate referrals, except as provided in Standard 2.02, Providing Services in Emergencies (#202) .

(c) Psychologists planning to provide services, teach, or conduct research involving populations, areas, techniques, or technologies new to them undertake relevant education, training, supervised experience, consultation, or study.

(d) When psychologists are asked to provide services to individuals for whom appropriate mental health services are not available and for which psychologists have not obtained the competence necessary, psychologists with closely related prior training or experience may provide such services in order to ensure that services are not denied if

they make a reasonable effort to obtain the competence required by using relevant research, training, consultation, or study.

(e) In those emerging areas in which generally recognized standards for preparatory training do not yet exist, psychologists nevertheless take reasonable steps to ensure the competence of their work and to protect clients/patients, students, supervisees, research participants, organizational clients, and others from harm.

(f) When assuming forensic roles, psychologists are or become reasonably familiar with the judicial or administrative rules governing their roles.

2.02 Providing Services in Emergencies

In emergencies, when psychologists provide services to individuals for whom other mental health services are not available and for which psychologists have not obtained the necessary training, psychologists may provide such services in order to ensure that services are not denied. The services are discontinued as soon as the emergency has ended or appropriate services are available.

2.03 Maintaining Competence

Psychologists undertake ongoing efforts to develop and maintain their competence.

2.04 Bases for Scientific and Professional Judgments

Psychologists' work is based upon established scientific and professional knowledge of the discipline. (See also Standards 2.01e, Boundaries of Competence (#201e) , and 10.01b, Informed Consent to Therapy (?item=13#1001b) .)

2.05 Delegation of Work to Others

Psychologists who delegate work to employees, supervisees, or research or teaching assistants or who use the services of others, such as interpreters, take reasonable steps to (1) avoid delegating such work to

persons who have a multiple relationship with those being served that would likely lead to exploitation or loss of objectivity; (2) authorize only those responsibilities that such persons can be expected to perform competently on the basis of their education, training, or experience, either independently or with the level of supervision being provided; and (3) see that such persons perform these services competently. (See also Standards 2.02, Providing Services in Emergencies (#202) ; 3.05, Multiple Relationships (?item=6#305) ; 4.01, Maintaining Confidentiality (?item=7#401) ; 9.01, Bases for Assessments (?item=12#901) ; 9.02, Use of Assessments (?item=12#902) ; 9.03, Informed Consent in Assessments (?item=12#903) ; and 9.07, Assessment by Unqualified Persons (?item=12#907) .)

2.06 Personal Problems and Conflicts

(a) Psychologists refrain from initiating an activity when they know or should know that there is a substantial likelihood that their personal problems will prevent them from performing their work-related activities in a competent manner.

(b) When psychologists become aware of personal problems that may interfere with their performing work-related duties adequately, they take appropriate measures, such as obtaining professional consultation or assistance, and determine whether they should limit, suspend, or terminate their work-related duties. (See also Standard 10.10, Terminating Therapy (?item=13#1010) .)

Section 3: Human Relations

3.01 Unfair Discrimination

In their work-related activities, psychologists do not engage in unfair discrimination based on age, gender, gender identity, race, ethnicity, culture, national origin, religion, sexual orientation, disability, socioeconomic status, or any basis proscribed by law.

3.02 Sexual Harassment

Psychologists do not engage in sexual harassment. Sexual harassment is sexual solicitation, physical advances, or verbal or nonverbal conduct that is sexual in nature, that occurs in connection with the psychologist's activities or roles as a psychologist, and that either (1) is unwelcome, is offensive, or creates a hostile workplace or educational environment, and the psychologist knows or is told this or (2) is sufficiently severe or intense to be abusive to a reasonable person in the context. Sexual harassment can consist of a single intense or severe act or of multiple persistent or pervasive acts. (See also Standard 1.08, Unfair Discrimination Against Complainants and Respondents (?item=4#108) .)

3.03 Other Harassment

Psychologists do not knowingly engage in behavior that is harassing or demeaning to persons with whom they interact in their work based on factors such as those persons' age, gender, gender identity, race, ethnicity, culture, national origin, religion, sexual orientation, disability, language, or socioeconomic status.

3.04 Avoiding Harm

(a) Psychologists take reasonable steps to avoid harming their clients/patients, students, supervisees, research participants, organizational clients, and others with whom they work, and to minimize harm where it is foreseeable and unavoidable.

(b) Psychologists do not participate in, facilitate, assist, or otherwise engage in torture, defined as any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person, or in any other cruel, inhuman, or degrading behavior that violates 3.04(a).

3.05 Multiple Relationships

(a) A multiple relationship occurs when a psychologist is in a professional role with a person and (1) at the same time is in another role with the same person, (2) at the same time is in a relationship with a person

closely associated with or related to the person with whom the psychologist has the professional relationship, or (3) promises to enter into another relationship in the future with the person or a person closely associated with or related to the person.

A psychologist refrains from entering into a multiple relationship if the multiple relationship could reasonably be expected to impair the psychologist's objectivity, competence, or effectiveness in performing his or her functions as a psychologist, or otherwise risks exploitation or harm to the person with whom the professional relationship exists.

Multiple relationships that would not reasonably be expected to cause impairment or risk exploitation or harm are not unethical.

(b) If a psychologist finds that, due to unforeseen factors, a potentially harmful multiple relationship has arisen, the psychologist takes reasonable steps to resolve it with due regard for the best interests of the affected person and maximal compliance with the Ethics Code.

(c) When psychologists are required by law, institutional policy, or extraordinary circumstances to serve in more than one role in judicial or administrative proceedings, at the outset they clarify role expectations and the extent of confidentiality and thereafter as changes occur. (See also Standards 3.04, Avoiding Harm (#304) , and 3.07, Third-Party Requests for Services (#307) .)

3.06 Conflict of Interest

Psychologists refrain from taking on a professional role when personal, scientific, professional, legal, financial, or other interests or relationships could reasonably be expected to (1) impair their objectivity, competence, or effectiveness in performing their functions as psychologists or (2) expose the person or organization with whom the professional relationship exists to harm or exploitation.

3.07 Third-Party Requests for Services

When psychologists agree to provide services to a person or entity at the request of a third party, psychologists attempt to clarify at the outset of the service the nature of the relationship with all individuals or organizations involved. This clarification includes the role of the psychologist (e.g., therapist, consultant, diagnostician, or expert witness), an identification of who is the client, the probable uses of the services provided or the information obtained, and the fact that there may be limits to confidentiality. (See also Standards 3.05, Multiple relationships (#305) , and 4.02, Discussing the Limits of Confidentiality.)

3.08 Exploitative Relationships

Psychologists do not exploit persons over whom they have supervisory, evaluative or other authority such as clients/patients, students, supervisees, research participants, and employees. (See also Standards 3.05, Multiple Relationships (#305) ; 6.04, Fees and Financial Arrangements (?item=9#604) ; 6.05, Barter with Clients/Patients (?item=9#605) ; 7.07, Sexual Relationships with Students and Supervisees (?item=10#707) ; 10.05, Sexual Intimacies with Current Therapy Clients/Patients (?item=13#1005) ; 10.06, Sexual Intimacies with Relatives or Significant Others of Current Therapy Clients/Patients (?item=13#1006) ; 10.07, Therapy with Former Sexual Partners (?item=13#1007) ; and 10.08, Sexual Intimacies with Former Therapy Clients/Patients (?item=13#1008) .)

3.09 Cooperation with Other Professionals

When indicated and professionally appropriate, psychologists cooperate with other professionals in order to serve their clients/patients effectively and appropriately. (See also Standard (javascript:goToItem(7);) 4.05, Disclosures (?item=7#405) .)

3.10 Informed Consent

(a) When psychologists conduct research or provide assessment, therapy, counseling, or consulting services in person or via electronic transmission or other forms of communication, they obtain the informed consent of the individual or individuals using language that is reasonably

understandable to that person or persons except when conducting such activities without consent is mandated by law or governmental regulation or as otherwise provided in this Ethics Code. (See also Standards 8.02, Informed Consent to Research (?item=11#802) ; 9.03, Informed Consent in Assessments (?item=12#903) ; and 10.01, Informed Consent to Therapy (?item=13#1001) .)

(b) For persons who are legally incapable of giving informed consent, psychologists nevertheless (1) provide an appropriate explanation, (2) seek the individual's assent, (3) consider such persons' preferences and best interests, and (4) obtain appropriate permission from a legally authorized person, if such substitute consent is permitted or required by law. When consent by a legally authorized person is not permitted or required by law, psychologists take reasonable steps to protect the individual's rights and welfare.

(c) When psychological services are court ordered or otherwise mandated, psychologists inform the individual of the nature of the anticipated services, including whether the services are court ordered or mandated and any limits of confidentiality, before proceeding.

(d) Psychologists appropriately document written or oral consent, permission, and assent. (See also Standards 8.02, Informed Consent to Research (?item=11#802) ; 9.03, Informed Consent in Assessments (?item=12#903) ; and 10.01, Informed Consent to Therapy (?item=13#1001) .)

3.11 Psychological Services Delivered to or Through Organizations

(a) Psychologists delivering services to or through organizations provide information beforehand to clients and when appropriate those directly affected by the services about (1) the nature and objectives of the services, (2) the intended recipients, (3) which of the individuals are clients, (4) the relationship the psychologist will have with each person and the organization, (5) the probable uses of services provided and information obtained, (6) who will have access to the information, and (7)

limits of confidentiality. As soon as feasible, they provide information about the results and conclusions of such services to appropriate persons.

(b) If psychologists will be precluded by law or by organizational roles from providing such information to particular individuals or groups, they so inform those individuals or groups at the outset of the service.

3.12 Interruption of Psychological Services

Unless otherwise covered by contract, psychologists make reasonable efforts to plan for facilitating services in the event that psychological services are interrupted by factors such as the psychologist's illness, death, unavailability, relocation, or retirement or by the client's/patient's relocation or financial limitations. (See also Standard 6.02c, Maintenance, Dissemination, and Disposal of Confidential Records of Professional and Scientific Work (?item=9#602c) .)

Section 4: Privacy and Confidentiality

4.01 Maintaining Confidentiality

Psychologists have a primary obligation and take reasonable precautions to protect confidential information obtained through or stored in any medium, recognizing that the extent and limits of confidentiality may be regulated by law or established by institutional rules or professional or scientific relationship. (See also Standard 2.05, Delegation of Work to Others (?item=5#205) .)

4.02 Discussing the Limits of Confidentiality

(a) Psychologists discuss with persons (including, to the extent feasible, persons who are legally incapable of giving informed consent and their legal representatives) and organizations with whom they establish a scientific or professional relationship (1) the relevant limits of confidentiality and (2) the foreseeable uses of the information generated

through their psychological activities. (See also Standard 3.10, Informed Consent (?item=6#310) .)

(b) Unless it is not feasible or is contraindicated, the discussion of confidentiality occurs at the outset of the relationship and thereafter as new circumstances may warrant.

(c) Psychologists who offer services, products, or information via electronic transmission inform clients/patients of the risks to privacy and limits of confidentiality.

4.03 Recording

Before recording the voices or images of individuals to whom they provide services, psychologists obtain permission from all such persons or their legal representatives. (See also Standards 8.03, Informed Consent for Recording Voices and Images in Research (?item=11#803) ; 8.05, Dispensing with Informed Consent for Research (?item=11#805) ; and 8.07, Deception in Research (?item=11#807) .)

4.04 Minimizing Intrusions on Privacy

(a) Psychologists include in written and oral reports and consultations, only information germane to the purpose for which the communication is made.

(b) Psychologists discuss confidential information obtained in their work only for appropriate scientific or professional purposes and only with persons clearly concerned with such matters.

4.05 Disclosures

(a) Psychologists may disclose confidential information with the appropriate consent of the organizational client, the individual client/patient, or another legally authorized person on behalf of the client/patient unless prohibited by law.

(b) Psychologists disclose confidential information without the consent of the individual only as mandated by law, or where permitted by law for a valid purpose such as to (1) provide needed professional services; (2) obtain appropriate professional consultations; (3) protect the client/patient, psychologist, or others from harm; or (4) obtain payment for services from a client/patient, in which instance disclosure is limited to the minimum that is necessary to achieve the purpose. (See also Standard 6.04e, Fees and Financial Arrangements (?item=9#604e) .)

4.06 Consultations

When consulting with colleagues, (1) psychologists do not disclose confidential information that reasonably could lead to the identification of a client/patient, research participant, or other person or organization with whom they have a confidential relationship unless they have obtained the prior consent of the person or organization or the disclosure cannot be avoided, and (2) they disclose information only to the extent necessary to achieve the purposes of the consultation. (See also Standard 4.01, Maintaining Confidentiality (#401) .)

4.07 Use of Confidential Information for Didactic or Other Purposes

Psychologists do not disclose in their writings, lectures, or other public media, confidential, personally identifiable information concerning their clients/patients, students, research participants, organizational clients, or other recipients of their services that they obtained during the course of their work, unless (1) they take reasonable steps to disguise the person or organization, (2) the person or organization has consented in writing, or (3) there is legal authorization for doing so.

Section 5: Advertising and Other Public Statements

5.01 Avoidance of False or Deceptive Statements

(a) Public statements include but are not limited to paid or unpaid advertising, product endorsements, grant applications, licensing applications, other credentialing applications, brochures, printed matter,

directory listings, personal resumes or curricula vitae, or comments for use in media such as print or electronic transmission, statements in legal proceedings, lectures and public oral presentations, and published materials. Psychologists do not knowingly make public statements that are false, deceptive, or fraudulent concerning their research, practice, or other work activities or those of persons or organizations with which they are affiliated.

(b) Psychologists do not make false, deceptive, or fraudulent statements concerning (1) their training, experience, or competence; (2) their academic degrees; (3) their credentials; (4) their institutional or association affiliations; (5) their services; (6) the scientific or clinical basis for, or results or degree of success of, their services; (7) their fees; or (8) their publications or research findings.

(c) Psychologists claim degrees as credentials for their health services only if those degrees (1) were earned from a regionally accredited educational institution or (2) were the basis for psychology licensure by the state in which they practice.

5.02 Statements by Others

(a) Psychologists who engage others to create or place public statements that promote their professional practice, products, or activities retain professional responsibility for such statements.

(b) Psychologists do not compensate employees of press, radio, television, or other communication media in return for publicity in a news item. (See also Standard 1.01, Misuse of Psychologists' Work (?item=4#101) .)

(c) A paid advertisement relating to psychologists' activities must be identified or clearly recognizable as such.

5.03 Descriptions of Workshops and Non-Degree-Granting Educational Programs

To the degree to which they exercise control, psychologists responsible for announcements, catalogs, brochures, or advertisements describing workshops, seminars, or other non-degree-granting educational programs ensure that they accurately describe the audience for which the program is intended, the educational objectives, the presenters, and the fees involved.

5.04 Media Presentations

When psychologists provide public advice or comment via print, Internet, or other electronic transmission, they take precautions to ensure that statements (1) are based on their professional knowledge, training, or experience in accord with appropriate psychological literature and practice; (2) are otherwise consistent with this Ethics Code; and (3) do not indicate that a professional relationship has been established with the recipient. (See also Standard 2.04, Bases for Scientific and Professional Judgments (?item=5#204) .)

5.05 Testimonials

Psychologists do not solicit testimonials from current therapy clients/patients or other persons who because of their particular circumstances are vulnerable to undue influence.

5.06 In-Person Solicitation

Psychologists do not engage, directly or through agents, in uninvited in-person solicitation of business from actual or potential therapy clients/patients or other persons who because of their particular circumstances are vulnerable to undue influence. However, this prohibition does not preclude (1) attempting to implement appropriate collateral contacts for the purpose of benefiting an already engaged therapy client/patient or (2) providing disaster or community outreach services.

Section 6: Record Keeping and Fees

6.01 Documentation of Professional and Scientific Work and Maintenance of Records

Psychologists create, and to the extent the records are under their control, maintain, disseminate, store, retain, and dispose of records and data relating to their professional and scientific work in order to (1) facilitate provision of services later by them or by other professionals, (2) allow for replication of research design and analyses, (3) meet institutional requirements, (4) ensure accuracy of billing and payments, and (5) ensure compliance with law. (See also Standard 4.01, Maintaining Confidentiality (?item=7#401) .)

6.02 Maintenance, Dissemination, and Disposal of Confidential Records of Professional and Scientific Work

(a) Psychologists maintain confidentiality in creating, storing, accessing, transferring, and disposing of records under their control, whether these are written, automated, or in any other medium. (See also Standards 4.01, Maintaining Confidentiality (?item=7#401) , and 6.01, Documentation of Professional and Scientific Work and Maintenance of Records (#601) .)

(b) If confidential information concerning recipients of psychological services is entered into databases or systems of records available to persons whose access has not been consented to by the recipient, psychologists use coding or other techniques to avoid the inclusion of personal identifiers.

(c) Psychologists make plans in advance to facilitate the appropriate transfer and to protect the confidentiality of records and data in the event of psychologists' withdrawal from positions or practice. (See also Standards 3.12, Interruption of Psychological Services (?item=6#312) , and 10.09, Interruption of Therapy (?item=13#1009) .)

6.03 Withholding Records for Nonpayment

Psychologists may not withhold records under their control that are

requested and needed for a client's/patient's emergency treatment solely because payment has not been received.

6.04 Fees and Financial Arrangements

(a) As early as is feasible in a professional or scientific relationship, psychologists and recipients of psychological services reach an agreement specifying compensation and billing arrangements.

(b) Psychologists' fee practices are consistent with law.

(c) Psychologists do not misrepresent their fees.

(d) If limitations to services can be anticipated because of limitations in financing, this is discussed with the recipient of services as early as is feasible. (See also Standards 10.09, Interruption of Therapy (?item=13#1009) , and 10.10, Terminating Therapy (?item=13#1010) .)

(e) If the recipient of services does not pay for services as agreed, and if psychologists intend to use collection agencies or legal measures to collect the fees, psychologists first inform the person that such measures will be taken and provide that person an opportunity to make prompt payment. (See also Standards 4.05, Disclosures (?item=7#405) ; 6.03, Withholding Records for Nonpayment (#603) ; and 10.01, Informed Consent to Therapy (?item=13#1001) .)

6.05 Barter with Clients/Patients

Barter is the acceptance of goods, services, or other nonmonetary remuneration from clients/patients in return for psychological services. Psychologists may barter only if (1) it is not clinically contraindicated, and (2) the resulting arrangement is not exploitative. (See also Standards 3.05, Multiple Relationships (?item=6#305) , and 6.04, Fees and Financial Arrangements (#604) .)

6.06 Accuracy in Reports to Payors and Funding Sources

In their reports to payors for services or sources of research funding,

psychologists take reasonable steps to ensure the accurate reporting of the nature of the service provided or research conducted, the fees, charges, or payments, and where applicable, the identity of the provider, the findings, and the diagnosis. (See also Standards 4.01, Maintaining Confidentiality (?item=7#401) ; 4.04, Minimizing Intrusions on Privacy (?item=7#404) ; and 4.05, Disclosures (?item=7#405) .)

6.07 Referrals and Fees

When psychologists pay, receive payment from, or divide fees with another professional, other than in an employer-employee relationship, the payment to each is based on the services provided (clinical, consultative, administrative, or other) and is not based on the referral itself. (See also Standard 3.09, Cooperation with Other Professionals (?item=6#309) .)

Section 7: Education and Training

7.01 Design of Education and Training Programs

Psychologists responsible for education and training programs take reasonable steps to ensure that the programs are designed to provide the appropriate knowledge and proper experiences, and to meet the requirements for licensure, certification, or other goals for which claims are made by the program. (See also Standard 5.03, Descriptions of Workshops and Non-Degree-Granting Educational Programs (?item=8#503) .)

7.02 Descriptions of Education and Training Programs

Psychologists responsible for education and training programs take reasonable steps to ensure that there is a current and accurate description of the program content (including participation in required course- or program-related counseling, psychotherapy, experiential groups, consulting projects, or community service), training goals and objectives, stipends and benefits, and requirements that must be met for

satisfactory completion of the program. This information must be made readily available to all interested parties.

7.03 Accuracy in Teaching

(a) Psychologists take reasonable steps to ensure that course syllabi are accurate regarding the subject matter to be covered, bases for evaluating progress, and the nature of course experiences. This standard does not preclude an instructor from modifying course content or requirements when the instructor considers it pedagogically necessary or desirable, so long as students are made aware of these modifications in a manner that enables them to fulfill course requirements. (See also Standard 5.01, Avoidance of False or Deceptive Statements (?item=8#501) .)

(b) When engaged in teaching or training, psychologists present psychological information accurately. (See also Standard 2.03, Maintaining Competence (?item=5#203) .)

7.04 Student Disclosure of Personal Information

Psychologists do not require students or supervisees to disclose personal information in course- or program-related activities, either orally or in writing, regarding sexual history, history of abuse and neglect, psychological treatment, and relationships with parents, peers, and spouses or significant others except if (1) the program or training facility has clearly identified this requirement in its admissions and program materials or (2) the information is necessary to evaluate or obtain assistance for students whose personal problems could reasonably be judged to be preventing them from performing their training- or professionally related activities in a competent manner or posing a threat to the students or others.

7.05 Mandatory Individual or Group Therapy

(a) When individual or group therapy is a program or course requirement, psychologists responsible for that program allow students in undergraduate and graduate programs the option of selecting such

therapy from practitioners unaffiliated with the program. (See also Standard 7.02, Descriptions of Education and Training Programs (#702) .)

(b) Faculty who are or are likely to be responsible for evaluating students' academic performance do not themselves provide that therapy. (See also Standard 3.05, Multiple Relationships (?item=6#305) .)

7.06 Assessing Student and Supervisee Performance
(a) In academic and supervisory relationships, psychologists establish a timely and specific process for providing feedback to students and supervisees. Information regarding the process is provided to the student at the beginning of supervision.

(b) Psychologists evaluate students and supervisees on the basis of their actual performance on relevant and established program requirements.

7.07 Sexual Relationships with Students and Supervisees
Psychologists do not engage in sexual relationships with students or supervisees who are in their department, agency, or training center or over whom psychologists have or are likely to have evaluative authority. (See also Standard 3.05, Multiple Relationships (?item=6#305) .)

Section 8: Research and Publication

8.01 Institutional Approval
When institutional approval is required, psychologists provide accurate information about their research proposals and obtain approval prior to conducting the research. They conduct the research in accordance with the approved research protocol.

8.02 Informed Consent to Research
(a) When obtaining informed consent as required in Standard 3.10, Informed Consent, psychologists inform participants about (1) the purpose of the research, expected duration, and procedures; (2) their

right to decline to participate and to withdraw from the research once participation has begun; (3) the foreseeable consequences of declining or withdrawing; (4) reasonably foreseeable factors that may be expected to influence their willingness to participate such as potential risks, discomfort, or adverse effects; (5) any prospective research benefits; (6) limits of confidentiality; (7) incentives for participation; and (8) whom to contact for questions about the research and research participants' rights. They provide opportunity for the prospective participants to ask questions and receive answers. (See also Standards 8.03, Informed Consent for Recording Voices and Images in Research (#803) ; 8.05, Dispensing with Informed Consent for Research (#805) ; and 8.07, Deception in Research (#807) .)

(b) Psychologists conducting intervention research involving the use of experimental treatments clarify to participants at the outset of the research (1) the experimental nature of the treatment; (2) the services that will or will not be available to the control group(s) if appropriate; (3) the means by which assignment to treatment and control groups will be made; (4) available treatment alternatives if an individual does not wish to participate in the research or wishes to withdraw once a study has begun; and (5) compensation for or monetary costs of participating including, if appropriate, whether reimbursement from the participant or a third-party payor will be sought. (See also Standard 8.02a, Informed Consent to Research (#802a) .)

8.03 Informed Consent for Recording Voices and Images in Research
Psychologists obtain informed consent from research participants prior to recording their voices or images for data collection unless (1) the research consists solely of naturalistic observations in public places, and it is not anticipated that the recording will be used in a manner that could cause personal identification or harm, or (2) the research design includes deception, and consent for the use of the recording is obtained during debriefing. (See also Standard 8.07, Deception in Research (#807) .)

8.04 Client/Patient, Student, and Subordinate Research Participants

(a) When psychologists conduct research with clients/patients, students, or subordinates as participants, psychologists take steps to protect the prospective participants from adverse consequences of declining or withdrawing from participation.

(b) When research participation is a course requirement or an opportunity for extra credit, the prospective participant is given the choice of equitable alternative activities.

8.05 Dispensing with Informed Consent for Research

Psychologists may dispense with informed consent only (1) where research would not reasonably be assumed to create distress or harm and involves (a) the study of normal educational practices, curricula, or classroom management methods conducted in educational settings; (b) only anonymous questionnaires, naturalistic observations, or archival research for which disclosure of responses would not place participants at risk of criminal or civil liability or damage their financial standing, employability, or reputation, and confidentiality is protected; or (c) the study of factors related to job or organization effectiveness conducted in organizational settings for which there is no risk to participants' employability, and confidentiality is protected or (2) where otherwise permitted by law or federal or institutional regulations.

8.06 Offering Inducements for Research Participation

(a) Psychologists make reasonable efforts to avoid offering excessive or inappropriate financial or other inducements for research participation when such inducements are likely to coerce participation.

(b) When offering professional services as an inducement for research participation, psychologists clarify the nature of the services, as well as the risks, obligations, and limitations. (See also Standard 6.05, Barter with Clients/Patients (?item=9#605) .)

8.07 Deception in Research

(a) Psychologists do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that effective nondeceptive alternative procedures are not feasible.

(b) Psychologists do not deceive prospective participants about research that is reasonably expected to cause physical pain or severe emotional distress.

(c) Psychologists explain any deception that is an integral feature of the design and conduct of an experiment to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data. (See also Standard 8.08, Debriefing (#808) .)

8.08 Debriefing

(a) Psychologists provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and they take reasonable steps to correct any misconceptions that participants may have of which the psychologists are aware.

(b) If scientific or humane values justify delaying or withholding this information, psychologists take reasonable measures to reduce the risk of harm.

(c) When psychologists become aware that research procedures have harmed a participant, they take reasonable steps to minimize the harm.

8.09 Humane Care and Use of Animals in Research

(a) Psychologists acquire, care for, use, and dispose of animals in compliance with current federal, state, and local laws and regulations, and with professional standards.

(b) Psychologists trained in research methods and experienced in the care of laboratory animals supervise all procedures involving animals and are responsible for ensuring appropriate consideration of their comfort, health, and humane treatment.

(c) Psychologists ensure that all individuals under their supervision who are using animals have received instruction in research methods and in the care, maintenance, and handling of the species being used, to the extent appropriate to their role. (See also Standard 2.05, Delegation of Work to Others (?item=5#205) .)

(d) Psychologists make reasonable efforts to minimize the discomfort, infection, illness, and pain of animal subjects.

(e) Psychologists use a procedure subjecting animals to pain, stress, or privation only when an alternative procedure is unavailable and the goal is justified by its prospective scientific, educational, or applied value.

(f) Psychologists perform surgical procedures under appropriate anesthesia and follow techniques to avoid infection and minimize pain during and after surgery.

(g) When it is appropriate that an animal's life be terminated, psychologists proceed rapidly, with an effort to minimize pain and in accordance with accepted procedures.

8.10 Reporting Research Results

(a) Psychologists do not fabricate data. (See also Standard 5.01a, Avoidance of False or Deceptive Statements (?item=8#501a) .)

(b) If psychologists discover significant errors in their published data, they take reasonable steps to correct such errors in a correction, retraction, erratum, or other appropriate publication means.

8.11 Plagiarism

Psychologists do not present portions of another's work or data as their own, even if the other work or data source is cited occasionally.

8.12 Publication Credit

(a) Psychologists take responsibility and credit, including authorship credit, only for work they have actually performed or to which they have substantially contributed. (See also Standard 8.12b, Publication Credit (#812b) .)

(b) Principal authorship and other publication credits accurately reflect the relative scientific or professional contributions of the individuals involved, regardless of their relative status. Mere possession of an institutional position, such as department chair, does not justify authorship credit. Minor contributions to the research or to the writing for publications are acknowledged appropriately, such as in footnotes or in an introductory statement.

(c) Except under exceptional circumstances, a student is listed as principal author on any multiple-authored article that is substantially based on the student's doctoral dissertation. Faculty advisors discuss publication credit with students as early as feasible and throughout the research and publication process as appropriate. (See also Standard 8.12b, Publication Credit (#812b) .)

8.13 Duplicate Publication of Data

Psychologists do not publish, as original data, data that have been previously published. This does not preclude republishing data when they are accompanied by proper acknowledgment.

8.14 Sharing Research Data for Verification

(a) After research results are published, psychologists do not withhold the data on which their conclusions are based from other competent professionals who seek to verify the substantive claims through reanalysis and who intend to use such data only for that purpose, provided that the

confidentiality of the participants can be protected and unless legal rights concerning proprietary data preclude their release. This does not preclude psychologists from requiring that such individuals or groups be responsible for costs associated with the provision of such information.

(b) Psychologists who request data from other psychologists to verify the substantive claims through reanalysis may use shared data only for the declared purpose. Requesting psychologists obtain prior written agreement for all other uses of the data.

8.15 Reviewers

Psychologists who review material submitted for presentation, publication, grant, or research proposal review respect the confidentiality of and the proprietary rights in such information of those who submitted it.

Section 9: Assessment

9.01 Bases for Assessments

(a) Psychologists base the opinions contained in their recommendations, reports, and diagnostic or evaluative statements, including forensic testimony, on information and techniques sufficient to substantiate their findings. (See also Standard 2.04, Bases for Scientific and Professional Judgments (?item=5#204) .)

(b) Except as noted in 9.01c (#901c) , psychologists provide opinions of the psychological characteristics of individuals only after they have conducted an examination of the individuals adequate to support their statements or conclusions. When, despite reasonable efforts, such an examination is not practical, psychologists document the efforts they made and the result of those efforts, clarify the probable impact of their limited information on the reliability and validity of their opinions, and appropriately limit the nature and extent of their conclusions or

recommendations. (See also Standards 2.01, Boundaries of Competence (?item=5#201) , and 9.06, Interpreting Assessment Results (#906) .)

(c) When psychologists conduct a record review or provide consultation or supervision and an individual examination is not warranted or necessary for the opinion, psychologists explain this and the sources of information on which they based their conclusions and recommendations.

9.02 Use of Assessments

(a) Psychologists administer, adapt, score, interpret, or use assessment techniques, interviews, tests, or instruments in a manner and for purposes that are appropriate in light of the research on or evidence of the usefulness and proper application of the techniques.

(b) Psychologists use assessment instruments whose validity and reliability have been established for use with members of the population tested. When such validity or reliability has not been established, psychologists describe the strengths and limitations of test results and interpretation.

(c) Psychologists use assessment methods that are appropriate to an individual's language preference and competence, unless the use of an alternative language is relevant to the assessment issues.

9.03 Informed Consent in Assessments

(a) Psychologists obtain informed consent for assessments, evaluations, or diagnostic services, as described in Standard 3.10, Informed Consent, except when (1) testing is mandated by law or governmental regulations; (2) informed consent is implied because testing is conducted as a routine educational, institutional, or organizational activity (e.g., when participants voluntarily agree to assessment when applying for a job); or (3) one purpose of the testing is to evaluate decisional capacity. Informed consent includes an explanation of the nature and purpose of the assessment, fees, involvement of third parties, and limits of

confidentiality and sufficient opportunity for the client/patient to ask questions and receive answers.

(b) Psychologists inform persons with questionable capacity to consent or for whom testing is mandated by law or governmental regulations about the nature and purpose of the proposed assessment services, using language that is reasonably understandable to the person being assessed.

(c) Psychologists using the services of an interpreter obtain informed consent from the client/patient to use that interpreter, ensure that confidentiality of test results and test security are maintained, and include in their recommendations, reports, and diagnostic or evaluative statements, including forensic testimony, discussion of any limitations on the data obtained. (See also Standards 2.05, Delegation of Work to Others (?item=5#205) ; 4.01, Maintaining Confidentiality (?item=7#401) ; 9.01, Bases for Assessments (#901) ; 9.06, Interpreting Assessment Results (#906) ; and 9.07, Assessment by Unqualified Persons (#907) .)

9.04 Release of Test Data

(a) The term *test data* refers to raw and scaled scores, client/patient responses to test questions or stimuli, and psychologists' notes and recordings concerning client/patient statements and behavior during an examination. Those portions of test materials that include client/patient responses are included in the definition of *test data* . Pursuant to a client/patient release, psychologists provide test data to the client/patient or other persons identified in the release. Psychologists may refrain from releasing test data to protect a client/patient or others from substantial harm or misuse or misrepresentation of the data or the test, recognizing that in many instances release of confidential information under these circumstances is regulated by law. (See also Standard 9.11, Maintaining Test Security (#911) .)

(b) In the absence of a client/patient release, psychologists provide test data only as required by law or court order.

9.05 Test Construction

Psychologists who develop tests and other assessment techniques use appropriate psychometric procedures and current scientific or professional knowledge for test design, standardization, validation, reduction or elimination of bias, and recommendations for use.

9.06 Interpreting Assessment Results

When interpreting assessment results, including automated interpretations, psychologists take into account the purpose of the assessment as well as the various test factors, test-taking abilities, and other characteristics of the person being assessed, such as situational, personal, linguistic, and cultural differences, that might affect psychologists' judgments or reduce the accuracy of their interpretations. They indicate any significant limitations of their interpretations. (See also Standards 2.01b and c, Boundaries of Competence (?item=5#201b) , and 3.01, Unfair Discrimination (?item=6#301) .)

9.07 Assessment by Unqualified Persons

Psychologists do not promote the use of psychological assessment techniques by unqualified persons, except when such use is conducted for training purposes with appropriate supervision. (See also Standard 2.05, Delegation of Work to Others (?item=5#205) .)

9.08 Obsolete Tests and Outdated Test Results

(a) Psychologists do not base their assessment or intervention decisions or recommendations on data or test results that are outdated for the current purpose.

(b) Psychologists do not base such decisions or recommendations on tests and measures that are obsolete and not useful for the current purpose.

9.09 Test Scoring and Interpretation Services

(a) Psychologists who offer assessment or scoring services to other professionals accurately describe the purpose, norms, validity, reliability,

and applications of the procedures and any special qualifications applicable to their use.

(b) Psychologists select scoring and interpretation services (including automated services) on the basis of evidence of the validity of the program and procedures as well as on other appropriate considerations. (See also Standard 2.01b and c, Boundaries of Competence (?item=5#201b) .)

(c) Psychologists retain responsibility for the appropriate application, interpretation, and use of assessment instruments, whether they score and interpret such tests themselves or use automated or other services.

9.10 Explaining Assessment Results

Regardless of whether the scoring and interpretation are done by psychologists, by employees or assistants, or by automated or other outside services, psychologists take reasonable steps to ensure that explanations of results are given to the individual or designated representative unless the nature of the relationship precludes provision of an explanation of results (such as in some organizational consulting, preemployment or security screenings, and forensic evaluations), and this fact has been clearly explained to the person being assessed in advance.

9.11 Maintaining Test Security

The term *test materials* refers to manuals, instruments, protocols, and test questions or stimuli and does not include *test data* as defined in Standard 9.04, Release of Test Data (#904) . Psychologists make reasonable efforts to maintain the integrity and security of test materials and other assessment techniques consistent with law and contractual obligations, and in a manner that permits adherence to this Ethics Code.

Section 10: Therapy

10.01 Informed Consent to Therapy

(a) When obtaining informed consent to therapy as required in Standard 3.10, Informed Consent (?item=6#310) , psychologists inform clients/patients as early as is feasible in the therapeutic relationship about the nature and anticipated course of therapy, fees, involvement of third parties, and limits of confidentiality and provide sufficient opportunity for the client/patient to ask questions and receive answers. (See also Standards 4.02, Discussing the Limits of Confidentiality (?item=7#402) , and 6.04, Fees and Financial Arrangements (?item=9#604) .)

(b) When obtaining informed consent for treatment for which generally recognized techniques and procedures have not been established, psychologists inform their clients/patients of the developing nature of the treatment, the potential risks involved, alternative treatments that may be available, and the voluntary nature of their participation. (See also Standards 2.01e, Boundaries of Competence (?item=5#201e) , and 3.10, Informed Consent (?item=6#310) .)

(c) When the therapist is a trainee and the legal responsibility for the treatment provided resides with the supervisor, the client/patient, as part of the informed consent procedure, is informed that the therapist is in training and is being supervised and is given the name of the supervisor.

10.02 Therapy Involving Couples or Families

(a) When psychologists agree to provide services to several persons who have a relationship (such as spouses, significant others, or parents and children), they take reasonable steps to clarify at the outset (1) which of the individuals are clients/patients and (2) the relationship the psychologist will have with each person. This clarification includes the psychologist's role and the probable uses of the services provided or the information obtained. (See also Standard 4.02, Discussing the Limits of Confidentiality (?item=7#402) .)

(b) If it becomes apparent that psychologists may be called on to perform potentially conflicting roles (such as family therapist and then witness for one party in divorce proceedings), psychologists take reasonable steps to clarify and modify, or withdraw from, roles appropriately. (See also Standard 3.05c, Multiple Relationships (?item=6#305c) .)

10.03 Group Therapy

When psychologists provide services to several persons in a group setting, they describe at the outset the roles and responsibilities of all parties and the limits of confidentiality.

10.04 Providing Therapy to Those Served by Others

In deciding whether to offer or provide services to those already receiving mental health services elsewhere, psychologists carefully consider the treatment issues and the potential client's/patient's welfare. Psychologists discuss these issues with the client/patient or another legally authorized person on behalf of the client/patient in order to minimize the risk of confusion and conflict, consult with the other service providers when appropriate, and proceed with caution and sensitivity to the therapeutic issues.

10.05 Sexual Intimacies with Current Therapy Clients/Patients

Psychologists do not engage in sexual intimacies with current therapy clients/patients.

10.06 Sexual Intimacies with Relatives or Significant Others of Current Therapy Clients/Patients

Psychologists do not engage in sexual intimacies with individuals they know to be close relatives, guardians, or significant others of current clients/patients. Psychologists do not terminate therapy to circumvent this standard.

10.07 Therapy with Former Sexual Partners

Psychologists do not accept as therapy clients/patients persons with

whom they have engaged in sexual intimacies.

10.08 Sexual Intimacies with Former Therapy Clients/Patients

(a) Psychologists do not engage in sexual intimacies with former clients/patients for at least two years after cessation or termination of therapy.

(b) Psychologists do not engage in sexual intimacies with former clients/patients even after a two-year interval except in the most unusual circumstances. Psychologists who engage in such activity after the two years following cessation or termination of therapy and of having no sexual contact with the former client/patient bear the burden of demonstrating that there has been no exploitation, in light of all relevant factors, including (1) the amount of time that has passed since therapy terminated; (2) the nature, duration, and intensity of the therapy; (3) the circumstances of termination; (4) the client's/patient's personal history; (5) the client's/patient's current mental status; (6) the likelihood of adverse impact on the client/patient; and (7) any statements or actions made by the therapist during the course of therapy suggesting or inviting the possibility of a posttermination sexual or romantic relationship with the client/patient. (See also Standard 3.05, Multiple Relationships (?item=6#305) .)

10.09 Interruption of Therapy

When entering into employment or contractual relationships, psychologists make reasonable efforts to provide for orderly and appropriate resolution of responsibility for client/patient care in the event that the employment or contractual relationship ends, with paramount consideration given to the welfare of the client/patient. (See also Standard 3.12, Interruption of Psychological Services (?item=6#312) .)

10.10 Terminating Therapy

(a) Psychologists terminate therapy when it becomes reasonably clear

that the client/patient no longer needs the service, is not likely to benefit, or is being harmed by continued service.

(b) Psychologists may terminate therapy when threatened or otherwise endangered by the client/patient or another person with whom the client/patient has a relationship.

(c) Except where precluded by the actions of clients/patients or third-party payors, prior to termination psychologists provide pretermination counseling and suggest alternative service providers as appropriate.

History and Effective Date

The American Psychological Association's Council of Representatives (/about/governance/council) adopted this version of the APA Ethics Code during its meeting on Aug. 21, 2002. The Code became effective on June 1, 2003. The Council of Representatives amended this version of the Ethics Code on Feb. 20, 2010, effective June 1, 2010, and on Aug. 3, 2016, effective Jan. 1, 2017. Inquiries concerning the substance or interpretation of the APA Ethics Code should be addressed to the Director, Office of Ethics, American Psychological Association, 750 First St. NE, Washington, DC 20002-4242. The standards in this Ethics Code will be used to adjudicate complaints brought concerning alleged conduct occurring on or after the effective date. Complaints will be adjudicated on the basis of the version of the Ethics Code that was in effect at the time the conduct occurred.

The APA has previously published its Ethics Code as follows:

American Psychological Association. (1953). *Ethical standards of psychologists*. Washington, DC: Author.

American Psychological Association. (1959). Ethical standards of psychologists. *American Psychologist*, *14*, 279-282.

American Psychological Association. (1963). Ethical standards of psychologists. *American Psychologist*, *18*, 56-60.

American Psychological Association. (1968). Ethical standards of psychologists. *American Psychologist*, *23*, 357-361.

American Psychological Association. (1977, March). Ethical standards of psychologists. *APA Monitor*, 22-23.

American Psychological Association. (1979). *Ethical standards of psychologists*. Washington, DC: Author.

American Psychological Association. (1981). Ethical principles of psychologists. *American Psychologist*, *36*, 633-638.

American Psychological Association. (1990). Ethical principles of psychologists (Amended June 2, 1989). *American Psychologist*, *45*, 390-395.

American Psychological Association. (1992). Ethical principles of psychologists and code of conduct. *American Psychologist*, *47*, 1597-1611.

American Psychological Association. (2002). Ethical principles of psychologists and code of conduct. *American Psychologist*, *57*, 1060-1073.

American Psychological Association. (2010). 2010 amendments to the 2002 "*Ethical Principles of Psychologists and Code of Conduct.*" *American Psychologist*, *65*, 493.

American Psychological Association. (2016). Revision of ethical standard 3.04 of the "*Ethical Principles of Psychologists and Code of Conduct*" (2002, as amended 2010). *American Psychologist*, *71*, 900.

Request copies of the APA's Ethical Principles of Psychologists and Code of Conduct from the APA Order Department, 750 First St. NE, Washington,

DC 20002-4242, or phone (202) 336-5510.

Amendments to the 2002 "Ethical Principles of Psychologists and Code of Conduct" in 2010 and 2016

2010 Amendments

Introduction and Applicability

If psychologists' ethical responsibilities conflict with law, regulations, or other governing legal authority, psychologists make known their commitment to this Ethics Code and take steps to resolve the conflict in a responsible manner ~~. If the conflict is unresolvable via such means, psychologists may adhere to the requirements of the law, regulations, or other governing authority~~ in keeping with basic principles of human rights.

1.02 Conflicts Between Ethics and Law, Regulations, or Other Governing Legal Authority

If psychologists' ethical responsibilities conflict with law, regulations, or other governing legal authority, psychologists clarify the nature of the conflict , make known their commitment to the Ethics Code, and take reasonable steps to resolve the conflict consistent with the General Principles and Ethical Standards of the Ethics Code . ~~If the conflict is unresolvable via such means, psychologists may adhere to the requirements of the law, regulations, or other governing legal authority.~~ Under no circumstances may this standard be used to justify or defend violating human rights .

1.03 Conflicts Between Ethics and Organizational Demands

If the demands of an organization with which psychologists are affiliated or for whom they are working are in conflict with this Ethics Code, psychologists clarify the nature of the conflict, make known their commitment to the Ethics Code, and ~~to the extent feasible, resolve the conflict in a way that permits adherence to the Ethics Code.~~ take

reasonable steps to resolve the conflict consistent with the General Principles and Ethical Standards of the Ethics Code. Under no circumstances may this standard be used to justify or defend violating human rights .

2016 Amendment

3.04 Avoiding Harm

(a) Psychologists take reasonable steps to avoid harming their clients/patients, students, supervisees, research participants, organizational clients, and others with whom they work, and to minimize harm where it is foreseeable and unavoidable.

(b) Psychologists do not participate in, facilitate, assist, or otherwise engage in torture, defined as any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person, or in any other cruel, inhuman, or degrading behavior that violates 3.04(a).

Date created: 2017

Find this article at:
https://www.apa.org/ethics/code

AMERICAN PSYCHOLOGICAL ASSOCIATION

APA Policy Statement on Affirming Evidence-Based Inclusive Care for Transgender, Gender Diverse, and Nonbinary Individuals, Addressing Misinformation, and the Role of Psychological Practice and Science

FEBRUARY 2024

Consistent with the American Psychological Association's mission to promote the advancement, communication, and application of psychological science and knowledge to benefit society and improve lives, this Policy Statement affirms APA's support for unobstructed access to healthcare and evidence-based clinical care for transgender, gender-diverse, and nonbinary children, adolescents, and adults, and for increased public accessibility to timely and accurate information founded in clinical and psychological science. Evidence-based clinical care, including gender-affirming care, should be noncoercive, adaptive to and centered on the needs of the individual receiving care, and rooted in psychological and clinical science, including recognition of gender diversity as a part of normal human diversity as well as recognition of limits in the current state of scientific knowledge.

Furthermore, this policy statement addresses the spread of misleading and unfounded narratives that mischaracterize gender dysphoria and affirming care, likely resulting in further stigmatization, marginalization, and lack of access to psychological and medical supports for transgender, gender diverse, and nonbinary individuals. Misinformation further creates distress and confusion for families and loved ones of transgender, gender-diverse, and nonbinary individuals, as they make decisions about their healthcare. The primary goal is to encourage psychologists to unite in their support for access to psychological and all appropriate healthcare services and treatment for transgender, gender-diverse, and nonbinary individuals.

Policy Statement:

WHEREAS gender diversity is present throughout the lifespan and has been present throughout history (Gill-Peterson, 2018; Hunt, 2016; Stryker, 2017); and

WHEREAS gender-based bias and mistreatment (e.g., discrimination, violence, non-affirmation, or rejection in response to gender diversity) pose significant harm, including risk of suicide, to the well-being of children, adolescents, adults, and families. (Delozier et al., 2020; Kosciw et al., 2022; Puckett et al., 2023; Trevor Project, 2023); and

WHEREAS transgender, gender diverse, and nonbinary individuals experiencing systemic discrimination and mistreatment targeting their gender identity or expression, may also face racial, ethnic, socioeconomic, religious, and other forms of discrimination, translated into greater discrimination and psychological distress than their counterparts (Castro-Ramirez et al., 2021; Hendricks & Testa, 2012; Lefevor et al., 2019; Lytle et al., 2016; Turban et al., 2020; van der Miesen et al., 2020); and

WHEREAS gender-related distress is a complex and nuanced psychological experience, informed by a rapidly evolving basis in new scientific findings and advances, which often requires specialized understanding and expertise (APA, 2015; Coleman et al., 2022); and

WHEREAS psychologists often play a vital role in assisting individuals experiencing gender dysphoria and their parents, caregivers, and families, offering valuable insights into their mental health and well-being (APA, 2015; dickey & Puckett, 2023; Hughto et al., 2015); and

WHEREAS psychologists can play an important and essential role in facilitating the support for client-led exploration of gender identity, assisting individuals in navigating their unique experiences (APA, 2015; Coleman et al., 2022); and

WHEREAS affirming mental health services provided by psychologists can positively contribute to the holistic care of individuals participating in gender-affirming healthcare or experiencing gender dysphoria, gender incongruence, and/or distress associated with discrimination and mistreatment (Anzani et al., 2019; Expósito-Campos et al., 2023; Hembree et al.,2017; Wittlin et al., 2023; World Health Organization, 2022); and

WHEREAS legislative efforts to restrict access to care have involved the dissemination of misleading and unfounded narratives (e.g., mischaracterizing gender dysphoria as a manifestation of traumatic stress or neurodivergence, and equating affirming care for transgender, gender-diverse, and nonbinary youth with child abuse), creating a distorted perception of the psychological and

medical support necessary for these youth and creating a hostile environment that adversely affects their mental health and wellbeing (APA, 2023; Ashley, 2023; Hughto et al., 2022; Kremen et al., 2021; McNamara et al., 2022); and

WHEREAS such misinformation is widely disseminated through formal and informal networks, yet credible scientific evidence has not been widely disseminated and is not readily accessible to the public, having the potential to further stigmatize and marginalize all transgender, gender-diverse, and nonbinary individuals, hindering their access to indicated and necessary healthcare, worsening existing geographic disparities in healthcare access, and fostering an environment that may lead to discrimination (DuBois et al., 2023; Goldenberg et al., 2020; Weixel & Wildman, 2022); and

WHEREAS state bans on gender-affirming care and the imposition of legal penalties on providers engaging in evidence-based care disregard the comprehensive body of psychological and medical research supporting the positive impact of gender-affirming treatments, which include as a standard of care noncoercive, developmentally appropriate support for gender exploration and decision-making in alleviating psychological distress and improving overall well-being for transgender, gender diverse, and nonbinary individuals across the lifespan (Achille et al., 2020; Ashley, 2023; Green et al., 2022; Ramos et al., 2021; Tordoff et al., 2022); and

WHEREAS state bans on gender-affirming care disrupt not only the role of providers in offering evidence-based care but also obstruct patient and parental rights in shared decision-making (Clark & Virani, 2021); and

WHEREAS the imposition of such bans poses a direct threat to the mental health and emotional well-being of transgender, gender-diverse, and nonbinary youth, exacerbating the already high rates of depression, anxiety, and suicide attempts among this vulnerable population (Abreu et al., 2022a; Abreu et al., 2022b; Hughes et al., 2021; Kidd et al., 2021); and

WHEREAS obstructing access to psychological and medical interventions, including gender-affirming care, heightens the risk of negative mental health outcomes among children, adolescents, and adults; (Chen et al., 2023; McGregor et al. 2023; Turban et al., 2020; Turban, et al. 2022; van der Miesen et al., 2020);

THEREFORE, BE IT RESOLVED that the American Psychological Association (APA) steadfastly supports evidence-based clinical care for all children, adolescents, and adults inclusive of gender identity and expression; and

THEREFORE, BE IT RESOLVED that the APA upholds the rights of all individuals to unbiased health insurance coverage, rejecting discrimination based on gender identity and advocating for the inclusion of gender-affirming care, including psychological care; and

THEREFORE, BE IT RESOLVED that the APA underscores the necessity for access to comprehensive, gender-affirming healthcare for transgender, gender-diverse, and nonbinary children, adolescents, and adults; and

THEREFORE, BE IT RESOLVED that the APA underscores the importance of an accurate understanding of evidence-based care—highlighting the continuous need for research and expansion of the scientific foundation to further ensure full access to competent and reliable healthcare—s as essential to promoting inclusivity; protecting the rights of transgender, gender-diverse, and nonbinary individuals; and ensuring that they receive the necessary support and full healthcare attention, inclusive of psychological and medical care, in a compassionate and affirming manner; and

THEREFORE, BE IT RESOLVED that the APA supports efforts to address and rectify the dissemination of false information to ensure the well-being and dignity of transgender, gender-diverse, and nonbinary individuals; and

THEREFORE, BE IT RESOLVED that the APA opposes state bans on gender-affirming care, which are contrary to the principles of evidence-based healthcare, human rights, and social justice, and which should be reconsidered in favor of policies that prioritize the well-being and autonomy of transgender, gender-diverse, and nonbinary individuals; and

THEREFORE, BE IT RESOLVED that insurance plans should extend coverage for healthcare services tailored to the developmental needs of children, adolescents, and adults identifying as transgender, gender-diverse, or nonbinary, encompassing both psychological and medical gender-affirming care; and

THEREFORE, BE IT RESOLVED that equitable health insurance access is necessary to facilitate essential gender-affirming care, including access to mental health supports; and

THEREFORE, BE IT RESOLVED that the APA opposes efforts to obstruct access to evidence-based interventions for children, adolescents, and adults, advocating for inclusive healthcare coverage without gender-based discrimination; and

THEREFORE, BE IT FURTHER RESOLVED that the APA emphasizes the importance of psychological and medical care from an intersectional perspective, which takes into consideration the many facets of an individual's experience and provides services that are antidiscriminatory in all areas, including opposing racial, ethnic, socioeconomic, religious, and gender-based discrimination; and

THEREFORE, BE IT FURTHER RESOLVED that the APA urges support for policies facilitating access to comprehensive, gender-affirming healthcare for children, adolescents, and adults, recognizing the positive impact on mental health outcomes; and

THEREFORE, BE IT FURTHER RESOLVED that the APA encourages insurance providers to offer coverage addressing the healthcare needs of children, adolescents, and adults who identify as transgender, gender diverse, or nonbinary; and

THEREFORE, BE IT FURTHER RESOLVED the APA affirms the essential role and legal rights of parents and caregivers in taking action to ensure the well-being of children and adolescents while honoring their expressed gender identity, including involvement in the process of healthcare decision-making, as well as the role of parents, caregivers, and providers in supporting developmentally appropriate youth self-advocacy.

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General

Gender Dysphoria and Its Non-Surgical and Surgical Treatments

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Gender dysphoria is defined by severe or persistent distress associated with an incongruence between one's gender identity and biological sex. It is estimated that 1.4 million Americans and 25 million people worldwide identify as transgender and that 0.6% of Americans experience gender dysphoria. The pathophysiology of gender dysphoria is multifactorial and incompletely understood. Genetics, androgen exposure, neuroanatomy, brain connectivity, history of trauma, parents with psychological disorders, and being raised by less than two parents are associated with gender dysphoria. Gender dysphoria most frequently presents in early teenage years but can present earlier or later. Anxiety and depression are the two most common comorbid diagnoses and may be the reason for presentation to medical care. Diagnosis is established through history and or validated questionnaires. Treatment includes psychosocial therapy, pharmacotherapy for underlying depression and/or anxiety, hormonal therapy, non-genital and/or genital feminization or masculinization operations. The frequency and severity of treatment related morbidity increases progressively as treatments go from conservative to more invasive. Gender dysphoria and its treatment is individualized and not completely understood.

INTRODUCTION

Gender dysphoria, also known as gender incongruence, is a condition that occurs when an individual's gender identity differs from their biological sex. This condition can cause severe physical and psychological stress.

One recent report finds that 1.4 million individuals or 0.6%, of the adult U.S. population identifies as transgender.[1] Another meta-analysis finds that prevalence is drastically different depending on how transgender is defined. There is a higher prevalence of people who self-report as transgender than there are of patients who are being treated for gender dysphoria.[2,3]

The pathophysiology of gender dysphoria is something under active investigation. There are twin studies with small sample sizes that demonstrate a genetic component of gender identity.[4] There is also evidence of neuroanatomical differences among transgender individuals.[5–7]

A diagnosis of gender dysphoria can be made if a patient is experiencing gender incongruence that causes significant distress. Individuals typically present with gender dysphoria during adolescence, but it is not uncommon for patients to present in early childhood or after the age of 18.[8,9]

Patients with gender dysphoria who receive treatment report happier lives. There is also a decreased rate of suicidality among patients who receive appropriate gender affirmation treatment.[10] Treatment starts with hormone therapy. Patients who have received hormone therapy for a year may qualify to undergo gender confirmation surgery. Adverse effects of certain treatments, especially surgical, can be significant.

This review paper aims to update the reader on the most recent research of all aspects of gender dysphoria.

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EPIDEMIOLOGY

It is estimated that there are 25 million transgender people worldwide.[11] Determining the prevalence of gender dysphoria and transgenderism is difficult as it varies based on the definition used. For example, there is a much higher prevalence of people who self-identify as transgender compared to people who have received hormone therapy or gender affirmation surgery.[2,3] Exact prevalence is difficult to quantify due to differences among geographical areas. One report shows that the prevalence among the total U.S. population is about 0.6%, but if broken down by state, it varies from 0.3%-0.76%.[1] This also holds true when comparing epidemiological studies of gender dysphoria across different countries.[3,12] Recent data shows that there has been an increase in the prevalence of individuals seeking treatment for gender dysphoria.[13] The aforementioned report shows that the prevalence of Americans identifying as transgender has doubled over the last 10 years.[1] The biggest increase is among children and adolescents.[14] It is unclear if this is due to an actual increase in the number of individuals with gender dysphoria or a societal shift towards openness and acceptance of variations in gender identity. Prior to the overall increase in prevalence, the sex ratio once favored birth assigned males to, now, favoring birth assigned females.[15] Recent data also suggests that individuals typically experience their first gender dysphoria symptoms by age 7 and often live for over 20 years before seeking treatment.[16]

PATHOPHYSIOLOGY/RISK FACTORS

There is growing evidence for a broad biological basis of gender identity. A variety of studies show evidence of genetic links, neuroanatomical differences, and prenatal androgen exposure that affect gender identity. Data in this field is more recent, as older studies mostly focused on psychosocial aspects of gender identity and gender dysphoria.

Genetic evidence is based on studies of sex hormone signaling genes and twin concordance studies. Foreman et al. finds statistically significant genetic differences in sex signaling genes in transgender women compared to cisgender males. These differences include differences in alleles, genotypes, and allele combinations mostly involving androgen receptor genes.[17] There are many, mostly small, twin heritability studies of gender dysphoria with a recent review showing that most estimates of heritability fall in the range of 30-60%.[18] Combined, this data supports a polygenic component of gender identity.

Neuroanatomical studies show the brains of gender dysphoric individuals resemble the gender they identify with as opposed to those of the gender they were assigned at birth. Studies in this field are mainly neuroimaging studies that find increased cortical thickness, and weaker connections in regions of the brain known for processing one's own body perception.[5–7] More recently, brain connectivity studies find that brain connectivity dynamics are similar among transgender individuals and the gender they identify with than with the gender they were assigned at birth.[19] While more studies need to be done to further elucidate the neuroanatomy and neurophysiology, the current research suggests that brain architecture and function play an important role in gender identity and gender dysphoria.

It is well established that androgens play a crucial role for the development of sex characteristics, sexual, and gender identity.[20,21] Studies show that women exposed to high levels of androgens due to congenital adrenal hyperplasia (CAH) are more likely to be dissatisfied with their gender assigned at birth.[20] On the other hand, patients with complete androgen insensitivity (CAIS) typically express female gender identification.[22] These individuals are XY, but develop female secondary sexual characteristics, and most often identify as females. This occurs due to androgen receptor defects which lead to androgen resistance. CAIS patients also have undescended male testis which cause them to have male levels of testosterone. Data from these patients shows a clear link between androgen exposure and gender identity.

There are also psychosocial factors that are associated with gender dysphoria. Early researchers hypothesized that gender dysphoria development was due to certain parental influences such as lack of paternal reinforcement and paternal absence among other factors. Some of these hypotheses have been tested but the data are not conclusive.[23,24] More recent data show that elevated levels of psychopathology in parents and childhood anxiety increase risk for development of gender dysphoria.[25,26] Overall, studies on the psychosocial factors of gender dysphoria are older and more scarce than recent data on the biological factors regarding gender identity.

CLINICAL PRESENTATION AND DIAGNOSIS

Gender dysphoria has become progressively more common and has been recognized and treated earlier over the last two decades.[27] The presentation and diagnosis of these individuals can often be a challenge due to the sensitive nature of the topic. These individuals often present in their adolescent and teenage years when their gender identity.[28] In studies of adolescents done in China, there was a high correlation between those who identified as transgender and non-binary and high scores on the generalized anxiety disorder scale as well as the suicidal ideation assessment. Early detection of adolescents with gender dysphoria helps establish psychiatric treatment of comorbid depression and anxiety.[29] The Diagnostic and Statistical Manual for Mental Disorders 5th edition (DSM-5) defined two criteria for the diagnosis of gender dysphoria in adolescents. The first is defined by "A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:

1. a marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics);
2. a strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incon-

gruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
3. a strong desire for the primary and/or secondary sex characteristics of the other gender.
4. a strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
5. a strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
6. a strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)".

The second criteria states that "The condition is associated with clinically significant distress or impairment in social, occupational or other important areas of functioning".[30] Most often these adolescents present during the early stages of puberty with incongruence between sex assigned at birth and gender identity.[31] This can present as many different behaviors such as changing one's hair, clothing, behaviors, or name to match their preferred gender. Distress can be observed as outbursts against parents or peers who may attempt to make the child conform to their birth sex.[32] Distress may also present as the child being resistant towards going to school through means of pretending to be sick. Distress may also present as signs of physical abuse from bullying such as bruises or scrapes.[27] Studies done in Germany showed that 26% of patients that presented to the clinic with gender dysphoria endorsed negative responses to their outings at school.[33] Comorbid depression and anxiety might also prompt patients to present to clinic, and further questioning is often required to reveal underlying gender dysphoria.[28] Treatment of underlying anxiety and depression is important in individuals who suffer from gender dysphoria as they have been shown to have higher rates of attempted and completed suicide compared to cis-gender counterparts. Studies also show that individuals who received gender-affirming treatment at younger ages had less suicidal ideation than those who received treatment later.[34] While it is most common for gender dysphoria to present in early teenage years, it is not uncommon for individuals to present in early adulthood. Almost 25-30% of patients with gender dysphoria present after the age of 18. In many of these cases, pressures from peers and family often delays presentation and treatment.[35] Another common risk factor for individuals with gender dysphoria is a history of childhood trauma. A survey conducted of 95 transgender individuals who previously self-reported having symptoms of gender dysphoria showed that 56% of these individuals experienced four or more early traumatic events in their childhood. Most often, these experiences were physical or emotional abuse from parents. Trans women had more events involving physical and psychological abuse from their father while being separated from their mothers. Trans men had more events involving their mothers and were frequently separated from and neglected by their father.[36] Studies have also shown that children who experience trauma early in life are more likely to develop disorganized attachments. This makes children more likely to develop dissociative and avoidant strategies for dealing with complex emotions and thoughts such as gender identity incongruence. Children and adolescents with significant history of trauma present later and are less likely to present to clinicians for evaluation.[37]

Several tools have been developed to help clinicians diagnose gender dysphoria. These tools include self-surveys that can be given to patients to assess thoughts and symptoms of gender dysphoria. The most common and well-studied of these questionnaires is the gender identity/gender dysphoria questionnaire for adolescents and adults (GIDYQ-AA). This questionnaire has been verified to aid in the identification of individuals with gender dysphoria. The questionnaire has a sensitivity of 90.4% in the 73 transgender patients and a 99.7% specificity for the control group which included 389 university students that were both heterosexual and homosexual.[37] Additionally, the generalized anxiety disorder assessment (GAD-7) and the patient health questionnaire (PHQ-9) should be used in all adolescents, but this is particularly important in patients with gender dysphoria due to their higher incidence of anxiety and depression.[33] Many other tools have been recently developed to help diagnose and assess gender dysphoria. The gender identity reflection and rumination scale was developed to assess how often a person thinks about their gender identity. Higher scores correlated to more thoughts on gender identity which in turn correlated to higher frequencies of gender dysphoria.[38,39] Another aspect of the prognosis of adolescents with gender dysphoria is their sense of belonging they feel with their home community. Many studies have shown that trans-gender individuals who feel accepted in their communities or home have lower incidences of comorbid anxiety, depression, and suicide than those who are raised in communities where they feel mistreated.[40]

TREATMENT

The treatment for gender dysphoria is often multi-disciplinary, combining the efforts of several behavioral health and medical professionals. The World Professional Association for Transgender Health (WPATH) has developed recommended standards of care for treatment, and it's clearly stated that these standards are "flexible" clinical guidelines.[41] The importance of this flexibility is to ensure individuality in treatment, as each patient may present with different goals or needs. The treatments can be divided into two main categories: non-operative and operative. Non-operative treatment focuses on implementing psychosocial therapy and/or medical management with hormone replacement therapy. Operative treatments range from small cosmetic procedures to much larger genital transformation surgeries. It is important to consider that an individual's overall treatment may require a combination of both operative and non-operative practices.

NON-OPERATIVE TREATMENT: PSYCHOSOCIAL THERAPY

Of the many recommended treatments for gender dysphoria, the first non-operative option is psychosocial therapy and counseling. The overall goal of psychosocial therapy is to improve the patient's quality of life through open and consistent communication.[41] There are numerous aspects to this, but the objective is to support patients as they begin to implement their gender identity to their loved ones and society. Mental health professionals provide support by answering questions and discussing body image regarding the society-based gender normative. In addition, these professionals guide patients with coming out to friends, family, and colleagues.[42] The true benefit to therapy is that it is ongoing, rather than a single experience; patients can utilize this support lifelong, which is a key component to maintaining positive outcomes. For those who may not have access to a mental health professional, numerous support systems exist, including peer groups and internet-based support groups.[43] The WPATH recognizes that psychotherapy successfully helps individuals with their gender identity without needing hormone based medical therapy or gender affirmation surgery.[41,42]

NON-OPERATIVE TREATMENT: HORMONE REPLACEMENT THERAPY

The second non-operative treatment option is medical management with hormone replacement therapy (HRT). According to the WPATH, numerous hormone combinations have been used in the treatment of gender dysphoria, however the data lacks an established standard regiment.[41] HRT requires a very in-depth pre-treatment work-up, which includes risk screening, thorough history and exam, as well as numerous laboratory studies to evaluate the patient's ability to safely tolerate hormone replacement.[44] Some aspects of this pre-treatment work-up include medical and family history accessing for previous cardiovascular or thromboembolic disease, exam findings including weight, blood pressure, and secondary sexual characteristics, and finally laboratory testing focused on blood, liver, and current hormonal function.[45] It is imperative to confirm the diagnosis and ensure that a written indication for HRT is established by a psychotherapist or psychiatrist.[44] The goal of hormone replacement therapy is to promote the characteristics of the patient's desired gender while minimizing the characteristics of their biological gender.[42]

We will first discuss feminizing therapy for male-to-female (MTF) gender dysphoria. Feminizing HRT generates the following effects on the genetically male body: it softens the skin, decreases body hair production, reduces muscle mass, reduces testicular size, and encourages breast growth. The onset of these effects may begin within 6 months, while the maximum effects are expected to take place between 1-2 years.[41,45,46] These effects are achieved with a combination of pro-estrogen and anti-androgen therapy. Several sources suggest that treatment with physiologic doses of estrogen alone is insufficient to suppress testosterone to the level of a normal female, hence the addition of anti-androgen therapy is needed.[46,47] Pro-estrogen therapy involves the oral or transdermal administration of 17β-estradiol, which activates estrogen receptors and produces the effects listed previously. The recommended anti-androgen therapy is spironolactone, which is an androgen receptor antagonist that is very effective at inhibiting the actions of testosterone; it also has some estrogenic activity.[48] Supplementing synthetic estrogen has its risks, and it is very important for clinicians to monitor serum estradiol levels routinely every 3 months. Although the risk of adverse effects is controversial, the data supports that elevated levels of blood estrogen may lead to increased risk of liver disease, cardiovascular disease, hypertension, hyperprolactinemia, hypertriglyceridemia, and thromboembolic events.[41,44,45,49]

The next discussion will be on masculinization therapy for female-to-male (FTM) gender dysphoria. This treatment is generally less complex than MTF therapy. Here, the primary hormone supplemented is testosterone. Several medications are available, which include testosterone enanthate and testosterone cypionate. These two specifically are administered via intramuscular injection, but other options are available that are administered via transdermal gels or patches. Administering testosterone activates androgen receptors which produces the following effects on the genetically female body: increased skin oiliness, increased facial and body hair production, increased muscle mass/strength, redistributed fat, halted menses, deepened voice, enlarged clitoris, and vaginal atrophy.[50,51] With FTM therapy, supplementing with testosterone provides individuals with the desired body changes. Anti-estrogen therapy is not needed to achieve the physiologic levels of testosterone in the normal male. This is what makes FTM therapy less complex than MTF therapy.[41,46] With testosterone supplementation, the adverse risks to screen and monitor for include erythrocytosis, liver disfunction, cerebrovascular disease, coronary artery disease, and breast or uterine cancer.[44,46,47,49]

OPERATIVE TREATMENT

Many patients with gender dysphoria require some form of surgery to fully achieve their desired body image and psychological gender identity. These procedures, both genital and non-genital, are collectively known as "Gender Confirmation Surgery" (GCS). Genital surgeries specifically are often the last recommended as part of the overall treatment of gender dysphoria. This is due to permanent alteration in fertility, as well as the risks that are associated with surgery in general. When applicable, GCS can be utilized by health care experts to enhance patients' gender identities in ways that psychotherapy and HRT may not be able to.[42,52] The WPATH recommends patients undergo some form of social transition utilizing psychotherapy and HRT prior to considering surgical treatment, but it is not a requirement for all procedures.[1] However, the WPATH has specific criteria for genital GCS, and this includes having at least 2 referrals from separate medical health professionals and complete patient compliance with at least 12 months of continued HRT. It is important to note that GCS is performed by many

surgical fields, including plastic surgery, urology, otolaryngology, gynecology, and general surgery.[41,52]

OPERATIVE TREATMENT: NON-GENITAL FEMINIZATION

There are several methods in which transgender women can surgically enhance their body image. The following are some of the procedures available: hair reconstruction and removal, voice modification, lipofilling, botulin toxin injections, mammoplasty, breast augmentation, gluteal augmentation, waist lipoplasty, and facial plastics. Facial plastics is the most sought after and contains an extensive array of options for patients. Some of the procedures that specifically fall under facial plastics include lip filler, face lifts, rhinoplasty, sinus surgery, forehead cranioplasty, supraorbital ridge reduction, mandibular reduction, and genioplasty.[50,53,54] There are several sources confirming that patients who undergo non-genital feminization surgery have high satisfaction rates and these procedures are often more desired compared to genital reconstruction surgery.[41,42,49,54]

OPERATIVE TREATMENT: GENITAL FEMINIZATION

The most important aspect to determining which type of genital feminization surgery a patient desires is whether the patient is wanting penetrative ability. If an individual desires just the feminine appearance without penetrable ability, the recommend procedure would be a bilateral orchiectomy with a penectomy and urethroplasty. The orchiectomy would remove the main source of endogenous testosterone production, while the penectomy and urethroplasty would remove the penis and leave a proper functioning urethra. If a natural appearing vulva without penetrative ability is desired, then the recommended surgery here would be a vulvoplasty with clitoro-labioplasty. Finally, if a patient desires the natural vulva appearance with penetrative ability, an even more complex procedure is recommended. Here, the surgeon would perform the previously mentioned procedures with the addition of a vaginoplasty.[52] The vagina would be created either by inverting the penile skin or utilizing an intestinal graft while the vulva will be shaped using various skin graft techniques.[55] There are numerous complications that may arise from these invasive procedures. The more prevalent complications include neovaginal bleeding, discharge, introital stenosis, misdirected urinary stream, urinary incontinence, would healing disorders, and infection.[56–58]

OPERATIVE TREATMENT: NON-GENITAL MASCULINIZATION

As compared to feminization surgery, there are fewer non-genital procedures performed for masculinization. The most popular and sought-after procedures involve masculinizing the chest which consists of subcutaneous mastectomy, chest contouring, pectoral implanting, and breast augmentation. For facial plastics, the most performed masculinization procedures are genioplasty, liposuction, and facial hair transplantation.[42,44,52,55] As with feminization, these non-genital masculinization procedures have high satisfactory rates from patients when combined with the additive effects HRT produces.[41,42,49,54] This is likely due to HRT for masculinization providing enough of an effect to reduce existing feminine characteristics.

OPERATIVE TREATMENT: GENITAL MASCULINIZATION

For genital altering masculinization, many transgender males prefer to start with removal of their biological reproductive organs. This consists of a complete hysterectomy, oophorectomy, and vaginectomy. Doing so permanently eliminates fertility and terminates menstruation; the termination of menstruation is one of the most desired outcomes. To achieve standing micturition, transgender males may undergo urethral lengthening. If the appearance of external male genitalia is desired, more complex procedures are required, such as metoidioplasty or phalloplasty with a scrotoplasty. The combination of these procedures allows transgender males to fully replicate external male genitalia.[58,59] As with feminization genital surgery, similar risks and complications exist with masculinization genital surgery which include including urinary incontinence, would healing disorders, and infection.[42,56,59]

CONCLUSION

In recent decades, changes in the acceptance of variations in gender identity have facilitated more individuals openly expressing themselves as transgender. This is evident by the increasing number of people who identify as transgender over the past decade.[1] There is also an increasing body of evidence of a biological basis of gender identity. The rate of increase of prevalence of transgender individuals has been highest among children and young adolescents.[14] These patients will often first present to their primary care providers (pediatricians in this case) with either complaints of depression or anxiety from suffering with their identity crisis, or questions or desire about gender transition treatment. Treatment decreases suicidality among individuals with gender dysphoria and leads to improved quality of life.[10] Treatment options include psychosocial therapy, medical treatment for underlying depression and/or anxiety, hormonal treatment, and more than a dozen possible surgical procedures. More invasive treatments are associated with more severe adverse effects. Gender identity research is increasing rapidly, but there are still gaps in knowledge. Also, there is a need for large studies of long-term health outcomes of transgender individuals receiving medical and/or surgical treatment for gender dysphoria. Overall, this review paper provides the most up to date information regarding gender dysphoria and its treatments.

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Meta-Analysis

Meta-Analysis

Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review

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Abbreviations: BDI, Beck Depression Inventory; ENIGI, European Network for the Investigation of Gender Incongruence; GnRH, gonadotropin-releasing hormone; HADS, Hospital Anxiety and Depression Scale; QOL, quality of life; RCT, randomized controlled trial; SF-36, Short Form-36 Health Survey; WPATH, World Professional Association for Transgender Health.

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Abstract

We sought to systematically review the effect of gender-affirming hormone therapy on psychological outcomes among transgender people. We searched PubMed, Embase, and PsycINFO through June 10, 2020 for studies evaluating quality of life (QOL), depression, anxiety, and death by suicide in the context of gender-affirming hormone therapy among transgender people of any age. We excluded case studies and studies reporting on less than 3 months of follow-up. We included 20 studies reported in 22 publications. Fifteen were trials or prospective cohorts, one was a retrospective cohort, and 4 were cross-sectional. Seven assessed QOL, 12 assessed depression, 8 assessed anxiety, and 1 assessed death by suicide. Three studies included trans-feminine people only; 7 included trans-masculine people only, and 10 included both. Three studies focused on adolescents. Hormone therapy was associated with increased QOL, decreased depression, and decreased anxiety. Associations were similar across gender identity and age. Certainty in this conclusion is limited by high risk of bias in study designs, small sample sizes, and confounding with other interventions. We could not draw any conclusions about death by suicide. Future studies should investigate the psychological benefits of hormone therapy among larger and more diverse groups of transgender people using study designs that more effectively isolate the effects of hormone treatment.

Key Words: Transgender, hormone therapy, sex hormones, mental health, systematic review

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Transgender people are those whose gender identity is different from the sex they were assigned at birth. Estimates of the size of the transgender population vary depending on how the data are collected [1]. In studies that rely on clinical records, estimates range between 1 and 30 people per 100 000 (0.001% to 0.03%) [2]. Studies that focus instead on self-report among nonclinical populations find estimates that range between 0.1% and 2% [2].

Many transgender people seek medical services to affirm their gender identity. According to the *Standards of Care for Transsexual, Transgender, and Gender Non-Conforming People* maintained by the World Professional Association for Transgender Health (WPATH), gender-affirming medical care is different for each individual and may include a variety of services and procedures, such as psychological support, hormone therapy, and surgeries [3]. Hormone therapy, which typically involves estrogens and anti-androgens for transgender women and other trans-feminine people and testosterone for transgender men and other trans-masculine people, is a common component of medical gender affirmation [4]. Because hormone treatment can have a powerful effect on physical appearance, it is often a priority for transgender people seeking medical gender affirmation [5]. Gender-affirming hormone therapy can be managed for most patients by primary care providers, as it typically involves long-term maintenance on doses similar to those used for cisgender patients with conditions such as hypogonadism [6, 7]. Some clinicians require a minimum period of psychological counseling before hormone therapy can be initiated, while others provide hormone therapy on the basis of informed consent [8].

The need for gender-affirming care is often characterized using psychiatric diagnoses such as gender dysphoria, which replaced gender identity disorder in the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) [9]. The 11th International Classification of Diseases (ICD-11) replaces these terms with a diagnosis called gender incongruence (codes: HA60, HA61, HA6Z), which is located in a new chapter on sexual health. These changes clarify that the target of gender-affirming medical interventions is not the person's gender identity itself but rather the clinically significant distress that can accompany a misalignment between gender identity and sex assigned at birth [10]. Some countries have further underscored that transgender identity is not a pathology by recognizing gender affirmation as fundamental to the human right to self-definition and removing requirements that transgender people seeking gender-affirming medical care present with a diagnosis such as gender dysphoria [11].

Several previous reviews have indicated that gender-affirming hormone therapy is associated with psychological benefits that include reductions in depression and anxiety and improvements in quality of life (QOL) among transgender people [12-17]. Most of these reviews did not require a minimum duration of hormone therapy [14-17]. One review that did impose a minimum follow-up requirement is 10 years old [12]. The other that required a minimum of 3 months of therapy included only uncontrolled prospective cohorts, which resulted in a sample of only 3 studies [13]. A comprehensive review without a minimum follow-up period assessed gender-affirming hormone therapy and surgeries only in adolescents [17]. By requiring a minimum duration of hormone treatment but considering all ages and a variety of study designs, we sought to update and more completely summarize the growing evidence base regarding the relationship between gender-affirming hormone therapy and psychological outcomes in transgender people.

Search Strategy and Selection Criteria

This review is one of a series of systematic reviews on gender-affirming care conducted for WPATH to inform the eighth revision of the *Standards of Care*. The protocol is registered on PROSPERO (CRD42018115379) [18], and we followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines in reporting our findings [19].

We searched PubMed, Embase, and PyscINFO from inception to October 2018 and updated the search through June 10, 2020, for studies assessing QOL, depression, anxiety, and death by suicide among transgender participants of any age in the context of gender-affirming hormone therapy [20]. We also reviewed the reference lists of previous reviews and hand-searched the *International Journal of Transgenderism*. Using DistillerSR [21], 2 reviewers independently screened titles, abstracts, and full-text articles. Differences were resolved through consensus adjudication.

We included studies that evaluated the psychological effects of any testosterone, estrogen, or anti-androgen formulation used for gender affirmation. We also considered gonadotropin-releasing hormone (GnRH) analogues used as anti-androgens or for puberty delay. Study participants must have been on hormone therapy for at least 3 months in order to reflect a minimum time for expected onset of effects [3]. Health care provider supervision was not required. We excluded studies that did not state therapy type and duration, including the range for cross-sectional studies. We included studies regardless of language (the search terms were in English) and country of origin, and we accepted any study design except case reports.

We created standardized forms for data extraction using the Systematic Review Data Repository system. The data extracted included participant demographics; study design

and methods; hormone therapy type, dose, and duration; potential confounders such as gender-affirming surgery status; outcome scales [20]; and psychological outcomes. From studies that used the Short Form-36 Health Survey (SF-36) to measure QOL, we extracted scores in all domains [22]. For studies that used measures with depression or anxiety subscales, we extracted only the subscale scores corresponding to the psychological outcomes of interest (eg, the depression subscale of the Minnesota Multiphasic Personality Inventory [MMPI]). We extracted comparisons with cisgender controls or general population norms only when longitudinal findings in a transgender population or comparisons with an untreated transgender control group were not reported. We used WebPlotDigitizer to extract data reported only in figures [23].

Two reviewers independently assessed risk of bias [20]. For randomized controlled trials (RCTs), we used the revised Cochrane tool [24]. For non-randomized studies, we used the Cochrane Risk of Bias Assessment Tool for Non-Randomized Studies of Interventions (ROBINS-I) [25]. One reviewer graded strength of evidence for each outcome using the Agency for Healthcare Research and Quality Methods Guide for Conducting Comparative Effectiveness Reviews [26]. We considered the directionality and magnitude of effects reported in cross-sectional studies as additional context for our evaluation of evidence from trials and prospective and retrospective cohorts. Each strength of evidence assessment was confirmed by a second reviewer.

WPATH provided the research question and reviewed the protocol, evidence tables, and report. WPATH had no role in study design, data collection, analysis, interpretation, or drafting. The corresponding author had full access to all the data and had final responsibility for the decision to submit for publication. The authors are responsible for all content, and statements in this report do not necessarily reflect the official views of or imply endorsement by WPATH.

Results

We retrieved 1753 nonduplicate studies for the broader systematic review project of which this review was a part (Fig. 1). After screening and full-text review for the specific research question on the psychological effects of gender-affirming hormone therapy, 20 studies reported in 22 publications were included (Table 1): 1 RCT [27], 2 before-after trials [28, 29], 12 prospective cohorts reported in 13 publications [30-42], 1 retrospective cohort reported in 2 publications [43, 44], and 4 cross-sectional studies [45-48]. De Vries (2014) [35] reported on a subset of the participants in de Vries (2011) [34] who continued in care. We counted these publications as a single study but extracted and reported data separately because the characteristics of the study's adolescent population changed substantially in the period between the 2 publications. Similarly, Asscheman (2011) [44] reported on an extension of Asscheman (1989) [43]; we counted these as a single study but extracted data separately. In Table 1 and in the subsequent tables for each outcome, studies are ordered first by study design (RCTs, before-after trials, prospective cohorts, retrospective cohorts, and cross-sectional studies); within these categories, studies are presented in the following order according to how the study results were reported: adult transgender women only, adult transgender men only, adult transgender women and transgender men together, and transgender adolescents (no study reported separate results by gender identity for transgender youth). Where multiple studies shared the same study design and population, they are additionally ordered chronologically.

The time frame covered in the included studies began in 1972 [43], but most studies dated from post-2000. Eight studies were conducted in Italy [27-29, 31, 32, 36, 39, 41]; 2 each in Belgium [37, 48], the Netherlands [34, 35, 43, 44], the United States [30, 47], and Spain [38, 45]; and 1 in the United Kingdom [33], Turkey [42], and France [46]. One study recruited participants from Switzerland and Germany [40]. One study was part of the European Network for the Investigation of Gender Incongruence (ENIGI), which is a research collaborative between clinics providing gender-affirming care to transgender people in Ghent (Belgium), Amsterdam (Netherlands), Oslo (Norway), and Hamburg (Germany). The ENIGI study included in this review drew participants only from the Ghent clinic [37].

The study sizes ranged from 20 to 1331, although most had fewer than 60 participants. Fourteen studies reported on testosterone formulations in adult transgender men [27, 29, 31-33, 36, 39-46, 48]. These formulations were typically injectable testosterone cypionate or enanthate, although some studies used long-acting injectable testosterone undecanoate or daily transdermal gels. Ten studies reported on estrogen formulations in adult transgender women, usually in conjunction with an anti-androgen such as cyproterone acetate or spironolactone [28, 31, 33, 36, 37, 39, 43-47]. Estrogen formulations included transdermal, oral, or injectable estradiol (commonly estradiol valerate) or conjugated estrogens. Three studies reported on the psychological effects of GnRH therapy for puberty delay among mixed-gender groups of transgender adolescents [30, 34, 35, 38]. No study reported on hormone therapy among nonbinary people.

All studies that reported information about recruitment drew their participants largely or exclusively from specialized clinics dedicated to providing gender-affirming care for transgender people. These clinics were typically part of larger systems such as university hospitals. Clinic-based

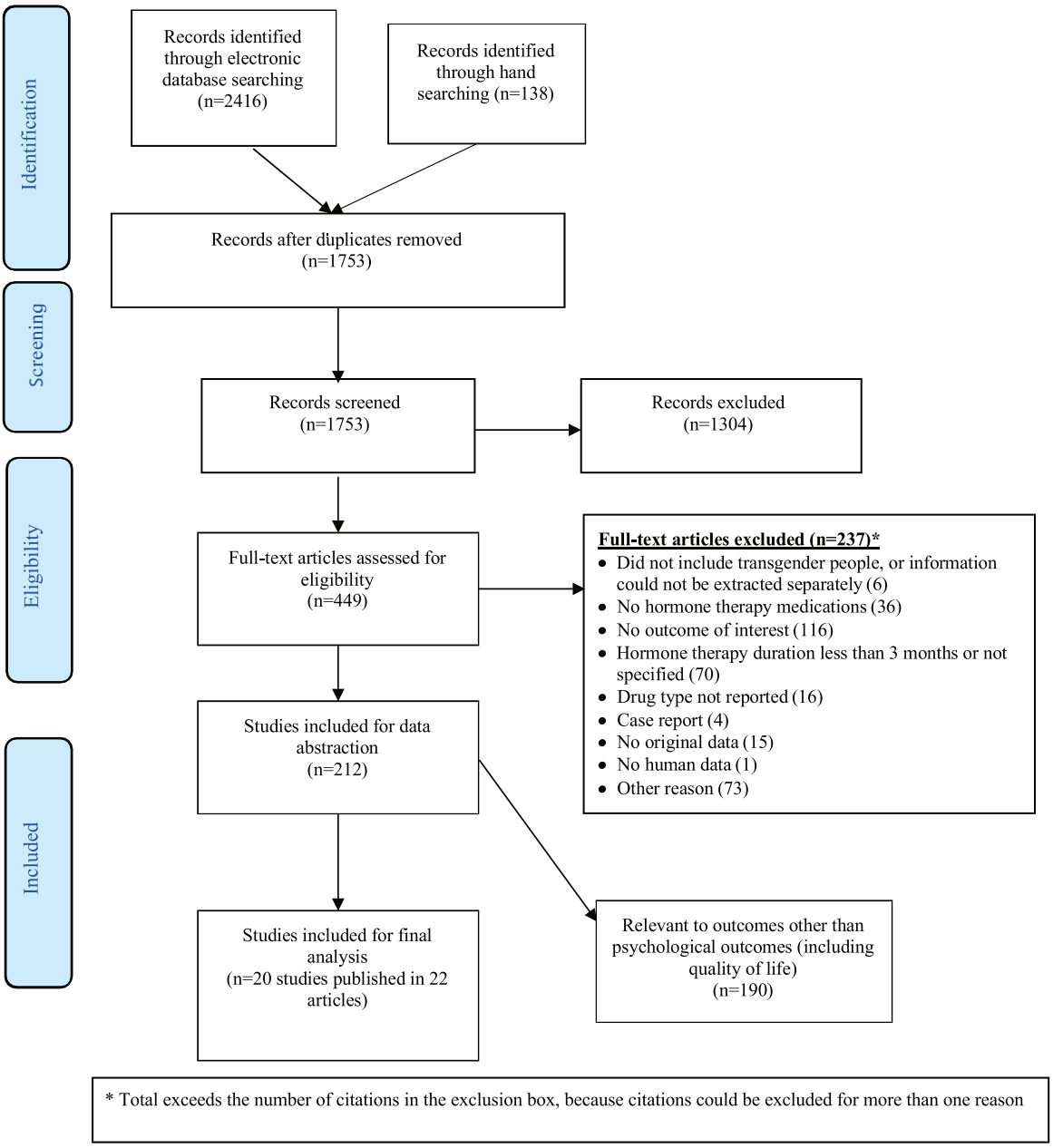

Figure 1. PRISMA flow diagram.

studies often applied strict eligibility criteria that included a period of psychiatric evaluation and a formal diagnosis of gender dysphoria before hormone therapy was initiated. Some studies also reported that psychological counseling was either available or required during the course of hormone therapy. In many cases, hormone therapy was considered a prerequisite for gender-affirming surgeries. The type and timing of gender-affirming surgeries and the proportion of participants for whom hormone therapy and surgeries were assessed simultaneously varied widely: some studies assessed only participants who had not had any type of gender-affirming surgery [27, 28, 30-32, 34, 36, 38-40, 42, 46, 47], while in others some or all participants underwent gender-affirming surgeries during the study period [29, 33, 35, 43-45, 48].

Quality of Life

Seven studies, including 1 RCT [27], 2 before-after trials [28, 29], 2 prospective cohorts [30, 39], and 2 cross-sectional studies [46, 48], assessed QOL (Table 2). An RCT found an improvement of approximately 5.5 points on a 10-point measure of life satisfaction across 3 groups of transgender men (n = 15 each) after 1 year of testosterone treatment ($P < 0.05$) [27]. A before-after trial similarly reported that life satisfaction scores almost

Table 1. Studies Reporting Effects of Gender-Affirming Hormone Therapy on Psychological Outcomes Among Transgender People

Author, year Location Study name	Study design	Start year	Transgender population	Overall N	Age in years	Baseline HT status	Outcomes	GAS status	Risk of bias
Pelusi, 2014 [27] Italy	Randomized controlled trial[a]	NR	Men	45	Mean: 29.5	No previous HT	QOL	No GAS before or during study	High
Gava, 2016 [28] Italy	Before-after trial	NR	Women	40	Mean: 3.2 (range, 19–55)	No previous HT	QOL, Depression	No GAS before or during study	Low
Gava, 2018 [29] Italy	Before-after trial[a]	NR	Men	50	Mean: 30.1 (range, 21–42)	No previous HT	QOL	72% (n = 36) had gonadectomy during study	Serious
Fuss, 2015 [37] Belgium ENIGI (NCT01072825)	Prospective cohort	2010	Women	20	Mean: 33.9 (range, 17–48)	No previous HT	Anxiety	NR	Serious
Costantino, 2013 [32] Italy	Prospective cohort	2001	Men	50	Mean: 29.8	No previous HT	Depression	No GAS before or during study	Serious
Motta, 2018 [41] Italy	Prospective cohort	2013	Men	52	Mean: 28.3	No previous HT	Anxiety	NR	Moderate
Turan, 2018 [42] Turkey	Prospective cohort[b]	NR	Men	37	Mean: 24.6	No previous HT	Depression, Anxiety	No GAS before or during study	Moderate
Metzger, 2019 [40] Switzerland, Germany	Prospective cohort[b]	2013	Men	23	Mean: 27.2 (range, 18–51)	No previous HT	Depression	No GAS before or during study	Moderate
Colizzi, 2014 [31] Italy	Prospective cohort	2008	Women and men	107	Mean: 29.2	No previous HT	Depression, Anxiety	No GAS before or during study	Low
Manieri, 2014 [39] Italy	Prospective cohort	NR	Women and men	83	Mean: 32.7 (women), 30.2 (men)	No previous HT	QOL	No GAS before or during study	Moderate
Fisher, 2016 [36] Italy	Prospective cohort	2012	Women and men	54	Mean: 32.5 (women), 26.3 (men)	No previous HT	Depression	No GAS before or during study	Low
Defreyne, 2018 [33] UK	Prospective cohort	2012	Women and men	155	Median: 27 (range, 18–52)	No previous HT	Depression, Anxiety	Some had GAS during study; % and type NR	Serious
Asscheman, 1989 [43] Netherlands	Retrospective cohort[b,d]	1972	Women and men	425	Median: 32 (women, range, 16–67); 25.4 (men, range, 16–54)	Previous HT for at least 6 months	Death by suicide	78% (n = 235) of transgender women had GAS during study; data NR for transgender men	Serious

Table 1. Continued

Author, year Location Study name	Study design	Start year	Transgender population	Overall N	Age in years	Baseline HT status	Outcomes	GAS status	Risk of bias
Asscheman, 2011 [44] Netherlands	Retrospective cohort[b,d]	1975	Women and men	1331	Mean: 31.4 (women, range, 16–76); 26.1 (men, range, 16–57)	Previous HT for at least 1 year	Death by suicide	87% (n = 834) of transgender women and 94% (n = 343) of transgender men had GAS during study	Serious
Leavitt, 1980 [47] US	Cross-sectional	1976	Women	41	Range, 18–35	54% (n = 22) on HT	Depression	No previous GAS	Serious
Wierckx, 2011 [48] Belgium	Cross-sectional[b]	2009	Men	47	Mean: 37 (range, 22–54)	100% on HT	QOL	100% had GAS, but not within previous year	Serious
Gómez-Gil, 2012 [45] Spain	Cross-sectional	NR	Women and men	187	Mean: 29.9 (range, 15–61)	64% (n = 120) on HT	Depression, Anxiety	42% (n = 79) of all participants and 64% (n = 77) of participants on HT had previous GAS	Serious
Gorin-Lazard, 2012 [46] France	Cross-sectional[b]	NR	Women and men	61	Mean: 34.7	72% (n = 44) on HT	QOL	No previous GAS	Serious
de Vries, 2011 [34] Netherlands	Prospective cohort	2000	Girls and boys	70	Mean: 14.8 (range, 11.3–18.6)	No previous HT	Depression, Anxiety	No GAS before or during study	Moderate
de Vries, 2014 [35] Netherlands	Prospective cohort[b,c]	2000	Girls and boys	55	Mean: 14.8 (range, 11.5–18.5)	No previous HT	Depression, Anxiety	100% had GAS during study	Serious
Achille, 2020 [30] US	Prospective cohort	2013	Girls and boys	50	Mean: 16.2	No previous HT	QOL, Depression	No GAS before or during study	Moderate
López de Lara, 2020 [38] Spain	Prospective cohort[b]	2018	Girls and boys	23	Mean: 16 (range, 14-18)	No previous HT	Depression, Anxiety	No GAS before or during study	Moderate

Abbreviations: ENIGI, European Network for the Investigation of Gender Incongruence; GAS, gender-affirming surgery; HT, hormone therapy; NR, not reported; QOL, quality of life.

[a]25 participants were included in both Pelusi [27] and Gava (2018) [29]

[b]Included a cisgender control group or a comparison to general population norms

[c]All participants were also included in de Vries (2011) [34]

[d]An unknown number of participants were included in both Asscheman (1989) [43] and Asscheman (2011) [44]

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Table 2. Effects of Gender-Affirming Hormone Therapy on Quality of Life Among Transgender People

Author, year Study design	Transgender population	Treatment / comparison (n)	QOL measures	Length of treatment	Findings
Pelusi, 2014 [27] RCT[a]	Men	Testoviron depot (15) vs testosterone gel (15) vs testosterone undecanoate (15)	VAS (general life satisfaction)	54 weeks	Mean QOL scores increased from 2.8 to 8.5 ($P < 0.05$) in the testoviron depot arm, from 3.2 to 8.9 ($P < 0.05$) in the testosterone gel arm, and from 2.6 to 8.0 ($P < 0.05$) in the testosterone undecanoate arm.[d] There was no difference across arms.
Gava, 2016 [28] Before-after trial	Women	Cyproterone acetate + estradiol (20) vs leuprolide acetate + estradiol (20)	VAS (general life satisfaction) SF-36	12 months	Mean QOL scores did not change in either arm. No comparisons across arms were reported.
Gava, 2018 [29] Before-after trial[a]	Men	Testosterone undecanoate (25)[c] vs testosterone enanthate (25)[c]	VAS (general satisfaction)	5 years	Mean QOL scores increased from 4.3 ± 3.1 to 8.1 ± 1.8 ($P < 0.001$) in the testosterone undecanoate arm and from 4.3 ± 3.8 to 8.3 ± 1.7 ($P < 0.001$) in the testosterone enanthate arm. No comparisons across arms were reported.
Manieri, 2014 [39] Prospective cohort	Women	HT (56)	WHOQOL	12 months	Mean QOL scores increased from 62.5 to 72.2 ($P < 0.05$).[d]
Manieri, 2014 [39] Prospective cohort	Men	HT (27)	WHOQOL	12 months	Mean QOL scores did not change.
Wierckx, 2011 [48] Cross-sectional[b]	Men	HT (47)[c]	SF-36	At least 3 years	Mean QOL scores on the VT and MH subscales were lower for transgender men than cisgender men (VT subscale: 62.1 ± 20.7 vs 71.9 ± 18.3, $P = 0.002$; MH subscale: 72.6 ± 19.2 vs 79.3 ± 16.4, $P = 0.020$). There were no other differences between transgender men and either cisgender men or cisgender women.
Gorin-Lazard, 2012 [46] Cross-sectional[b]	Women and men	HT (44) vs no HT (17)	SF-36	Median: 20 months (range, 12–42 months)	Mean QOL scores were generally higher in the group receiving HT vs the group not receiving HT (MCS: 51.0 ± 7.7 vs 39.8 ± 12.7, $P = 0.003$; MH subscale: 76.4 ± 14.1 vs 59.1 ± 19.6, $P = 0.004$; RE subscale: 88.6 ± 22.7 vs 54.9 ± 40.7, $P = 0.001$; SF subscale: 83.2 ± 23.3 vs 69.9 ± 24.2, $P = 0.026$). There were no differences in the other subscales.
Achille, 2020 [30] Prospective cohort	Girls and boys	GnRH treatment + HT (47)	Q-LES-Q-SF	12 months	Mean QOL scores did not change.

Abbreviations: GnRH, gonadotropin-releasing hormone; HT, hormone therapy; MCS, Mental Component Summary; MH, mental health; QOL, quality of life; RCT, randomized controlled trial; RE, role functioning/emotional; SF, social functioning; SF-36, Short Form-36 Health Survey; VAS, visual analog scale; VT, vitality; WHOQOL, World Health Organization Quality of Life measure.

[a]10 participants on testosterone enanthate and 15 participants on testosterone undecanoate were included in both Pelusi [27] and Gava (2018) [29]

[b]Included a cisgender control group or a comparison to general population norms

[c]Included participants who had undergone gender-affirming surgery/surgeries, or surgery status not reported

[d]No standard deviations reported

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doubled among transgender men (n = 50) over 5 years [29]. A prospective study found a 16% improvement in QOL scores among transgender women (n = 56) after 1 year of treatment ($P < 0.05$) but no change among transgender men (n = 27) [39]. Another before-after trial reported no difference in SF-36 scores among 2 groups of transgender women (n = 20 each) after 1 year [28]. Among adolescents, a mixed-gender prospective cohort (n = 50) showed no difference in QOL scores after a year of endocrine interventions, which included combinations of GnRH analogues and estrogen or testosterone formulations [30]. No study found that hormone therapy decreased QOL scores. We conclude that hormone therapy may improve QOL among transgender people. The strength of evidence for this conclusion is low due to concerns about bias in study designs, imprecision in measurement because of small sample sizes, and confounding by factors such as gender-affirming surgery status.

Depression

Twelve studies, including 1 before-after trial [28], 9 prospective cohorts [30-36, 38, 40, 42], and 2 cross-sectional studies [45, 47], assessed depression (Table 3). A prospective study found that the proportion of transgender men and transgender women (n = 107) showing symptoms of depression decreased from 42% to 22% over 12 months of treatment ($P < 0.001$) [31]. In 2 other prospective cohorts, Beck Depression Inventory (BDI-II) scores improved by more than half among both transgender men (n = 26) and transgender women (n = 28) after 24 months of therapy ($P < 0.001$) [36] and improved from 15.7 ± 12.3 to 8.1 ± 6.2 among transgender men (n = 23) after 6 months ($P < 0.001$) [40]. A fourth prospective study reported improvements of 1.05 points (95% CI: −1.87, −0.22) and 1.42 points (95% CI: −2.61, −0.24) on the 21-point Hospital Anxiety and Depression Scale (HADS) among 91 transgender women and 64 transgender men after 12 months ($P = 0.013$ and $P = 0.019$, respectively) [33]. A before-after trial, however, found no change in BDI-II scores among 2 groups of transgender women (n = 20 each) after 1 year [28]. Two prospective studies reported no difference among transgender men (n = 37) after 24 weeks [42] or among transgender men (n = 50) after 12 months [32], although in the latter study this outcome did not change from a baseline median of 0.0 ("not at all depressed") on an unvalidated 4-point scale. Among adolescents, 2 mixed-gender prospective cohorts (n = 50 and n = 23, respectively) showed improvements in depression scores after 1 year of treatment with GnRH analogues and estrogen or testosterone formulations (both $P < 0.001$) [30, 38]. Another prospective study reported that BDI scores improved almost by half among adolescents (n = 41) after a mean of 1.88 years of treatment with GnRH analogues to delay puberty ($P = 0.004$) [34]. The overall improvement after several subsequent years of testosterone or estrogen therapy in this cohort (n = 32) was smaller, however, resulting in no significant change from baseline [35]. No study found that hormone therapy increased depression. We conclude that hormone therapy may decrease depression among transgender people. The strength of evidence for this conclusion is low due to concerns about study designs, small sample sizes, and confounding.

Anxiety

Eight studies, including 7 prospective cohorts [31, 33-35, 37, 38, 41, 42] and 1 cross-sectional study [45], assessed anxiety (Table 4). One prospective study found that Symptom Checklist 90-Revised scores indicating a probable anxiety disorder among a mixed-gender group of adults (n = 107) improved from borderline to normal over 12 months ($P < 0.001$) [31]. Another prospective study, however, did not find a difference in HADS anxiety scores among either transgender men (n = 64) or transgender women (n = 91) after 1 year [33], and a third study reported no change in the number of transgender men (6/52, 12%) with a diagnosed anxiety disorder after 7 months [41]. Likewise, 2 other prospective studies found no difference in anxiety scores among transgender men (n = 37) after 24 weeks of treatment [42] or transgender women (n = 20) after 12 months [37], although this latter finding represented no change from a baseline median score of 0 (answering "no" to the question, "do you feel anxious?") on an unvalidated 3-point scale. Among adolescents, 1 prospective study saw mean anxiety scores in a mixed-gender group (n = 23) improve from 33.0 ± 7.2 to 18.5 ± 8.4 after 1 year ($P < 0.001$) [38], but another reported no changes in anxiety after approximately 2 years of puberty delay treatment with GnRH analogues and 4 years of hormone therapy (n = 32) [35]. No study found that hormone therapy increased anxiety. We conclude that hormone therapy may decrease anxiety among transgender people. The strength of evidence for this conclusion is low due to concerns about study designs, small sample sizes, and confounding.

Death by Suicide

One retrospective study reported in 2 publications assessed death by suicide (Table 5) [43, 44]. The first publication reported that 3 transgender women in the Amsterdam gender dysphoria study cohort (n = 303) died by suicide between 1972 and 1986 [43]. The authors calculated the number of suicide deaths expected in an age-matched stratum of

Table 3. Effects of Gender-Affirming Hormone Therapy on Depression Among Transgender People

Author, year Study design	Transgender population	Treatment / comparison (n)	Depression measures	Length of treatment	Findings
Gava, 2016 [28] Before-after trial	Women	Cyproterone acetate + estradiol (20) vs Leuprolide acetate + estradiol (20)	BDI-II	12 months	Mean depression scores did not change in either arm. No comparisons across arms were reported.
Fisher, 2016 [37] Prospective cohort	Women	HT (28)	BDI-II	24 months	Mean depression score decreased from 10.12 to 4.58 ($P < 0.001$).[d,e]
Defreyne, 2018 [33] Prospective cohort	Women	HT (91)[c]	HADS (depression subscale)	1 year	Median depression score decreased by 1.05 (95% CI: −1.87, −0.22) on a 21-point scale ($P = 0.013$).
Costantino, 2013 [32] Prospective cohort	Men	HT (50)	Ad hoc questionnaire	12 months	Depression score did not change from a median of 0.0 at baseline (IQR: 0.0, 1.0).
Fisher, 2016 [36] Prospective cohort	Men	HT (26)	BDI-II	24 months	Mean depression score decreased from 9.31 to 4.25 ($P < 0.001$).[d,e]
Defreyne, 2018 [33] Prospective cohort	Men	HT (64)[c]	HADS (depression subscale)	1 year	Median depression score decreased by 1.42 (95% CI: −2.61, −0.24) on a 21-point scale ($P = 0.019$).
Turan, 2018 [42] Prospective cohort[b]	Men	HT (37)	SCL-90-R (depression subscale)	24 weeks	Mean depression score did not change.
Metzger, 2019 [40] Prospective cohort[b]	Men	HT (23)	BDI-II	6 months	Mean depression score decreased from 15.7 ± 12.3 to 8.1 ± 6.2 ($P < 0.001$).
Colizzi, 2014 [31] Prospective cohort	Women and men	HT (107)	Zung SDS SCL-90-R (depression subscale)	12 months	Mean Zung SDS score improved from 48.40 ± 10.5 to 39.98 ± 10.79 ($P < 0.001$), and the proportion with Zung SDS scores indicating mild, moderate, or severe depression (vs no depression) decreased from 42% to 22% ($\chi^2 = 19.05$, $P < 0.001$). Mean SCL-90-R score decreased from 0.83 ± 0.74 to 0.51 ± 0.49 ($P < 0.001$), which represents an improvement from possible borderline depression to no depression.
Leavitt, 1980 [47] Cross-sectional	Women	HT (22) vs No HT (19)	MMPI (depression subscale)	At least 12 months	Mean depression score was lower in the group receiving HT vs the group not receiving HT (53.1 ± 14.7 vs 65.7 ± 11.2, $P = 0.004$).

Table 3. Continued

Author, year Study design	Transgender population	Treatment / comparison (n)	Depression measures	Length of treatment	Findings
Gómez-Gil, 2012 [45] Cross-sectional	Women and men	HT (120)[c] vs No HT (67)[c]	HADS (depression subscale)	Mean: 11.0 years (women, range, 1–46 years); 4.7 years (men, range, 1–22 years)	Mean depression score was lower in the group receiving HT vs the group not receiving HT (3.3 ± 3.2 vs 5.2 ± 4.2, $P = 0.002$).[f] The proportion with scores indicating depression (vs no depression) was larger in the group not receiving HT (31% vs 8%, $\chi^2 = 16.46$, $P = 0.001$).[f]
de Vries, 2011 [34] Prospective cohort	Girls and boys	GnRH treatment (41)	BDI	1.88 years	Mean depression score decreased from 8.31 ± 7.12 to 4.95 ± 6.72 ($P = 0.004$).
de Vries, 2014 [35] Prospective cohort[a,b]	Girls and boys	GnRH treatment + HT (32)[c]	BDI	5.9 years	Mean depression score did not change.
Achille, 2020 [30] Prospective cohort	Girls and boys	GnRH treatment + HT (47)	CESD-R, PHQ-9 (modified for adolescents)	12 months	Mean CESD-R score decreased from 21.4 to 13.9 ($P < 0.001$);[d] a score of <16 indicates no clinical depression. Mean PHQ-9 score decreased from 9.0 to 5.4 ($P < 0.001$).[d]
López de Lara, 2020 [38] Prospective cohort[b]	Girls and boys	GnRH treatment + HT (23)	BDI-II	1 year	Mean depression score decreased from 19.3 ± 5.5 to 9.7 ± 3.9 ($P < 0.001$).

Abbreviations: BDI/BDI-II, Beck Depression Inventory; GAS, gender-affirming surgery; GnRH, gonadotropin-releasing hormone; HADS, Hospital Anxiety and Depression Scale; HT, hormone therapy; IQR, interquartile range; MMPI, Minnesota Multiphasic Personality Inventory; NA, not applicable; SCL-90-R, Symptom Checklist 90-Revised; Zung SDS, Zung Self-Rating Depression Scale.

[a]All participants were also included in de Vries (2011) [34]

[b]Included a cisgender control group or a comparison to general population norms

[c]Included participants who had undergone gender-affirming surgery/surgeries, or surgery status not reported

[d]No standard deviations reported

[e]Adjusted for age, gender role, and surgery status

[f]Adjusted for age, gender, and education level

Table 4. Effects of Gender-Affirming Hormone Therapy on Anxiety Among Transgender People

Author, year	Transgender population	Treatment / comparison (n)	Anxiety measures	Length of treatment	Findings
Fuss, 2015 [37] Prospective cohort	Women	HT (20)[c]	Ad hoc questionnaire	12 months	Anxiety score did not change from a median of 0.0 at baseline.
Defreyne, 2018 [33] Prospective cohort	Women	HT (91)[c]	HADS (anxiety subscale)	1 year	Median anxiety score did not change.
Defreyne, 2018 [33] Prospective cohort	Men	HT (64)[c]	HADS (anxiety subscale)	1 year	Median anxiety score did not change.
Motta, 2018 [41] Prospective cohort	Men	HT (46)[c]	DSM	7 months	Proportion diagnosed with an anxiety disorder (6/46, 12%) did not change.
Turan, 2018 [42] Prospective cohort[b]	Men	HT (37)	SCL-90-R (anxiety subscale)	24 weeks	Mean anxiety score did not change.
Colizzi, 2014 [31] Prospective cohort	Women and men	HT (107)	SCL-90-R (anxiety subscale) Zung SAS	12 months	Mean SCL-90-R score decreased from 1.05 ± 0.95 to 0.54 ± 0.56 ($P < 0.001$), which represents an improvement from borderline anxiety disorder to no anxiety disorder. Mean Zung SAS score improved from 44.91 ± 9.59 to 37.90 ± 8.97 ($P < 0.001$), and the proportion with Zung SAS scores indicating mild, moderate, or severe anxiety (vs no anxiety) decreased from 50% to 17% ($\chi^2 = 33.03$, $P < 0.001$).
Gómez-Gil, 2012 [45] Cross-sectional	Women and men	HT (120)[c] vs No HT (67)[c]	HADS (anxiety subscale) SADS	Mean: 11.0 years (women, range, 1-46 years); 4.7 years (men, range, 1-22 years)	Mean HADS and SADS scores were lower in the group receiving HT vs the group not receiving HT (6.4 ± 3.7 vs 9.0 ± 4.0, $P = 0.001$; 8.5 ± 7.8 vs 11.0 ± 7.3, $P = 0.038$, respectively).[d] The proportion with scores indicating anxiety (vs no anxiety) was higher in the group not receiving HT ($\chi^2 = 14.46$, $P < 0.001$).[d]
de Vries, 2011 [34] Prospective cohort	Girls and boys	GnRH treatment (41)	STAI (trait subscale)	1.88 years	Mean anxiety score did not change.
de Vries, 2014 [35] Prospective cohort[a,b]	Girls and boys	GnRH treatment + HT (32)[c]	STAI (trait subscale)	5.9 years	Mean anxiety score did not change.
López de Lara, 2020 [38] Prospective cohort[b]	Girls and boys	GnRH treatment + HT (23)	STAI (trait subscale)	1 year	Mean anxiety score decreased from 33.0 ± 7.2 to 18.5 ± 8.4 ($P < 0.001$).

Abbreviations: BAI, Beck Anxiety Inventory; DSM, Diagnostic and Statistical Manual of Mental Disorders; GAS, gender-affirming surgery; GnRH, gonadotropin-releasing hormone; HADS, Hospital Anxiety and Depression Scale; HT, hormone therapy; IQR, interquartile range; SADS, Social Avoidance and Distress Scale; SCL-90-R, Symptom Checklist 90-Revised; STAI, State-Trait Anxiety Inventory; Zung SAS, Zung Self-Rating Anxiety Scale.

[a]All participants were also included in de Vries (2011) [34]

[b]Included a cisgender control group or a comparison to general population norms

[c]Included participants who have undergone gender-affirming surgery/surgeries, or surgery status not reported

[d]Adjusted for age, gender, and education level

the general male Dutch population over this period to be 0.208. No data were reported for transgender men (n = 122). An update to this study reported 17 deaths by suicide among transgender women (n = 966) and 1 among transgender men (n = 365) between 1975 and 2007 [44]. The age- and sex-stratified standardized mortality ratios were 5.70 (95% CI: 4.93, 6.54) and 2.22 (95% CI: 0.53, 6.18), respectively. The risk of bias for this study was serious due to the difficulty of identifying appropriate comparison groups and uncontrolled confounding by surgery

Table 5. Effects of Gender-Affirming Hormone Therapy on Death by Suicide Among Transgender People

Author, year	Transgender population	Treatment / comparison (n)	Measures	Length of treatment	Findings
Asscheman, 1989 [43] Retrospective cohort[a,b]	Women	HT (303)[c]	Death by suicide (confirmed by autopsy report)	Median: 4.4 years (range, 6 months to 13 years)	3 transgender women (1%) died by suicide between 1972 and 1986. The adjusted number of suicide deaths expected among the general Dutch male population was 0.208.
Asscheman, 2011 [44] Retrospective cohort[a,b]	Women	HT (966)[c]	Death by suicide (confirmed by medical report or physician information)	Median: 18.6 years (range, 0.7–44.5 years)	17 transgender women (2%) died by suicide between 1975 and 2007. The age-stratified SMR compared to the general Dutch male population was 5.70 (95% CI: 4.93, 6.54).
Asscheman, 1989 [43] Retrospective cohort[a,b]	Men	HT (122)[c]	Death by suicide (confirmation procedure NR)	Median: 3.6 years (range, 6 months to 13 years)	No deaths by suicide among transgender men were reported during the study period.
Asscheman, 2011 [44] Retrospective cohort[a,b]	Men	HT (365)[c]	Death by suicide (confirmed by medical report or physician information)	Median: 18.4 years (range, 4.7–42.6 years)	1 transgender man (0.3%) died by suicide between 1975 and 2007. The age-stratified SMR compared to the general Dutch female population was 2.22 (95% CI: 0.53, 6.18).

Abbreviations: HT, hormone therapy; NR, not reported; SMR, standardized mortality ratio.
[a]An unknown number of participants were included in both Asscheman (1989) [43] and Asscheman (2011) [44]
[b]Included a cisgender control group or a comparison to general population norms
[c]Includes participants who had undergone gender-affirming surgery/surgeries, or surgery status not reported

status and socioeconomic variables such as unemployment. We cannot draw any conclusions on the basis of this single study about whether hormone therapy affects death by suicide among transgender people.

Discussion

This systematic review of 20 studies found evidence that gender-affirming hormone therapy may be associated with improvements in QOL scores and decreases in depression and anxiety symptoms among transgender people. Associations were similar across gender identity and age. The strength of evidence for these conclusions is low due to methodological limitations (Table 6). It was impossible to draw conclusions about the effects of hormone therapy on death by suicide.

Uncontrolled confounding was a major limitation in this literature. Many studies simultaneously assessed different types of gender-affirming care and did not control for gender-affirming surgery status, making it difficult to isolate the effects of hormone therapy. Others failed to report complete information about surgery status. Additional factors that may influence both access to care and psychological outcomes, including extent of social or legal gender affirmation and exposure to determinants of health such as discrimination, were typically not considered. In addition, some evidence indicates that cyproterone acetate, a common anti-androgen assessed in many studies alongside estrogen therapy, may increase depression, which may be a source of confounding [49].

Another source of potential bias was recruitment of participants from specialized clinics that impose strict diagnostic criteria as a prerequisite for gender-affirming care. The dual role of clinicians and researchers as both gatekeepers and investigators may force transgender study participants to over- or understate aspects of their mental health in order to access gender-affirming care [8]. Similarly, transgender clinic patients may feel that they cannot opt out of research-related activities, which is a serious concern for the validity of psychological outcome measurements.

Clinic-based recruitment also overlooks transgender people who cannot access these clinics for financial or other reasons and misses those whose need for gender affirmation does not fit into current medical models. This is a particular concern for nonbinary and other gender-diverse people, for whom a model of gender affirmation as a linear transition from one binary gender to another is inaccurate [50].

Most studies used well-known scales for measuring psychological outcomes. None of these scales, however, have been specifically validated for use in transgender populations [51]. Furthermore, many scales are normed

Table 6. Strength of Evidence of Studies that Evaluate the Psychological Effects of Hormone Therapy Among Transgender People

Outcome	Number of studies (n)	Strength of evidence	Summary[a]
Quality of life	1 randomized controlled trial [27] (45)[b] 2 before-after trials [28, 29] (65)[b] 2 prospective cohorts [30, 39] (133) 2 cross-sectional studies [46, 48] (108)	Low[e]	Hormone therapy may improve quality of life among transgender people.[g]
Depression	1 before-after trial [28] (40) 9 prospective cohorts [30-36, 38, 40, 42] (569)[c] 2 cross-sectional [45, 47] (228)	Low[e]	Hormone therapy may alleviate depression among transgender people.[g]
Anxiety	7 prospective cohorts [31, 33-35, 37, 38, 41, 42] (464)[c] 1 cross-sectional [45] (187)	Low[e]	Hormone therapy may alleviate anxiety among transgender people.[g]
Death by suicide	1 retrospective cohort [43, 44] (1756)[d]	Insufficient[f]	There is insufficient evidence to draw a conclusion about the effect of hormone therapy on death by suicide among transgender people.

[a]Due to similarity of findings, the summary is the same for transgender men and transgender women and for adolescents and adults
[b]25 participants are included in both Pelusi [27] and Gava (2018) [29] and are counted once
[c]All 55 participants in de Vries (2014) [35] were also included among the 70 participants in de Vries (2011) [34] and are counted once
[d]An unknown number of participants were included in both Asscheman (1989) [43] and Asscheman (2011), [44] so the unique sample size is smaller than indicated here
[e]Evidence downgraded due to study limitations, including uncontrolled confounding, and imprecision because of small sample sizes
[f]Evidence downgraded due to study limitations, including confounding and a lack of meaningful comparison groups, and imprecision in measurement of a rare event
[g]The body of cross-sectional evidence tended to align with the conclusion

separately for (presumed cisgender) men and women [52]. Inconsistency in identification of appropriate general population norms hinders comparisons between transgender and cisgender groups, which is a major related research question that requires further investigation.

Beyond methodological concerns in the studies we assessed, our review has other limitations. First, it is likely subject to publication bias, as we may have missed studies not published in the peer-reviewed literature. Second, a number of potentially relevant studies could not be included because the authors did not report on a minimum of 3 months of treatment or did not clearly state the type and/or duration of therapy, including the range for cross-sectional studies [53-65]. Finally, even where outcome measurements were similar across studies, heterogeneity in study designs, study populations, intervention characteristics, and reporting of results (ie, some studies reported results separately by gender identity, while others did not), prevented us from quantitatively pooling results.

More research is needed to further explore the relationship between gender-affirming hormone therapy and QOL, death by suicide, and other psychological outcomes, especially among adolescents. Future studies should investigate these outcomes in larger groups of diverse participants recruited outside clinical settings. Studies assessing the relationship between gender-affirming hormone therapy and mental health outcomes in transgender populations should be prospective or use strong quasi-experimental designs; consistently report type, dose, and duration of hormone therapy; adjust for possible confounding by gender-affirming surgery status; control for other variables that may independently influence psychological outcomes; and report results separately by gender identity. Despite the limitations of the available evidence, however, our review indicates that gender-affirming hormone therapy is likely associated with improvements in QOL, depression, and anxiety. No studies showed that hormone therapy harms mental health or quality of life among transgender people. These benefits make hormone therapy an essential component of care that promotes the health and well-being of transgender people.

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Gender Differences in Risks of Suicide and Suicidal Behaviors in the USA: A Narrative Review

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Abstract

Purpose of Review—We review recent research (2018–2023) on gender differences in suicidal behaviors (i.e., suicidal ideations and attempts, death by suicide). We examine research studies in the following areas: developmental period, substance use, and special populations (Veterans, sexual and gender minorities).

Recent Findings—Novel results were found in these different areas. For example, suicide rates for female youth are increasing at a faster rate relative to male youth. Further, some evidence suggests that heavy alcohol use/binge drinking is a significant and growing risk factor for suicidal behaviors in women. Military service may be a more significant risk factor for suicidal behaviors among male Veterans compared to female Veterans. Additionally, suicide rates are rising for gender minority youth/young adults.

Summary—Recent research on gender differences in suicide outcomes demonstrates findings that align with previous research, as well as new insights on this important topic.

Keywords

Suicide gender differences; Youth suicide; Adult suicide; Substance use suicide; Veteran suicide; LGBT suicide

Introduction

Suicide, or death caused by intentionally harming oneself with the intent to die, is a significant public health concern in the USA [1]. In 2021, suicide was among the top nine leading causes of death for individuals ages 10–64. In addition to death by suicide, suicidal behaviors include suicide attempts as well as thoughts about suicide that are never acted upon. Gender differences in risk factors for and prevalence rates of suicidal behaviors have been well documented. For example, findings have consistently demonstrated greater rates

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of suicidal ideation and attempts in women, and a higher prevalence of death by suicide in men [2].

In addition, temporal trends in suicide rates also indicate gender differences. For example, while a recent report by the Centers for Disease Control (CDC) found that age-adjusted suicide rates mostly increased for men and women in the past 20 years, gender differences in trends across shorter periods of time between 2000 and 2021 were observed [3]. For example, the increase in suicide for men after 2008 was much larger than it was for females. This may be attributable to the 2008 economic crisis, which has been linked to an increase in suicide among men in particular [4]. In addition, rises in rates among both genders between 2020 and 2021 may reflect increases in mental health and substance use issues induced by the pandemic, contributing to a greater risk for suicide outcomes [5].

In this narrative review, we examined recent research (2018–2023) on gender differences in suicidal behaviors. We focus our review on studies published using US samples and organize our review in terms of areas in which recent studies on gender differences in suicidal behaviors have been most published: developmental period (preadolescents and adolescents, adults), substance use, and special populations (Veterans, sexual and gender minorities (SGM)). While most studies on gender differences in suicidal behaviors measure gender in terms of sex assigned at birth, in our review of research on gender minorities (GM), we consider gender differences in terms of gender identity, or how individuals experience their gender and what label they use to describe their gender.

Developmental Period

Preadolescents and Adolescents

In considering gender differences in suicide across developmental periods/age groups, most research in the past 5 years has been conducted on preadolescents and adolescents. Between 2010 and 2019, among preadolescents (children under 12), males made up the majority of youth suicide rates (66.7%) despite similar population estimates for males and females (51% and 49% respectively; Table 1) [6•]. Suicide rates for both genders grew between 2010 and 2019. However, this rise in rates was especially pronounced among female youth, increasing 300% ($r = 0.92$) during this period.

Upward temporal trends in poisoning-related suicide attempts and deaths by suicide have also been observed among female youth under age 18 [7]. Poisoning-related suicide outcomes increased significantly in females when comparing 2000–2010 and 2010–2018 percentage rates, whereas rates remained stable for males. These two studies provide some evidence to suggest that suicidal behaviors in female youth are increasing over time at a faster rate than male youth. Future research should continue to monitor gender differences in youth suicide rates over time especially given these concerning trends among female youth.

Recent cross-sectional research on gender differences in suicidal behaviors among preadolescents revealed mixed findings [8, 9]. Lawrence and colleagues found that female preadolescents, compared to males, had a decreased odds of suicidal ideation (OR = 0.71), whereas no gender differences were indicated for odds of suicide attempts [8]. Alternatively,

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findings from another study indicated that female preadolescents had an increased odds of experiencing past year suicidal ideation in 2007 (OR = 1.47) and 2010 (OR = 1.50) [9]. However, similar to the study by Lawrence and others, gender did not significantly predict past-year suicide attempts in either year. The lack of gender differences in suicide attempts consists of a developmental perspective of suicidal behaviors, which suggests that gender differences in suicidal behaviors do not develop until adolescence [9, 10].

Current research has also focused on how risk factors for suicide outcomes differ between male and female adolescents. Cromer and colleagues found that symptoms of depression at age 16 were associated with a greater risk of suicidal ideation at age 18 in females (b = 0.09), but not males [11]. The odds of having suicidal ideation were 1.09 times greater for each one-unit increase in depression symptoms in females while no change due to depression symptoms was observed for males. Further, findings from this study revealed that the indirect effect between cumulative victimization (i.e., childhood physical and sexual abuse, exposure to family violence) and suicidal ideation through depression was significant for females (unstandardized indirect effect = 0.08), but not males. Another study similarly found that among adolescents, depression played a mediating role in the indirect link between victimization (i.e., bullying victimization and sexual dating violence victimization) and suicide attempts, and these indirect effects were stronger for female adolescents (β = 0.045 and β = 0.028 respectively) compared to male adolescents (β = 0.029 and β = 0.009 respectively) [12]. The direct effect of depression on suicide attempts was also greater for female adolescents (β = 0.286) relative to males (β = 0.247). Consistent with previous research [13], these results suggest that depression is a gender-specific risk factor for suicide outcomes in youth, heightening the risk for females more so than males.

Research on youth suicide decedents also revealed gender differences in risk factors for death by suicide. Findings from the National Violent Death Reporting System (NVDRS) indicated that female youth (ages 10–18) suicide decedents, compared to male youth suicide decedents, had higher rates of current mental health problems and treatment history, leaving a suicide note, history of suicidal ideation and attempts, and interpersonal and intimate partner problems contributing to their suicide [14]. The only gender-specific risk factors that emerged for male youth suicide decedents were criminal legal problems and experiencing school problems that contributed to their suicide. These findings are relevant to research indicating externalizing disorders as a risk factor for death by suicide in male adolescents [15], as externalizing problems may include physical fights both in and outside of school. However, other issues that fall under the NVDRS definition for “school problems” include academic problems, problems with a teacher, bullying or isolation at school, detention/suspension, and performance pressures. Future research is needed to disentangle which of these school-related problems are contributing to male youth suicide [14].

Adults

To the authors’ knowledge, only one recent study has focused on gender differences in suicide among a US general sample of adults [16]. Using the National Epidemiologic Survey on Alcohol and Related Conditions-Wave III (NESARC-III), Bommersbach and colleagues found that adult females (OR = 1.78) had a greater lifetime prevalence of suicide attempts

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compared to adult males [16]. While both genders shared many risk factors for suicide attempts, other factors appeared to differ between men and women in the magnitude of their association with suicide attempts. Specifically, lifetime incarceration, previous trauma, and earning less than $40,000 emerged as a greater risk for suicide attempts in women, whereas borderline personality disorder, schizophrenia/psychosis, and a parental history of suicide attempt increased risk more for men. While limited new research exists on gender differences in suicidal behaviors among adults in the USA (not including substance use-related suicide and among special populations), multiple studies have been published using adult samples from other countries [e.g., 17, 18]. Future research would benefit from examining gender differences in suicidal behaviors among adults from an international perspective.

Substance Use

Alcohol Use

Multiple studies published in the past 5 years investigated suicide risk by gender among individuals with substance use issues, and alcohol and cannabis use in particular [19•, 20–23]. Lange and colleagues examined alcohol use (defined as blood alcohol concentration [BAC] of ≥ 0.04 g/dl for moderate use or ≥ 0.08 g/dl for heavy use) prior to suicide deaths among adults using data from NVDRS [19•; Table 2]. Between 2003 and 2018, alcohol-related suicide increased among women of all age groups for both moderate (2.80% for young women; 2.20% for middle-aged women; and 4.11% for older women) and heavy (3.09% for young women; 2.03% middle-aged women, and 10.48% for older women) alcohol use. Alternatively, only alcohol-related suicide increased for moderate alcohol use among middle-aged men (0.81%). While previous research has indicated a greater risk of being intoxicated with alcohol before death by suicide in women relative to men [24], this current study suggests that this risk may be increasing.

Two other recent studies focused on alcohol use and suicidal behaviors [20, 21]. Kittel and colleagues found that binge drinking was associated with suicide attempts in women (OR = 1.37), but not in men between 2008 and 2014 [20]. No association was found between binge drinking and suicidal ideation in either men or women. In the other study, which examined adults with depressive symptoms, men with co-morbid alcohol use disorder were more likely to report suicidal behaviors, including suicidal ideation and suicide attempts [21]. However, except for active suicidal ideation, no differences were observed between men and women with co-morbid binge drinking and passive suicidal ideation, suicide plans, and suicide attempts.

Results from these three studies indicate somewhat mixed findings. However, preliminary evidence points to heavy alcohol use/binge drinking in particular as a significant (and growing) risk factor for suicidal behaviors in women. This may be related to converging alcohol use rates between men and women in the past years [25, 26], coupled with poisoning as a more common suicide method in women compared to men [27]. Given growing rates of alcohol use disorder and heavy drinking in women, the association between alcohol use and the risk of suicide is a cause for concern.

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Cannabis Use

Two studies examined gender differences in the link between cannabis use and suicidal behaviors, with one focusing on adolescents and the other on adults [22, 23]. Flores and colleagues found that both male and female adolescents with weekly or more frequent cannabis use, relative to their male and female counterparts with no use, had significantly higher rates of any suicidal ideation (+ 14.8 percentage-points and + 12.8 percentage-points respectively) and attempt (+ 13.3 percentage-points and + 18.4 percentage-points respectively) [22]. For any suicide plan, only female adolescents with weekly-plus use indicated a significantly greater rate (+ 15.0 percentage-points), whereas there were no differences between male users and non-users. Among adults ages 18–34, women with cannabis use disorder (CUD) showed higher adjusted prevalence rates of suicidal ideation (13.9% vs. 9.9%), plans (4.1% vs. 2.7%), and attempts (3.0% vs 1.5%) [23]. These significantly higher rates for women with CUD compared to men with CUD remained regardless of whether they had depression. Thus, it is possible that other mental health issues or sociodemographic factors may explain the greater link between CUD and suicidality in women compared to men. Results from these studies provide preliminary evidence to suggest that cannabis use may serve as a more significant risk factor for suicidal behaviors in females relative to males. No recent studies examined gender differences in suicide outcomes for other substances, such as opioids and cocaine.

Special Populations

Veterans

Since 2018, several studies have focused on gender differences in suicide outcomes among the Veteran population [28, 29, 30•, 31]. In general, Veterans have a greater risk of dying by suicide compared to non-Veterans [32]. According to the 2022 National Veteran Suicide Prevention Annual Report, the suicide death rate for Veterans was 57.3% greater compared to non-Veteran US adults [28; Table 3]. Temporal trends in age-adjusted suicide rates were fairly similar between male and female Veterans. Between 2001 and 2020, suicide rates for Veteran men were highest in 2018 (approximately 41.0 per 100,000), then decreased through 2020 (approximately 39.0). For Veteran women, these rates were greatest in 2017 (approximately 20.0), then declined through 2020 (approximately 14.0). In general, rates of veteran suicide have increased since 2001, and especially among younger veterans. Peaking rates in men and women in 2018 and 2017 (respectively) may be due to unique risk factors for suicide associated with serving in post 9/11 wars (e.g., decreased approval of war, increased length of war, higher rates of traumatic brain injury) [29].

Similar to findings from non-Veteran samples, recent research has found that female Veterans indicated higher rates of lifetime and past-year suicidal ideation and lifetime suicide attempts compared to male Veterans [30•, 31]. A study of post-9/11 Veterans found that among both male and female Veterans, the odds of experiencing suicidal ideation were associated with military time period, with increasing odds across comparisons of periods (i.e., during military to premilitary, postmilitary to premilitary, postmilitary to during military) [30•]. The odds of experiencing suicidal ideation postmilitary relative to premilitary was higher for male Veterans (OR = 3.39) compared to female Veterans (OR

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= 1.70). In addition, the link between suicide attempts and military period was significant for male Veterans (OR = 2.69), but not female Veterans. While the rate of suicide attempts increased for male Veterans from premilitary (1.3%) to postmilitary (3.4%), it remained largely stable for female Veterans (6.0% to 5.8%). These results suggest that experiences during military service are a greater risk factor for suicidal behaviors in male Veterans compared to female Veterans.

Current research has also identified other gender-specific risk factors for suicidal behaviors in Veterans. Stefanovics and colleagues found that for female Veterans, significant risk factors for suicidal ideation were lower psychological resilience (44.4% of the variance explained), history of non-suicidal self-injury (24.4%), and alcohol use disorder (20.6%) [31]. For male Veterans, significant risk factors were loneliness (19.5%), hostility (19.1%), and lack of purpose in life (16.3%). Among a sample of Veterans experiencing housing instability, male and female Veterans had mostly similar risk factors for suicidal ideation and attempts [32]. For female Veterans, suicidal ideation was associated with being under 40, having a mental health or substance use disorder, and experiencing military sexual trauma. Risk factors for suicide attempts also included having a mental health or substance use disorder and experiencing MST in addition to being younger than 65 and having a service-connected disability. For male Veterans, both suicidal ideation and attempts were similarly linked to being younger than 65, having a mental health or substance use disorder, experiencing MST, and having a service-connected disability.

Sexual and Gender Minorities

SGMs (i.e., non-heterosexual individuals and those whose gender identity does not align with their sex assigned at birth) experience greater rates of suicidal behaviors compared to heterosexual, cisgender individuals [34, 35, 36•, 37–41]. Most of this research has indicated greater rates of suicidal behaviors in GM adolescents and young adults compared to cisgender adolescents and young adults [36•, 37, 38]. For example, among a sample of both SGM and non-SGM suicide decedents ages 11 to 29, there was a significant increase in death by suicide for transgender individuals 2016 [36•] (Table 4). Specifically, prior to 2016, 2.0% of adolescent/young adult suicide decedents identified as transgender, while after 2016, this rate increased to 6.5%. No significant increases were evident for both sexual minority (SM) and heterosexual cisgender male and female adolescents and young adults. Death by suicide happening after 2016 (compared to before 2016) was linked to a 366% increase in relative risk of the victim being a transgender adolescent/young adult. Because in recent years transgender individuals are increasingly disclosing their gender identity at younger ages, they are more vulnerable to experiences that may confer greater risk for suicide (e.g., family rejection, bullying/victimization) in adolescence/young adulthood [33]. Up-to-date trend analyses for suicidal behaviors in transgender youth will continue to be important given the increasing rate of death by suicide in this population.

Two studies also indicated greater rates of suicidal ideation and attempts in GMs compared to cisgender individuals among samples of college students [37, 38]. Horwitz and colleagues found that among college students screening positive for suicidal ideation and attempts, GMs (female-to-male transgender, male-to-female transgender, female-assigned

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genderqueer/nonbinary, male-assigned genderqueer/non-binary) showed increased rates of suicidal ideation (35.3–46.4%) and attempts (23.8–30.19%) compared to both male (10.4% and 3.7% respectively) and female (13.5% and 6.6% respectively) cisgender students [37]. Another study also found that among college students indicating a history of suicidal ideation and attempts, transgender students had higher rates on both suicide outcomes (68.4% and 38.2% respectively) relative to male (21.8% and 7.7% respectively) and female (25.1% and 9.8% respectively) cisgender students [38]. However, while transgender identity (OR = 2.32) and cisgender male identity (OR = 1.07) were linked to greater suicidal ideation, only transgender identity was linked to more suicide attempts (OR = 2.05). These findings are consistent with recent research among GM suicide decedents (35.8%) across all age groups; transgender decedents were more likely to have a history of suicide attempts compared to heterosexual cisgender decedents (19.9%) [39]. Additionally, risk factors for death by suicide independently associated with transgender status compared to heterosexual cisgender status included a depressed mood (OR = 1.87) and having a mental health problem (OR = 4.34).

As is evident in these studies, there is variation in how GM status is measured (e.g., transgender *and* non-binary/gender queer categories versus transgender category only) in research investigating suicidal behaviors among GMs relative to cisgender persons. Future research on differences in suicidal behaviors between GM and cisgender individuals would benefit from including multiple categories of identification (e.g., transgender, genderqueer, nonbinary) in order to encompass a broader range of GMs, as solely using a “transgender” category may not fully capture the experiences of GMs who do not identify as transgender [35]. This is especially important given that younger GM individuals are increasingly using alternative labels such as “genderqueer” to describe their gender identity [42].

Research on gender differences in suicidal behaviors among SMs has revealed mixed results [40, 41]. Using an inpatient sample, Decou and Lynch found that while female adolescents (OR = 2.44) were more likely than male adolescents to attempt suicide, there was no significant interaction between SM status and gender [40]. These findings are consistent with research prior to 2018 on gender differences in suicidal ideation and attempts in SM adolescents [43, 44]. Among a sample of adults ages 18–60, SM women had the highest rate of suicide attempts, followed by SM men, then heterosexual men and women [41]. Additionally, SM women were significantly more likely to report suicide attempts compared to SM men, but only from ages 30 to 42. These findings provide preliminary evidence that gender differences in suicidal behaviors among SMs may vary based on age, with SM youth showing no gender differences, and adults demonstrating greater risk for SM women compared to SM men. However, more research is needed in order to support this conclusion.

Conclusion

Since 2018, research on gender differences in suicidal behaviors using US samples has predominantly focused on specific developmental periods, the role of substance use, and special populations including Veterans and SGMs. The current research covering these different areas suggests trends that align with previous research on gender differences in suicidal behaviors, as well as new insights on this topic.

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Regarding youth suicide, current research has pointed to increasing trends in suicide among preadolescent and adolescent females, suggesting that suicide rates may be growing faster for female youths compared to male youths [6•, 7]. Future research should continue to monitor this trend as well as investigate potential explanations for climbing suicide rates in female youth. Consistent with previous research, current findings indicated depression as a greater risk factor for suicidal ideation and attempts in female youth relative to male youth [11, 12]. When considering death by suicide, one study identified school problems as a gender-specific risk factor for male youth [14]. A potential direction for future studies may be to investigate what aspects/types of school problems are contributing to death by suicide in male youth.

Only one study from 2018 to 2023 examined gender differences in suicide outcomes among the US adult general population [16]. This study found a greater rate of lifetime suicide attempts among women compared to men, which is consistent with previous research. However, between 2018 and 2023, multiple studies were published on this topic using non-US adult samples [e.g., 17, 18]. It may be important for future reviews on gender differences in suicidal behaviors to consider the inclusion of studies from different countries beyond the USA in order to provide an international perspective on gender differences in adult suicide.

While some findings were mixed, research on the links between both alcohol and cannabis use and suicidal behaviors suggests that women may be particularly at risk. Specifically, current research identified growing rates of alcohol-related suicide (for both moderate and heavy alcohol intoxication levels) among young, middle-aged, and older women, while increases were only observed for middle-aged men with moderate alcohol intoxication prior to suicide [19•]. Other studies identified binge drinking and cannabis use as risk factors for suicidal behaviors in women, but not men [20, 22, 23]. Given converging drinking rates between men and women in the past years, future research might hone in on alcohol-related suicidal behaviors among women in particular [25, 26].

Several recent studies examined gender-specific risk factors for suicidal behaviors among Veterans [30•, 31, 32]. Notably, the link between military period and suicide attempts was significant for male Veterans but not female Veterans, suggesting that experiences during military service may take a significant toll on male Veterans' mental health. Traumatic experiences (e.g., combat trauma, military sexual trauma) endured during military service may contribute to the development of PTSD, and in turn increased suicidal behaviors [44]. However, minimal research has addressed gender differences in the link between PTSD and suicidal behaviors among Veterans [45]. Future research might focus on elucidating these differences in order to further understand why military period is a risk factor for suicide attempts in male Veterans but not female Veterans.

Current research on gender differences in suicidal behaviors among SGMs has paid particular attention to differences between GMs and cisgender individuals. Results from these studies revealed upward trends in suicide rates for transgender individuals, but not cisgender SM males and females [36•], as well as greater rates of suicidal ideation and attempts in GMs compared to cisgender individuals [37, 38]. These concerning findings

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suggest the need for continued monitoring of temporal trends in GM suicide rates as well as the evaluation and continued development of GM-tailored suicide prevention and intervention efforts. Additionally, a limitation of previous and current research is the lack of inclusive measurement of GM identification. Future research would benefit from incorporating additional labels (e.g., genderqueer, non-binary) for measurement beyond "transgender" to be more inclusive of the GM population within suicide research.

Recent research on gender differences in suicidal behaviors is lacking in a couple areas. Firstly, to our knowledge, only one study within the last 5 years examined how suicide outcomes vary by gender in the general US adult population. Future research should attend to this population (and middle-aged and older adults in particular), especially given that gender differences in adult suicide rates vary over time and are impacted by global events (e.g., economic recession, pandemic). Additionally, there was no research using US samples that examined gender differences in suicidal behaviors among individuals using substances other than alcohol and cannabis. A recent study using NSDUH data found a substantial increase in suicidal ideation among individuals with opioid use disorders between 2009 and 2020 [46]. Future studies should address how suicidal behaviors in individuals struggling with opioid use (in addition to other substances (e.g., cocaine, methamphetamine, polysubstance)) vary based on gender. However, similar to recent suicide research with general adult populations, multiple studies using *non-US* samples have investigated gender differences in suicide outcomes among people struggling with the use of other substances beyond alcohol and cannabis [47–50].

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Table 1

Gender differences in suicidal behaviors across developmental periods

Authors	Setting; study design; data source	Suicide outcome	Suicide measure	Findings	Other potential risk/ moderating factors
Bommersbach et al. [16]	Epidemiological sample; cross-sectional; survey data (National Epidemiologic Survey on Alcohol and Related Conditions-III (NESARC-III))	Suicide attempts	Self-reported; indication of lifetime suicide attempt vs. no lifetime suicide attempt	Women were more likely than men to indicate a lifetime suicide attempt (OR = 1.78, 95% CI 1.61–1.96).	Any lifetime incarceration, any lifetime experience of a traumatic event, income less than $40,000, borderline personality disorder, schizophrenia/ psychosis, parental history of suicide attempt
Cromer et al. [11]	Epidemiological sample; longitudinal; survey data (Longitudinal Studies of Child Abuse and Neglect (LONGSCAN))	Suicidal ideation	Self-reported; past year thoughts about attempting suicide	Depression symptoms at age 16 were associated with a greater risk for suicidal ideation at age 18 in females ($b = 0.09$, $p < 0.05$, 95% CI 0.02–0.15), but not males. The indirect relationship between victimization and suicidal ideation through depression symptoms was significant for females (unstandardized indirect effect = 0.08, 95% CI 0.02–0.16), but not males	N/A
Kim et al. [12]	Epidemiological sample; cross-sectional; survey data (Youth Risk Behavior Surveillance System (YRBSS))	Suicide attempts	Self-reported; past-year number of suicide attempts	The indirect effects of school bullying and sexual dating violence victimization on suicide attempts via depression were significantly greater for female adolescent students ($\beta = 0.045$ and $\beta = 0.028$ respectively) compared to male adolescent students ($\beta = 0.029$ and $\beta = 0.009$ respectively)	N/A
Lawrence et al. [8]	Epidemiological sample; cross-sectional; survey data (Adolescent Brain Cognitive Development Study (ABCD Study))	Suicidal ideation and attempts	Self- and parent-reported; lifetime or current (past 2 weeks) suicidal ideation and attempts (questions from Kiddie Schedule for Affective Disorders and Schizophrenia-Present and Lifetime Version for DSM-5)	Female preadolescents, compared to male preadolescents, had a decreased odds of suicidal ideation (OR = 0.71, 95% CI 0.62–0.81); no gender differences were found for odds of suicide attempts	SM status, race, parental marriage status, family income, having any psychiatric condition, have two or more psychiatric conditions
Lee and Wong [14]	National sample; cross-sectional; mortality data (National Violent Death Reporting System; NVDRS)	Death by suicide	Medical examiner, coroner, and/or law enforcement recorded; ICD-10 cause-of-death codes or manner of death specified as suicide	Female youth suicide decedents (aged 10–18) had higher rates of current mental health problems (OR = 1.76, $p < 0.001$) and treatment (OR = 1.76, $p < 0.001$), leaving a suicide note (OR = 1.90, $p < 0.001$), history of suicidal ideation (OR = 1.78, $p < 0.001$) and attempts (OR = 3.30, $p < 0.001$), interpersonal (OR= 1.31, $p < 0.001$) and intimate partner (OR= 1.31, $p < 0.001$) problems that contributed to their suicide compared to male youth suicide decedents, whereas male youth decedents (female reference group) were more likely to have experienced school problems (OR = 0.64, $p < 0.001$) and criminal legal problems (0.48, $p < 0.001$) that contributed to their suicide	Race
Price and Khubchandani [6•]	National sample; cross-sectional; mortality data (Centers for Disease Control and Prevention's Web Based Injury Statistics Query and	Death by suicide	Medical examiner, coroner, and/or law enforcement recorded; ICD-10 cause-of-death codes or manner of death specified as suicide	Between 2010 and 2019, males made up 66.7% of child suicides and females made up 33.3%. The rate of child suicides for males during this time increased by 95.0% (r=0.99; $p < .0.05$) and for females increased by 300% (r– 0.92: $p < 0.05$)	N/A

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Authors	Setting; study design; data source	Suicide outcome	Suicide measure	Findings	Other potential risk/ moderating factors
	Reporting System; CDC's WISQARS)				
Spiller et al. [7]	National sample; cross-sectional; survey data (National Poison Data System (NPDS))	Suicide attempts or death by suicide	Healthcare professional reported; exposure to poison from the use of "…a substance for self-harm or for self-destructive or manipulative reasons"	Poisoning-related suicide outcomes increased significantly in females under 18 when comparing 2000–2010 and 2010–2018 percentage rates ($p < 0.05$), with an inflection point occurring in 2011. For males under 18, percentage rates remained largely stable from 2000 to 2018. For males and females ages 19–24, no significant changes were found	Age
Walsh et al. (2020) [9]	State sample; cross-sectional; survey data (Minnesota Student Survey (MSS))	Suicidal ideation and attempts	Self-reported; lifetime any thoughts about suicide and history of attempts (coded as past year if response option chosen was "yes, during the last year")	Female preadolescents (ages 11 and 12) had an increased odds of experiencing past-year suicidal ideation in 2007 (OR = 1.47, 95% CI 1.34–1.58) and 2010 (OR = 1.50, 95% CI 1.38–1.63). Gender did not significantly predict past-year suicide attempts in either year	Free or reduced lunch, low parental support, lifetime physical and sexual abuse, low teachers support, negative attitude towards attending school, low perceived safety at school, low peer social support, bullying victim, threatened at school, physically assaulted at school

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Table 2

Gender differences in suicidal behaviors with comorbid substance use

Author	Setting; study design; data source	Suicide outcome	Suicide measure	Findings	Other potential risk/ moderating factors
Han et al. (2021) [23]	Epidemiological sample; cross-sectional; survey data (NSDUH)	Suicidal ideation, plans, and attempts	Self-reported; past-year suicidal ideation, plans, and attempts	The prevalence of suicidal ideation, plans, and attempts was higher among women with cannabis use disorder (13.9% vs. 9.9% and 4.1% vs. 2.7% and 3.0% vs 1.5%, respectively)	Major depressive episode
Flores et al. [22]	Epidemiological sample; cross-sectional; survey data (NSDUH)	Suicidal ideation, plans, and attempts	Self-reported; past-year suicidal ideation, plans, and attempts	Relative to their no cannabis use counterparts, females with weekly-plus cannabis use had higher rates of any suicide plan (+ 15.0 percentage-points; 95% CI 8.9–21.2%; $p < 0.001$), while both male and females had higher rates of any suicidal ideation (+ 14.8 percentage-points; 95% CI 7.7–21.9%; $p < 0.001$ and + 12.8 percentage-points; 95% CI 7.4–18.1%; $p < 0.001$, respectively) and any suicide attempt (+ 13.3 percentage-points; 95% CI 5.0–21.8%; $p < 0.01$ and + 18.4 percentage-points; 95% CI 11.1−25.8%; $p < 0.001$, respectively)	N/A
Kelly et al. [21]	Epidemiological sample; cross-sectional; survey data (National Survey on Drug Use and Health (NSDUH))	Suicidal ideation, plans, and attempts	Self-reported; past-year suicidal ideation, plans, and attempts	Among study participants with depressive, men were more likely than women to report all types of suicidal behaviors (i.e., passive and active suicidal ideation, suicide plans, suicide attempts) comorbid with alcohol use disorder (ORs = 1.38–1.84)	N/A
Kittel et al. (2019) [20]	Epidemiological sample; cross-sectional; survey data (NSDUH)	Suicidal ideation, plans, and attempts	Self-reported; past-year suicidal ideation, plans, and attempts	Binge drinking was associated with suicide attempts in females (OR = 1.37, 95% CI 1.09–1.73) but not in males (OR = 1.07, 95% CI 0.80–1.43). Binge drinking was not associated with suicidal ideation in either males or females	N/A
Lange et al. [19•]	Nation sample; cross-sectional; mortality data (NVDRS)	Death by suicide	Medical examiner, coroner, and/or law enforcement recorded; ICD-10 cause-of-death codes or manner of death specified as suicide	From 2003 to 2018, the proportion of suicides that were alcohol-involved wherein the decedent had a BAC ≥ 0.08 g/day significantly increased on average annually for women of all age groups, including young women (average annual percentage change (AAPC) = 3.09%, 95% CI 1.70–4.49%), middle-aged women (AAPC = 2.03%, 95% CI 1.12–2.95%), and older women (AAPC = 10.48%, 95% CI 1.17–20.65%), while only middle-aged men experienced a significant average annual percentage increase (AAPC = 0.81%, 95% CI 0.003–1.62%)	N/A

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Table 3

Gender differences in suicidal behaviors among Veterans

Authors	Setting; study design; data source	Suicide outcome	Suicide measure	Findings	Other potential risk/ moderating factors
Hoffmire et al. [30•]	Epidemiological sample; cross-sectional; survey data (Comparative Health Assessment Interview Study (CHAI))	Suicidal ideation and attempts	Self-reported; adapted version of Columbia-Suicide Severity Rating Scale	Prevalence of lifetime suicidal ideation and attempt was significantly higher for female veterans (28.8%; 12.4%) compared to male veterans (24.0%; 5.6%). Prevalence of suicidal ideation for both men (6.5 to 18.7%) and women (13.3 to 19.9%) increased across military service (premilitary, during-military, postmilitary); whereas for suicide attempt, prevalence increased for men (1.3 to 3.4%) but remained stable for women (6.0 to 5.8%)	Childhood vs adulthood, military service period
Montgomery et al. [32]	Veteran Health Administration (VHA) medical center; cross-sectional; electronic medical record and administrative data	Suicidal ideation and attempts	Clinician-reported; indication of suicidal ideation and/or attempt identified via ICD codes and/or indication in Veteran Health Administration internal suicide event tracking system (Suicide Prevention Applications Network)	For female veterans with housing instability, suicidal ideation was associated with being younger than 40, having a mental health/ substance use disorder, and experiencing military sexual trauma (MST); suicide attempt was associated with being younger than 65, having a mental health/substance use disorder, experiencing MST, and having a service-connected disability. For male veterans with housing instability, both suicidal ideation and attempt were associated with being younger than 65, having a mental health/substance use disorder, experiencing MST, and having a service-connected disability	N/A
Stefanovics et al. [31]	Epidemiological sample; cross-sectional; survey data (The National Health and Resilience in Veterans Study (NHRVS))	Suicidal ideation	Self-reported; past-year thoughts about suicide (question 2 of Suicide Behaviors Questionnaire-Revised)	Male veterans were less likely to report past-year suicidal ideation compared to female veterans (OR = 0.6; 95% CI 0.4–0.8). For female veterans, significant risk factors for suicidal ideation were lower psychological resilience (44.4% variance explained), history of non-suicidal self-injury (24.4%) and alcohol use disorder (20.6%); whereas for male veterans, they were loneliness (19.5%), hostility (19.1%), and lack of purpose in life (16.3%)	Homelessness, incarceration, military sexual trauma, ACEs and trauma history, severity of somatic symptoms, mental health and drug use disorders, psychiatric distress, medical conditions, disability, poorer physical health, lack of social support, insecure attachment style
U.S Department of Veteran Affairs [28]	VHA sites; cross-sectional; electronic medical record and mortality data	Death by suicide	Healthcare professional or other recorded; Veteran Health Administration suicide indicators, site-documented suicides, on-campus suicides, VHA emergency department data, national death certificates	Between 2001 and 2020, the suicide rate for Veteran men was highest in 2018 (approximately 41.0 per 100,000), which then decreased through 2020 (approximately 39.0); whereas for Veteran women, the suicide rate was highest in 2017 (approximately 20.0), then similar to male Veterans, decreased through 2020 (approximately 14.0)	N/A

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Table 4

Gender differences in suicidal behaviors among sexual and gender minorities

Authors	Setting; study design; data source	Suicide outcome	Suicide measure	Findings	Other potential risk/ moderating factors
DeCou and Lynch [40]	Psychiatric hospital; cross-sectional; electronic medical record data	Suicide attempts	Clinician recorded; lifetime suicide attempt	Female adolescents (ages 11 to 17) were more than 2 times more likely than male adolescents (OR = 2.44, 95% CI 1.50–3.97) to attempt suicide, but there was no interaction between SM orientation and gender	Age, high rurality, history of sexual abuse, substance use
Fish et al. [41]	Epidemiological sample; cross-sectional; survey data (NESARC-III)	Suicide attempts	Self-reported; suicide attempt in the last 5 years vs. no suicide attempt or suicide attempt more than 5 years ago	SM women had the highest rate of suicide attempts, followed by SM men, then heterosexual men and women Between ages 30 and 41, SM women had a significantly greater risk of previous suicide attempts relative to SM men	Anti-SM discrimination
Horwitz et al. [37]	Community sample; cross-sectional; survey data	Suicidal ideation and attempts	Self-reported; past-year thoughts about suicide and lifetime suicide attempt	Gender minority (male-to-female and female-to-male transgender, non-binary/gender queer male- and female-assigned) college students had significantly higher rates of suicidal ideation (35.3–46.4% across all gender minority groups) and attempts (23.8–30.9%) relative to male cisgender (10.4% and 3.7% respectively) and female cisgender (13.5% and 6.6% respectively) college students	None
Liu et al. [38]	Epidemiological sample; cross-sectional; survey data (American Health Association-National College Health Assessment (NCHA))	Suicidal ideation and attempts	Self-reported; if/when (e.g., in the last 12 months, in the last 30 days) seriously considered suicide and attempted suicide	Transgender (OR = 2.32; 95% CI 1.62–3.32) and male college students (OR = 1.07; 95% CI 1.01–1.13) were more likely to indicate suicidal ideation; whereas transgender college students only (OR = 2.05; 95% CI 1.47–2.87) were more likely to indicate a suicide attempt	Race, sexual orientation, transfer student status, number of stressful events
Patten et al. [39]	National sample; cross-sectional; mortality data (NVDRS)	Death by suicide	Medical examiner, coroner, and/or law enforcement recorded; ICD-10 cause-of-death codes or manner of death specified as suicide	Transgender suicide decedents were more likely to have a history of suicide attempts relative to heterosexual cisgender suicide decedents (35.8% vs. 19.9%, $p < 0.001$)	Age, depressed mood, weapon type, mental health problem, current and history of mental illness treatment, history of child abuse, suicide intent disclosed to a family member
Ream [36•]	National sample; cross-sectional; mortality data (NVDRS)	Death by suicide	Medical examiner, coroner, and/or law enforcement recorded; ICD-10 cause-of-death codes or manner of death specified as suicide	Transgender adolescents and young adults (ages 11 to 29) showed a greater increase in death by suicide from prior to 2016 (2.0%) to after 2016 (6.5%; relative risk ratio = 3.66, $p < 0.001$) compared to cisgender adolescents and young adults	Age, race, urbanicity, veteran status

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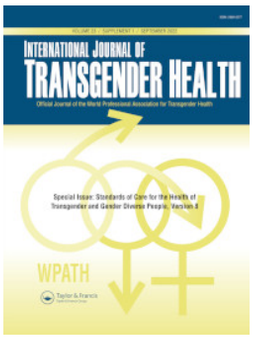

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REPORT

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Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

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ABSTRACT

Background: Transgender healthcare is a rapidly evolving interdisciplinary field. In the last decade, there has been an unprecedented increase in the number and visibility of transgender and gender diverse (TGD) people seeking support and gender-affirming medical treatment in parallel with a significant rise in the scientific literature in this area. The World Professional Association for Transgender Health (WPATH) is an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, public policy, and respect in transgender health. One of the main functions of WPATH is to promote the highest standards of health care for TGD people through the Standards of Care (SOC). The SOC was initially developed in 1979 and the last version (SOC-7) was published in 2012. In view of the increasing scientific evidence, WPATH commissioned a new version of the Standards of Care, the SOC-8.

Aim: The overall goal of SOC-8 is to provide health care professionals (HCPs) with clinical guidance to assist TGD people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment.

Methods: The SOC-8 is based on the best available science and expert professional consensus in transgender health. International professionals and stakeholders were selected to serve on the SOC-8 committee. Recommendation statements were developed based on data derived from independent systematic literature reviews, where available, background reviews and expert opinions. Grading of recommendations was based on the available evidence supporting interventions, a discussion of risks and harms, as well as the feasibility and acceptability within different contexts and country settings.

Results: A total of 18 chapters were developed as part of the SOC-8. They contain recommendations for health care professionals who provide care and treatment for TGD people. Each of the recommendations is followed by explanatory text with relevant references. General areas related to transgender health are covered in the chapters Terminology, Global Applicability, Population Estimates, and Education. The chapters developed for the diverse population of TGD people include Assessment of Adults, Adolescents, Children, Nonbinary, Eunuchs, and Intersex Individuals, and people living in Institutional Environments. Finally, the chapters related to gender-affirming treatment are Hormone Therapy, Surgery and Postoperative Care, Voice and Communication, Primary Care, Reproductive Health, Sexual Health, and Mental Health.

Conclusions: The SOC-8 guidelines are intended to be flexible to meet the diverse health care needs of TGD people globally. While adaptable, they offer standards for promoting optimal health care and guidance for the treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria set forth in this document for gender-affirming medical interventions are clinical guidelines; individual health care professionals and programs may modify these in consultation with the TGD person.

KEYWORDS

adolescents; assessment; children; communication; education; endocrinology; eunuch; gender diverse; health care professional; institutional settings; intersex; mental health; nonbinary; population; postoperative care; primary care; reproductive health; sexual health; SOC8; Standards of Care; surgery; terminology; transgender; voice

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INTRODUCTION

Purpose and use of the Standards of Care

The overall goal of the World Professional Association for Transgender Health's (WPATH) Standards of Care—Eighth Edition (SOC-8) is to provide clinical guidance to health care professionals to assist transgender and gender diverse (TGD) people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment. This assistance may include but is not limited to hormonal and surgical treatments, voice and communication therapy, primary care, hair removal, reproductive and sexual health, and mental health care. Healthcare systems should provide medically necessary gender-affirming health care for TGD people: See Chapter 2—Global Applicability, Statement 2.1.

WPATH is an international, multidisciplinary, professional association whose mission is to promote evidence-based care, education, research, public policy, and respect in transgender health. Founded in 1979, the organization currently has over 3,000 health care professionals, social scientists, and legal professionals, all of whom are engaged in clinical practice, research, education and advocacy that affects the lives of TGD people. WPATH envisions a world wherein people of all gender identities and gender expressions have access to evidence-based health care, social services, justice, and equality.

One of the main functions of WPATH is to promote the highest standards of health care for individuals through the Standards of Care (SOC) for the health of TGD people. The SOC-8 is based on the best available science and expert professional consensus. The SOC was initially developed in 1979, and the last version was published in 2012.

Most of the research and experience in this field comes from a North American and Western European perspective; thus, adaptations of the SOC-8 to other parts of the world are necessary. Suggestions for approaches to cultural relativity and cultural competence are included in this version of the SOC.

WPATH recognizes that health is not only dependent upon high-quality clinical care but also relies on social and political climates that ensure social tolerance, equality, and the full rights of citizenship. Health is promoted through public policies and legal reforms that advance tolerance and equity for gender diversity and that eliminate prejudice, discrimination, and stigma. WPATH is committed to advocacy for these policy and legal changes. Thus, health care professionals who provide care to TGD people are called upon to advocate for improved access to safe and licensed gender-affirming care while respecting the autonomy of individuals.

While this is primarily a document for health care professionals, individuals, their families, and social institutions may also use the SOC-8 to understand how it can assist with promoting optimal health for members of this diverse population.

The SOC-8 has 18 chapters containing recommendations for health care professionals working with TGD people. Each of the recommendations is followed by explanatory text with relevant references. The recommendations for the initiation of gender-affirming medical and/or surgical treatments (GAMSTs) for adults and adolescents are contained in their respective chapters (see Assessment for Adults and Adolescent chapters). A summary of the recommendations and criteria for GAMST can be found in Appendix D.

Populations included in the SOC-8

In this document, we use the phrase transgender and gender diverse (TGD) to be as broad and comprehensive as possible in describing members of the many varied communities that exist globally of people with gender identities or expressions that differ from the gender socially attributed to the sex assigned to them at birth. This includes people who have culturally specific and/or language-specific experiences, identities or expressions, which may or may not be based on or encompassed by Western conceptualizations of gender or the language used to describe it.

WPATH SOC-8 expands who is included under the TGD umbrella, and the settings in which these guidelines should be applied to promote equity and human rights.

Globally, TGD people encompass a diverse array of gender identities and expressions and have differing needs for gender-affirming care across their lifespan that is related to individual goals and characteristics, available health care resources, and sociocultural and political contexts. When standards of care are absent for certain groups this vacuum can result in a multiplicity of therapeutic approaches, including those that may be counterproductive or harmful. The SOC-8 includes recommendations to promote health and well-being for gender diverse groups that have often been neglected and/or marginalized, including nonbinary people, eunuch, and intersex individuals.

The SOC-8 continues to outline the appropriate care of TGD youth, which includes, when indicated, the use of puberty suppression and, when indicated, the use of gender-affirming hormones.

Worldwide, TGD people commonly experience transphobia, stigmatization, ignorance, and refusal of care when seeking health care services, which contributes to significant health disparities. TGD people often report having to teach their medical providers how to care for them due to the latter's insufficient knowledge and training. Intersectional forms of discrimination, social marginalization, and hate crimes against TGD people lead to minority stress. Minority stress is associated with mental health disparities exemplified by increased rates of depression, suicidality, and non-suicidal self-injuries than rates in cisgender populations. Professionals from every discipline should consider the marked vulnerability of many TGD people. WPATH urges health care authorities, policymakers, and medical societies to discourage and combat transphobia among health care professionals and ensure every effort is made to refer TGD people to professionals with experience and willingness to provide gender-affirming care.

Flexibility in the SOC

The SOC-8 guidelines are intended to be flexible to meet the diverse health care needs of TGD people globally. While adaptable, they offer standards for promoting optimal health care and for guiding treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria put forth in this document for gender-affirming interventions are clinical guidelines; individual health care professionals and programs may modify them in consultation with the TGD person. Clinical departures from the SOC may come about because of a patient's unique anatomic, social, or psychological situation; an experienced health care professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies. These departures should be recognized as such, explained to the patient, and documented for quality patient care and legal protection. This documentation is also valuable for the accumulation of new data, which can be retrospectively examined to allow for health care—and the SOC—to evolve.

The SOC-8 supports the role of informed decision-making and the value of harm reduction approaches. In addition, this version of the SOC recognizes and validates various expressions of gender that may not necessitate psychological, hormonal, or surgical treatments. Health care professionals can use the SOC to help patients consider the full range of health services open to them in accordance with their clinical needs for gender expression.

Diversity versus Diagnosis

The expression of gender characteristics, including identities, that are not stereotypically associated with one's sex assigned at birth is a common and a culturally diverse human phenomenon that should not be seen as inherently negative or pathological. Unfortunately, gender nonconformity and diversity in gender identity and expression is stigmatized in many societies around the world. Such stigma can lead to prejudice and discrimination, resulting in "minority stress." Minority stress is unique (additive to general stressors experienced by all people), socially based, and chronic, and may make TGD individuals more vulnerable to developing mental health concerns such as anxiety and depression. In addition to prejudice and discrimination in society at large, stigma can contribute to abuse and

neglect in one's interpersonal relationships, which in turn can lead to psychological distress. However, these symptoms are socially induced and are not inherent to being TGD.

While Gender Dysphoria (GD) is still considered a mental health condition in the Diagnostic and Statistical Manual of Mental Disorders, (DSM-5-TR) of the American Psychiatric Association. Gender incongruence is no longer seen as pathological or a mental disorder in the world health community. Gender Incongruence is recognized as a condition in the International Classification of Diseases and Related Health Problems, 11th Version of the World Health Organization (ICD-11). Because of historical and current stigma, TGD people can experience distress or dysphoria that may be addressed with various gender-affirming treatment options. While nomenclature is subject to change and new terminology and classifications may be adopted by various health organizations or administrative bodies, the medical necessity of treatment and care is clearly recognized for the many people who experience dissonance between their sex assigned at birth and their gender identity.

Not all societies, countries, or health care systems require a diagnosis for treatment. However, in some countries these diagnoses may facilitate access to medically necessary health care and can guide further research into effective treatments.

Health care services

The goal of gender-affirming care is to partner with TGD people to holistically address their social, mental, and medical health needs and well-being while respectfully affirming their gender identity. Gender-affirming care supports TGD people across the lifespan—from the very first signs of gender incongruence in childhood through adulthood and into older age—as well as people with concerns and uncertainty about their gender identity, either prior to or after transition.

Transgender health care is greater than the sum of its parts, involving holistic inter- and multidisciplinary care between endocrinology, surgery, voice and communication, primary care, reproductive health, sexual health and mental health disciplines to support gender-affirming interventions as well as preventive care and chronic disease management. Gender-affirming interventions include puberty suppression, hormone therapy, and gender-affirming surgeries among others. It should be emphasized there is no 'one-size-fits-all' approach and TGD people may need to undergo all, some, or none of these interventions to support their gender affirmation. These guidelines encourage the use of a patient-centered care model for initiation of gender- affirming interventions and update many previous requirements to reduce barriers to care.

Ideally, communication and coordination of care should occur between providers to optimize outcomes and the timing of gender-affirming interventions centered on the patient's needs and desires and to minimize harm. In well-resourced settings, multidisciplinary consultation and care coordination is often routine, but many regions worldwide lack facilities dedicated to transgender care. For these regions, if possible, it is strongly recommended that individual care providers create a network to facilitate transgender health care that is not available locally.

Worldwide, TGD people are sometime forced by family members or religious communities to undergo conversion therapy. WPATH strongly recommends against any use of reparative or conversion therapy (see statements 6.5 and 18.10).

Health care settings

The SOC-8 are guidelines rooted in the fundamental rights of TGD people that apply to all settings in which health care is provided regardless of an individual's social or medical circumstances. This includes a recommendation to apply the standards of care for TGD people who are incarcerated or living in other institutional settings.

Due to a lack of knowledgeable providers, untimely access, cost barriers and/or previous stigmatizing health care experiences, many TGD people take non-prescribed hormone therapy. This poses health risks associated with the use of unmonitored therapy in potentially supratherapeutic doses and the potential exposure to blood-borne illnesses if needles are shared for administration. However, for many individuals, it is the only means of acquiring medically necessary

gender-affirming treatment that is otherwise inaccessible. Non-prescribed hormone use should be approached with a harm-reduction lens to ensure individuals are connected with providers who can prescribe safe and monitored hormone therapy.

In some countries, the rights of TGD are increasingly being recognized, and gender clinics are being established that can serve as templates for care. In other countries, however, such facilities are lacking and care may be more fragmented and under-resourced. Nonetheless, different models of care are being pioneered, including efforts to decentralize gender-affirming care within primary care settings and establish telehealth services to reduce barriers and improve access. Regardless of the method of care delivery, the principles of gender-affirming care as outlined in the SOC-8 should be adapted to align with local sociocultural, political, and medical contexts.

Methodology

This version of the Standards of Care (SOC-8) is based upon a more rigorous and methodological evidence-based approach than previous versions. This evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion. Evidence-based guidelines include recommendations intended to optimize patient care that are informed by a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility.

While evidence-based research provides the basis for sound clinical practice guidelines and recommendations, it must be balanced by the realities and feasibility of providing care in diverse settings. The process for development of the SOC-8 incorporated the recommendations on clinical practice guideline development set forth by the National Academies of Medicine and the World Health Organization, which addressed transparency, conflict-of-interest policy, committee composition, and group process.

The SOC-8 guidelines committee was multidisciplinary and consisted of subject matter experts, health care professionals, researchers, and stakeholders with diverse perspectives and geographic representation. A guideline methodologist assisted with the planning and development of questions and systematic reviews with additional input provided by an international advisory committee and during the public comment period. All committee members completed conflict of interest declarations. Recommendations in the SOC-8 are based on available evidence supporting interventions, a discussion of risks and harms, as well as feasibility and acceptability within different contexts and country settings. Consensus on the final recommendations was attained using the Delphi process that included all members of the guidelines committee and required that recommendation statements were approved by at least 75% of members. A detailed overview of the SOC-8 Methodology is included in Appendix A.

SOC-8 Chapters Summary

The SOC-8 represents a significant advancement from previous versions. Changes in this version are based upon a fundamentally different methodology, significant cultural shifts, advances in clinical knowledge, and appreciation of the many health care issues that can arise for TGD people beyond hormone therapy and surgery.

These updated guidelines continue the process started with the SOC-7 in 2011 to broaden in scope and move from a narrow focus on psychological requirements for "diagnosing transgenderism" and medical treatments for alleviation of gender dysphoria to gender-affirming care for the whole person. WPATH SOC-8 expands guidelines specifying who is included under the TGD umbrella, what should and should not be offered with gender-affirming care, and the settings in which these guidelines should be applied to promote equity and human rights.

The SOC-8 has several new chapters such as the Assessment of Adults, Education, Eunuchs, and a Nonbinary chapter. In addition, the chapter for children and adolescents of the SOC-7 has been divided into two different chapters. Overall, the SOC-8 is considerably longer than previous versions and provides a more in-depth introduction and recommendations for health care professionals. A summary of every chapter of the SOC-8 can be found below:

Chapter 1—Terminology

This new chapter lays the framework for language used in the SOC-8 and offers consensually agreed upon recommendations for the use of terminology. The chapter provides (1) terms and definitions, and (2) best practices for utilizing them. This document is accompanied by a glossary (see Appendix B) of common terms and language to provide a framework for use and interpretation of the SOC-8.

Chapter 2—Global Applicability

This chapter references key literature related to development and delivery of health care services, broader advocacy care for TGD people from beyond Western Europe and North America and provides recommendations for adapting and translating the SOC-8 to varied contexts.

Chapter 3—Population Estimates

This chapter updates the population estimates of TGD people in society. Based on the current evidence, this proportion may range from a fraction of a percent to several percentage points depending on the inclusion criteria, age group, and geographic location.

Chapter 4—Education

This new chapter provides a general review of the literature related to education in TGD health care. It offers recommendations at governmental, nongovernmental, institutional and provider levels to increase access to competent, compassionate health care. The intent is to lay the groundwork in the education area and invite a much broader and deeper discussion among educators and health care professionals.

Chapter 5—Assessment of Adults

This new chapter provides guidance on the assessment of TGD adults who are requesting gender-affirming medical and surgical treatments (GAMSTs). It describes and updates the assessment process as part of a patient-centered approach and the criteria that health care professionals may follow in order to recommend GAMSTs to TGD adults.

Chapter 6—Adolescents

This new chapter is dedicated to TGD adolescents, is distinct from the child chapter, and has been created for this 8th edition of the Standards of Care given (1) the exponential growth in adolescent referral rates; (2) the increase in studies available specific to adolescent gender diversity-related care; and (3) the unique developmental and gender-affirming care issues of this age group. This chapter provides recommendations regarding the assessment process of adolescents requiring GAMSTs as well as recommendations when working with TGD youth and their families.

Chapter 7—Children

This new chapter pertains to prepubescent gender diverse children and focuses on developmentally appropriate psychosocial practices and therapeutic approaches.

Chapter 8—Nonbinary

This new chapter in the SOC-8 consists of a broad description of the term nonbinary and its usage from a biopsychosocial, cultural, and intersectional perspective. The need for access to gender-affirming care, specific gender-affirming medical interventions, as well as an appropriate level of support is discussed.

Chapter 9—Eunuchs

This new chapter describes the unique needs of eunuchs, and how the SOC can be applied to this population.

Chapter 10—Intersex

This chapter focuses on the clinical care of intersex individuals. It addresses the evolving terminology, prevalence, and diverse presentations of such individuals and provides recommendations for providing psychosocial and medical care with their evidence-based explanations.

Chapter 11—Institutional Environments

This chapter has been expanded to include both carceral and non-carceral settings and has been built upon the last 3 versions of the SOC. This chapter describes how the SOC-8 can be applied to individuals living in these settings.

Chapter 12—Hormone Therapy

This chapter describes the initiation of gender-affirming hormone therapy, the recommended regimens, screening for health concerns before and during hormone therapy, and specific considerations regarding hormone therapy prior to surgery. It includes an expanded discussion about the safety of gonadotropin releasing hormone (GnRH) agonists in youth, various hormone regimens, monitoring to include the development of potential therapy-related health concerns, and guidance on how hormone providers should collaborate with surgeons.

Chapter 13—Surgery and Postoperative Care

This chapter describes a spectrum of gender-affirming surgical procedures for the diverse and heterogeneous community of individuals who identify as TGD. It provides a discussion about the optimal surgical training in GAS procedures, post-surgical aftercare and follow-up, access to surgery by adults and adolescents, and individually customized surgeries.

Chapter 14—Voice and Communication

This chapter describes professional voice and communication support and interventions that are inclusive of and attentive to all aspects of diversity and no longer limited only to voice feminization and masculinization. Recommendations are now framed as affirming the roles and responsibilities of professionals involved in voice and communication support.

Chapter 15—Primary Care

This chapter discusses the importance of primary care for TGD individuals, including topics of cardiovascular and metabolic health, cancer screening, and primary care systems.

Chapter 16—Reproductive Health

This chapter provides recent data on fertility perspectives and parenthood goals in gender diverse youth and adults, advances in fertility preservation methods (including tissue cryopreservation), guidance regarding preconception and pregnancy care, prenatal counseling, and chest feeding. Contraceptive methods and considerations for TGD individuals are also reviewed.

Chapter 17—Sexual Health

This new chapter acknowledges the profound impact of sexual health on physical and psychological well-being for TGD people. The chapter advocates for sexual functioning, pleasure, and satisfaction to be included in TGD-related care.

Chapter 18—Mental Health

This chapter discusses principles of care for managing mental health conditions in TGD adults and the nexus of mental health care and transition care. Psychotherapy may be beneficial but should not be a requirement for gender-affirming treatment, and conversion treatment should not be offered.

CHAPTER 1 Terminology

This chapter will lay the framework for language used in the SOC-8. It offers recommendations for use of terminology. It provides (1) terms and definitions, and (2) best practices for utilizing them. This document is accompanied by a glossary of common terms and language to provide a framework for use and interpretation of the SOC-8. See Appendix B for glossary.

Terminology

In this document, we use the phrase transgender and gender diverse (TGD) to be as broad and comprehensive as possible in describing members of the many varied communities globally of people with gender identities or expressions that differ from the gender socially attributed to the sex assigned to them at birth. This includes people who have culturally specific and/or language-specific experiences, identities or expressions, and/or that are not based on or encompassed by Western conceptualizations of gender, or the language used to describe it. TGD is used for convenience as a shorthand for transgender and gender diverse.

The decision to use transgender and gender diverse resulted from an active process and was not without controversy. Discussions centered on avoiding over-emphasis on the term transgender, integrating nonbinary gender identities and experiences, recognizing global variations in understandings of gender, avoiding the term gender nonconforming, and recognizing the changing nature of language because what is current now may not be so in coming years. Thus, the term transgender and gender diverse was chosen with the intent to be most inclusive and to highlight the many diverse gender identities, expressions, experiences, and health care needs of TGD people. A Delphi process was used wherein SOC-8 chapter authors were anonymously and iteratively surveyed over several rounds to obtain consensus on terms. The SOC-8 presents standards of care that strive to be applicable to TGD people globally, no matter how a person self-identifies or expresses their gender.

Context

The language selected in this chapter may not be (nor ever could be) comprehensive of every culture and geographic region/locale. Differences and debates over appropriate terms and specific terminologies are common, and no single term can be used without controversy. The goal of this chapter is to be as inclusive as possible and offer a shared vocabulary that is respectful and reflective of varied experiences of TGD people while remaining accessible to health practitioners and providers, and the public, for the purposes of this document. Ultimately, access to transition-related health care should be based on providing adequate information and obtaining informed consent from the individual, and not on what words TGD people, or their service providers, use to describe their identities. Using language and terminology that is respectful and culturally responsive is a basic foundation in the provision of affirming care, as is reducing the stigma and harm experienced by many TGD people seeking health care. It is vital for service providers to discuss with service users what language is most comfortable for them and to use that language whenever possible.

This chapter explains why current terms are being used in preference to others. Rather than use specific terms for medical, legal, and advocacy groups, the aim is to foster a shared language and understanding in the field of TGD health, and the many related fields (e.g., epidemiology, law), in order to optimize the health of transgender and gender diverse people.

Sex, gender, gender identity, and gender expression are used in the English language as descriptors that can apply to all people—those who are TGD, and those who are not. There are complex reasons why very specific language may be the *most* respectful, *most* inclusive, or *most* accepted by global TGD communities, including the presence or absence of words to describe these concepts in languages other than English; the structural relationship between sex and gender; legal landscapes at the local, national, and international levels; and the consequences of historical and present-day stigma that TGD people face.

Statements of Recommendations

1.1- We recommend health care professionals use culturally relevant language (including terms to describe transgender and gender diverse people) when applying the Standards of Care in different global settings.
1.2- We recommend health care professionals use language in health care settings that uphold the principles of safety, dignity, and respect.
1.3- We recommend health care professionals discuss with transgender and gender diverse people what language or terminology they prefer.

Because at present, the field of TGD health is heavily dominated by the English language, there are two specific problems that constantly arise in setting the context for terminology. The first problem is that words exist in English that do not exist in other languages (e.g., "sex" and "gender" are only represented by one word in Urdu and many other languages). The second problem is that there are words that exist outside of English that do not have a direct translation into English (e.g., *travesti*, *fa'afafine*, *hijra*, *selrata*, *muxe*, *kathoey*, *transpinoy*, *waria*, *machi*). Practically, this means the heavy influence of English in this field impacts both what terms are widely used and which people or identities are most represented or validated by those terms. The words used also shape the narratives that contribute to beliefs and perceptions. While in past versions of the Standards of Care, World Professional Association for Transgender Health (WPATH) has used only transgender as a broadly defined umbrella term, version 8 broadens this language to use TGD as the umbrella term throughout the document (see Chapter 2—Global Applicability).

Furthermore, the ever-evolving nature of language is impacted by external factors and the social, structural, and personal pressures and violence enacted on TGD people and their bodies. Many of the terms and phrases used historically have been marred by how, when, and why they were used in discussing TGD people, and have thus fallen out of use or are hotly contested among TGD people, with some individuals preferring terms others find offensive. Some wish that these Standards of Care could provide a coherent set of universally accepted terms to describe TGD people, identities, and related health services. Such a list, however, does not and cannot exist without exclusion of some people and without reinforcing structural oppressions, with regards to race, national origin, Indigenous status, socioeconomic status, religion, language(s) spoken, and ethnicity, among other intersectionalities. It is very likely that at least some of the terminology used in SOC-8 will be outdated by the time version 9 is developed. Some people will be frustrated by this reality, but it is hoped it will be seen instead as an opportunity for individuals and communities to develop and refine their own lexicons and for people to develop a still more nuanced understanding of the lives and needs of TGD people, including TGD people's resilience and resistance to oppression.

Finally, law and the work of legal professionals are within the remit of these Standards of Care. As such, language used most widely in international law is included here to help with the development of the functional definitions of these terms and encourage their usage in legal contexts in lieu of more antiquated and/or offensive terms. The currently most thorough document in international human rights law uses the term "gender diverse."[1]

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 1.1

We recommend health care professionals use culturally relevant language (including terms to describe transgender and gender diverse people) when applying the Standards of Care in different global settings.

Culturally relevant language is used to describe TGD people in different global settings. For example, the concepts of sex, gender, and gender diversity differ across contexts, as does the language used to describe them. Thus, the language used when caring

for TGD people in Thailand is not going to be the same as that used for TGD care in Nigeria. When applying the Standards of Care globally, we recommend health care professionals (HCPs) utilize local language and terms to deliver care in their specific cultural and/or geographical locale.

Gender affirmation refers to the process of recognizing or affirming TGD people in their gender identity—whether socially, medically, legally, behaviorally, or some combination of these (Reisner, Poteat et al., 2016). Health care that is gender-affirming or trans-competent utilizes culturally specific language in caring for TGD people. Gender-affirming care is not synonymous with transition-related care. Provision of transition-related care, such as medical gender affirmation via hormones or surgery, does not alone ensure provision of gender-affirming care, nor does it indicate the quality or safety of the health care provided.

Consultation and partnerships with TGD communities can help to ensure relevancy and inclusivity of the language used in providing health care locally in a particular context and setting.

Statement 1.2

We recommend health care professionals use language in health care settings that upholds the principles of safety, dignity, and respect.

Safety, dignity, and respect are basic human rights (International Commission of Jurists, 2007). We recommend HCPs utilize language and terminology that uphold these human rights when providing care for TGD people. Many TGD people have experienced stigma, discrimination, and mistreatment in health care settings, resulting in suboptimal care and poor health outcomes (Reisner, Poteat et al., 2016; Safer et al., 2016; Winter, Settle et al., 2016). Such experiences include misgendering, being refused care or denied services when sick or injured and having to educate HCPs to be able to receive adequate care (James et al., 2016). Consequently, many TGD people feel unsafe accessing health care. They may avoid health care systems and seek other means of getting health-related needs met, such as taking hormones without a medical prescription or monitoring and relying on peers for medical advice. Furthermore, previous negative experiences in health care settings are associated with future avoidance of care among TGD people.

Many TGD people have been treated unjustly, with prejudice, and without dignity or respect by HCPs, and lack of trust is often a barrier to care. Using language grounded in the principles of safety, dignity, and respect in health care settings is paramount to ensure the health, well-being, and rights of TGD people globally. Language is a significant component of gender-affirming care, but language alone does not resolve or mitigate the systematic abuse and sometimes violence TGD people face globally in care settings. Language is but one important step toward patient/client-centered and equitable health care among TGD people. Other concrete actions HCPs can take include obtaining informed consent and refraining from making assumptions about a person's needs based on their gender or TGD status.

Statement 1.3

We recommend health care professionals discuss with transgender and gender diverse people what language or terminology they prefer.

In providing health care to TGD people, we recommend HCPs discuss with their patients what language or terminology they prefer be used when referring to them. This discussion includes asking TGD people how they would like to be addressed in terms of name and pronouns, how they self-identify their gender, and about the language that should be used to describe their body parts. Utilizing affirming language or terminology is a key component of TGD-affirming care (Lightfoot et al., 2021; Vermeir et al., 2018). Furthermore, these discussions and communications can serve to build rapport and reduce the mistrust many TGD people feel toward HCPs and experience within health care systems. Discussions and usage of language or terminology can also facilitate engagement and retention in care that is not specifically TGD-related, such as uptake of routine preventive screenings and any necessary medical follow-up of findings. In electronic health records, organ/anatomical inventories can be standardly used to inform appropriate clinical care, rather than relying solely on assigned sex at birth and/or gender identity designations.

HCPs and health care settings can implement standardized procedures to facilitate these conversations such as: using intake forms that include chosen pronouns and name, inviting

all staff (regardless of gender, i.e., cisgender, TGD) to use pronouns in introductions, having pronouns accompany names on a document for all patients, and not using gendered honorifics (e.g., Ms., Mr.). Policies for HCPs and health care settings can be put in place to ensure a TGD person's privacy and right to confidentiality, including when they disclose being a TGD person, and if/how to appropriately document. For example, a clinic policy may be to record this information as private and confidential between HCPs and patients/clients, and that it should only be disclosed on a "need to know" basis.

Note

1. A/73/152, Report of the Independent Expert on protection against violence and discrimination based on sexual orientation and gender identity

CHAPTER 2 Global Applicability

People who defy cultural boundaries of sex and gender have existed in cultures worldwide since ancient times, sometimes acknowledged in local language terms (Feinberg, 1996). In contrast to the more recent pathologization of gender diversity as an illness, some cultures traditionally celebrated and welcomed this diversity (e.g., Nanda, 2014; Peletz, 2009). Today, the English language umbrella term transgender and gender diverse (TGD) describes a huge variety of gender identities and expressions, and therefore a population with diverse health care experiences and needs. Together, TGD people represent important aspects of human diversity the World Professional Association for Transgender Health (WPATH) asserts should be valued and celebrated. TGD people continue to make vital contributions to the societies in which they live, although often these are unrecognized.

Disturbingly, many TGD people in the modern world experience stigma, prejudice, discrimination, harassment, abuse and violence, resulting in social, economic and legal marginalization, poor mental and physical health, and even death—a process that has been characterized as a stigma-sickness slope (Winter, Diamond et al., 2016). Experiences such as these (and the anticipation or fear of encountering such experiences) leads to what Meyer has described as minority stress (Meyer, 2003; see also Bockting et al., 2013 writing specifically about TGD people), and are associated with poor physical (e.g. Rich et al, 2020) and psychological (e.g., Bränström et al., 2022; Scandurra et al., 2017; Shipherd et al., 2019, Tan et al., 2021) health outcomes.

Violence against TGD people is a particular problem. Seen from a global perspective, it is widespread, diverse in nature (emotional, sexual and physical, e.g., see Mujugira et al., 2021), and involves a range of perpetrators (including State actors). Statistics on murder, the form of violence most extreme in its consequences, are alarming. Worldwide, there were over 4,000 documented killings between January 2008 and September 2021; a statistic widely regarded as flawed by under-reporting (TGEU, 2020).

Since the publication of the Standards of Care Version 7 (SOC-7), there have been dramatic changes in perspectives on TGD people and their health care. Mainstream global medicine no longer classifies TGD identities as a mental disorder. In the Diagnostic and Statistical Manual Version 5 (DSM-5) from the American Psychiatric Association (APA, 2013), the diagnosis of *Gender Dysphoria* focuses on any distress and discomfort that accompanies being TGD, rather than on the gender identity itself. A text revision (DSM-5-TR) was published in 2022. In the International Classification of Diseases, Version 11 (ICD-11), the diagnostic manual of the World Health Organization (WHO, 2019b), the *Gender Incongruence* diagnosis is placed in a chapter on sexual health and focuses on the person's experienced identity and any need for gender-affirming treatment that might stem from that identity. Such developments, involving a depathologization (or more precisely a de-psychopathologization) of transgender identities, are fundamentally important on a number of grounds. In the field of health care, they may have helped support a care model that emphasizes patients' active participation in decision-making about their own health care, supported by primary health care professionals (HCPs) (Baleige et al., 2021). It is reasonable to suppose these developments may also promote more socially inclusive policies such as legislative reform regarding gender recognition that facilitates a rights-based approach, without imposing requirements for diagnosis, hormone therapy and/or surgery. TGD people who have changed gender markers on key documents enjoy better mental health (e.g., Bauer et al., 2015; Scheim et al., 2020). A more rights-based approach in this area may contribute greatly to the overall health and well-being of TGD people (Arístegui et al., 2017).

Previous editions of the SOC have revealed much of the recorded clinical experience and knowledge in this area is derived from North American and Western European sources. They have focused on gender-affirming health care in high income countries that enjoy relatively well-resourced health care systems (including those with trained mental health providers, endocrinologists, surgeons and other specialists) and where services are often funded publicly or (at least for some patients) through private insurance.

For many countries, health care provision for TGD people is aspirational; with resourcing in this area limited or non-existent, and services often unavailable, inappropriate, difficult to access and/or unaffordable. Few if any HCPs (primary or specialist) may exist. Funding for gender-affirming health care may be absent, with patients often bearing the full costs of whatever health care they access. Health care providers often lack clinical and/or cultural competence in this area. Training for work with these patients may be limited (e.g., Martins et al., 2020). For all these reasons and because of mainstream "Western" medicine's historical view of TGD people as mentally disordered (a perspective that has only recently changed), TGD people have commonly found themselves disempowered as health care consumers.

Health care providers have found the relevant literature is largely North American and European, which present particular challenges for persons working in health care systems that are especially poorly resourced. Recent initiatives that often involve TGD stakeholders as partners are changing this situation somewhat by providing a body of knowledge about good practice in other regions, including how to provide effective, culturally-competent TGD health care in low- and middle-income countries outside the global north.

Within the field, a wide range of valuable health care resources have been developed in recent years. Dahlen et al (2021) review twelve international clinical practice guidelines; over half those reviewed originate from professional bodies based in North America (e.g., Hembree et al., 2017) or Europe (e.g., T'Sjoen et al., 2020). Three are from WHO (the most recent being WHO, 2016). Nowadays, there are numerous other resources, not on Dahlen et al.'s list, that explicitly draw on expertise from regions outside North America and Europe. Examples can be found in Asia and the Pacific (APTN, 2022; Health Policy Project et al., 2015), the Caribbean (PAHO, 2014), Thailand, Australia (Telfer et al., 2020), Aotearoa New Zealand (Oliphant et al., 2018), and South Africa (Tomson et al., 2021) (see also TRANSIT (UNDP et al., 2016)). These resources have commonly been created through the initiatives of or in partnership with TGD communities locally or internationally. This partnership approach, focused on meeting local needs in culturally safe and competent ways, can also have broad international relevance. Some of these publications may be of particular value to those planning, organizing and delivering services in low-income, low-resource countries. There are likely to be other resources published in languages other than English of which we are unaware.

Globally, TGD identities may be associated with differing conceptual frameworks of sex, gender, and sexuality and exist in widely diverse cultural (and sometimes spiritual) contexts and histories. Considering the complex relationships between social and cultural factors, the law, and the demand for and provisions of gender-affirming health care, the SOC-8 should be interpreted through a lens that is appropriate for and within the context of each HCP's individual practice while maintaining alignment to the core principles that underscore it (APTN and UNDP, 2012; Health Policy Project et al., 2015; PAHO, 2014).

It is within this context and by drawing broadly on the experiences of TGD people and health care providers internationally that we consider the global applicability of SOC-8 within this chapter. We set out key considerations for HCPs and conclude by recommending core principles and practices fundamental to contemporary health care for TGD people, regardless of where they live or whether there are resources available to those who seek to provide such health care.

Statement 2.1

We recommend health care systems should provide medically necessary gender-affirming health care for transgender and gender diverse people.

Medical necessity is a term common to health care coverage and insurance policies globally. A common definition of medical necessity as used by insurers or insurance companies is "Health care services that a physician and/or health care professional, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: (a) in accordance with generally accepted standards of medical practice; (b) clinically

Statements of Recommendations

2.1- We recommend health care systems should provide medically necessary gender-affirming health care for transgender and gender diverse people.
2.2- We recommend health care professionals and other users of the Standards of Care, Version 8 (SOC-8) apply the recommendations in ways that meet the needs of local transgender and gender diverse communities, by providing culturally sensitive care that recognizes the realities of the countries they are practicing in.
2.3- We recommend health care providers understand the impact of social attitudes, laws, economic circumstances, and health systems on the lived experiences of transgender and gender diverse people worldwide.
2.4- We recommend translations of the SOC focus on cross-cultural, conceptual, and literal equivalence to ensure alignment with the core principles that underpin the SOC-8.
2.5- We recommend health care professionals and policymakers always apply the SOC-8 core principles to their work with transgender and gender diverse people to ensure respect for human rights and access to appropriate and competent health care, including:

General principles
- Be empowering and inclusive. Work to reduce stigma and facilitate access to appropriate health care for all who seek it;
- Respect diversity. Respect all clients and all gender identities. Do not pathologize differences in gender identity or expression;
- Respect universal human rights including the right to bodily and mental integrity, autonomy and self-determination; freedom from discrimination, and the right to the highest attainable standard of health.

Principles around developing and implementing appropriate services and accessible health care
- Involve transgender and gender diverse people in the development and implementation of services;
- Become aware of social, cultural, economic, and legal factors that might impact the health (and health care needs) of transgender and gender diverse people, as well as the willingness and the capacity of the person to access services;
- Provide health care (or refer to knowledgeable colleagues) that affirms gender identities and expressions, including health care that reduces the distress associated with gender dysphoria (if this is present);
- Reject approaches that have the goal or effect of conversion and avoid providing any direct or indirect support for such approaches or services.

Principles around delivering competent services
- Become knowledgeable (get training, where possible) about the health care needs of transgender and gender diverse people, including the benefits and risks of gender-affirming care;
- Match the treatment approach to the specific needs of clients, particularly their goals for gender identity and expression;
- Focus on promoting health and well-being rather than solely the reduction of gender dysphoria, which may or may not be present;
- Commit to harm reduction approaches where appropriate;
- Enable the full and ongoing informed participation of transgender and gender diverse people in decisions about their health and well-being;
- Improve experiences of health services including those related to administrative systems and continuity of care.

Principles around working towards improved health through wider community approaches
- Put people in touch with communities and peer support networks;
- Support and advocate for clients within their families and communities (schools, workplaces, and other settings) where appropriate.

appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury, or disease; and (c) not primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease." The treating HCP asserts and documents that a proposed treatment is medically necessary for treatment of the condition (American Medical Association, 2016).

Generally, "accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, designated Medical Specialty Societies and/or legitimate Medical Colleges' recommendations, and the views of physicians and/or HCPs practicing in relevant clinical areas.

Medical necessity is central to payment, subsidy, and/or reimbursement for health care in parts of the world. The treating HCP may assert and document that a given treatment is medically necessary for the prevention or treatment of the condition. If health policies and practices challenge the medical necessity of a treatment, there may be an opportunity to appeal to a governmental agency or other entity for an independent medical review.

It should be recognized gender diversity is common to all human beings and is not pathological. However, gender incongruence that causes clinically significant distress and impairment often requires medically necessary clinical

interventions. In many countries, medically necessary gender-affirming care is documented by the treating health professional as treatment for Gender Incongruence (HA60 in ICD-11; WHO, 2019b) and/or as treatment for Gender Dysphoria (F64.0 in DSM-5-TR; APA, 2022).

There is strong evidence demonstrating the benefits in quality of life and well-being of gender-affirming treatments, including endocrine and surgical procedures, properly indicated and performed as outlined by the Standards of Care (Version 8), in TGD people in need of these treatments (e.g., Ainsworth & Spiegel, 2010; Aires et al., 2020; Aldridge et al., 2020; Almazan & Keuroghlian, 2021; Al-Tamimi et al., 2019; Balakrishnan et al., 2020; Baker et al., 2021; Buncamper et al., 2016; Cardoso da Silva et al., 2016; Eftekhar Ardebili, 2020; Javier et al., 2022; Lindqvist et al., 2017; Mullins et al., 2021; Nobili et al., 2018; Owen-Smith et al., 2018; Özkan et al., 2018; T'Sjoen et al., 2019; van de Grift, Elaut et al., 2018; White Hughto & Reisner, Poteat et al., 2016; Wierckx, van Caenegem et al., 2014; Yang, Zhao et al., 2016). Gender-affirming interventions may also include hair removal/transplant procedures, voice therapy/surgery, counseling, and other medical procedures required to effectively affirm an individual's gender identity and reduce gender incongruence and dysphoria. Additionally, legal name and sex or gender change on identity documents can also be beneficial and, in some jurisdictions, are contingent on medical documentation that patients may call on practitioners to produce.

Gender-affirming interventions are based on decades of clinical experience and research; therefore, they are not considered experimental, cosmetic, or for the mere convenience of a patient. They are safe and effective at reducing gender incongruence and gender dysphoria (e.g., Aires et al., 2020; Aldridge et al., 2020; Al-Tamimi et al., 2019; Balakrishnan et al., 2020; Baker et al., 2021; Bertrand et al., 2017; Buncamper et al., 2016; Claes et al., 2018; Eftekhar Ardebili, 2020; Esmonde et al., 2019; Javier et al., 2022; Lindqvist et al., 2017; Lo Russo et al., 2017; Marinkovic & Newfield, 2017; Mullins et al., 2021; Nobili et al., 2018; Olson-Kennedy, Rosenthal et al., 2018; Özkan et al., 2018; Poudrier et al., 2019; T'Sjoen et al., 2019; van de Grift, Elaut et al., 2018; White Hughto & Reisner, Poteat et al., 2016; Wierckx, van Caenegem et al., 2014; Wolter et al., 2015; Wolter et al., 2018).

Consequently, WPATH urges health care systems to provide these medically necessary treatments and eliminate any exclusions from their policy documents and medical guidelines that preclude coverage for any medically necessary procedures or treatments for the health and well-being of TGD individuals. In other words, governments should ensure health care services for TGD people are established, extended or enhanced (as appropriate) as elements in any Universal Health Care, public health, government-subsidized systems, or government-regulated private systems that may exist. Health care systems should ensure ongoing health care, both routine and specialized, is readily accessible and affordable to all citizens on an equitable basis.

Medically necessary gender-affirming interventions are discussed in SOC-8. These include but are not limited to hysterectomy +/- bilateral salpingo-oophorectomy; bilateral mastectomy, chest reconstruction or feminizing mammoplasty, nipple resizing or placement of breast prostheses; genital reconstruction, for example, phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty; hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process; gender-affirming facial surgery and body contouring; voice therapy and/or surgery; as well as puberty blocking medication and gender-affirming hormones; counseling or psychotherapeutic treatment as appropriate for the patient and based on a review of the patient's individual circumstances and needs.

Statement 2.2

We recommend health care professionals and other users of the Standards of Care, Version 8 (SOC-8) apply the recommendations in ways that meet the needs of local transgender and gender diverse communities, by providing culturally sensitive care that recognizes the realities of the countries they are practicing in.

TGD people identify in many different ways worldwide, and those identities exist within a cultural context. In English speaking countries, TGD people variously identify as *transsexual,*

trans, gender nonconforming, *gender queer or diverse, nonbinary,* or indeed *transgender and/or gender diverse,* as well as by other identities; including (for many identifying inside the gender binary) *male* or *female.* (e.g., James et al., 2016; Strauss et al., 2017; Veale et al., 2019).

Elsewhere, identities include but are not limited to *travesti* (across much of Latin America), *hijra* (across much of South Asia), *khwaja sira* (in Pakistan), *achout* (in Myanmar), *maknyah, paknyah* (in Malaysia), *waria* (Indonesia) *kathoey, phuying kham phet, sao praphet song* (Thailand), *bakla, transpinay, transpinoy* (Philippines), *fa'afafine* (Samoa), *mahu* (French Polynesia, Hawai'i), *leiti* (Tonga), *fakafifine* (Niue), *pinapinaaine* (Tuvalu and Kiribati), *vakasalewalewa* (Fiji), *palopa* (Papua Niugini), *brotherboys* and *sistergirls* (Aboriginal and Torres Strait Islander people in Australia), and *akava'ine* (Cook Islands) (e.g., APTN and UNDP, 2012; Health Policy Project et al., 2015; Kerry, 2014). There are also a large number of *two spirit* identities across North America (e.g., *nadleehi* in Navajo (Diné) culture) (Sheppard & Mayo, 2013). The identities to which each of these terms refer are often culturally complex and may exist in a spiritual or religious context. Depending on the cultures and the identities concerned, some may be regarded as so-called "third genders" lying beyond the gender binary (e.g., Graham, 2010; Nanda, 2014; Peletz, 2009). Some TGD identities are less firmly established than others. In many places worldwide, the visibility of transgender men and nonbinary trans masculine identities is relatively recent, with few or no applicable traditional terms in local languages (Health Policy Project et al., 2015). Regardless of where or with whom HCPs work (including those working with ethnic minority persons, migrants and refugees), they need to be aware of the cultural context in which people have grown up and live as well as the consequences for health care.

Worldwide the availability, accessibility, acceptability and quality of health care vary greatly, with resulting inequities within and across countries (OECD, 2019). In some countries, formal health care systems exist alongside established traditional and folk health care systems, with indigenous models of health underpinning the importance of holistic health care (WHO, 2019a). HCPs should be aware of the traditions and realities within which health care is available and provide support that is sensitive to the local needs and identities of TGD people and provide them with culturally competent and safe care.

Statement 2.3

We recommend health care providers understand the impact of social attitudes, laws, economic circumstances, and health systems on the lived experiences of transgender and gender diverse people worldwide.

TGD people's lived experiences vary greatly, depending on a range of factors, including social, cultural (including spiritual), legal, economic and geographic. When TGD people live in environments that affirm their gender and/or cultural identities, then these experiences can be very positive. Families are particularly important in this regard (e.g., Pariseau et al., 2019; Yadegarfard et al., 2014; Zhou et al., 2021). However, when viewed from a global perspective, the circumstances in which TGD people live are often challenging. They are commonly denied widely accepted rights in international human rights law. These include rights to education, health and protection from medical abuses, work and an adequate standard of living, housing, freedom of movement and expression, privacy, security, life, family, freedom from arbitrary deprivation of liberty, fair trial, treatment with humanity while in detention, and freedom from torture, inhuman or degrading treatment or punishment (International Commission of Jurists, 2007, 2017).

It is widely accepted that denial of rights can impact sexual and gender minority health and well-being (e.g., OHCHR et al., 2016; WHO, 2015). We therefore reaffirm here the importance of the rights listed above for TGD people and note WPATH's previous rights advocacy, including through numerous policy documents (e.g., WPATH, 2016, 2017, 2019). HCPs can play an important role in rights advocacy, including the right to quality gender-affirming health care that is appropriate, affordable, and accessible.

Across the world, a large number of studies detail the challenges TGD people face in their lives, and the impact on their health and well-being (e.g., Aurat Foundation, 2016;

Bhattacharya & Ghosh, 2020; Chumakov et al., 2021; Coleman et al., 2018; Heylens, Elaut et al., 2014; Human Rights Watch, 2014; James et al, 2016; Lee, Operario et al., 2020; Luz et al., 2022; McNeil et al., 2012, 2013; Motmans et al., 2017; Muller et al., 2019; Scandurra et al., 2017; Strauss et al., 2019; Suen et al., 2017; Valashany & Janghorbani, 2019; Veale et al., 2019; Wu et al., 2017). The research shows TGD people often experience stigma and prejudice as well as discrimination and harassment, abuse and violence, or they live in anticipation and fear of such actions. Social values and attitudes hostile to TGD people, often communicated to young people in school curricula (e.g., Olivier & Thurasukam, 2018), are also expressed in family rejection (e.g., Yadegarfard et al., 2014), and perpetuated in laws, policies and practices that limit freedom to express one's gender identity and sexuality and hinder access to housing, public spaces, education, employment and services (including health care). The end result is TGD people are commonly deprived of a wide range of opportunities available to their cisgender counterparts and are pushed to the margins of society, without family supports. To make matters worse, across much of the world TGD people's access to legal gender recognition is restricted or non-existent (e.g., ILGA World, 2020a; TGEU, 2021; UNDP and APTN, 2017). In some countries, such barriers nowadays draw on support from "gender-critical theorists" (as critiqued by e.g., Madrigal-Borloz, 2021; Zanghellini, 2020).

Gender identity change efforts (gender reparative or gender conversion programs aimed at making the person cisgender) are widespread, cause harm to TGD people (e.g., APTN, 2020a, 2020b, 2020c, 2021; Bishop, 2019; GIRES et al., 2020; Turban, Beckwith et al., 2020), and (like efforts targeting sexual orientation) are considered unethical (e.g., APS, 2021; Trispiotis and Purshouse, 2021; Various, 2019, 2021). These efforts may be viewed as a form of violence. The UN independent expert on protection against violence and discrimination based on sexual orientation and gender identity has called for a global ban on such practices (Madrigal-Borloz, 2020). An increasing number of jurisdictions are outlawing such work (ILGA World, 2020b).

Inequities arise from a range of factors, including economic considerations and values underpinning the provision of health care systems, particularly with regard to the emphasis placed on public-, private- and self-funding of health care. Lack of access to appropriate and affordable health care can lead to a greater reliance on informal knowledge systems. This includes information about self-administration of hormones, which, in many cases, is undertaken without necessary medical monitoring or supervision (e.g., Do et al., 2018; Liu et al., 2020; Rashid et al., 2022; Reisner et al., 2021; Winter & Doussantousse, 2009).

In some parts of the world, large numbers of transgender women employ silicone as a means of modifying their bodies, drawing on the services of silicone "pumpers" and/or attending pumping "parties", often within their communities. The immediate results of silicone pumping contrast with significant downstream health risks (e.g., Aguayo-Romero et al., 2015; Bertin et al., 2019; Regmi et al., 2021), particularly where industrial silicone or other injectable substances have been used and where surgical removal may be difficult.

Finally, sexual health outcomes for TGD people are poor. HIV prevalence for transgender women reporting to clinical organizations in metropolitan areas is approximately 19% worldwide, which is 49 times higher than the background prevalence rate in the general population (Baral et al., 2013). Sexual health outcomes for transgender men are also problematic (e.g., Mujugira et al., 2021).

Statement 2.4

We recommend translations of the SOC focus on cross-cultural, conceptual and literal equivalence to ensure alignment with the core principles that underpin the SOC-8.

Much of the research literature on TGD people is produced in high-income and English-speaking countries. global northern perspectives about TGD people (including those related to health care needs and provision) dominate this literature. A May 2021 Scopus database search undertaken by the current authors shows 99% of the literature on transgender health care comes out of Europe, North America, Australia, or New Zealand. Overall, 96% of the literature is in the English language. TGD people of the Global

South have received relatively little attention in the English language literature, and the work of those HCPs who interact with them has often gone unrecognized and unpublished or has not been translated into English. Applying resources produced in the global north risks overlooking the relevance and nuance of local knowledge, cultural frameworks and practices, and missed opportunities to learn from the work of others.

When translating the principles set out in the SOC, we recommend following best practice guidelines for language translation to ensure high quality written resources are produced that are culturally and linguistically appropriate to the local situation. It is important translators have knowledge about TGD identities and cultures to check that literal translations are culturally competent and safe for local TGD people. It is also important translation should follow established processes for quality assurance (Centers for Medicare & Medicaid Services, 2010; Sprager & Martinez, 2015)

Statement 2.5

We recommend health care professionals and policymakers always apply the SOC-8 core principles to their work with transgender and gender diverse people to ensure respect for human rights and access to appropriate and competent health care, including:

General principles

- Be empowering and inclusive. Work to reduce stigma and facilitate access to appropriate health care, for all who seek it;
- Respect diversity. Respect all clients and all gender identities. Do not pathologize differences in gender identity or expression;
- Respect universal human rights, including the right to bodily and mental integrity, autonomy, and self-determination; freedom from discrimination and the right to the highest attainable standard of health.

Principles around developing and implementing appropriate services and accessible health care

- Involve TGD people in the development and implementation of services;
- Become aware of social, cultural, economic, and legal factors that might impact the health (and health care needs) of transgender and gender diverse people, as well as the willingness and capacity of the person to access services;
- Provide health care (or refer to knowledgeable colleagues) that affirms gender identities and expressions, including health care that reduces the distress associated with gender dysphoria (if this is present);
- Reject approaches that have the goal or effect of conversion, and avoid providing any direct or indirect support for such approaches or services

Principles around delivering competent services

- Become knowledgeable (get training, where possible) about the health care needs of transgender and gender diverse people, including the benefits and risks of gender-affirming care;
- Match the treatment approach to the specific needs of clients, particularly their goals for gender identity and expression;
- Focus on promoting health and well-being rather than solely the reduction of gender dysphoria, which may or may not be present;
- Commit to harm reduction approaches where appropriate;
- Enable the full and ongoing informed participation of transgender and gender diverse people in decisions about their health and well-being;
- Improve experiences of health services, including those associated with administrative systems and continuity of care.

Principles around working towards improved health through wider community approaches

- Put people in touch with communities and peer support networks;
- Support and advocate for clients within their families and communities (schools, workplaces, and other settings) where appropriate.

We have already cited research detailing the broad range of challenges TGD people may face; social economic and legal obstacles, as well those related to health care access. While overall health care services are diverse across the world (in terms of availability, accessibility, and quality), those services available to TGD people are often inadequate. Numerous reports from diverse regions worldwide show, while TGD people may report positive health care experiences, many others do not (e.g., Callander et al., 2019; Costa, da Rosa Filho et al., 2018; Do et al., 2018; Gourab et al., 2019; Health Policy Project et al., 2015; Liu et al., 2020; Motmans et al., 2017; Muller et al., 2019; PAHO, 2014; Reisner et al., 2021; Strauss et al., 2017; TGEU, 2017). Mainstream health care options often do not meet their needs for general, sexual, or gender-affirming health care. Standard patient management procedures at clinics and hospitals often fail to recognize the gender identities of their TGD patients (including where outside of the binary their patients identify). Patients may be housed in wards that are gender inappropriate for them, putting them at risk of sexual harassment. TGD patients often encounter unsupportive or hostile attitudes from HCPs and ancillary staff and may even be refused service. Of great concern, HCPs in some parts of the world are involved in gender identity change efforts of the sort described earlier in this chapter.

Throughout the world, there are many other barriers to the provision of gender-affirming health care. Health care professionals may often be unwilling to provide the services TGD people seek. In some countries, there may be laws or regulations inhibiting or preventing them from doing so. When general practitioners and other health care providers do not have access to clear guidelines in their own language, they may be deterred from providing services. Even in situations where health care is available, patients may find it is difficult to access because of distance, gatekeeping practices, supply and demand issues that result in long wait lists or cost increases. Indeed, gender-affirming procedures may not be incorporated into a universal health care provision or be covered by private insurance, even though similar procedures may be covered for cisgender patients.

For all these reasons, many TGD people avoid formal health care services whenever they can. Their own communities commonly fill the void, acting as important resources for their members. They provide social and emotional support, often in an otherwise hostile environment. In addition, they often act as reservoirs of shared information about available options for health care, including parallel and informal health care options outside of (and more accessible and affordable than) mainstream medicine. As we saw earlier in this chapter, this often includes sharing of information about silicone and other injectable substances for bodily transformation and about hormones that are self-administered without necessary medical monitoring or supervision. WHO notes TGD individuals who self-administer gender-affirming hormones would benefit from access to evidence-based information, quality products, and sterile injection equipment (WHO, 2021). Access to such information can form part of a broader harm reduction approach (e.g., Idrus & Hyman, 2014).

Putting the important core principles outlined above into practice can improve health care experiences and promote respect for TGD people in all local contexts. This can occur regardless of the realities of a health care system (including the cultural, social, legal, economic context in which health care is provided), the level of provision available, or the TGD people seeking such services.

CHAPTER 3 Population Estimates

In the previous edition of its Standards of Care, Version 7, World Professional Association for Transgender Health (WPATH) identified only a small number of articles attempting to estimate the size of the transgender and gender diverse (TGD) population and characterized the state-of-the-science as "a starting point" requiring further systematic study (Coleman et al., 2012). Since then, the literature on this topic has expanded considerably as evidenced by a number of recent reviews that have sought to synthesize the available evidence (Arcelus et al., 2015; Collin et al., 2016; Goodman et al., 2019; Meier & Labuski, 2013; Zhang et al., 2020).

In reviewing epidemiologic data pertaining to the TGD population, it may be best to avoid the terms "incidence" and "prevalence." Avoiding these and similar terms may preclude inappropriate pathologizing of TGD people (Adams et al., 2017; Bouman et al., 2017). Moreover, the term "incidence" may not be applicable in this situation because it assumes TGD status has an easily identifiable time of onset, a prerequisite for calculating incidence estimates (Celentano & Szklo, 2019). For all the above reasons, we recommend using the terms "number" and "proportion" to signify the absolute and the relative size of the TGD population.

Perhaps the most important consideration in reviewing this literature is the variable definition applied to the TGD population (Collin et al., 2016; Meier & Labuski, 2013). In clinic-based studies, the data on TGD people are typically limited to individuals who received transgender-related diagnoses or counseling or those who requested or underwent gender-affirming therapy, whereas survey-based research typically relies on a broader, more inclusive definition based on self-reported gender identities.

Another methodological consideration in assessing the size and distribution of the TGD population is the need to understand what constitutes the sampling frame. As noted in recent reviews (Goodman et al., 2019; Zhang et al., 2020), many of the published studies, especially those conducted more than a decade ago, first assessed the number of patients seen at a particular clinical center and then divided that number by an approximated population size. This was unlikely to produce an accurate estimate because the numerator in the calculations is not necessarily included in the denominator, and the true size of the denominator often remains unknown.

With these considerations in mind, it is advisable to focus specifically on recent (published within the last decade) peer-reviewed studies that utilized sound methodology in identifying TGD people within a well-defined sampling frame. For all of the above reasons, the present chapter is focused on studies that met the following inclusion criteria 1) appeared in press in 2009 or later; 2) used a clear definition of TGD status; 3) calculated proportions of TGD people based on a well-defined population denominator; and 4) were peer-reviewed. These types of studies can provide more accurate contemporary estimates.

The available studies can be assigned into three groups 1) those that reported proportions of TGD people among individuals enrolled in large health care systems; 2) those that presented results from population surveys of predominantly adult participants; and 3) those that were based on surveys of youth conducted in schools. Of these three categories, the most informative and methodologically sound studies are summarized below. Additional details about these and other similar studies can be found in recent literature reviews (Goodman et al., 2019; Zhang et al., 2020).

Among studies that estimated the size of the TGD population enrolled in large health care systems, all were conducted in the US, and all relied on information obtained from electronic health records. Four of those health system-based studies relied exclusively on diagnostic codes to ascertain the TGD population; two studies (Blosnich et al., 2013; Kauth et al., 2014) used data from the Veterans Health Affairs system, which provides care to over 9 million people, and two studies (Dragon et al., 2017; Ewald et al., 2019) used claims data from Medicare, the federal health insurance program that primarily covers people 65 years of age or older. The proportions of TGD people reported in these diagnostic code-based studies ranged from approximately 0.02% to 0.03%. Another more recent publication also used Medicare data along with commercial insurance claims to identify TGD people and applied expanded inclusion criteria to supplement

diagnostic codes with information on procedures and hormone therapy (Jasuja et al., 2020). Using this methodology, the proportion of TGD people among all persons enrolled in the participating health plans was 0.03%. The sixth health systems-based study (Quinn et al., 2017) was conducted at Kaiser Permanente plans in the states of Georgia and California; these plans provide care to approximately 8 million members enrolled through employers, government programs, or individually. The TGD population in the Kaiser Permanente study was ascertained across all age groups using both diagnostic codes and free-text clinical notes. The proportions of TGD people identified at Kaiser Permanente were higher than the corresponding proportions reported in the Veterans Health Affairs and Medicare studies with the most recent estimates ranging from 0.04 to 0.08%.

In contrast to results from the health system-based studies, findings from surveys that relied on self-reported TGD status produced much higher estimates. Two US studies took advantage of the Behavioral Risk Factor Surveillance Study (BRFSS), which is an annual telephone survey conducted in all 50 states and US territories (Conron et al., 2012; Crissman et al., 2017). The first study used data from the 2007–2009 BRFSS cycles in the state of Massachusetts, and the second study used the 2014 BRFSS data from 19 states and the territory of Guam. Both studies reported that approximately 0.5% of adult participants (at least 18 years of age) responded *"Yes"* to the question *"Do you consider yourself to be transgender?"*

An internet-based survey administered to a sample of the Dutch population 15–70 years of age (Kuyper & Wijsen, 2014) asked participants to score the following two questions using a 5-point Likert scale: *"Could you indicate to which degree you psychologically experience yourself as a man?"* and *"Could you indicate to which degree you psychologically experience yourself as a woman?"* The respondents were considered "gender ambivalent" if they gave the same score to both statements and "gender incongruent" when they reported a lower score for their sex assigned at birth than for their gender identity. The proportions of participants reporting incongruent and ambivalent gender identity were 1.1% and 4.6%, respectively, for persons who were assigned male at birth (AMAB), and 0.8% and 3.2%, respectively, for persons assigned female at birth (AFAB).

A similarly designed study estimated the proportion of TGD residents in the Flanders region of Belgium using a sample drawn from the country's National Register (Van Caenegem, Wierckx et al., 2015). Participants were asked to score the following statements: *"I feel like a woman"* and *"I feel like a man"* on a 5-point Likert scale. Using the same definitions applied in the Dutch study (Kuyper & Wijsen, 2014), the proportion of gender incongruent individuals was 0.7% for AMAB people and 0.6% for AFAB people. The corresponding estimates for gender ambivalence among AMAB and AFAB people were 2.2% and 1.9%, respectively.

A more recent population-based study evaluated the proportion of TGD people among approximately 50,000 adult residents of Stockholm County, Sweden (Åhs et al., 2018). The numerator was determined by asking participants the following question: *"I would like hormones or surgery to be more like someone of a different sex."* Two additional items were designed to identify individuals experiencing gender incongruence: *"I feel like someone of a different sex"* and *"I would like to live as or be treated as someone of a different sex."* The need for either hormone therapy or gender-affirming surgery was reported by 0.5% of participants. Individuals who expressed feeling like someone of a different sex and those who wanted to live as or be treated as a person of another sex constituted 2.3% and 2.8% of the total sample, respectively.

Population-based data outside of North America and Western Europe are less common. One recent study offers valuable data from a large representative survey of 6,000 adults in Brazil (Spizzirri et al., 2021). Gender identity of participants was assessed based on the following three questions 1) *"Which of the following options best describes how you currently feel?"* (Options: I feel I am a man, I feel I am a woman, and I feel I am neither a man nor a woman); 2) *"What is the sex on your birth certificate?"* (Options: male, female, and undetermined); and 3) *"Which of*

these situations do you most closely relate to?" (Options: I was born male, but I have felt female since childhood; I was born female, but I have felt male since childhood; I was born male, and I feel comfortable with my body; I was born female, and I feel comfortable with my body). Based on the responses to these three questions, the authors determined 1.9% of the survey respondents were TGD (0.7% defined as transgender, and 1.2% defined as nonbinary).

The literature on the population proportions of TGD youth (persons under 19 years of age) includes several survey studies conducted in schools. A 2012 national cross-sectional survey in New Zealand collected information on TGD identity among high school students (Clark et al., 2014). Among over 8,000 survey participants, 1.2% self-identified as TGD and 2.5% reported they were not sure. Another study of schoolchildren was based on a 2016 survey of 9th and 11th grade students (ages 14–18 years) in the US state of Minnesota (Eisenberg et al., 2017). Of the nearly 81,000 survey respondents, 2.7% reported being TGD. A more recent study (Johns et al., 2019) presented results of the Youth Risk Behavior Survey (YRBS), which is conducted biennially among local, state, and nationally representative samples of US high school students in grades 9–12 (approximate age range 13–19 years). The 2017 YRBS cycle was carried out in 10 states and 9 large urban areas and included the following sequence: "*Some people describe themselves as transgender when their sex at birth does not match the way they think or feel about their gender. Are you transgender*?" Among nearly 120,000 participants across the 19 sites, 1.8% responded "*Yes, I am transgender,*" and 1.6% responded "*I am not sure if I am transgender.*"

Another recently published school-based study in the US presented results of a 2015 survey conducted in Florida and California with the aim of identifying gender diverse children and adolescents in a sample of just over 6,000 students in grades 9–12 (Lowry et al., 2018). "High gender-nonconforming" was used to define AMAB children who reported being very/mostly/somewhat feminine or AFAB children who reported being very/mostly/somewhat masculine. Based on these definitions, the proportions of TGD participants were reported to be 13% among AMAB students, 4% among AFAB students, and 8.4% overall.

Only one study examined the proportion of self-identified TGD children in a younger age group. Shields et al. analyzed the data from a 2011 survey of 2,700 students in grades 6–8 (age range 11–13 years) across 22 San Francisco public middle schools (Shields et al., 2013). Thirty-three children self-identified as TGD based on the question *"What is your gender?"* where the possible responses were *"female, male, or transgender."* The resulting proportion of transgender survey respondents was 1.3%. However, this definition would exclude TGD persons self-identifying as nonbinary and those who do not explicitly identify as transgender.

Taken together, these data indicate among health system-based studies that relied on diagnostic codes or other evidence documented in the medical records (Blosnich et al., 2013; Dragon et al., 2017; Ewald et al., 2019; Kauth et al., 2014; Quinn et al., 2017), the proportions of TGD people reported in recent years (2011–2016) ranged from 0.02% to 0.08%. By contrast, when the TGD status was ascertained based on self-report, the corresponding proportions were orders of magnitude higher and reasonably consistent, if the studies used similar definitions. When the surveys specifically inquired about "transgender" identity, the estimates ranged from 0.3% to 0.5% among adults and from 1.2% to 2.7% in children and adolescents. When the definition was expanded to include broader manifestations of gender diversity, such as gender incongruence or gender ambivalence, the corresponding proportions were higher: 0.5% to 4.5% among adults and 2.5% to 8.4% among children and adolescents.

As reviewed elsewhere (Goodman et al., 2019), another noteworthy observation is the continuous increase in both the size and the composition of the TGD population with upward trends in the proportion of TGD people observed in health care systems, through population-based surveys, as well as in the data on legal gender recognition. The higher estimates observed in more recent literature support some of the previous publications indicating the size of TGD population was

Summary of reported proportions of TGD people in the general population

Health systems-based studies: 0.02–0.1%
Survey-based studies of adults: 0.3–0.5% (transgender), 0.3–4.5% (all TGD)
Survey-based studies of children and adolescents: 1.2–2.7% (transgender), 2.5–8.4% (all TGD)

likely underestimated in earlier studies (Olyslager & Conway, 2008).

The temporal trends in AMAB to AFAB ratio have also been reported in studies analyzing referrals to clinics as well as data from integrated health systems; this ratio has changed from predominantly AMAB in previous decades to predominantly AFAB in recent years, especially among TGD youth (Aitken et al., 2015; de Graaf, Carmichael et al., 2018; de Graaf, Giovanardi et al. 2018; Steensma et al., 2018; Zhang et al., 2021). The trend towards a greater proportion of TGD people in younger age groups and the age-related differences in the AMAB to AFAB ratio likely represent the "cohort effect," which reflects sociopolitical advances, changes in referral patterns, increased access to health care and to medical information, less pronounced cultural stigma, and other changes that have a differential impact across generations (Ashley 2019d; Pang et al., 2020; Zhang et al., 2020).

Despite recent improvements in the quality of published studies, an important limitation of the existing literature is the relative paucity of peer-reviewed publications from regions outside of Western Europe or North America. Some of the relevant information on global estimates can be obtained from reports supported by the governments or non-governmental organizations (Fisher et al., 2019; Kasianczuk & Trofymenko, 2020), but these reports may be difficult to systematically identify and evaluate until they appear in peer-reviewed literature. Other barriers to evaluating the global distribution of the TGD populations include inadequate access to demographic data and over-representation of English-language journals in the world literature.

These limitations notwithstanding, the available highest-quality data clearly indicate TGD people represent a sizable and growing proportion of the general population. Based on the credible evidence available to date, this proportion may range from a fraction of a percent to several percentage points depending on the inclusion criteria, age group, and geographic location. Accurate estimates of the proportion, distribution, and composition of the TGD population as well as a projection of resources required to adequately support the health needs of TGD people should rely on systematically collected high-quality data, which are now increasingly available. Continuous and routine collection of these data is needed to decrease variability and minimize over- and under-estimation of the reported results. For example, far more accurate and precise estimates should become available when population censuses begin systematically collecting and reporting data on sex assigned at birth and gender identity, including asexual and nonbinary categories, using the now well-validated two-step method. The first such census-based estimate was released by the national statistical office of Canada. Based on the 2021 census data, 100,815 of 30.5 million Canadians self-identified as transgender or nonbinary; this accounted for 0.33% of the population 15 years of age or older (Statistics Canada, 2022). Consistent with the published literature, the proportions of transgender and nonbinary people were much higher for Generation Z (born between 1997 and 2006, 0.79%) and millennials (born between 1981 and 1996, 0.51%) than for Generation X (born between 1966 and 1980, 0.19%), baby boomers (born between 1946 and 1965, 0.15%), and the Interwar and Greatest Generations (born in 1945 or earlier, 0.12%). While these results represent the highest quality data available to date, it is not clear how the population proportions reported in Canada may compare with those in other countries. The variability in the definitions of what constitutes the TGD population and the differences in data collection methods can be reduced further by improving international collaborations.

CHAPTER 4 Education

This chapter will provide a general review of the literature related to education in transgender and gender diverse (TGD) health care. Recommendations are offered at governmental, nongovernmental, institutional, and provider levels with the goal of increasing access to competent, compassionate health care. In turn, this increased access should improve health outcomes in TGD populations. As this is a novel chapter in the World Professional Association for Transgender Health (WPATH) Standards of Care, the intent is to lay the groundwork for the education area and invite a broader and deeper discussion among educators and health professionals.

Health professionals involved in transgender care encompass a broad range of disciplines. Health professional education varies considerably by country or region in terms of structure, licensure, and policy. Published literature on education in TGD health care is predominantly from North America, Europe, Australia and New Zealand. This chapter does not provide a review of the education literature for each discipline, the needs specific to each discipline (which can be found in the relevant chapters), or the needs specific to each country/region's health education system. Greater understanding and research are needed on the intersection of health education systems, licensure, and transgender health across the world.

On a global level, TGD health education is imperative if national and international health disparities are to be addressed. Cultural competency related to TGD communities continues to be lacking. The World Bank Group (2018) reports widespread discrimination, harassment, violence, and abuse affecting TGD people. They also report TGD people face the highest rates of violence and discrimination (World Bank Group, 2018). Although many higher income countries have national antidiscrimination laws with gender identity as a protected characteristic, discrimination in the workplace, in education, and in health care remains problematic (World Bank Group, 2018).

Across disciplines, curricula at all levels—undergraduate, graduate, residency, or continuing education—historically have ignored TGD cultural or clinical education. The Joint Commission (US) has recommended health care organizations "provide educational programs and forums that support the unique needs of the LGBT community" and "offer educational opportunities that address LGBT health issues" (The Joint Commission, 2011). However, this is not enforced.

On an individual level, several questions need answers. What type of education interventions can most effectively address transphobia and lead to long-standing changes in attitudes? What interventions translate into increasing the number of care providers in this area as well as the number of TGD people receiving care? Does clinical exposure increase the confidence of providers over time? What educational interventions lead to improved health outcomes in the TGD population and, if so, when and how did these interventions accomplish this? Although health professions have begun to incorporate TGD health into education using a variety of modalities and at varying levels of training, efforts differ by health profession and are neither systemic nor systematic in nature (e.g., Brennan et al., 2012; Chinn, 2013; Eliason et al., 2010; Lim et al., 2015; Obedin-Maliver et al., 2011; Rondahl, 2009).

Attaining cultural humility with the full appreciation of the intersectionality of humanity is an ultimate educational goal. That said, this initial call for education is focused on building the foundation in cultural awareness and cultural competency that is currently weak or non-existent in much of the world.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statements of Recommendations

4.1- We recommend all personnel working in governmental, nongovernmental, and private agencies receive cultural-awareness training focused on treating transgender and gender diverse individuals with dignity and respect.
4.2- We recommend all members of the health care workforce receive cultural-awareness training focused on treating transgender and gender diverse individuals with dignity during orientation and as part of annual or continuing education.
4.3- We recommend institutions involved in the training of health professionals develop competencies and learning objectives for transgender and gender diverse health within each of the competency areas for their specialty.

Recommendation 4.1

We recommend all personnel working in governmental, nongovernmental, and private agencies receive cultural-knowledge training focused on treating transgender and gender diverse individuals with dignity and respect.

Article 1 of the United Nations Universal Declaration of Human Rights states, "All human beings are born free and equal in dignity and rights" (United Nations, 1948). Only recently has this fundamental statement included the recognition that TGD rights are human rights (UNOCHR, 2018). Globally, training at all levels about TGD communities continues to be lacking. As recently as 2002, only 3% of Fortune 500 companies had antidiscrimination protection for TGD employees, and none offered insurance coverage for gender-affirming health care (Human Rights Campaign Foundation, 2017). By 2022, 91% of Fortune 500 companies included gender identity in US non-discrimination policies, and 66% offered TGD-inclusive insurance coverage. However, only 72% provide any form of lesbian, gay, bisexual, transgender and queer/questioning (LGBTQ) cultural knowledge training for their workforce (Human Rights Campaign Foundation, 2022). This lack of understanding fosters discrimination across the board. Taken together, these inconsistencies negatively affect the health of individuals and communities and exacerbate the health disparities and inequities they face. In Britain, only 28% of TGD workers felt the senior leadership were committed to TGD equality; only 21% of TGD employees would consider reporting transphobic harassment in the workplace (Stonewall, 2018). For those who are openly TGD, 34% were excluded by their co-workers, 35% were abused by customers, 24% were denied promotion due to their gender identity, and 11% were fired (Stonewall, 2018). In southeastern Europe, the World Bank stated there is widespread discrimination, harassment, violence, and abuse, and TGD people in that region faced the highest rates of violence and discrimination (World Bank Group, 2018). Often the discrimination went unreported with 60% of individuals not filing a report because of a lack of faith the complaint would be addressed, a fear of further discrimination or ridicule, and a reluctance to be outed (World Bank Group, 2018). Although many countries in the region have national antidiscrimination laws with gender identity as a protected characteristic, discrimination in the workplace, in education, and in health care remains problematic (World Bank Group, 2018). It is the responsibility of the governmental, nongovernmental, and private agencies in these countries with anti-discrimination laws to ensure the rights of the TGD population. They are, therefore, obligated to find ways in which discrimination and stigma can be decreased. One of these is through education. Local cultures that foster anti-TGD attitudes are often a barrier to this needed education. Although cultural competency trainings have led to equivocal results, Shepherd (2019) recommends that providing cultural knowledge training that prioritizes local cultural issues and focuses on the values of openness, non-judgment, and responsiveness may lead to the desired results. Implementing cultural knowledge training requires a leadership willing to prioritize the training and to dedicate the time, money, and human capital to delivering initial and ongoing training.

Recommendation 4.2

We recommend all members of the health care workforce receive cultural-knowledge training focused on treating transgender and gender diverse individuals with dignity during orientation and as part of annual or continuing education.

Across disciplines, curricula at all levels—undergraduate, graduate, residency, or continuing

education—historically have ignored TGD cultural or clinical education. Factors contributing to this lack of inclusion include lack of faculty knowledge, experience, comfort with the subject matter, faculty bias, limited space within the existing curriculum, and lack of guidance on how to integrate the topics (McDowell & Bower, 2016). Research into the lack of and the need for such education does not specifically address TGD health concerns. Rather, the existing literature subsumes TGD health education within the broader discussion of the lack of LGBTQ-focused cultural and clinical-competency training. As an example, nursing baccalaureate programs included only an average of 2.12 hours of instruction on LGBTQ health (Lim et al., 2015). A fair assumption is that the amount of time devoted to TGD-specific health issues constituted only a fraction of this time.

Within the broader context of LGBTQ competency, the lack of TGD cultural- and clinical-competency training is a long-known shortfall of health care education (Aldridge et al., 2021). In the US, the Department of Health and Human Services' *Healthy People 2020,* (United States Department of Health and Human Services (2013, April 10)), the National Academy of Medicine (The Institute of Medicine, 2011), and the Joint Commission (The Joint Commission, 2011) all recognized lack of education negatively impacts the ability of LGBTQ people, including TGD individuals, to obtain appropriate, medically necessary care. The UK's House of Commons Women and Equalities Committee found lack of education contributed to TGD health disparities in the National Health Service (House of Commons Women and Equalities Committee, 2015, December 8). The lack of TGD health care education has been identified in the US (Obedin-Maliver et al., 2011), UK (Tollemache et al., 2021), South Africa (de Vries et al., 2020; Taylor et al., 2018; Wilson et al., 2014), Canada (Bauer et al., 2014), Australia (Riggs & Bartholomaeus, 2016), Sweden, Spain, Serbia, Poland (Burgwal et al., 2021), and Pakistan (Martins et al., 2020) among other countries.

In addition to developing curriculum, Shepherd (2022) states both clinical and organizational components are necessary to improve clinical encounters and consumer satisfaction. On an organizational level, it must be feasible as well as locally and practically oriented (Shepherd, 2022). On an individual level, in addition to knowledge training, health care professionals are better served employing generic traits that focus on the values of openness, non-judgment, and responsiveness (Shepherd, 2018).

Recommendation 4.3.

We recommend institutions involved in the training of health professionals develop competencies and learning objectives for transgender and gender diverse health within each of the competency areas for their specialty.

Each health profession has its own educational institutions, administrative, and licensing bodies, which vary by country and specialization within the profession. No major health professional organizations, educational institutions, or licensing bodies appear to require training in TGD health. While these organizations increasingly recommend including LGBTQ intersex health, rarely do they specify competencies, skills, or learning objectives for working with TGD people within their specialty. Published material on health professional education in TGD health is focused primarily on nursing, medicine, and mental health and is predominantly from North America, Europe, Australia, and New Zealand. An increased understanding of transgender health and medical/health professional education systems and requirements globally is essential.

Despite the increasing visibility of TGD people, access to knowledgeable and culturally- competent health professionals remain an overwhelming need around the world (James et al., 2016; Lerner et al., 2020; Müller, 2017). Lack of knowledgeable providers is a major barrier to gender-affirming care for transgender persons (Puckett et al., 2018; Safer et al., 2016) and contributes to large health disparities (Giffort & Underman, 2016; Reisman et al., 2019). The lack of adequate professional education in TGD health is a global problem (Do & Nguyen, 2020; Martins et al., 2020; Parameshwaran et al., 2017) that occurs at all levels of training (Dubin et al., 2018) and traverses health disciplines (Glick et al., 2020; Gunjawate et al., 2020; Johnson & Federman,

2014) and medical specialties (Fung et al., 2020; Korpaisarn and Safer, 2018).

Challenges remain as studies to date have small sample sizes, involve one-time training, include multiple disciplines at multiple career levels, focus on short-term outcomes, and often cover all LGBTQI topics rather than TGD-specific ones that are usually acquired post-licensure and are not the focus of most currently studied educational interventions (Dubin et al., 2018).

To successfully implement the recommendations, institutions may need to consider developing 1) systemic and systematic approaches to developing and implementing competencies for each health discipline across the professional lifespan; 2) standardized assessments for learners, with input from the TGD community; and 3) allotment of curricular resources, including trained faculty, as well as time in accordance with clear, consensual learning objectives (Dubin et al., 2018; Pratt-Chapman, 2020). In addition, evaluations of these interventions should not only focus on outcomes but also strive to understand how, when, and why these outcomes are occurring (Allen et al., 2021).

CHAPTER 5 Assessment of Adults

This chapter provides guidance for the assessment of transgender and gender diverse (TGD) adults who are requesting medically necessary gender-affirming medical and/or surgical treatments (GAMSTs) to better align their body with their gender identity (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1).

TGD adults are people at or above the age of majority in their country, who have some form of gender diversity. The developmental elements of the adolescent chapter, including the importance of parental/caregiver involvement, may be relevant for the care of young adults too, even if they are above the age of majority.

This chapter includes all forms of gender identities and transitions including, but not limited to, male, female, gender diverse, nonbinary, agender, and eunuch. The population of TGD adults is heterogeneous and will vary according to their clinical need, biological, psychological, and social situations, as well as their access to health care. As such, any assessment for GAMSTs will need to be adapted to the scientific, clinical, and community knowledge base of the presenting gender identity as well as local circumstances. This chapter recognizes individuals may experience different local levels of clinical or regulatory oversight when the state or others are providing health care.

An individual's gender identity is an internal identification and experience. The role of the assessor is to assess for the presence of gender incongruence and identify any co-existing mental health concerns, to offer information about GAMSTs, to support the TGD person in considering the effects/risks of GAMSTs, and to assess if the TGD person has the capacity to understand the treatment being offered and if the treatment is likely to be of benefit. The assessor can also assist a TGD person to consider choices that could improve their GAMST outcomes. The GAMST assessment approach described in this chapter recognizes the lived experience and self-knowledge of the TGD person and the clinical knowledge of the assessing health care professional (HCP). Consequently, with this approach, the decision to move forward with GAMSTs is shared between the TGD person and the assessing HCP, with both playing a key part in collaborative decision-making.

Some systems use a model of care for TGD adults seeking GAMSTs that prioritizes the TGD adult as the decision maker with the HCP acting as an advisor, barring serious contraindications. These models are used when considering hormone therapy rather than surgery and are often called "informed consent" models (Deutsch, 2011, 2016a). Many such models utilize an abbreviated assessment that focuses primarily on the ability of a TGD person to grant informed consent and to utilize information about GAMSTs to inform their medical decision-making. There is significant variability in such models across jurisdictions, systems, and HCPs (Deutsch, 2011; Morenz et al., 2020). Informed consent models have been used for some time for hormone prescription in many local settings.

This chapter is intended to offer flexible global guidance that must be adapted to local circumstances. HCPs will need to determine which assessment approaches best meet the needs in their local settings. The evaluation of these approaches is best undertaken in collaboration with TGD people.

Since TGD people represent a diverse array of gender identities and expressions and have differing needs for GAMSTs, no single assessment process will fit every person or every situation. Some TGD people may need a comparatively brief assessment process for GAMSTs. For TGD adults with a complex presentation or for those who are requesting less common treatments or treatments with limited research evidence, more comprehensive assessments with different members of a multidisciplinary team will be required. Assessments may be in person or through telehealth. While psychometric assessment tools have been used in some instances, they are not a required part of the assessment for GAMSTs. Counseling or psychotherapy can be helpful when requested by a TGD person. However, counseling or psychotherapy specifically focused on their TGD identity is not a requirement for the assessment or initiation of GAMSTs. Genital exams are not a prerequisite for initiation of GAMTs and should be performed only when clinically indicated.

GAMSTs can be delivered in diverse settings. Settings will depend on available health care systems within each country and may include nationalized/public health care, private sector settings, community health care settings, and charitable institutions. Local and regional circumstances may therefore influence the availability of health care. Regardless of the setting, health care offered to TGD people should be of the highest possible quality. World Professional Organization for Transgender Health (WPATH) advocates for assessment and treatment to be readily available. Access to assessment and treatment for TGD people seeking GAMSTs is critical given the clear medical necessity of these interventions and the profound benefits they offer to TGD people (Aldridge et al., 2020; Byne et al., 2012). The guidance in this chapter will need to be adapted according to local, as well as individual, clinical, and social circumstances.

The statements below are based on significant background literature, including literature demonstrating the strong positive impact of access to GAMSTs; available empirical evidence; a favorable risk-benefit ratio; and consensus of professional best practice. The empirical evidence base for the

Statements of Recommendations

5.1- We recommend health care professionals assessing transgender and gender diverse adults for physical treatments:
5.1.a- Are licensed by their statutory body and hold, at a minimum, a master's degree or equivalent training in a clinical field relevant to this role and granted by a nationally accredited statutory institution.
5.1.b- For countries requiring a diagnosis for access to care, the health care professional should be competent using the latest edition of the World Health Organization's International Classification of Diseases (ICD) for diagnosis. In countries that have not implemented the latest ICD, other taxonomies may be used; efforts should be undertaken to utilize the latest ICD as soon as practicable.
5.1.c- Are able to identify co-existing mental health or other psychosocial concerns and distinguish these from gender dysphoria, incongruence, and diversity.
5.1.d- Are able to assess capacity to consent for treatment.
5.1.e- Have experience or be qualified to assess clinical aspects of gender dysphoria, incongruence, and diversity.
5.1.f- Undergo continuing education in health care relating to gender dysphoria, incongruence, and diversity.
5.2- We suggest health care professionals assessing transgender and gender diverse adults seeking gender-affirming treatment liaise with professionals from different disciplines within the field of transgender health for consultation and referral, if required.

The following recommendations are made regarding the requirements for gender-affirming medical and surgical treatment (all should be met):
5.3- We recommend health care professionals assessing transgender and gender diverse adults for gender-affirming medical and surgical treatment:
5.3.a- Only recommend gender-affirming medical treatment requested by a TGD person when the experience of gender incongruence is marked and sustained.
5.3.b- Ensure fulfillment of diagnostic criteria prior to initiating gender-affirming treatments in regions where a diagnosis is necessary to access health care.
5.3.c- Identify and exclude other possible causes of apparent gender incongruence prior to the initiation of gender-affirming treatments.
5.3.d- Ensure that any mental health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.
5.3.e- Ensure any physical health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.
5.3.f- Assess the capacity to consent for the specific physical treatment prior to the initiation of this treatment.
5.3.g- Assess the capacity of the gender diverse and transgender adult to understand the effect of gender-affirming treatment on reproduction and explore reproductive options with the individual prior to the initiation of gender-affirming treatment.
5.4- We suggest, as part of the assessment for gender-affirming hormonal or surgical treatment, professionals who have competencies in the assessment of transgender and gender diverse people wishing gender-related medical treatment consider the role of social transition together with the individual.
5.5- We recommend transgender and gender diverse adults who fulfill the criteria for gender-affirming medical and surgical treatment require a single opinion for the initiation of this treatment from a professional who has competencies in the assessment of transgender and gender diverse people wishing gender-related medical and surgical treatment.
5.6- We suggest health care professionals assessing transgender and gender diverse people seeking gonadectomy consider a minimum of 6 months of hormone therapy as appropriate to the TGD person's gender goals before the TGD person undergoes irreversible surgical intervention (unless hormones are not clinically indicated for the individual).
5.7- We recommend health care professionals assessing adults who wish to detransition and seek gender-related hormone intervention, surgical intervention, or both, utilize a comprehensive multidisciplinary assessment that will include additional viewpoints from experienced health care professional in transgender health and that considers, together with the individual, the role of social transition as part of the assessment process.

assessment of TGD adults is limited. It primarily includes an assessment approach that uses specific criteria that are examined by an HCP in close cooperation with a TGD adult and does not include randomized controlled trials or long-term longitudinal research (Olsen-Kennedy et al., 2016). This is understandable given the complexity and ethical considerations of allocating patients in need of care to different assessment groups and the lack of funding for research and other resources to assess long-term outcomes of assessment approaches.

The creation of this guidance has been a complex undertaking. The criteria in this chapter have been significantly revised from SOC-7 to reduce requirements and unnecessary barriers to care. It is hoped that future research will explore the effectiveness of this model as well as evolving assessment models for hormone therapy and for surgery that will allow continued improvements to be made.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 5.1.

We recommend health care professional assessing transgender and gender diverse adults for gender-affirming treatments:

Statement 5.1.a

Are licensed by their statutory body and hold, at a minimum, a master's degree or equivalent training in a clinical field relevant to this role and granted by a nationally accredited statutory institution.

TGD people, as with all other people seeking health care, should have the highest quality of care accessible that is commensurate with the quality of care provided to all people utilizing health services (The Yogyakarta Principles, 2017). As this will vary around the globe, the nature of the professional completing an assessment for GAMSTs will vary according to the nature of health care in the local setting as well as the regulatory requirements set by licensing and registration boards. It is important the health care provided includes an assessment conducted by a competent, statutorily regulated HCP who has the competence to identify gender incongruence and conditions that can be mistaken for gender incongruence and who can support the TGD person throughout the assessment process (RCGP, 2019). Assessors must be able to refer to HCPs licensed to provide GAMSTs.

HCPs should have at a minimum a masters-level qualification in a clinical field related to transgender health or equivalent further clinical training and be statutorily regulated; examples include a mental health professional (MHP), general medical practitioner, nurse, or other qualified HCP. In some settings, statutorily regulated HCPs with lower levels of qualification may practice under the clinical supervision of a qualified HCP who takes ultimate clinical responsibility for the quality and accuracy of the completed GAMST assessment. For additional information see Chapter 4—Education.

Accessing a competent, statutorily regulated, HCP with expertise in GAMST assessment can sometimes be difficult. Consequently, ensuring continuity of care and minimizing gaps in accessible care or significantly delayed care (e.g., a long waiting list) may require that a statutorily regulated HCP without expertise provide care and support the assessment of a TGD person for GAMSTs. Avoiding unnecessary delays in care is critically important. However, TGD people should be supported to access care with an experienced HCP as soon as possible (RCGP, 2019).

Established practice requires the competence to identify and diagnose gender incongruence (Hembree et al., 2017; Reed et al., 2016; T'Sjoen et al., 2020) and the ability to identify differentials or conditions that may be mistaken as gender incongruence (Byne et al., 2018; Dhejne et al., 2016; Hembree et al., 2017). Established practice also strongly emphasizes the need for ongoing continuing education in the assessment and provision of care of TGD people (American Psychological Association, 2015; T'Sjoen et al., 2020). For more information see Chapter 4—Education.

Statement 5.1.b

For countries requiring a diagnosis for access to care, the health care professional should be competent using the latest edition of the World Health

Organization's International Classification of Diseases (ICD) for diagnosis. In countries that have not implemented the latest ICD, other taxonomies may be used; efforts should be undertaken to utilize the latest ICD as soon as practicable.

In some countries, a diagnosis of gender incongruence may be necessary to access GAMSTs (as described below). HCPs assessing TGD people in those countries should be competent to diagnose gender incongruence using the most current classification system necessary for TGD people to access GAMSTs. The ICD-11 (WHO, 2019a) is a classification system that focuses on the TGD person's experienced identity and any need for GAMSTs and does not consider a TGD identity to be a mental illness.

Statement 5.1.c

Are able to identify co-existing mental health or other psychosocial concerns and distinguish these from gender dysphoria, incongruence, and diversity.

Gender diversity is a natural variation in people and is not inherently pathological (American Psychological Association, 2015). However, assessment is best provided by an HCP who possesses some expertise in mental health in order to identify conditions that can be mistaken for gender incongruence. Such conditions are rare and, when present, are often psychological in nature (Byne et al., 2012; Byne et al., 2018; Hembree et al., 2017).

The need to include an HCP with some expertise in mental health does not require the inclusion of a psychologist, psychiatrist, or social worker in each assessment. Instead, a general medical practitioner, nurse, or other qualified HCP could also fulfill this requirement if they have sufficient expertise to identify gender incongruence, recognize mental health concerns, distinguish between these concerns and gender dysphoria, incongruence, and diversity, assist a TGD person in care planning and preparation for GAMSTs, and refer to a mental health professional (MHP), if needed. As discussed in greater depth in the mental health chapter, MHPs have an important role to play in the care of TGD people. For example, the prejudice and discrimination experienced by some TGD people (Robles et al., 2016) can lead to depression, anxiety, or worsening of other mental health conditions. In such cases, an MHP can diagnose, clarify, and treat mental health conditions. MHPs and HCPs with expertise in mental health are well-placed to assess for GAMSTs, as well as to support TGD people who require or request mental health input or support during their transition. For additional information see Chapter 18—Mental Health.

Statement 5.1.d

Are able to assess capacity to consent for treatment.

An assessment for GAMSTs must include an examination of the TGD person's ability to consent to the proposed treatment. Consent requires the cognitive capacity to understand the risks and benefits of a treatment and the potential negative and positive outcomes. It also requires the ability to retain that information for the purposes of making the decision (using aids as necessary) as well as the cognitive ability to use that understanding to make an informed decision (American Medical Association, 2021; Applebaum, 2007).

Some TGD individuals will have the capacity to grant consent immediately during the assessment. Some TGD individuals may need a longer process to be able to consent through ongoing discussion and the practice of medical decision-making skills. The presence of psychiatric illness or mental health symptoms do not pose a barrier to GAMSTs unless the psychiatric illness or mental health symptoms affect the TGD person's capacity to consent to the specific treatment being requested or affect their ability to receive treatment. This is especially important because GAMSTs have been found to reduce mental health symptomatology for TGD people (Aldridge et al., 2020).

Health care systems can consider GAMSTs for individuals who may not be able to directly consent if an appropriate legal guardian or regulator-approved independent decision maker with the power to determine health care treatment grants consent and confirms the proposed treatment is in alignment with the TGD individual's needs and wishes.

Statement 5.1.e

Have experience or be qualified to assess clinical aspects of gender dysphoria, incongruence, and diversity. For supporting text, see Statement 5.1.f.

Statement 5.1.f

Undergo continuing education in health care relating to gender dysphoria, incongruence, and diversity.

As in any other area of clinical practice, it is vital HCPs who are providing assessment for the initiation of GAMSTs are knowledgeable and experienced in the health care of TGD people. If this is not possible in the local context, the HCP providing the assessment should work closely with an HCP who is knowledgeable and experienced. As part of their clinical practice, HCPs should commit to ongoing training in TGD health care, become a member of relevant professional bodies, attend relevant professional meetings, workshops or seminars, consult with an HCP with relevant experience, and/or engage with the TGD community. This is particularly important in TGD health care as it is a relatively new field, and the knowledge and terminology are constantly changing (American Psychological Association, 2015; Thorne, Yip et al., 2019). Consequently, keeping up to date in the areas of TGD health is vital for anyone involved in an assessment for GAMSTs.

Statement 5.2

We suggest health care professionals assessing transgender and gender diverse adults seeking gender-affirming treatment liaise with professionals from different disciplines within the field of transgender health for consultation and referral, if required.

If required and if possible, assessment for GAMST should be conducted by a multidisciplinary team (Costa, Rosa-e-Silva et al., 2018; Hembree et al., 2017; Karasic & Fraser, 2018; T'Sjoen et al., 2020) with team members who have timely and adequate contact with one another. This could include an MHP, an endocrinologist, a primary care provider, a surgeon, a voice and communication specialist, TGD peer navigator, and others. In some cases, a multidisciplinary team may not be required; however, should a multidisciplinary team be needed, it is critical HCPs be able to access colleagues from different disciplines in a timely manner to complete the GAMST assessment and best support the needs of the TGD person. It is also critical TGD people be supported with follow-up appointments with any HCP who was involved during the assessment for GAMSTs, prior to, during, and after the initiation of gender-affirming treatments.

The following recommendations are made regarding the requirements for gender-affirming medical and surgical treatment (all should be met):

Statement 5.3

We recommend health care professionals assessing transgender and gender diverse adults for gender-affirming medical and surgical treatment:

Statement 5.3.a

Only recommend gender-affirming medical treatment requested by a TGD person when the experience of gender incongruence is marked and sustained.

To access GAMSTs, a TGD person's gender incongruence must be marked and sustained. This can include a need for GAMSTs and a desire to be accepted as a person of the experienced gender. Consequently, a consideration of the nature, length and consistency of gender incongruence is important. This can include such factors as a change of name and identity documents, telling others about one's gender, health care documentation, or changes in gender expression. However, marked and sustained gender incongruence can exist in the absence of disclosure to others by the TGD person (Brumbaugh-Johnson & Hull, 2019; Saeed et al., 2018; Sequeira et al., 2020). An abrupt or superficial change in gender identity or lack of persistence is insufficient to initiate gender- affirming treatments, and further assessment is recommended. In such circumstances, ongoing assessment is helpful to ensure the consistency and persistence of gender incongruence before GAMSTs are initiated.

While marked and sustained gender incongruence should be present, it is not necessary for TGD people to experience severe levels of distress regarding their gender identity to access gender- affirming treatments. In fact, access to gender-affirming treatment can act as a prophylactic measure to prevent distress (Becker et al., 2018; Giovanardi et al., 2021; Nieder et al., 2021; Nobili et al., 2018; Robles et al., 2016). A TGD adult can have sustained gender incongruence without significant distress and still benefit from GAMSTs.

Established clinical practice examines the persistence of gender incongruence when considering the initiation of GAMSTs (Chen & Loshak, 2020). In a review of 200 clinical notes, Jones, Brewin et al. (2017) identified the importance of the "stability of gender identity" when planning care. Providing GAMSTs to TGD people with persistent gender incongruence has been associated with low rates of patient regret and high rates of patient satisfaction (Becker et al., 2018; El-Hadi et al., 2018; Staples et al., 2020; Wiepjes et al., 2018). However, while the ICD 11 (WHO, 2019a) requires the presence of marked and persistent gender incongruence for a diagnosis of gender incongruence to be made, there is little specific evidence concerning the length of persistence required for treatment in adults. HCPs involved in an assessment of a TGD person for GAMSTs are encouraged to give due consideration to the life stage, history, and current circumstances of the adult being assessed.

Statement 5.3.b

Ensure fulfillment of diagnostic criteria prior to initiating gender-affirming treatments in regions where a diagnosis is necessary to access health care.

A diagnosis of gender incongruence may be necessary in some regions to access transition-related care. When a diagnosis is necessary to access GAMSTs, the assessment for GAMSTs will involve determining and assigning a diagnosis. In these instances, HCPs should have competence using the latest International Classification of Diseases and Related Health Problems (ICD) (WHO, 2019a). In regions where a diagnosis is necessary to access health care, a diagnosis of HA60 *Gender Incongruence of Adolescence or Adulthood* should be determined prior to gender-affirming interventions. Gender-affirming interventions secondary to a diagnosis of *HA6Z Gender Incongruence, Unspecified* may be considered in the context of a more comprehensive assessment by the multidisciplinary team.

There is evidence the use of rigid assessment tools for "transition readiness" may reduce access to care and are not always in the best interest of the TGD person (MacKinnon et al., 2020). Therefore, in situations where the assignment of a diagnosis is mandatory to access care, the process should be approached with trust and transparency between the HCP and the TGD individual requesting GAMST, with the needs of the TGD individual in mind. Indeed, high quality relationships between TGD people and their HCPs are associated with lower emotional distress and better outcomes (Kattari et al., 2016). Because many TGD people fear HCPs will erroneously conflate transgender identity with mental illness (Ellis et al., 2015), a diagnostic assessment should be undertaken with sensitivity to facilitate the best relationship between the provider and the TGD individual.

Statement 5.3.c

Identify and exclude other possible causes of apparent gender incongruence prior to the initiation of gender-affirming treatments.

In rare cases, TGD individuals might have a condition that may be mistaken for gender incongruence or may have another reason for seeking treatment aside from the alleviation of gender incongruence. In these cases, and when there is ambiguity regarding the diagnosis of gender incongruence, a more detailed and comprehensive assessment is important. For example, further assessment might be required to determine if gender incongruence persists outside of an acute psychotic episode. If gender incongruence persists after an acute psychotic episode resolves, GAMSTs may be considered as long as the TGD person has the capacity to consent to and undergo the specific treatment. If gender incongruence does not persist and only occurs during such an episode, treatment should not be considered. It is important such circumstances be identified and excluded prior to the initiation of GAMSTs (Byne et al., 2012, 2018; Hembree et al., 2017). It is important to understand, however, TGD people may present with gender incongruence and with a mental health condition, autistic spectrum disorder, or other neurodiversity (Glidden et al., 2016). Indeed, some mental health conditions, such as anxiety (Bouman et al., 2017), depression (Heylens, Elaut et al., 2014; Witcomb et al., 2018), and self-harm (Arcelus et al., 2016; Claes et al., 2015) are more prevalent in TGD people who have not accessed GAMSTs. Recent longitudinal studies suggest mental health symptoms experienced by TGD people tend to improve following GAMSTs (Aldridge et al., 2020; Heylens, Verroken et al., 2014;

White Hughto & Reisner, 2016). There is no evidence to suggest a benefit of withholding GAMSTs from TGD people who have gender incongruence simply on the basis that they have a mental health or neurodevelopmental condition. For more information see Chapter 18—Mental Health.

Statement 5.3.d

Ensure any mental health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.

Like their cisgender counterparts, TGD people may have mental health problems. Treatment for mental health problems can and should occur in conjunction with GAMSTs when medical transition is needed. It is vital gender-affirming care is not impeded unless, in some extremely rare cases, there is robust evidence that doing so is necessary to prevent significant decompensation with a risk of harm to self or others. In those cases, it is also important to consider the risks delaying GAMSTs poses to a TGD person's mental and physical health (Byne et al., 2018).

In general, social and medical transition of TDG people are both associated with a reduction in mental health problems (Aldridge et al., 2020; Bouman et al., 2017; Durwood et al., 2017; Glynn et al., 2016; Hughto & Reisner, 2016; Wilson et al., 2015; Witcomb et al., 2018). Unfortunately, the loss of social support and the physical and financial stress that can be associated with the initiation of GAMSTs may exacerbate pre-existing mental health problems and warrant additional support from the treating HCP (Budge et al., 2013; Yang, Wang et al., 2016). An assessment of mental health symptoms can improve transition outcomes, particularly when the assessment is used to facilitate access to psychological and social support during transition (Byne et al., 2012). A delay of transition in rare circumstances may be considered if, for example, the TGD person is unable to engage with the process of transition or would be unable to manage aftercare following surgery, even with support. Where a delay in GAMST as a last resort has been found to be necessary, the HCP should offer resources and support to improve mental health and facilitate re-engagement with the GAMST process as soon as practicable. It should be noted access to medical transition for TGD people facilitates social transition and improves safety in public (Rood et al., 2017). In turn, the degree to which TGD people's appearance conforms to their gender identity is the best predictor of quality of life and mental health outcomes following medical transition (Austin & Goodman, 2017). Delaying access to GAMSTs due to the presence of mental health problems may exacerbate symptoms (Owen-Smith et al., 2018) and damage rapport; consequently, this should be done only when all other avenues have been exhausted.

Statement 5.3.e

Ensure any physical health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.

In rare cases, GAMSTs, such as hormonal and surgical interventions, may have iatrogenic consequences or may exacerbate pre-existing physical health conditions (Hembree et al., 2017). In these instances, care should be taken, whenever possible, to manage pre-existing physical health conditions while initiating (if appropriate) or continuing gender-affirming treatments. Any interruptions in treatment should be as brief as possible and with treatment re-initiated as soon as practicable. Limited data and inconsistent findings suggest an association between cardiovascular and metabolic risks and hormone therapy in TGD adults (Getahun, 2018; Iwamoto, Defreyne et al., 2019; Iwamoto et al., 2021; Spanos et al., 2020). Because of the possible harm related to long-term treatment and the probable benefits expected from the preventive measures applied before and during hormone treatment, a careful assessment of physical health conditions prior to initiation of treatment is important. Some specific conditions, such as a history of hormone-sensitive cancer, may require further assessment and management that may preclude hormone treatment (Center of Excellence for Transgender Health, 2016; Hembree et al., 2017).

Similar concerns may be present for TGD adults who wish to access surgical interventions. Each gender-affirming surgical intervention has specific risks and potentially unfavorable consequences (Bryson & Honig, 2019; Nassiri et al., 2020; Remington et al., 2018). However, intervention-specific risks associated with the presence of specific physical conditions have not been well researched. Thus, the kinds of medical concerns raised by TGD people during the assessment are typically no different from those of any other surgical candidate.

Taking into consideration the mental and physical health disparities (Brown & Jones, 2016) and barriers to health care (Safer et al., 2016) experienced by TGD people, the assessment of physical conditions by HCPs should not be limited to a history of medical interventions. If the TGD person has physical health conditions, it is important these conditions are managed while initiating or continuing GAMSTs whenever possible. Any interruption in treatment should be made with a view toward re-initiating treatment as soon as practicable. It is also important HCPs develop a treatment strategy for managing physical conditions that facilitates health and promotes consistent adherence to a treatment plan.

Statement 5.3.f

Assess the capacity to consent for the specific gender-affirming treatments prior to the initiation of this treatment.

The practice of informed consent to treatment is central to the provision of health care. Informed consent is couched in the ethical principle that recipients of health care should understand the health care they receive and any potential consequences that could result. The importance of informed consent is embedded in many legislative and regulatory practices that guide HCPs around the world (Jefford & Moore, 2008). It is not possible to know all the potential consequences of a health care treatment; instead, considering what would be "reasonable" to expect is often used as a minimum criterion for consent (Jefford & Moore, 2008; Spatz et al., 2016) and remains the case with GAMSTs. Being able to consent to a health care procedure or clinical intervention requires several complex cognitive processes. Consent requires the cognitive capacity to understand the risks and benefits of a treatment and the potential negative and positive outcomes in addition to the ability to retain that information for the purposes of making the decision (using aids as necessary) and the cognitive ability to use that understanding to make an informed decision (American Medical Association, 2021; Applebaum, 2007). It is vital the TGD person and the assessing HCP consider a priori the nature of the treatment sought and the potential positive and negative effects it may have on the biological, psychological, and social domains of the TGD person's life.

It is important to recognize mental illness, in particular symptoms of cognitive impairment or psychosis, can impact a person's ability to grant consent for GAMSTs (Hostiuc et al., 2018). However, the presence of such symptoms does not necessarily equate to an inability to give consent because many people with significant mental health symptoms are able to understand the risks and benefits of treatment enough to make an informed decision (Carpenter et al., 2000). Instead, it is important a careful assessment is carried out that examines each TGD person's ability to comprehend the nature of the specific GAMST being considered, consider treatment options, including risks and benefits, appreciate the potential short- and long-term consequences of the decision, and communicate their choice in order to receive the treatment (Grootens-Wiegers et al., 2017).

There may be instances in which an individual lacks the capacity to consent to health care, such as during an acute episode of psychosis or in situations where an individual has long-term cognitive impairment. However, limits to capacity to consent to treatment should not prevent individuals from receiving appropriate GAMSTs. For some, understanding the risks and benefits may require the use of repeated explanations in jargon-free language over time or the use of diagrams to facilitate explanation and aid comprehension. A comprehensive and thorough assessment undertaken by the multidisciplinary health care team can further inform this process. For others, an alternative decision maker, such as a legal guardian or regulator-approved,

independent decision maker may need to be appointed. These situations need to be considered on a case-by-case basis with the aim of ensuring the most affirmative and least restrictive health care is provided to the individual. Also see Chapter 11—Institutional Environments.

Statement 5.3.g

Assess the capacity of the gender diverse and transgender adult to understand the effect of gender-affirming treatment on reproduction and explore reproductive options with the individual prior to the initiation of gender-affirming treatment.

As gender-affirming medical interventions often affect reproductive capacity, HCPs should ensure a TGD person is aware of the implications for reproduction of the treatments and is familiar with gamete storage and assistive reproductive options. Gender-affirming hormone treatments have been shown to impact reproductive functions and fertility, although the consequences are heterogenous for people of all birth-assigned sexes (Adeleye et al., 2019; Jindarak et al., 2018; Taub et al., 2020). There may be individual differences and fluctuations in these effects on TGD adults. It is therefore essential that HCPs inform a TGD person about the possible impact of the treatment on their reproductive potential during the assessment and as part of the evaluation of the person's capacity to consent for GAMSTs. Reproductive options should be considered and discussed prior to the initiation of gender-affirming treatments. Because the literature is unclear about the possibility of conception while on hormone therapy, information about the necessity of using contraception to avoid unwanted pregnancy and the different methods of contraception available may need to be provided (Light et al., 2014; Schubert & Carey,2020).

Cross-sectional studies in clinical and nonclinical samples from different populations consistently report TGD adults express parental desire and wish to pursue fertility preservation with varying rates that are related to age, gender, and the duration of gender-affirming hormone treatment (Auer et al., 2018; De Sutter et al., 2002; Defreyne, Van Schuvlenbergh et al., 2020; Wierckx, Stuyver et al., 2012). In a small sample, provision of fertility information was found to have an influence on decision-making related to the use of fertility preservation (Chen et al., 2019). Although there was no comparison made between groups who did and did not receive fertility counseling, high fertility preservation rates occurred following comprehensive fertility counseling among transgender individuals (Amir et al., 2020). Further, one study suggested consultation with a specialist reduced regret related to the decision about whether to pursue fertility preservation procedures (Vyas et al., 2021). For more information see Chapter 16—Reproductive Health.

Statement 5.4

We suggest, as part of the assessment for gender-affirming hormonal or surgical treatment, professionals who have competencies in the assessment of transgender and gender diverse people wishing gender-related medical treatment consider the role of social transition together with the individual.

Social transition can be extremely beneficial to many TGD people although not all TGD people are able to socially transition or wish to socially transition (Bränström & Pachankis, 2021; Koehler et al., 2018; Nieder, Eyssel et al., 2020). Consequently, some TGD people seek gender-affirming interventions after social transition, some before, some during, and some in the absence of social transition.

Social transition and gender identity disclosure can improve the mental health of a TGD person seeking gender-affirming interventions (Hughto et al., 2020; McDowell et al., 2019). In addition, chest and facial surgeries prior to hormone therapy can facilitate social transition (Altman, 2012; Davis & Colton Meier, 2014; Olson-Kennedy, Warus et al. 2018; Van Boerum et al., 2019). As part of the assessment process, HCPs should discuss which social role is most comfortable for the TGD person, if a social transition is planned, and the timing for any planned social transition (Barker & Wylie, 2008). It is imperative during the assessment process, HCPs are respectful of the wide diversity of gendered social roles, including nonbinary as well as binary identities and presentations, which vary

according to cultural, local community, and individual understandings.

Not everyone who requests GAMSTs will wish to or be able to socially transition. Little is known about TGD people who do not socially transition before, during, or after medical treatment, as this has not been systematically studied. The most frequent reasons that have been identified for avoiding social transition are fear of being abandoned by family or friends, fearing economic loss (Bradford et al., 2013), and being discriminated against and stigmatized (Langenderfer-Magruder et al., 2016; McDowell et al., 2019; White Hughto et al., 2015). However, some people do not pursue social transition because they feel hormonal or surgical treatments offer enough subjective improvement to reduce gender dysphoria.

If there is no clear plan for social transition or if social transition is unwanted, additional assessment is important to determine the specific nature and advisability of the treatment request, especially if surgical treatment is requested. Additional assessment can offer the TGD person an opportunity to consider the possible effects of not socially transitioning while still obtaining GAMSTs. Given the lack of data on health outcomes for TGD people who do not socially transition (Evans et al., 2021; Levine, 2009; Turban, Loo et al., 2021), GAMSTs should be approached cautiously in such circumstances.

Statement 5.5

We recommend transgender and gender diverse adults who fulfill the criteria for gender-affirming medical and surgical treatment require a single opinion for the initiation of this treatment from a professional who has competencies in the assessment of transgender and gender diverse people wishing gender-related medical and surgical treatment.

Previous versions of the SOC guidelines have required TGD individuals to be assessed for GAMSTs by two qualified HCPs. It was believed having two independent opinions was best practice as it ensured safety for both TGD people and HCPs. For example, it was assumed that seeing two HCPs offered assuredness for both TGD people and their assessing HCPs when pursuing irreversible medical interventions.

However, the limited research in the area indicates two opinions are largely unnecessary. For example, Jones, Brewin et al. (2017) reviewed the case notes of experienced HCPs working within a state-funded gender service and found there was an overwhelming correlation between both opinions—arguably making one of them redundant. Further, Bouman et al. (2014) determined the requirement for two independent assessors reflected paternalism in health care services and raised a potential breach of the autonomy of TGD individuals. The authors posited when clients are adequately prepared and assessed under the care of a multidisciplinary team, a second independent assessment is unnecessary.

Consequently, if written documentation or a letter is required to recommend gender-affirming medical and surgical treatment (GAMST), TGD people seeking treatments including hormones, and genital, chest, facial and other gender-affirming surgeries require a single written opinion/signature from an HCP competent to independently assess and diagnose (Bouman et al., 2014; Yuan et al, 2021). Further written opinions/signatures may be requested where there is a specific clinical need.

Statement 5.6

We suggest health care professionals assessing transgender and gender diverse people seeking gonadectomy consider a minimum of 6 months of hormone therapy as appropriate to the TGD person's gender goals before the TGD person undergoes irreversible surgical intervention (unless hormones are not clinically indicated for the individual).

The Endocrine Society Clinical Practice Guidelines advise a period of consistent hormone treatment prior to genital surgery (Hembree et al., 2017). While there was limited supportive research, this recommendation was considered to be good clinical practice as it allows a more reversible experience prior to the irreversible experience of surgery. For example, there can be changes in sexual desire after genital surgery that removes the testicles (Lawrence, 2005; Wierckx, Van de Peer et al., 2014). In this context, reversible testosterone suppression can offer a TGD person a period of time to experience the absence of testosterone and decide if this feels right for

them. It should be noted the effects of reduced estrogen on a TGD person's sexual desire and functioning following an oophorectomy is less well documented.

Surgery that removes gonads is an irreversible procedure that leads to loss of fertility and loss of the effects of endogenous sex steroids. Both effects must be discussed as a component of the assessment process. For additional information see Chapter 16—Reproductive Health. Of course, hormones are not clinically indicated for TGD adults who do not want them or in cases where they are contraindicated due to health reasons. For more information see Chapter 13—Surgery and Postoperative Care.

Statement 5.7

We recommend health care professionals assessing adults who wish to detransition and seek gender-related hormone intervention, surgical intervention, or both, utilize a comprehensive multidisciplinary assessment that will include additional viewpoints from experienced health care professionals in transgender health and that considers, together with the individual, the role of social transition as part of the assessment process.

Many TGD adults may consider a range of identities and elements of gender presentation while they are exploring their gender identity and are considering transition options. Accordingly, people may spend some time in a gender identity or presentation before they discover it does not feel comfortable and later adapt it or shift to an earlier identity or presentation (Turban, King et al., 2021). Some TGD adults may also experience a change in gender identity over time so that their needs for medical treatment evolve. This is a healthy and reasonable process for determining the most comfortable and congruent way of living, which is informed by the person's gender identity and the context of their life. This process of identity exploration should not necessarily be equated with regret, confusion, or poor decision-making because a TGD adult's gender identity may change without devaluing previous transition decisions (MacKinnon et al., 2021; Turban, Loo et al., 2021). TGD adults should be assisted in this exploration and any other changes in their identity (Expósito-Campos, 2021). While exploration continues, gender-affirming treatments that are irreversible should be avoided until clarity about long-term goals and outcomes is achieved.

The decision to detransition appears to be rare (Defreyne, Motmans et al., 2017; Hadje-Moussa et al., 2019; Wiepjes et al., 2018). Estimates of the number of people who detransition due to a change in identity are likely to be overinflated due to research blending different cohorts (Expósito-Campos, 2021). For example, detransition research cohorts often include TGD adults who chose to detransition because of a change in their identity as well as TGD adults who chose to detransition without a change in identity. While little research has been conducted to systematically examine variables that correlate with a TGD adult's decision to halt a transition process or to detransition, a recent study found the vast majority of TGD people who opted to detransition did so due to external factors, such as stigma and lack of social support and not because of changes in gender identity (Turban, King et al., 2021). TGD adults who have not experienced a change in identity may choose to halt transition or to detransition because of oppression, violence, and social/relational conflict, surgical complications, health concerns, physical contraindications, a lack of resources, or dissatisfaction with the results (Expósito-Campos, 2021). In such cases, MHPs are well placed to assist the TGD person with these challenges.

While the choice to detransition is proportionally rare, it is expected an overall increase in the number of adults who identify as TGD would result in an increase in the absolute number of people seeking to halt or reverse a transition. However, while the absolute numbers may increase, the percentage of people seeking to halt or reverse permanent physical changes should remain static and low. The existence of these rare requests must not be used as a justification to interrupt critical, medically necessary care, including hormone and surgical treatments, for the vast majority of TGD adults.

Due to the limited research in this area, clinical guidance is based primarily on individual case studies and the expert opinion of HCPs

working with TGD adults (Expósito-Campos, 2021; Richards & Barrett, 2020). Accordingly, if a TGD adult has undergone permanent physical changes and seeks to undo them, the assessing HCP should be a member of a comprehensive multidisciplinary assessment team. A multidisciplinary team allows for the contribution of additional viewpoints from HCPs experienced in transgender health. In collaboration with the TGD adult, the multidisciplinary team is encouraged to thoroughly understand the motivations for the original treatment and for the decision to detransition. Any concerns with the previous physical changes should be carefully explored and a significant effort made to ensure similar concerns are not replicated by the reversal.

To ensure the greatest likelihood of satisfaction and comfort with a reversal of permanent physical changes, the TGD adult and the multidisciplinary team should explore the role of social transition in the assessment and in preparation for the reversal. In such instances, it is highly likely a prolonged period of living in role will be necessary before further physical changes are recommended. HCPs should support the TGD adult through any social changes, as well as any feelings of failure, shame, depression, or guilt in deciding to make such a change. In addition, people should be supported in coping with any prejudice or social difficulties they may have experienced that could have led to a decision to detransition or that may have resulted from such a decision. It is also important to help the person remain engaged with health care throughout the process (Narayan et al., 2021).

While available research shows consistent positive outcomes for the majority of TGD adults who choose to transition (Aldridge et al., 2020; Byne et al., 2012; Gorin-Lazard et al., 2012; Owen-Smith et al., 2018; White Hughto & Reisner, 2016), some TGD adults may decompensate or experience a worsened condition following transition. Little research has been conducted to systematically examine variables that correlate with poor or worsened biological, psychological, or social conditions following transition (Hall et al., 2021; Littman, 2021); however, this occurrence appears to be rare (Hall et al., 2021; Wiepjes et al., 2018). In cases where people decompensate after physical or social transition and then remain in a poorer biological, psychological, or social state than they were in prior to transition, serious consideration should be given as to whether transition is helpful at this time, for this person, or both. In cases where treatment is no longer supported, assistance should be arranged to support the person to manage the process of stopping treatment and to manage any concomitant difficulties (Narayan et al., 2021).

It is vital that people who detransition, for any reason, be supported. It should be remembered, however, this is a rare occurrence and the literature shows consistently positive outcomes for the vast majority of TGD adults who transition to a gender that is comfortable for them, including those who receive GAMSTs (Byne et al., 2012; Green & Fleming, 1990; Lawrence, 2003; Motmans et al., 2012; Van de Grift, Elaut et al., 2018).

CHAPTER 6 Adolescents

Historical context and changes since previous Standards of Care

Specialized health care for transgender adolescents began in the 1980s when a few specialized gender clinics for youth were developed around the world that served relatively small numbers of children and adolescents. In more recent years, there has been a sharp increase in the number of adolescents requesting gender care (Arnoldussen et al., 2019; Kaltiala, Bergman et al., 2020). Since then, new clinics have been founded, but clinical services in many places have not kept pace with the increasing number of youth seeking care. Hence, there are often long waitlists for services, and barriers to care exist for many transgender youth around the world (Tollit et al., 2018).

Until recently, there was limited information regarding the prevalence of gender diversity among adolescents. Studies from high school samples indicate much higher rates than earlier thought, with reports of up to 1.2% of participants identifying as transgender (Clark et al., 2014) and up to 2.7% or more (e.g., 7–9%) experiencing some level of self-reported gender diversity (Eisenberg et al., 2017; Kidd et al., 2021; Wang et al., 2020). These studies suggest gender diversity in youth should no longer be viewed as rare. Additionally, a pattern of uneven ratios by assigned sex has been reported in gender clinics, with adolescents assigned female at birth (AFAB) initiating care 2.5–7.1 times more frequently as compared to adolescents who are assigned male at birth (AMAB) (Aitken et al., 2015; Arnoldussen et al., 2019; Bauer et al., 2021; de Graaf, Carmichael et al., 2018; Kaltiala et al., 2015; Kaltiala, Bergman et al., 2020).

A specific World Professional Association for Transgender Health's (WPATH) Standards of Care section dedicated to the needs of children and adolescents was first included in the 1998 WPATH Standards of Care, 5th version (Levine et al., 1998). Youth aged 16 or older were deemed potentially eligible for gender-affirming medical care, but only in select cases. The subsequent 6th (Meyer et al., 2005) and 7th (Coleman et al., 2012) versions divided medical-affirming treatment for adolescents into three categories and presented eligibility criteria regarding age/puberty stage—namely fully reversible puberty delaying blockers as soon as puberty had started; partially reversible hormone therapy (testosterone, estrogen) for adolescents at the age of majority, which was age 16 in certain European countries; and irreversible surgeries at age 18 or older, except for chest "masculinizing" mastectomy, which had an age minimum of 16 years. Additional eligibility criteria for gender-related medical care included a persistent, long (childhood) history of gender "non-conformity"/dysphoria, emerging or intensifying at the onset of puberty; absence or management of psychological, medical, or social problems that interfere with treatment; provision of support for commencing the intervention by the parents/caregivers; and provision of informed consent. A chapter dedicated to transgender and gender diverse (TGD) adolescents, distinct from the child chapter, has been created for this 8th edition of the Standards of Care given 1) the exponential growth in adolescent referral rates; 2) the increased number of studies specific to adolescent gender diversity-related care; and 3) the unique developmental and gender-affirming care issues of this age group.

Non-specific terms for gender-related care are avoided (e.g., gender-affirming model, gender exploratory model) as these terms do not represent unified practices, but instead heterogenous care practices that are defined differently in various settings.

Adolescence overview

Adolescence is a developmental period characterized by relatively rapid physical and psychological maturation, bridging childhood and adulthood (Sanders, 2013). Multiple developmental processes occur simultaneously, including pubertal-signaled changes. Cognitive, emotional, and social systems mature, and physical changes associated with puberty progress. These processes do not all begin and end at the same time for a given individual, nor do they occur at the same age for all persons. Therefore, the lower and upper borders of adolescence are imprecise and cannot be defined exclusively by age. For example, physical pubertal changes may

begin in late childhood and executive control neural systems continue to develop well into the mid-20s (Ferguson et al., 2021). There is a lack of uniformity in how countries and governments define the age of majority (i.e., legal decision-making status; Dick et al., 2014). While many specify the age of majority as 18 years of age, in some countries it is as young as 15 years (e.g., Indonesia and Myanmar), and in others as high as 21 years (e.g., the U.S. state of Mississippi and Singapore).

For clarity, this chapter applies to adolescents from the start of puberty until the legal age of majority (in most cases 18 years), however there are developmental elements of this chapter, including the importance of parental/caregiver involvement, that are often relevant for the care of transitional-aged young adults and should be considered appropriately.

Cognitive development in adolescence is often characterized by gains in abstract thinking, complex reasoning, and metacognition (i.e., a young person's ability to think about their own feelings in relation to how others perceive them; Sanders, 2013). The ability to reason hypothetical situations enables a young person to conceptualize implications regarding a particular decision. However, adolescence is also often associated with increased risk-taking behaviors. Along with these notable changes, adolescence is often characterized by individuation from parents and the development of increased personal autonomy. There is often a heightened focus on peer relationships, which can be both positive and detrimental (Gardner & Steinberg, 2005). Adolescents often experience a sense of urgency that stems from hypersensitivity to reward, and their sense of timing has been shown to be different from that of older individuals (Van Leijenhorst et al., 2010). Social-emotional development typically advances during adolescence, although there is a great variability among young people in terms of the level of maturity applied to inter- and intra-personal communication and insight (Grootens-Wiegers et al., 2017). For TGD adolescents making decisions about gender-affirming treatments—decisions that may have lifelong consequences—it is critical to understand how all these aspects of development may impact decision-making for a given young person within their specific cultural context.

Gender identity development in adolescence

Our understanding of gender identity development in adolescence is continuing to evolve. When providing clinical care to gender diverse young people and their families, it is important to know what is and is not known about gender identity during development (Berenbaum, 2018). When considering treatments, families may have questions regarding the development of their adolescent's gender identity, and whether or not their adolescent's declared gender will remain the same over time. For some adolescents, a declared gender identity that differs from the assigned sex at birth comes as no surprise to their parents/caregivers as their history of gender diverse expression dates back to childhood (Leibowitz & de Vries, 2016). For others, the declaration does not happen until the emergence of pubertal changes or even well into adolescence (McCallion et al., 2021; Sorbara et al., 2020).

Historically, social learning and cognitive developmental research on gender development was conducted primarily with youth who were not gender diverse in identity or expression and was carried out under the assumption that sex correlated with a specific gender; therefore, little attention was given to gender identity development. In addition to biological factors influencing gender development, this research demonstrated psychological and social factors also play a role (Perry & Pauletti, 2011). While there has been less focus on gender identity development in TGD youth, there is ample reason to suppose, apart from biological factors, psychosocial factors are also involved (Steensma, Kreukels et al., 2013). For some youth, gender identity development appears fixed and is often expressed from a young age, while for others there may be a developmental process that contributes to gender identity development over time.

Neuroimaging studies, genetic studies, and other hormone studies in intersex individuals demonstrate a biological contribution to the development of gender identity for some

individuals whose gender identity does not match their assigned sex at birth (Steensma, Kreukels et al., 2013). As families often have questions about this very issue, it is important to note it is not possible to distinguish between those for whom gender identity may seem fixed from birth and those for whom gender identity development appears to be a developmental process. Since it is impossible to definitively delineate the contribution of various factors contributing to gender identity development for any given young person, a comprehensive clinical approach is important and necessary (see Statement 3). Future research would shed more light on gender identity development if conducted over long periods of time with diverse cohort groups. Conceptualization of gender identity by shifting from dichotomous (e.g., binary) categorization of male and female to a dimensional gender spectrum along a continuum (APA, 2013) would also be necessary.

Adolescence may be a critical period for the development of gender identity for gender diverse young people (Steensma, Kreukels et al., 2013). Dutch longitudinal clinical follow-up studies of adolescents with childhood gender dysphoria who received puberty suppression, gender-affirming hormones, or both, found that none of the youth in adulthood regretted the decisions they had taken in adolescence (Cohen-Kettenis & van Goozen, 1997; de Vries et al., 2014). These findings suggest adolescents who were comprehensively assessed and determined emotionally mature enough to make treatment decisions regarding gender- affirming medical care presented with stability of gender identity over the time period when the studies were conducted.

When extrapolating findings from the longer-term longitudinal Dutch cohort studies to present-day gender diverse adolescents seeking care, it is critical to consider the societal changes that have occurred over time in relation to TGD people. Given the increase in visibility of TGD identities, it is important to understand how increased awareness may impact gender development in different ways (Kornienko et al., 2016). One trend identified is that more young people are presenting to gender clinics with nonbinary identities (Twist & de Graaf, 2019). Another phenomenon occurring in clinical practice is the increased number of adolescents seeking care who have not seemingly experienced, expressed (or experienced and expressed) gender diversity during their childhood years. One researcher attempted to study and describe a specific form of later-presenting gender diversity experience (Littman, 2018). However, the findings of the study must be considered within the context of significant methodological challenges, including 1) the study surveyed parents and not youth perspectives; and 2) recruitment included parents from community settings in which treatments for gender dysphoria are viewed with scepticism and are criticized. However, these findings have not been replicated. For a select subgroup of young people, susceptibility to social influence impacting gender may be an important differential to consider (Kornienko et al., 2016). However, caution must be taken to avoid assuming these phenomena occur prematurely in an individual adolescent while relying on information from datasets that may have been ascertained with potential sampling bias (Bauer et al., 2022; WPATH, 2018). It is important to consider the benefits that social connectedness may have for youth who are linked with supportive people (Tuzun et al., 2022)(see Statement 4).

Given the emerging nature of knowledge regarding adolescent gender identity development, an individualized approach to clinical care is considered both ethical and necessary. As is the case in all areas of medicine, each study has methodological limitations, and conclusions drawn from research cannot and should not be universally applied to all adolescents. This is also true when grappling with common parental questions regarding the stability versus instability of a particular young person's gender identity development. While future research will help advance scientific understanding of gender identity development, there may always be some gaps. Furthermore, given the ethics of self-determination in care, these gaps should not leave the TGD adolescent without important and necessary care.

Research evidence of gender-affirming medical treatment for transgender adolescents

A key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness of medically necessary gender-affirming medical

and surgical treatments (GAMSTs) (see medically necessary statement in the Global chapter, Statement 2.1), over time. Given the lifelong implications of medical treatment and the young age at which treatments may be started, adolescents, their parents, and care providers should be informed about the nature of the evidence base. It seems reasonable that decisions to move forward with medical and surgical treatments should be made carefully. Despite the slowly growing body of evidence supporting the effectiveness of early medical intervention, the number of studies is still low, and there are few outcome studies that follow youth into adulthood. Therefore, a systematic review regarding outcomes of treatment in adolescents is not possible. A short narrative review is provided instead.

At the time of this chapter's writing, there were several longer-term longitudinal cohort follow-up studies reporting positive results of early (i.e., adolescent) medical treatment; for a significant period of time, many of these studies were conducted through one Dutch clinic (e.g., Cohen-Kettenis & van Goozen, 1997; de Vries, Steensma et al., 2011; de Vries et al., 2014; Smith et al., 2001, 2005). The findings demonstrated the resolution of gender dysphoria is associated with improved psychological functioning and body image satisfaction. Most of these studies followed a pre-post methodological design and compared baseline psychological functioning with outcomes after the provision of medical gender-affirming treatments. Different studies evaluated individual aspects or combinations of treatment interventions and included 1) gender-affirming hormones and surgeries (Cohen-Kettenis & van Goozen, 1997; Smith et al., 2001, 2005); 2) puberty suppression (de Vries, Steensma et al., 2011); and 3) puberty suppression, affirming hormones, and surgeries (de Vries et al., 2014). The 2014 long-term follow-up study is the only study that followed youth from early adolescence (pretreatment, mean age of 13.6) through young adulthood (posttreatment, mean age of 20.7). This was the first study to show gender-affirming treatment enabled transgender adolescents to make age-appropriate developmental transitions while living as their affirmed gender with satisfactory objective and subjective outcomes in adulthood (de Vries et al., 2014). While the study employed a small (n = 55), select, and socially supported sample, the results were convincing. Of note, the participants were part of the Dutch clinic known for employing a multidisciplinary approach, including provision of comprehensive, ongoing assessment and management of gender dysphoria, and support aimed at emotional well-being.

Several more recently published longitudinal studies followed and evaluated participants at different stages of their gender-affirming treatments. In these studies, some participants may not have started gender-affirming medical treatments, some had been treated with puberty suppression, while still others had started gender-affirming hormones or had even undergone gender-affirming surgery (GAS) (Achille et al., 2020; Allen et al., 2019; Becker-Hebly et al., 2021; Carmichael et al., 2021; Costa et al., 2015; Kuper et al., 2020, Tordoff et al., 2022). Given the heterogeneity of treatments and methods, this type of design makes interpreting outcomes more challenging. Nonetheless, when compared with baseline assessments, the data consistently demonstrate improved or stable psychological functioning, body image, and treatment satisfaction varying from three months to up to two years from the initiation of treatment.

Cross-sectional studies provide another design for evaluating the effects of gender-affirming treatments. One such study compared psychological functioning in transgender adolescents at baseline and while undergoing puberty suppression with that of cisgender high school peers at two different time points. At baseline, the transgender youth demonstrated lower psychological functioning compared with cisgender peers, whereas when undergoing puberty suppression, they demonstrated better functioning than their peers (van der Miesen et al., 2020). Grannis et al. (2021) demonstrated transgender males who started testosterone had lower internalizing mental health symptoms (depression and anxiety) compared with those who had not started testosterone treatment.

Four additional studies followed different outcome designs. In a retrospective chart study, Kaltiala, Heino et al. (2020) reported transgender

adolescents with few or no mental health challenges prior to commencing gender-affirming hormones generally did well during the treatment. However, adolescents with more mental health challenges at baseline continued to experience the manifestations of those mental health challenges over the course of gender-affirming medical treatment. Nieder et al. (2021) studied satisfaction with care as an outcome measure and demonstrated transgender adolescents were more satisfied the further they progressed with the treatments they initially started. Hisle-Gorman et al. (2021) compared health care utilization pre- and post-initiation of gender-affirming pharmaceuticals as indicators of the severity of mental health conditions among 3,754 TGD adolescents in a large health care data set. Somewhat contrary to the authors' hypothesis of improved mental health, mental health care use did not significantly change, and psychotropic medication prescriptions increased. In a large non-probability sample of transgender-identified adults, Turban et al. (2022) found those who reported access to gender-affirming hormones in adolescence had lower odds of past-year suicidality compared with transgender people accessing gender- affirming hormones in adulthood.

Providers may consider the possibility an adolescent may regret gender-affirming decisions made during adolescence, and a young person will want to stop treatment and return to living in the birth-assigned gender role in the future. Two Dutch studies report low rates of adolescents (1.9% and 3.5%) choosing to stop puberty suppression (Brik et al., 2019; Wiepjes et al., 2018). Again, these studies were conducted in clinics that follow a protocol that includes a comprehensive assessment before the gender-affirming medical treatment is started. At present, no clinical cohort studies have reported on profiles of adolescents who regret their initial decision or detransition after irreversible affirming treatment. Recent research indicate there are adolescents who detransition, but do not regret initiating treatment as they experienced the start of treatment as a part of understanding their gender-related care needs (Turban, 2018). However, this may not be the predominant perspective of people who detransition (Littman, 2021; Vandenbussche, 2021). Some adolescents may regret the steps they have taken (Dyer, 2020). Therefore, it is important to present the full range of possible outcomes when assisting transgender adolescents. Providers may discuss this topic in a collaborative and trusting manner (i.e., as a "potential future experience and consideration") with the adolescent and their parents/caregivers before gender-affirming medical treatments are started. Also, providers should be prepared to support adolescents who detransition. In an internet convenience sample survey of 237 self-identified detransitioners with a mean age of 25.02 years, which consisted of over 90% of birth assigned females, 25% had medically transitioned before age 18 and 14% detransitioned before age 18 (Vandenbussche, 2021). Although an internet convenience sample is subject to selection of respondents, this study suggests detransitioning may occur in young transgender adolescents and health care professionals should be aware of this. Many of them expressed difficulties finding help during their detransition process and reported their detransition was an isolating experience during which they did not receive either sufficient or appropriate support (Vandenbussche, 2021).

To conclude, although the existing samples reported on relatively small groups of youth (e.g., n = 22-101 per study) and the time to follow-up varied across studies (6 months–7 years), this emerging evidence base indicates a general improvement in the lives of transgender adolescents who, following careful assessment, receive medically necessary gender-affirming medical treatment. Further, rates of reported regret during the study monitoring periods are low. Taken as a whole, the data show early medical intervention—as part of broader combined assessment and treatment approaches focused on gender dysphoria and general well-being—can be effective and helpful for many transgender adolescents seeking these treatments.

Ethical and human rights perspectives

Medical ethics and human rights perspectives were also considered while formulating the

Statements of Recommendations

6.1- We recommend health care professionals working with gender diverse adolescents:
6.1.a- Are licensed by their statutory body and hold a postgraduate degree or its equivalent in a clinical field relevant to this role granted by a nationally accredited statutory institution.
6.1.b- Receive theoretical and evidenced-based training and develop expertise in general child, adolescent, and family mental health across the developmental spectrum.
6.1.c- Receive training and have expertise in gender identity development, gender diversity in children and adolescents, have the ability to assess capacity to assent/consent, and possess general knowledge of gender diversity across the life span.
6.1.d- Receive training and develop expertise in autism spectrum disorders and other neurodevelopmental presentations or collaborate with a developmental disability expert when working with autistic/neurodivergent gender diverse adolescents.
6.1.e- Continue engaging in professional development in all areas relevant to gender diverse children, adolescents, and families.
6.2- We recommend health care professionals working with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particular identity is favored.
6.3- We recommend health care professionals working with gender diverse adolescents undertake a comprehensive biopsychosocial assessment of adolescents who present with gender identity-related concerns and seek medical/surgical transition-related care, and that this be accomplished in a collaborative and supportive manner.
6.4- We recommend health care professionals work with families, schools, and other relevant settings to promote acceptance of gender diverse expressions of behavior and identities of the adolescent.
6.5- We recommend against offering reparative and conversion therapy aimed at trying to change a person's gender and lived gender expression to become more congruent with the sex assigned at birth.
6.6- We suggest health care professionals provide transgender and gender diverse adolescents with health education on chest binding and genital tucking, including a review of the benefits and risks.
6.7- We recommend providers consider prescribing menstrual suppression agents for adolescents experiencing gender incongruence who may not desire testosterone therapy, who desire but have not yet begun testosterone therapy, or in conjunction with testosterone therapy for breakthrough bleeding.
6.8- We recommend health care professionals maintain an ongoing relationship with the gender diverse and transgender adolescent and any relevant caregivers to support the adolescent in their decision-making throughout the duration of puberty suppression treatment, hormonal treatment, and gender- related surgery until the transition is made to adult care.
6.9- We recommend health care professionals involve relevant disciplines, including mental health and medical professionals, to reach a decision about whether puberty suppression, hormone initiation, or gender-related surgery for gender diverse and transgender adolescents are appropriate and remain indicated throughout the course of treatment until the transition is made to adult care.
6.10- We recommend health care professionals working with transgender and gender diverse adolescents requesting gender-affirming medical or surgical treatments inform them, prior to initiating treatment, of the reproductive effects including the potential loss of fertility and available options to preserve fertility within the context of the youth's stage of pubertal development.
6.11- We recommend when gender-affirming medical or surgical treatments are indicated for adolescents, health care professionals working with transgender and gender diverse adolescents involve parent(s)/guardian(s) in the assessment and treatment process, unless their involvement is determined to be harmful to the adolescent or not feasible.

The following recommendations are made regarding the requirements for gender-affirming medical and surgical treatment (All of them must be met):
6.12- We recommend health care professionals assessing transgender and gender diverse adolescents only recommend gender-affirming medical or surgical treatments requested by the patient when:
6.12.a- The adolescent meets the diagnostic criteria of gender incongruence as per the ICD-11 in situations where a diagnosis is necessary to access health care. In countries that have not implemented the latest ICD, other taxonomies may be used although efforts should be undertaken to utilize the latest ICD as soon as practicable.
6.12.b- The experience of gender diversity/incongruence is marked and sustained over time.
6.12.c- The adolescent demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment.
6.12.d- The adolescent's mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed.
6.12.e- The adolescent has been informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility, and these have been discussed in the context of the adolescent's stage of pubertal development.
6.12.f- The adolescent has reached Tanner stage 2 of puberty for pubertal suppression to be initiated.
6.12.g- The adolescent had at least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.

adolescent SOC statements. For example, allowing irreversible puberty to progress in adolescents who experience gender incongruence is not a neutral act given that it may have immediate and lifelong harmful effects for the transgender young person (Giordano, 2009; Giordano & Holm, 2020; Kreukels & Cohen-Kettenis, 2011). From a human rights perspective, considering gender diversity as a normal and expected variation within the broader diversity of the human experience, it is an adolescent's right to participate in their own decision-making

process about their health and lives, including access to gender health services (Amnesty International, 2020).

Short summary of statements and unique issues in adolescence

These guidelines are designed to account for what is known and what is not known about gender identity development in adolescence, the evidence for gender-affirming care in adolescence, and the unique aspects that distinguish adolescence from other developmental stages.

Identity exploration: A defining feature of adolescence is the solidifying of aspects of identity, including gender identity. Statement 6.2 addresses identity exploration in the context of gender identity development. Statement 6.12.b accounts for the length of time needed for a young person to experience a gender diverse identity, express a gender diverse identity, or both, so as to make a meaningful decision regarding gender-affirming care.

Consent and decision-making: In adolescence, consent and decision-making require assessment of the individual's emotional, cognitive, and psychosocial development. Statement 6.12.c directly addresses emotional and cognitive maturity and describes the necessary components of the evaluation process used to assess decision-making capacity.

Caregivers/parent involvement: Adolescents are typically dependent on their caregivers/parents for guidance in numerous ways. This is also true as the young person navigates through the process of deciding about treatment options. Statement 6.11 addresses the importance of involving caregivers/parents and discusses the role they play in the assessment and treatment. No set of guidelines can account for every set of individual circumstances on a global scale.

Statement 6.1

We recommend health care professionals working with gender diverse adolescents:

a. **Are licensed by their statutory body and hold a postgraduate degree or its equivalent in a clinical field relevant to this role granted by a nationally accredited statutory institution.**
b. **Receive theoretical and evidenced-based training and develop expertise in general child, adolescent, and family mental health across the developmental spectrum.**
c. **Receive training and have expertise in gender identity development, gender diversity in children and adolescents, have the ability to assess capacity to assent/consent, and possess general knowledge of gender diversity across the life span.**
d. **Receive training and develop expertise in autism spectrum disorders and other neurodevelopmental presentations or collaborate with a developmental disability expert when working with autistic/neurodivergent gender diverse adolescents.**
e. **Continue engaging in professional development in all areas relevant to gender diverse children, adolescents, and families.**

When assessing and supporting TGD adolescents and their families, care providers/health care professionals (HCPs) need both general as well as gender-specific knowledge and training. Providers who are trained to work with adolescents and families play an important role in navigating aspects of adolescent development and family dynamics when caring for youth and families (Adelson et al., 2012; American Psychological Association, 2015; Hembree et al., 2017). Other chapters in these standards of care describe these criteria for professionals who provide gender care in more detail (see Chapter 5—Assessment for Adults; Chapter 7—Children; or Chapter 13—Surgery and Postoperative Care). Professionals working with adolescents should understand what is and is not known regarding adolescent gender identity development, and how this knowledge base differs from what applies to adults and prepubertal children. Among HCPs, the mental health professional (MHP) has the most appropriate training and dedicated clinical time to conduct an assessment and elucidate treatment priorities and goals when working with transgender youth, including those seeking gender-affirming medical/surgical care. Understanding and managing the dynamics of family members who may share differing perspectives regarding the history and needs of the

young person is an important competency that MHPs are often most prepared to address.

When access to professionals trained in child and adolescent development is not possible, HCPs should make a commitment to obtain training in the areas of family dynamics and adolescent development, including gender identity development. Similarly, considering autistic/neurodivergent transgender youth represent a substantial minority subpopulation of youth served in gender clinics globally, it is important HCPs seek additional training in the field of autism and understand the unique elements of care autistic gender diverse youth may require (Strang, Meagher et al., 2018). If these qualifications are not possible, then consultation and collaboration with a provider who specializes in autism and neurodiversity is advised.

Statement 6.2

We recommend health care professionals working with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particular identity is favored.

Adolescence is a developmental period that involves physical and psychological changes characterized by individuation and the transition to independence from caregivers (Berenbaum et al., 2015; Steinberg, 2009). It is a period during which young people may explore different aspects of identity, including gender identity.

Adolescents differ regarding the degree to which they explore and commit to aspects of their identity (Meeus et al., 2012). For some adolescents, the pace to achieving consolidation of identity is fast, while for others it is slower. For some adolescents, physical, emotional, and psychological development occur over the same general timeline, while for others, there are certain gaps between these aspects of development. Similarly, there is variation in the timeline for gender identity development (Arnoldussen et al., 2020; Katz-Wise et al., 2017). For some young people, gender identity development is a clear process that starts in early childhood, while for others pubertal changes contribute to a person's experience of themselves as a particular gender (Steensma, Kreukels et al., 2013), and for many others a process may begin well after pubertal changes are completed. Given these variations, there is no one particular pace, process, or outcome that can be predicted for an individual adolescent seeking gender-affirming care.

Therefore, HCPs working with adolescents should promote supportive environments that simultaneously respect an adolescent's affirmed gender identity and also allows the adolescent to openly explore gender needs, including social, medical, and physical gender-affirming interventions should they change or evolve over time.

Statement 6.3

We recommend health care professionals working with gender diverse adolescents undertake a comprehensive biopsychosocial assessment of adolescents who present with gender identity-related concerns and seek medical/surgical transition-related care, and that this be accomplished in a collaborative and supportive manner.

Given the many ways identity may unfold during adolescence, we recommend using a comprehensive biopsychosocial assessment to guide treatment decisions and optimize outcomes. This assessment should aim to understand the adolescent's strengths, vulnerabilities, diagnostic profile, and unique needs to individualize their care. As mentioned in Statement 6.1, MHPs have the most appropriate training, experience, and dedicated clinical time required to obtain the information discussed here. The assessment process should be approached collaboratively with the adolescent and their caregiver(s), both separately and together, as described in more detail in Statement 6.11. An assessment should occur prior to any medically necessary medical or surgical intervention under consideration (e.g., puberty blocking medication, gender-affirming hormones, surgeries). See medically necessary statement in Chapter 2—Global Applicability, Statement 2.1; see also Chapter 12—Hormone Therapy and Chapter 13—Surgery and Postoperative Care.

Youth may experience many different gender identity trajectories. Sociocultural definitions and experiences of gender continue to evolve over time, and youth are increasingly presenting with a range of identities and ways of describing their experiences and gender-related needs (Twist & de

Graaf, 2019). For example, some youth will realize they are transgender or more broadly gender diverse and pursue steps to present accordingly. For some youth, obtaining gender-affirming medical treatment is important while for others these steps may not be necessary. For example, a process of exploration over time might not result in the young person self-affirming or embodying a different gender in relation to their assigned sex at birth and would not involve the use of medical interventions (Arnoldussen et al., 2019).

The most robust longitudinal evidence supporting the benefits of gender-affirming medical and surgical treatments in adolescence was obtained in a clinical setting that incorporated a detailed comprehensive diagnostic assessment process over time into its delivery of care protocol (de Vries & Cohen-Kettenis, 2012; de Vries et al., 2014). Given this research and the ongoing evolution of gender diverse experiences in society, a comprehensive diagnostic biopsychosocial assessment during adolescence is both evidence-based and preserves the integrity of the decision-making process. In the absence of a full diagnostic profile, other mental health entities that need to be prioritized and treated may not be detected. There are no studies of the long-term outcomes of gender-related medical treatments for youth who have not undergone a comprehensive assessment. Treatment in this context (e.g., with limited or no assessment) has no empirical support and therefore carries the risk that the decision to start gender-affirming medical interventions may not be in the long-term best interest of the young person at that time.

As delivery of health care and access to specialists varies globally, designing a particular assessment process to adapt existing resources is often necessary. In some cases, a more extended assessment process may be useful, such as for youth with more complex presentations (e.g., complicating mental health histories (Leibowitz & de Vries, 2016)), co-occurring autism spectrum characteristics (Strang, Powers et al., 2018), and/or an absence of experienced childhood gender incongruence (Ristori & Steensma, 2016). Given the unique cultural, financial, and geographical factors that exist for specific populations, providers should design assessment models that are flexible and allow for appropriately timed care for as many young people as possible, so long as the assessment effectively obtains information about the adolescent's strengths, vulnerabilities, diagnostic profile, and individual needs. Psychometrically validated psychosocial and gender measures can also be used to provide additional information.

The multidisciplinary assessment for youth seeking gender-affirming medical/surgical interventions includes the following domains that correspond to the relevant statements:

- **Gender Identity Development:** Statements 6.12.a and 6.12.b elaborate on the factors associated with gender identity development within the specific cultural context when assessing TGD adolescents.
- **Social Development and Support; Intersectionality:** Statements 6.4 and 6.11 elaborate on the importance of assessing gender minority stress, family dynamics, and other aspects contributing to social development and intersectionality.
- **Diagnostic Assessment of Possible Co-Occurring Mental Health and/or Developmental Concerns:** Statement 6.12.d elaborates on the importance of understanding the relationship that exists, if at all, between any co-occurring mental health or developmental concerns and the young person's gender identity/gender diverse expression.
- **Capacity for Decision-Making:** Statement 6.12.c elaborates on the assessment of a young person's emotional maturity and the relevance when an adolescent is considering gender affirming-medical/surgical treatments.

Statement 6.4

We recommend health care professionals work with families, schools, and other relevant settings to promote acceptance of gender diverse expressions of behavior and identities of the adolescent.

Multiple studies and related expert consensus support the implementation of approaches that promote acceptance and affirmation of gender diverse youth across all settings, including families, schools, health care facilities, and all other organizations and communities with which they

interact (e.g., Pariseau et al., 2019; Russell et al., 2018; Simons et al., 2013; Toomey et al., 2010; Travers et al., 2012). Acceptance and affirmation are accomplished through a range of approaches, actions, and policies we recommend be enacted across the various relationships and settings in which a young person exists and functions. It is important for the family members and community members involved in the adolescent's life to work collaboratively in these efforts unless their involvement is considered harmful to the adolescent. Examples proposed by Pariseau et al. (2019) and others of acceptance and affirmation of gender diversity and contemplation and expression of identity that can be implemented by family, staff, and organizations include:

1. Actions that are supportive of youth drawn to engaging in gender-expansive (e.g., nonconforming) activities and interests;
2. Communications that are supportive when youth express their experiences about their gender and gender exploration;
3. Use of the youth's asserted name/pronouns;
4. Support for youth wearing clothing/uniforms, hairstyles, and items (e.g., jewelry, makeup) they feel affirm their gender;
5. Positive and supportive communication with youth about their gender and gender concerns;
6. Education about gender diversity issues for people in the young person's life (e.g., family members, health care providers, social support networks), as needed, including information about how to advocate for gender diverse youth in community, school, health care, and other settings;
7. Support for gender diverse youth to connect with communities of support (e.g., LGBTQ groups, events, friends);
8. Provision of opportunities to discuss, consider, and explore medical treatment options when indicated;
9. Antibullying policies that are enforced;
10. Inclusion of nonbinary experiences in daily life, reading materials, and curricula (e.g., books, health, and sex education classes, assigned essay topics that move beyond the binary, LGBTQ, and ally groups);
11. Gender inclusive facilities that the youth can readily access without segregation from nongender diverse peers (e.g., bathrooms, locker rooms).

We recommend HCPs work with parents, schools, and other organizations/groups to promote acceptance and affirmation of TGD identities and expressions, whether social or medical interventions are implemented or not as acceptance and affirmation are associated with fewer negative mental health and behavioral symptoms and more positive mental health and behavioral functioning (Day et al., 2015; de Vries et al., 2016; Greytak et al., 2013; Pariseau et al., 2019; Peng et al., 2019; Russell et al., 2018; Simons et al., 2013; Taliaferro et al., 2019; Toomey et al., 2010; Travers et al., 2012). Russell et al. (2018) found mental health improvement increases with more acceptance and affirmation across more settings (e.g., home, school, work, and friends). Rejection by family, peers, and school staff (e.g., intentionally using the name and pronoun the youth does not identify with, not acknowledging affirmed gender identity, bullying, harassment, verbal and physical abuse, poor relationships, rejection for being TGD, eviction) was strongly linked to negative outcomes, such as anxiety, depression, suicidal ideation, suicide attempts, and substance use (Grossman et al., 2005; Klein & Golub; 2016; Pariseau et al., 2019; Peng et al., 2019; Reisner, Greytak et al., 2015; Roberts et al., 2013). It is important to be aware that negative symptoms increase with increased levels of rejection and continue into adulthood (Roberts et al., 2013).

Neutral or indifferent responses to a youth's gender diversity and exploration (e.g., letting a child tell others their chosen name but not using the name, not telling family or friends when the youth wants them to disclose, not advocating for the child about rejecting behavior from school staff or peers, not engaging or participating in other support mechanisms (e.g., with psychotherapists and support groups) have also been found to have negative consequences, such as increased depressive symptoms (Pariseau et al., 2019). For these reasons, it is important not to ignore a youth's gender questioning or delay consideration of the youth's gender-related

care needs. There is particular value in professionals recognizing youth need individualized approaches, support, and consideration of needs around gender expression, identity, and embodiment over time and across domains and relationships. Youth may need help coping with the tension of tolerating others' processing/adjusting to an adolescent's identity exploration and changes (e.g., Kuper, Lindley et al., 2019). It is important professionals collaborate with parents and others as they process their concerns and feelings and educate themselves about gender diversity because such processes may not necessarily reflect rejection or neutrality but may rather represent efforts to develop attitudes and gather information that foster acceptance (e.g., Katz-Wise et al., 2017).

Statement 6.5

We recommend against offering reparative and conversion therapy aimed at trying to change a person's gender and lived gender expression to become more congruent with the sex assigned at birth.

Some health care providers, secular or religious organizations, and rejecting families may undertake efforts to thwart an adolescent's expression of gender diversity or assertion of a gender identity other than the expression and behavior that conforms to the sex assigned at birth. Such efforts at blocking reversible social expression or transition may include choosing not to use the youth's identified name and pronouns or restricting self-expression in clothing and hairstyles (Craig et al., 2017; Green et al., 2020). These disaffirming behaviors typically aim to reinforce views that a young person's gender identity/expression must match the gender associated with the sex assigned at birth or expectations based on the sex assigned at birth. Activities and approaches (sometimes referred to as "treatments") aimed at trying to change a person's gender identity and expression to become more congruent with the sex assigned at birth have been attempted, but these approaches have not resulted in changes in gender identity (Craig et al., 2017; Green et al., 2020). We recommend against such efforts because they have been found to be ineffective and are associated with increases in mental illness and poorer psychological functioning (Craig et al., 2017; Green et al., 2020; Turban, Beckwith et al., 2020).

Much of the research evaluating "conversion therapy" and "reparative therapy" has investigated the impact of efforts to change gender expression (masculinity or femininity) and has conflated sexual orientation with gender identity (APA, 2009; Burnes et al., 2016; Craig et al., 2017). Some of these efforts have targeted both gender identity and expression (AACAP, 2018). Conversion/reparative therapy has been linked to increased anxiety, depression, suicidal ideation, suicide attempts, and health care avoidance (Craig et al., 2017; Green et al., 2020; Turban, Beckwith et al., 2020). Although some of these studies have been criticized for their methodologies and conclusions (e.g., D'Angelo et al., 2020), this should not detract from the importance of emphasizing efforts undertaken a priori to change a person's identity are clinically and ethically unsound. We recommend against any type of conversion or attempts to change a person's gender identity because 1) both secular and religion-based efforts to change gender identity/expression have been associated with negative psychological functioning that endures into adulthood (Turban, Beckwith et al., 2020); and 2) larger ethical reasons exist that should underscore respect for gender diverse identities.

It is important to note potential factors driving a young person's gender-related experience and report of gender incongruence, when carried out in the context of supporting an adolescent with self-discovery, is not considered reparative therapy as long as there is no a priori goal to change or promote one particular gender identity or expression (AACAP, 2018; see Statement 6.2). To ensure these explorations are therapeutic, we recommend employing affirmative consideration and supportive tone in discussing what steps have been tried, considered, and planned for a youth's gender expression. These discussion topics may include what felt helpful or affirming, what felt unhelpful or distressing and why. We recommend employing affirmative responses to these steps and discussions, such as those identified in SOC-8 Statement 6.4.

Statement 6.6

We suggest health care professionals provide transgender and gender diverse adolescents with health education on chest binding and genital tucking, including review of the benefits and risks.

TGD youth may experience distress related to chest and genital anatomy. Practices such as chest binding, chest padding, genital tucking, and genital packing are reversible, nonmedical interventions that may help alleviate this distress (Callen-Lorde, 2020a, 2020b; Deutsch, 2016a; Olson-Kennedy, Rosenthal et al., 2018; Transcare BC, 2020). It is important to assess the degree of distress related to physical development or anatomy, educate youth about potential nonmedical interventions to address this distress, and discuss the safe use of these interventions.

Chest binding involves compression of the breast tissue to create a flatter appearance of the chest. Studies suggest that up to 87% of trans masculine patients report a history of binding (Jones, 2015; Peitzmeier, 2017). Binding methods may include the use of commercial binders, sports bras, layering of shirts, layering of sports bras, or the use of elastics or other bandages (Peitzmeier, 2017). Currently, most youth report learning about binding practices from online communities composed of peers (Julian, 2019). Providers can play an important role in ensuring youth receive accurate and reliable information about the potential benefits and risks of chest binding. Additionally, providers can counsel patients about safe binding practices and monitor for potential negative health effects. While there are potential negative physical impacts of binding, youth who bind report many benefits, including increased comfort, improved safety, and lower rates of misgendering (Julian, 2019). Common negative health impacts of chest binding in youth include back/chest pain, shortness of breath, and overheating (Julian, 2019). More serious negative health impacts such as skin infections, respiratory infections, and rib fractures are uncommon and have been associated with chest binding in adults (Peitzmeier, 2017). If binding is employed, youth should be advised to use only those methods considered safe for binding—such as binders specifically designed for the gender diverse population—to reduce the risk of serious negative health effects. Methods that are considered unsafe for binding include the use of duct tape, ace wraps, and plastic wrap as these can restrict blood flow, damage skin, and restrict breathing. If youth report negative health impacts from chest binding, these should ideally be addressed by a gender-affirming medical provider with experience working with TGD youth.

Genital tucking is the practice of positioning the penis and testes to reduce the outward appearance of a genital bulge. Methods of tucking include tucking the penis and testes between the legs or tucking the testes inside the inguinal canal and pulling the penis back between the legs. Typically, genitals are held in place by underwear or a gaff, a garment that can be made or purchased. Limited studies are available on the specific risks and benefits of tucking in adults, and none have been carried out in youth. Previous studies have reported tight undergarments are associated with decreased sperm concentration and motility. In addition, elevated scrotal temperatures can be associated with poor sperm characteristics, and genital tucking could theoretically affect spermatogenesis and fertility (Marsh, 2019) although there are no definitive studies evaluating these adverse outcomes. Further research is needed to determine the specific benefits and risks of tucking in youth.

Statement 6.7

We recommend providers consider prescribing menstrual suppression agents for adolescents experiencing gender incongruence who may not desire testosterone therapy, who desire but have not yet begun testosterone therapy, or in conjunction with testosterone therapy for breakthrough bleeding.

When discussing the available options of menstrual-suppressing medications with gender diverse youth, providers should engage in shared decision-making, use gender-inclusive language (e.g., asking patients which terms they utilize to refer to their menses, reproductive organs, and genitalia) and perform physical exams in a sensitive, gender-affirmative manner (Bonnington et al., 2020; Krempasky et al., 2020). There is no formal research evaluating how menstrual

suppression may impact gender incongruence and/or dysphoria. However, the use of menstrual suppression can be an initial intervention that allows for further exploration of gender-related goals of care, prioritization of other mental health care, or both, especially for those who experience a worsening of gender dysphoria from unwanted uterine bleeding (see Statement 6.12d; Mehringer & Dowshen, 2019). When testosterone is not used, menstrual suppression can be achieved via a progestin. To exclude any underlying menstrual disorders, it is important to obtain a detailed menstrual history and evaluation prior to implementing menstrual-suppressing therapy (Carswell & Roberts, 2017). As part of the discussion about menstrual-suppressing medications, the need for contraception and information regarding the effectiveness of menstrual-suppressing medications as methods of contraception also need to be addressed (Bonnington et al., 2020). A variety of menstrual suppression options, such as combined estrogen-progestin medications, oral progestins, depot and subdermal progestin, and intrauterine devices (IUDs), should be offered to allow for individualized treatment plans while properly considering availability, cost and insurance coverage, as well as contraindications and side effects (Kanj et al., 2019).

Progestin-only hormonal medication are options, especially in trans masculine or nonbinary youth who are not interested in estrogen-containing medical therapies as well as those at risk for thromboembolic events or who have other contraindications to estrogen therapy (Carswell & Roberts, 2017). Progestin-only hormonal medications include oral progestins, depo-medroxyprogesterone injection, etonogestrel implant, and levonorgestrel IUD (Schwartz et al., 2019). Progestin-only hormonal options vary in terms of efficacy in achieving menstrual suppression and have lower rates of achieving amenorrhea than combined oral contraception (Pradhan & Gomez-Lobo, 2019). A more detailed description of the relevant clinical studies is presented in Chapter 12—Hormone Therapy. HCPs should not make assumptions regarding the individual's preferred method of administration as some trans masculine youth may prefer vaginal rings or IUD implants (Akgul et al., 2019). Although hormonal medications require monitoring for potential mood lability, depressive effects, or both, the benefits and risks of untreated menstrual suppression in the setting of gender dysphoria should be evaluated on an individual basis. Some patients may opt for combined oral contraception that includes different combinations of ethinyl estradiol, with ranging doses, and different generations of progestins (Pradhan & Gomez-Lobo, 2019). Lower dose ethinyl estradiol components of combined oral contraceptive pills are associated with increased breakthrough uterine bleeding. Continuous combined oral contraceptives may be used to allow for continuous menstrual suppression and can be delivered as transdermal or vaginal rings.

The use of gonadotropin releasing hormone (GnRH) analogues may also result in menstrual suppression. However, it is recommended gender diverse youth meet the eligibility criteria (as outlined in Statement 6.12) before this medication is considered solely for this purpose (Carswell & Roberts, 2017; Pradhan & Gomez-Lobo, 2019). Finally, menstrual-suppression medications may be indicated as an adjunctive therapy for breakthrough uterine bleeding that may occur while on exogenous testosterone or as a bridging medication while awaiting menstrual suppression with testosterone therapy. When exogenous testosterone is employed as a gender-affirming hormone, menstrual suppression is typically achieved in the first six months of therapy (Ahmad & Leinung, 2017). However, it is vital adolescents be counseled ovulation and pregnancy can still occur in the setting of amenorrhea (Gomez et al., 2020; Kanj et al., 2019).

Statement 6.8

We recommend health care professionals maintain an ongoing relationship with the gender diverse and transgender adolescent and any relevant caregivers to support the adolescent in their decision-making throughout the duration of puberty suppression treatment, hormonal treatment, and gender-related surgery until the transition is made to adult care.

HCPs with expertise in child and adolescent development, as described in Statement 6.1, play an important role in the continuity of care for

young people over the course of their gender-related treatment needs. Supporting adolescents and their families necessitates approaching care using a developmental lens through which understanding a young person's evolving emotional maturity and care needs can take place over time. As gender-affirming treatment pathways differ based on the needs and experiences of individual TGD adolescents, decision-making for these treatments (puberty suppression, estrogens/androgens, gender-affirmation surgeries) can occur at different points in time within a span of several years. Longitudinal research demonstrating the benefits of pubertal suppression and gender-affirming hormone treatment (GAHT) was carried out in a setting where an ongoing clinical relationship between the adolescents/families and the multidisciplinary team was maintained (de Vries et al., 2014).

Clinical settings that offer longer appointment times provide space for adolescents and caregivers to share important psychosocial aspects of emotional well-being (e.g., family dynamics, school, romantic, and sexual experiences) that contextualize individualized gender-affirming treatment needs and decisions as described elsewhere in the chapter. An ongoing clinical relationship can take place across settings, whether that be within a multidisciplinary team or with providers in different locations who collaborate with one another. Given the wide variability in the ability to obtain access to specialized gender care centers, particularly for marginalized groups who experience disparities with access, it is important for the HCP to appreciate the existence of any barriers to care while maintaining flexibility when defining how an ongoing clinical relationship can take place in that specific context.

An ongoing clinical relationship that increases resilience in the youth and provides support to parents/caregivers who may have their own treatment needs may ultimately lead to increased parental acceptance—when needed—which is associated with better mental health outcomes in youth (Ryan, Huebner et al., 2009).

Statement 6.9

We recommend health care professionals involve relevant disciplines, including mental health and medical professionals, to reach a decision about whether puberty suppression, hormone initiation, or gender-related surgery for gender diverse and transgender adolescents are appropriate and remain indicated throughout the course of treatment until the transition is made to adult care.

TGD adolescents with gender dysphoria/gender incongruence who seek gender-affirming medical and surgical treatments benefit from the involvement of health care professionals (HCPs) from different disciplines. Providing care to TGD adolescents includes addressing 1) diagnostic considerations (see Statements 6.3, 6.12a, and 6.12b) conducted by a specialized gender HCP (as defined in Statement 6.1) whenever possible and necessary; and 2) treatment considerations when prescribing, managing, and monitoring medications for gender-affirming medical and surgical care, requiring the training of the relevant medical/surgical professional. The list of key disciplines includes but is not limited to adolescent medicine/primary care, endocrinology, psychology, psychiatry, speech/language pathology, social work, support staff, and the surgical team.

The evolving evidence has shown a clinical benefit for transgender youth who receive their gender-affirming treatments in multidisciplinary gender clinics (de Vries et al., 2014; Kuper et al., 2020; Tollit et al., 2019). Finally, adolescents seeking gender-affirming care in multidisciplinary clinics are presenting with significant complexity necessitating close collaboration between mental health, medical, and/or surgical professionals (McCallion et al., 2021; Sorbara et al., 2020; Tishelman et al., 2015).

As not all patients and families are in the position or in a location to access multidisciplinary care, the lack of available disciplines should not preclude a young person from accessing needed care in a timely manner. When disciplines are available, particularly in centers with existing multidisciplinary teams, disciplines, or both, it is recommended efforts be made to include the relevant providers when developing a gender care team. However, this does not mean all disciplines are necessary to provide care to a particular youth and family.

If written documentation or a letter is required to recommend gender-affirming medical and surgical treatment (GAMST) for an adolescent, only one letter of assessment from a member of the multidisciplinary team is needed. This letter needs to reflect the assessment and opinion from the team that involves both medical HCPs and MHPs (American Psychological Association, 2015; Hembree et al., 2017; Telfer et al., 2018). Further assessment results and written opinions may be requested when there is a specific clinical need or when team members are in different locations or choose to write their own summaries. For further information see Chapter 5—Assessment for Adults, Statement 5.5.

Statement 6.10

We recommend health care professionals working with transgender and gender diverse adolescents requesting gender-affirming medical or surgical treatments inform them, prior to the initiation of treatment, of the reproductive effects, including the potential loss of fertility and available options to preserve fertility within the context of the youth's stage of pubertal development.

While assessing adolescents seeking gender-affirming medical or surgical treatments, HCPs should discuss the specific ways in which the required treatment may affect reproductive capacity. Fertility issues and the specific preservation options are more thoroughly discussed in Chapter 12—Hormone Therapy and Chapter 16—Reproductive Health.

It is important HCPs understand what fertility preservation options exist so they can relay the information to adolescents. Parents are advised to be involved in this process and should also understand the pros and cons of the different options. HCPs should acknowledge adolescents and parents may have different views around reproductive capacity and may therefore come to different decisions (Quain et al., 2020), which is why HCPs can be helpful in guiding this process.

HCPs should specifically pay attention to the developmental and psychological aspects of fertility preservation and decision-making competency for the individual adolescent. While adolescents may think they have made up their minds concerning their reproductive capacity, the possibility their opinions about having biologically related children in the future might change over time needs to be discussed with an HCP who has sufficient experience, is knowledgeable about adolescent development, and has experience working with parents.

Addressing the long-term consequences on fertility of gender-affirming medical treatments and ensuring transgender adolescents have realistic expectations concerning fertility preservation options or adoption cannot not be addressed with a one-time discussion but should be part of an ongoing conversation. This conversation should occur not only before initiating any medical intervention (puberty suppression, hormones, or surgeries), but also during further treatment and during transition.

Currently, there are only preliminary results from retrospective studies evaluating transgender adults and the decisions they made when they were young regarding the consequences of medical-affirming treatment on reproductive capacity. It is important not to make assumptions about what future adult goals an adolescent may have. Research in childhood cancer survivors found participants who acknowledged missed opportunities for fertility preservation reported distress and regret surrounding potential infertility (Armuand et al., 2014; Ellis et al., 2016; Lehmann et al., 2017). Furthermore, individuals with cancer who did not prioritize having biological children before treatment have reported "changing their minds" in survivorship (Armuand et al., 2014).

Given the complexities of the different fertility preservation options and the challenges HCPs may experience discussing fertility with the adolescent and the family (Tishelman et al., 2019), a fertility consultation is an important consideration for every transgender adolescent who pursues medical-affirming treatments unless the local situation is such that a fertility consultation is not covered by insurance or public health care plans, is not available locally, or the individual circumstances make this unpreferable.

Statement 6.11

We recommend when gender-affirming medical or surgical treatments are indicated for adolescents, health care professionals working with transgender and gender diverse adolescents

involve parent(s)/guardian(s) in the assessment and treatment process, unless their involvement is determined to be harmful to the adolescent or not feasible.

When there is an indication an adolescent might benefit from a gender-affirming medical or surgical treatment, involving the parent(s) or primary caregiver(s) in the assessment process is recommended in almost all situations (Edwards-Leeper & Spack, 2012; Rafferty et al., 2018). Exceptions to this might include situations in which an adolescent is in foster care, child protective services, or both, and custody and parent involvement would be impossible, inappropriate, or harmful. Parent and family support of TGD youth is a primary predictor of youth well-being and is protective of the mental health of TGD youth (Gower, Rider, Coleman et al., 2018; Grossman et al., 2019; Lefevor et al., 2019; McConnell et al., 2015; Pariseau et al., 2019; Ryan, 2009; Ryan et al., 2010; Simons et al., 2013; Wilson et al., 2016). Therefore, including parent(s)/caregiver(s) in the assessment process to encourage and facilitate increased parental understanding and support of the adolescent may be one of the most helpful practices available.

Parent(s)/caregiver(s) may provide key information for the clinical team, such as the young person's gender and overall developmental, medical, and mental health history as well as insights into the young person's level of current support, general functioning, and well-being. Concordance or divergence of reports given by the adolescent and their parent(s)/caregiver(s) may be important information for the assessment team and can aid in designing and shaping individualized youth and family supports (De Los Reyes et al., 2019; Katz-Wise et al., 2017). Knowledge of the family context, including resilience factors and challenges, can help providers know where special supports would be needed during the medical treatment process. Engagement of parent(s)/caregiver(s) is also important for educating families about various treatment approaches, ongoing follow-up and care needs, and potential treatment complications. Through psychoeducation regarding clinical gender care options and participation in the assessment process, which may unfold over time, parent(s)/caregiver(s) may better understand their adolescent child's gender-related experience and needs (Andrzejewski et al., 2020; Katz-Wise et al., 2017).

Parent/caregiver concerns or questions regarding the stability of gender-related needs over time and implications of various gender-affirming interventions are common and should not be dismissed. It is appropriate for parent(s)/caregiver(s) to ask these questions, and there are cases in which the parent(s)/caregiver(s)' questions or concerns are particularly helpful in informing treatment decisions and plans. For example, a parent/caregiver report may provide critical context in situations in which a young person experiences very recent or sudden self-awareness of gender diversity and a corresponding gender treatment request, or when there is concern for possible excessive peer and social media influence on a young person's current self-gender concept. Contextualization of the parent/caregiver report is also critical, as the report of a young person's gender history as provided by parent(s)/caregiver(s) may or may not align with the young person's self-report. Importantly, gender histories may be unknown to parent(s)/caregiver(s) because gender may be internal experience for youth, not known by others unless it is discussed. For this reason, an adolescent's report of their gender history and experience is central to the assessment process.

Some parents may present with unsupportive or antagonistic beliefs about TGD identities, clinical gender care, or both (Clark et al., 2020). Such unsupportive perspectives are an important therapeutic target for families. Although challenging parent perspectives may in some cases seem rigid, providers should not assume this is the case. There are many examples of parent(s)/caregiver(s) who, over time with support and psychoeducation, have become increasingly accepting of their TGD child's gender diversity and care needs.

Helping youth and parent(s)/caregiver(s) work together on important gender care decisions is a primary goal. However, in some cases, parent(s)/caregiver(s) may be too rejecting of their adolescent child and their child's gender needs to be part of the clinical evaluation process. In these situations, youth may require the engagement of larger systems of advocacy and support to move

forward with the necessary support and care (Dubin et al., 2020).

Statement 6.12

We recommend health care professionals assessing transgender and gender diverse adolescents only recommend gender-affirming medical or surgical treatments requested by the patient when:

Statement 6.12.a

The adolescent meets the diagnostic criteria of gender incongruence as per the ICD-11 in situations where a diagnosis is necessary to access health care. In countries that have not implemented the latest ICD, other taxonomies may be used although efforts should be undertaken to utilize the latest ICD as soon as practicable.

When working with TGD adolescents, HCPs should realize while a classification may give access to care, pathologizing transgender identities may be experienced as stigmatizing (Beek et al., 2016). Assessments related to gender health and gender diversity have been criticized, and controversies exist around diagnostic systems (Drescher, 2016).

HCPs should assess the overall gender-related history and gender care-related needs of youth. Through this assessment process, HCPs may provide a diagnosis when it is required to get access to transgender-related care.

Gender incongruence and gender dysphoria are the two diagnostic terms used in the World Health Organization's International Classification of Diseases (ICD) and the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM), respectively. Of these two widely used classification systems, the DSM is for psychiatric classifications only and the ICD contains all diseases and conditions related to physical as well as mental health. The most recent versions of these two systems, the DSM-5 and the ICD-11, reflect a long history of reconceptualizing and de-psychopathologizing gender-related diagnoses (American Psychiatric Association, 2013; World Health Organization, 2019a). Compared with the earlier version, the DSM-5 replaced gender identity disorder with gender dysphoria, acknowledging the distress experienced by some people stemming from the incongruence between experienced gender identity and the sex assigned at birth. In the most recent revision, the DSM-5-TR, no changes in the diagnostic criteria for gender dysphoria are made. However, terminology was adapted into the most appropriate current language (e.g., birth-assigned gender instead of natal-gender and gender-affirming treatment instead of gender reassignment (American Psychiatric Association, 2022). Compared with the ICD 10th edition, the gender incongruence classification was moved from the Mental Health chapter to the Conditions Related to Sexual Health chapter in the ICD-11. When compared with the DSM-5 classification of gender dysphoria, one important reconceptualization is distress is not a required indicator of the ICD-11 classification of gender incongruence (WHO, 2019a). After all, when growing up in a supporting and accepting environment, the distress and impairment criterion, an inherent part of every mental health condition, may not be applicable (Drescher, 2012). As such, the ICD-11 classification of gender incongruence may better capture the fullness of gender diversity experiences and related clinical gender needs.

Criteria for the ICD-11 classification gender incongruence of adolescence or adulthood require a marked and persistent incongruence between an individual´s experienced gender and the assigned sex, which often leads to a need to "transition" to live and be accepted as a person of the experienced gender. For some, this includes hormonal treatment, surgery, or other health care services to enable the individual´s body to align as much as required, and to the extent possible, with the person's experienced gender. Relevant for adolescents is the indicator that a classification cannot be assigned "prior to the onset of puberty." Finally, it is noted "that gender variant behaviour and preferences alone are not a basis for assigning the classification" (WHO, ICD-11, 2019a).

Criteria for the DSM-5 and DSM-5-TR classification of gender dysphoria in adolescence and adulthood denote "a marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration' (criterion A, fulfilled when 2 of 6 subcriteria are manifest; DSM-5, APA, 2013; DSM 5-TR, APA, 2022).

Of note, although a gender-related classification is one of the requirements for receiving medical gender-affirming care, such a classification alone does not indicate a person needs medical-affirming care. The range of youth experiences of gender incongruence necessitates professionals provide a range of treatments or interventions based on the individual's needs. Counseling, gender exploration, mental health assessment and, when needed, treatment with MHPs trained in gender development may all be indicated with or without the implementation of medical-affirming care.

Statement 6.12.b

The experience of gender diversity/incongruence is marked and sustained over time.

Identity exploration and consolidation are experienced by many adolescents (Klimstra et al., 2010; Topolewska-Siedzik & Cieciuch, 2018). Identity exploration during adolescence may include a process of self-discovery around gender and gender identity (Steensma, Kreukels et al., 2013). Little is known about how processes that underlie consolidation of gender identity during adolescence (e.g., the process of commitment to specific identities) may impact a young person's experience(s) or needs over time.

Therefore, the level of reversibility of a gender-affirming medical intervention should be considered along with the sustained duration of a young person's experience of gender incongruence when initiating treatment. Given potential shifts in gender-related experiences and needs during adolescence, it is important to establish the young person has experienced several years of persistent gender diversity/incongruence prior to initiating less reversible treatments such as gender-affirming hormones or surgeries. Puberty suppression treatment, which provides more time for younger adolescents to engage their decision-making capacities, also raises important considerations (see Statement 6.12f and Chapter 12—Hormone Therapy) suggesting the importance of a sustained experience of gender incongruence/diversity prior to initiation. However, in this age group of younger adolescents, several years is not always practical nor necessary given the premise of the treatment as a means to buy time while avoiding distress from irreversible pubertal changes. For youth who have experienced a shorter duration of gender incongruence, social transition-related and/or other medical supports (e.g., menstrual suppression/androgen blocking) may also provide some relief as well as furnishing additional information to the clinical team regarding a young person's broad gender care needs (see Statements 6.4, 6.6, and 6.7).

Establishing evidence of persistent gender diversity/incongruence typically requires careful assessment with the young person over time (see Statement 6.3). Whenever possible and when appropriate, the assessment and discernment process should also include the parent(s)/caregiver(s) (see Statement 6.11). Evidence demonstrating gender diversity/incongruence sustained over time can be provided via history obtained directly from the adolescent and parents/caregivers when this information is not documented in the medical records.

The research literature on continuity versus discontinuity of gender-affirming medical care needs/requests is complex and somewhat difficult to interpret. A series of studies conducted over the last several decades, including some with methodological challenges (as noted by Temple Newhook et al., 2018; Winters et al., 2018) suggest the experience of gender incongruence is not consistent for all children as they progress into adolescence. For example, a subset of youth who experienced gender incongruence or who socially transitioned prior to puberty over time can show a reduction in or even full discontinuation of gender incongruence (de Vries et al., 2010; Olson et al., 2022; Ristori & Steensma, 2016; Singh et al., 2021; Wagner et al., 2021). However, there has been less research focused on rates of continuity and discontinuity of gender incongruence and gender-related needs in pubertal and adolescent populations. The data available regarding broad unselected gender-referred pubertal/adolescent cohorts (from the Amsterdam transgender clinic) suggest that, following extended assessments over time, a subset of adolescents with gender incongruence presenting for gender care elect not to pursue gender-affirming medical care

(Arnoldussen et al., 2019; de Vries, Steensma et al., 2011). Importantly, findings from studies of gender incongruent pubertal/adolescent cohorts, in which participants who have undergone comprehensive gender evaluation over time, have shown persistent gender incongruence and gender-related need and have received referrals for medical gender care, suggest low levels of regret regarding gender-related medical care decisions (de Vries et al., 2014; Wiepjes et al., 2018). Critically, these findings of low regret can only currently be applied to youth who have demonstrated sustained gender incongruence and gender-related needs over time as established through a comprehensive and iterative assessment (see Statement 6.3).

Statement 6.12.c

The adolescent demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment.

The process of informed consent includes communication between a patient and their provider regarding the patient's understanding of a potential intervention as well as, ultimately, the patient's decision whether to receive the intervention. In most settings, for minors, the legal guardian is integral to the informed consent process: if a treatment is to be given, the legal guardian (often the parent[s]/caregiver[s]) provides the informed consent to do so. In most settings, assent is a somewhat parallel process in which the minor and the provider communicate about the intervention and the provider assesses the level of understanding and intention.

A necessary step in the informed consent/assent process for considering gender-affirming medical care is a careful discussion with qualified HCPs trained to assess the emotional and cognitive maturity of adolescents. The reversible and irreversible effects of the treatment, as well as fertility preservation options (when applicable), and all potential risks and benefits of the intervention are important components of the discussion. These discussions are required when obtaining informed consent/assent. Assessment of cognitive and emotional maturity is important because it helps the care team understand the adolescent's capacity to be informed.

The skills necessary to assent/consent to any medical intervention or treatment include the ability to 1) comprehend the nature of the treatment; 2) reason about treatment options, including the risks and benefits; 3) appreciate the nature of the decision, including the long-term consequences; and 4) communicate choice (Grootens-Wiegers et al., 2017). In the case of gender- affirming medical treatments, a young person should be well-informed about what the treatment may and may not accomplish, typical timelines for changes to appear (e.g., with gender-affirming hormones), and any implications of stopping the treatment. Gender-diverse youth should fully understand the reversible, partially reversible, and irreversible aspects of a treatment, as well as the limits of what is known about certain treatments (e.g., the impact of pubertal suppression on brain development (Chen and Loshak, 2020)). Gender-diverse youth should also understand, although many gender-diverse youth begin gender- affirming medical care and experience that care as a good fit for them long-term, there is a subset of individuals who over time discover this care is not a fit for them (Wiepjes et al., 2018). Youth should know such shifts are sometimes connected to a change in gender needs over time, and in some cases, a shift in gender identity itself. Given this information, gender diverse youth must be able to reason thoughtfully about treatment options, considering the implications of the choices at hand. Furthermore, as a foundation for providing assent, the gender-diverse young person needs to be able to communicate their choice.

The skills needed to accomplish the tasks required for assent/consent may not emerge at specific ages per se (Grootens-Wiegers et al., 2017). There may be variability in these capacities related to developmental differences and mental health presentations (Shumer & Tishelman, 2015) and dependent on the opportunities a young person has had to practice these skills (Alderson, 2007). Further, assessment of emotional and cognitive maturity must be conducted separately for each gender-related treatment decision (Vrouenraets et al., 2021).

The following questions may be useful to consider in assessing a young person's emotional and

cognitive readiness to assent or consent to a specific gender-affirming treatment:

- Can the young person think carefully into the future and consider the implications of a partially or fully irreversible intervention?
- Does the young person have sufficient self-reflective capacity to consider the possibility that gender-related needs and priorities can develop over time, and gender-related priorities at a certain point in time might change?
- Has the young person, to some extent, thought through the implications of what they might do if their priorities around gender do change in the future?
- Is the young person able to understand and manage the day-to-day short- and long-term aspects of a specific medical treatment (e.g., medication adherence, administration, and necessary medical follow-ups)?

Assessment of emotional and cognitive maturity may be accomplished over time as the care team continues to engage in conversations about the treatment options and affords the young person the opportunity to practice thinking into the future and flexibly consider options and implications. For youth with neurodevelopmental and/or some types of mental health differences, skills for future thinking, planning, big picture thinking, and self-reflection may be less-well developed (Dubbelink & Geurts, 2017). In these cases, a more careful approach to consent and assent may be required, and this may include additional time and structured opportunities for the young person to practice the skills necessary for medical decision-making (Strang, Powers et al., 2018).

For unique situations in which an adolescent minor is consenting for their own treatment without parental permission (see Statement 6.11), extra care must be taken to support the adolescent's informed decision-making. This will typically require greater levels of engagement of and collaboration between the HCPs working with the adolescent to provide the young person appropriate cognitive and emotional support to consider options, weigh benefits and potential challenges/costs, and develop a plan for any needed (and potentially ongoing) supports associated with the treatment.

Statement 6.12.d

The adolescent's mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and/or gender-affirming medical treatments have been addressed.

Evidence indicates TGD adolescents are at increased risk of mental health challenges, often related to family/caregiver rejection, non-affirming community environments, and neurodiversity-related factors (e.g., de Vries et al., 2016; Pariseau et al., 2019; Ryan et al., 2010; Weinhardt et al., 2017). A young person's mental health challenges may impact their conceptualization of their gender development history and gender identity-related needs, the adolescent's capacity to consent, and the ability of the young person to engage in or receive medical treatment. Additionally, like cisgender youth, TGD youth may experience mental health concerns irrespective of the presence of gender dysphoria or gender incongruence. In particular, depression and self-harm may be of specific concern; many studies reveal depression scores and emotional and behavioral problems comparable to those reported in populations referred to mental health clinics (Leibowitz & de Vries, 2016). Higher rates of suicidal ideation, suicide attempts, and self-harm have also been reported (de Graaf et al., 2020). In addition, eating disorders occur more frequently than expected in non-referred populations (Khatchadourian et al., 2013; Ristori et al., 2019; Spack et al., 2012). Importantly, TGD adolescents show high rates of autism spectrum disorder/characteristics (Øien et al., 2018; van der Miesen et al., 2016; see also Statement 6.1d). Other neurodevelopmental presentations and/or mental health challenges may also be present, (e.g., ADHD, intellectual disability, and psychotic disorders (de Vries, Doreleijers et al., 2011; Meijer et al., 2018; Parkes & Hall, 2006).

Of note, many transgender adolescents are well-functioning and experience few if any mental health concerns. For example, socially transitioned pubertal adolescents who receive medical

gender- affirming treatment at specialized gender clinics may experience mental health outcomes equivalent to those of their cisgender peers (e.g., de Vries et al., 2014; van der Miesen et al., 2020). A provider's key task is to assess the direction of the relationships that exist between any mental health challenges and the young person's self-understanding of gender care needs and then prioritize accordingly.

Mental health difficulties may challenge the assessment and treatment of gender-related needs of TGD adolescents in various ways:

1. First, when a TGD adolescent is experiencing acute suicidality, self-harm, eating disorders, or other mental health crises that threaten physical health, safety must be prioritized. According to the local context and existing guidelines, appropriate care should seek to mitigate the threat or crisis so there is sufficient time and stabilization for thoughtful gender-related assessment and decision-making. For example, an actively suicidal adolescent may not be emotionally able to make an informed decision regarding gender-affirming medical/surgical treatment. If indicated, safety-related interventions should not preclude starting gender-affirming care.
2. Second, mental health can also complicate the assessment of gender development and gender identity-related needs. For example, it is critical to differentiate gender incongruence from specific mental health presentations, such as obsessions and compulsions, special interests in autism, rigid thinking, broader identity problems, parent/child interaction difficulties, severe developmental anxieties (e.g., fear of growing up and pubertal changes unrelated to gender identity), trauma, or psychotic thoughts. Mental health challenges that interfere with the clarity of identity development and gender-related decision-making should be prioritized and addressed.
3. Third, decision-making regarding gender-affirming medical treatments that have life-long consequences requires thoughtful, future-oriented thinking by the adolescent, with support from the parents/caregivers, as indicated (see Statement 6.11). To be able to make such an informed decision, an adolescent should be able to understand the issues, express a choice, appreciate and give careful thought regarding the wish for medical-affirming treatment (see Statement 6.12c). Neurodevelopmental differences, such as autistic features or autism spectrum disorder (see Statement 6.1d, e.g., communication differences; a preference for concrete or rigid thinking; differences in self-awareness, future thinking and planning), may challenge the assessment and decision-making process; neurodivergent youth may require extra support, structure, psychoeducation, and time built into the assessment process (Strang, Powers et al., 2018). Other mental health presentations that involve reduced communication and self-advocacy, difficulty engaging in assessment, memory and concentration difficulties, hopelessness, and difficulty engaging in future-oriented thinking may complicate assessment and decision-making. In such cases, extended time is often necessary before any decisions regarding medical-affirming treatment can be made.
4. Finally, while addressing mental health concerns is important during the course of medical treatment, it does not mean all mental health challenges can or should be resolved completely. However, it is important any mental health concerns are addressed sufficiently so that gender -affirming medical treatment can be provided optimally (e.g., medication adherence, attending follow-up medical appointments, and self-care, particularly during a postoperative course).

Statement 6.12.e

The adolescent has been informed of the reproductive effects, including the potential loss of fertility, and available options to preserve fertility, and these have been discussed in the context of the adolescent's stage of pubertal development.

For guidelines regarding the clinical approach, the scientific background, and the rationale, see Chapter 12—Hormone Therapy and Chapter 16—Reproductive Health.

Statement 6.12.f

The adolescent has reached Tanner stage 2 of puberty for pubertal suppression to be initiated.

The onset of puberty is a pivotal point for many gender diverse youth. For some, it creates an intensification of their gender incongruence, and for others, pubertal onset may lead to gender fluidity (e.g., a transition from binary to nonbinary gender identity) or even attenuation of a previously affirmed gender identity (Drummond et al., 2008; Steensma et al., 2011, Steensma, Kreukels et al., 2013; Wallien & Cohen-Kettenis, 2008). The use of puberty-blocking medications, such as GnRH analogues, is not recommended until children have achieved a minimum of Tanner stage 2 of puberty because the experience of physical puberty may be critical for further gender identity development for some TGD adolescents (Steensma et al., 2011). Therefore, puberty blockers should not be implemented in prepubertal gender diverse youth (Waal & Cohen-Kettenis, 2006). For some youth, GnRH agonists may be appropriate in late stages or in the post-pubertal period (e.g., Tanner stage 4 or 5), and this should be highly individualized. See Chapter 12—Hormone Therapy for a more comprehensive review of the use of GnRH agonists.

Variations in the timing of pubertal onset is due to multiple factors (e.g., sex assigned at birth, genetics, nutrition, etc.). Tanner staging refers to five stages of pubertal development ranging from prepubertal (Tanner stage 1) to post-pubertal, and adult sexual maturity (Tanner stage 5) (Marshall & Tanner, 1969, 1970). For assigned females at birth, pubertal onset (e.g., gonadarche) is defined by the occurrence of breast budding (Tanner stage 2), and for birth-assigned males, the achievement of a testicular volume of greater than or equal to 4 mL (Roberts & Kaiser, 2020). An experienced medical provider should be relied on to differentiate the onset of puberty from physical changes such as pubic hair and apocrine body odor due to sex steroids produced by the adrenal gland (e.g., adrenarche) as adrenarche does not warrant the use of puberty-blocking medications (Roberts & Kaiser, 2020). Educating parents and families about the difference between adrenarche and gonadarche helps families understand the timing during which shared decision-making about gender-affirming medical therapies should be undertaken with their multidisciplinary team.

The importance of addressing other risks and benefits of pubertal suppression, both hypothetical and actual, cannot be overstated. Evidence supports the existence of surgical implications for transgender girls who proceed with pubertal suppression (van de Grift et al., 2020). Longitudinal data exists to demonstrate improvement in romantic and sexual satisfaction for adolescents receiving puberty suppression, hormone treatment and surgery (Bungener et al., 2020). A study on surgical outcomes of laparoscopic intestinal vaginoplasty (performed because of limited genital tissue after the use of puberty blockers) in transgender women revealed that the majority experienced orgasm after surgery (84%), although a specific correlation between sexual pleasure outcomes and the timing of pubertal suppression initiation was not discussed in the study (Bouman, van der Sluis et al., 2016), nor does the study apply to those who would prefer a different surgical procedure. This underscores the importance of engaging in discussions with families about the future unknowns related to surgical and sexual health outcomes.

Statement 6.12.g

The adolescent had at least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.

GAHT leads to anatomical, physiological, and psychological changes. The onset of the anatomic effects (e.g., clitoral growth, breast growth, vaginal mucosal atrophy) may begin early after the initiation of therapy, and the peak effect is expected at 1–2 years (T'Sjoen et al., 2019). To

ensure sufficient time for psychological adaptations to the physical change during an important developmental time for the adolescent, 12 months of hormone treatment is suggested. Depending upon the surgical result required, a period of hormone treatment may need to be longer (e.g., sufficient clitoral virilization prior to metoidioplasty/phalloplasty, breast growth and skin expansion prior to breast augmentation, softening of skin and changes in facial fat distribution prior to facial GAS) (de Blok et al., 2021).

For individuals who are not taking hormones prior to surgical interventions, it is important surgeons review the impact of hormone therapy on the proposed surgery. In addition, for individuals undergoing gonadectomy who are not taking hormones, a plan for hormone replacement can be developed with their prescribing professional prior to surgery.

Consideration of ages for gender-affirming medical and surgical treatment for adolescents

Age has a strong, albeit imperfect, correlation with cognitive and psychosocial development and may be a useful objective marker for determining the potential timing of interventions (Ferguson et al., 2021). Higher (i.e., more advanced) ages may be required for treatments with greater irreversibility, complexity, or both. This approach allows for continued cognitive/emotional maturation that may be required for the adolescent to fully consider and consent to increasingly complex treatments (see Statement 6.12c).

A growing body of evidence indicates providing gender-affirming treatment for gender diverse youth who meet criteria leads to positive outcomes (Achille et al., 2020; de Vries et al., 2014; Kuper et al., 2020). There is, however, limited data on the optimal timing of gender-affirming interventions as well as the long-term physical, psychological, and neurodevelopmental outcomes in youth (Chen et al., 2020; Chew et al., 2018; Olson-Kennedy et al., 2016). Currently, the only existing longitudinal studies evaluating gender diverse youth and adult outcomes are based on a specific model (i.e., the Dutch approach) that involved a comprehensive initial assessment with follow-up. In this approach, pubertal suppression was considered at age 12, GAHT at age 16, and surgical interventions after age 18 with exceptions in some cases. It is not clear if deviations from this approach would lead to the same or different outcomes. Longitudinal studies are currently underway to better define outcomes as well as the safety and efficacy of gender-affirming treatments in youth (Olson-Kennedy, Garofalo et al., 2019; Olson-Kennedy, Rosenthal et al., 2019). While the long-term effects of gender-affirming treatments initiated in adolescence are not fully known, the potential negative health consequences of delaying treatment should also be considered (de Vries et al., 2021). As the evidence base regarding outcomes of gender-affirming interventions in youth continues to grow, recommendations on the timing and readiness for these interventions may be updated.

Previous guidelines regarding gender-affirming treatment of adolescents recommended partially reversible GAHT could be initiated at approximately 16 years of age (Coleman et al., 2012; Hembree et al., 2009). More recent guidelines suggest there may be compelling reasons to initiate GAHT prior to the age of 16, although there are limited studies on youth who have initiated hormones prior to 14 years of age (Hembree et al., 2017). A compelling reason for earlier initiation of GAHT, for example, might be to avoid prolonged pubertal suppression, given potential bone health concerns and the psychosocial implications of delaying puberty as described in more detail in Chapter 12—Hormone Therapy (Klink, Caris et al., 2015; Schagen et al., 2020; Vlot et al., 2017; Zhu & Chan, 2017). Puberty is a time of significant brain and cognitive development. The potential neurodevelopmental impact of extended pubertal suppression in gender diverse youth has been specifically identified as an area in need of continued study (Chen et al., 2020). While GnRH analogs have been shown to be safe when used for the treatment of precocious puberty, there are concerns delaying exposure to sex hormones (endogenous or exogenous) at a time of peak bone mineralization may lead to decreased bone mineral density. The potential decrease in bone mineral density as well as the clinical significance of any decrease requires continued study (Klink, Caris et al., 2015; Lee, Finlayson et al.,

2020; Schagen et al., 2020). The potential negative psychosocial implications of not initiating puberty with peers may place additional stress on gender diverse youth, although this has not been explicitly studied. When considering the timing of initiation of gender-affirming hormones, providers should compare the potential physical and psychological benefits and risks of starting treatment with the potential risks and benefits of delaying treatment. This process can also help identify compelling factors that may warrant an individualized approach.

Studies carried out with trans masculine youth have demonstrated chest dysphoria is associated with higher rates of anxiety, depression, and distress and can lead to functional limitations, such as avoiding exercising or bathing (Mehringer et al., 2021; Olson-Kennedy, Warus et al., 2018; Sood et al., 2021). Testosterone unfortunately does little to alleviate this distress, although chest masculinization is an option for some individuals to address this distress long-term. Studies with youth who sought chest masculinization surgery to alleviate chest dysphoria demonstrated good surgical outcomes, satisfaction with results, and minimal regret during the study monitoring period (Marinkovic & Newfield, 2017; Olson-Kennedy, Warus et al., 2018). Chest masculinization surgery can be considered in minors when clinically and developmentally appropriate as determined by a multidisciplinary team experienced in adolescent and gender development (see relevant statements in this chapter). The duration or current use of testosterone therapy should not preclude surgery if otherwise indicated. The needs of some TGD youth may be met by chest masculinization surgery alone. Breast augmentation may be needed by trans feminine youth, although there is less data about this procedure in youth, possibly due to fewer individuals requesting this procedure (Boskey et al., 2019; James, 2016). GAHT, specifically estrogen, can help with development of breast tissue, and it is recommended youth have a minimum of 12 months of hormone therapy, or longer as is surgically indicated, prior to breast augmentation unless hormone therapy is not clinically indicated or is medically contraindicated.

Data are limited on the optimal timing for initiating other gender-affirming surgical treatments in adolescents. This is partly due to the limited access to these treatments, which varies in different geographical locations (Mahfouda et al., 2019). Data indicate rates of gender-affirming surgeries have increased since 2000, and there has been an increase in the number of TGD youth seeking vaginoplasty (Mahfouda et al., 2019; Milrod & Karasic, 2017). A 2017 study of 20 WPATH-affiliated surgeons in the US reported slightly more than half had performed vaginoplasty in minors (Milrod & Karasic, 2017). Limited data are available on the outcomes for youth undergoing vaginoplasty. Small studies have reported improved psychosocial functioning and decreased gender dysphoria in adolescents who have undergone vaginoplasty (Becker et al., 2018; Cohen-Kettenis & van Goozen, 1997; Smith et al.,2001). While the sample sizes are small, these studies suggest there may be a benefit for some adolescents to having these procedures performed before the age of 18. Factors that may support pursuing these procedures for youth under 18 years of age include the increased availability of support from family members, greater ease of managing postoperative care prior to transitioning to tasks of early adulthood (e.g., entering university or the workforce), and safety concerns in public spaces (i.e., to reduce transphobic violence) (Boskey et al., 2018; Boskey et al., 2019; Mahfouda et al., 2019). Given the complexity and irreversibility of these procedures, an assessment of the adolescent's ability to adhere to postsurgical care recommendations and to comprehend the long-term impacts of these procedures on reproductive and sexual function is crucial (Boskey et al., 2019). Given the complexity of phalloplasty, and current high rates of complications in comparison to other gender-affirming surgical treatments, it is not recommended this surgery be considered in youth under 18 at this time (see Chapter 13—Surgery and Postoperative Care).

Additional key factors that should be taken into consideration when discussing the timing of interventions with youth and families are addressed in detail in statements 6.12a-f. For a summary of the criteria/recommendations for medically necessary gender-affirming medical treatment in adolescents, see Appendix D.

CHAPTER 7 Children

These Standards of Care pertain to prepubescent gender diverse children and are based on research, ethical principles, and accumulated expert knowledge. The principles underlying these standards include the following 1) childhood gender diversity is an expected aspect of general human development (Endocrine Society and Pediatric Endocrine Society, 2020; Telfer et al., 2018); 2) childhood gender diversity is not a pathology or mental health disorder (Endocrine Society and Pediatric Endocrine Society, 2020; Oliphant et al., 2018; Telfer et al., 2018); 3) diverse gender expressions in children cannot always be assumed to reflect a transgender identity or gender incongruence (Ehrensaft, 2016; Ehrensaft, 2018; Rael et al., 2019); 4) guidance from mental health professionals (MHPs) with expertise in gender care for children can be helpful in supporting positive adaptation as well as discernment of gender-related needs over time (APA, 2015; Ehrensaft, 2018; Telfer et al., 2018); 5) conversion therapies for gender diversity in children (i.e., any "therapeutic" attempts to compel a gender diverse child through words, actions, or both to identify with, or behave in accordance with, the gender associated with the sex assigned at birth are harmful and we repudiate their use (APA, 2021; Ashley, 2019b, Paré, 2020; SAMHSA, 2015; Telfer et al., 2018; UN Human Rights Council, 2020).

Throughout the text, the term "health care professional" (HCP) is used broadly to refer to professionals working with gender diverse children. Unlike pubescent youth and adults, prepubescent gender diverse children are not eligible to access medical intervention (Pediatric Endocrine Society, 2020); therefore, when professional input is sought, it is most likely to be from an HCP specialized in psychosocial supports and gender development. Thus, this chapter is uniquely focused on developmentally appropriate psychosocial practices, although other HCPs, such as pediatricians and family practice HCPs may also find these standards useful as they engage in professional work with gender diverse children and their families.

This chapter employs the term "gender diverse" given that gender trajectories in prepubescent children cannot be predicted and may evolve over time (Steensma, Kreukels et al., 2013). At the same time, this chapter recognizes some children will remain stable in a gender identity they articulate early in life that is discrepant from the sex assigned at birth (Olson et al., 2022). The term, "gender diverse" includes transgender binary and nonbinary children, as well as gender diverse children who will ultimately not identify as transgender later in life. Terminology is inherently culturally bound and evolves over time. Thus, it is possible terms used here may become outdated and we will find better descriptors.

This chapter describes aspects of medical necessary care intended to promote the well-being and gender-related needs of children (see medically necessary statement in the Global Applicability chapter, Statement 2.1). This chapter advocates everyone employs these standards, to the extent possible. There may be situations or locations in which the recommended resources are not fully available. HCPs/teams lacking resources need to work toward meeting these standards. However, if unavoidable limitations preclude components of these recommendations, this should not hinder providing the best services currently available. In those locations where some but not all recommended services exist, choosing not to implement potentially beneficial care services risks harm to a child (Murchison et al., 2016; Telfer et al., 2018; Riggs et al., 2020). Overall, it is imperative to prioritize a child's best interests.

A vast empirical psychological literature indicates early childhood experiences frequently set the stage for lifelong patterns of risk and/or resilience and contribute to a trajectory of development more or less conducive to well-being and a positive quality of life (Anda et al., 2010; Masten & Cicchetti, 2010; Shonkoff & Garner, 2012). The available research indicates, in general, gender diverse youth are at greater risk for experiencing psychological difficulties (Ristori & Steensma, 2016) than age- matched cisgender peers as a result of encountering destructive experiences, including trauma and maltreatment stemming from gender diversity-related rejection and other harsh, non-accepting interactions (Barrow & Apostle, 2018; Giovanardi et al., 2018; Gower, Rider, Brown et al., 2018; Grossman & D'Augelli, 2006; Hendricks & Testa, 2012; Reisner, Greytak

et al., 2015; Roberts et al., 2014; Tishelman & Neumann-Mascis, 2018). Further, literature indicates prepubescent children who are well accepted in their gender diverse identities are generally well-adjusted (Malpas et al., 2018; Olson et al., 2016). Assessment and treatment of children typically emphasizes an *ecological* approach, recognizing children need to be safe and nurtured in each setting they frequent (Belsky, 1993; Bronfenbrenner, 1979; Kaufman & Tishelman, 2018; Lynch & Cicchetti, 1998; Tishelman et al., 2010; Zielinski & Bradshaw, 2006). Thus, the perspective of this chapter draws on basic psychological literature and knowledge of the unique risks to gender diverse children and emphasizes the integration of an ecological approach to understanding their needs and to facilitating positive mental health in all gender care. This perspective prioritizes fostering well-being and quality of life for a child throughout their development. Additionally, this chapter also embraces the viewpoint, supported by the substantial psychological research cited above, that psychosocial gender-affirming care (Hidalgo et al., 2013) for prepubescent children offers a window of opportunity to promote a trajectory of well-being that will sustain them over time and during the transition to adolescence. This approach potentially can mitigate some of the common mental health risks faced by transgender and gender diverse (TGD) teens, as frequently described in literature (Chen et al., 2021; Edwards-Leeper et al., 2017; Haas et al., 2011; Leibowitz & de Vries, 2016; Reisner, Bradford et al., 2015; Reisner, Greytak et al., 2015).

Developmental research has focused on understanding various aspects of gender development in the earliest years of childhood based on a general population of prepubescent children. This research has typically relied on the assumption that child research participants are cisgender (Olezeski et al., 2020) and has reported gender identity stability is established in the preschool years for the general population of children, most of whom are likely not gender diverse (Kohlberg, 1966; Steensma, Kreukels et al., 2013). Recently, developmental research has demonstrated gender diversity can be observed and identified in young prepubescent children (Fast & Olson, 2018; Olson & Gülgöz, 2018; Robles et al., 2016). Nonetheless, empirical study in this area is limited, and at this time there are no psychometrically sound assessment measures capable of reliably and/or fully ascertaining a prepubescent child's self-understanding of their own gender and/or gender-related needs and preferences (Bloom et al., 2021). Therefore, this chapter emphasizes the importance of a nuanced and individualized clinical approach to gender assessment, consistent with the recommendations from various guidelines and literature (Berg & Edwards-Leeper, 2018; de Vries & Cohen-Kettenis, 2012; Ehrensaft, 2018; Steensma & Wensing-Kruger, 2019). Research and clinical experience have indicated gender diversity in prepubescent children may, for some, be fluid; there are no reliable means of predicting an individual child's gender evolution (Edwards-Leeper et al., 2016; Ehrensaft, 2018; Steensma, Kreukels et al., 2013), and the gender-related needs for a particular child may vary over the course of their childhood.

It is important to understand the meaning of the term "assessment" (sometimes used synonymously with the term "evaluation"). There are multiple contexts for assessment (Krishnamurthy et al., 2004) including rapid assessments that take place during an immediate crisis (e.g., safety assessment when a child may be suicidal) and focused assessments when a family may have a circumscribed question, often in the context of a relatively brief consultation (Berg & Edwards-Leeper, 2018). The term assessment is also often used in reference to "diagnostic assessment," which can also be called an "intake" and is for the purpose of determining whether there is an issue that is diagnosable and/or could benefit from a therapeutic process. This chapter focus on comprehensive assessments, useful for understanding a child and family's needs and goals (APA, 2015; de Vries & Cohen-Kettenis, 2012; Srinath et al., 2019; Steensma & Wensing-Kruger, 2019). This type of psychosocial assessment is not necessary for all gender diverse children, but may be requested for a number of reasons. Assessments may present a useful opportunity to start a process of support for a gender diverse child and their family, with the understanding that gender diverse children benefit when their family dynamics include

Statements of Recommendations

7.1- We recommend health care professionals working with gender diverse children receive training and have expertise in gender development and gender diversity in children and possess a general knowledge of gender diversity across the life span.
7.2- We recommend health care professionals working with gender diverse children receive theoretical and evidenced-based training and develop expertise in general child and family mental health across the developmental spectrum.
7.3- We recommend health care professionals working with gender diverse children receive training and develop expertise in autism spectrum disorders and other neurodiversity or collaborate with an expert with relevant expertise when working with autistic/neurodivergent, gender diverse children.
7.4- We recommend health care professionals working with gender diverse children engage in continuing education related to gender diverse children and families.
7.5- We recommend health care professionals conducting an assessment with gender diverse children access and integrate information from multiple sources as part of the assessment.
7.6- We recommend health care professionals conducting an assessment with gender diverse children consider relevant developmental factors, neurocognitive functioning, and language skills.
7.7- We recommend health care professionals conducting an assessment with gender diverse children consider factors that may constrain accurate reporting of gender identity/gender expression by the child and/or family/caregiver(s).
7.8- We recommend health care professionals consider consultation, psychotherapy, or both for a gender diverse child and family/caregivers when families and health care professionals believe this would benefit the well-being and development of a child and/or family.
7.9- We recommend health care professionals offering consultation, psychotherapy, or both to gender diverse children and families/caregivers work with other settings and individuals important to the child to promote the child's resilience and emotional well-being.
7.10- We recommend health care professionals offering consultation, psychotherapy, or both to gender diverse children and families/caregivers provide both parties with age-appropriate psychoeducation about gender development.
7.11- We recommend that health care professionals provide information to gender diverse children and their families/caregivers as the child approaches puberty about potential gender affirming medical interventions, the effects of these treatments on future fertility, and options for fertility preservation.
7.12- We recommend parents/caregivers and health care professionals respond supportively to children who desire to be acknowledged as the gender that matches their internal sense of gender identity.
7.13- We recommend health care professionals and parents/caregivers support children to continue to explore their gender throughout the pre-pubescent years, regardless of social transition.
7.14- We recommend the health care professionals discuss the potential benefits and risks of a social transition with families who are considering it.
7.15- We suggest health care professionals consider working collaboratively with other professionals and organizations to promote the well-being of gender diverse children and minimize the adversities they may face.

acceptance of their gender diversity and parenting guidance when requested. Comprehensive assessments are appropriate when solicited by a family requesting a full understanding of the child's gender and mental health needs in the context of gender diversity.

In these circumstances, family member mental health issues, family dynamics, and social and cultural contexts, all of which impact a gender diverse child, should be taken into consideration (Barrow & Apostle, 2018; Brown & Mar, 2018; Cohen-Kettenis et al., 2003; Hendricks & Testa, 2012; Kaufman & Tishelman, 2018; Ristori & Steensma, 2016; Tishelman & Neumann-Mascis, 2018). This is further elaborated upon in the text below.

It is important HCPs working with gender diverse children strive to understand the child and the family's various aspects of identity and experience: racial, ethnic, immigrant/refugee status, religious, geographic, and socio-economic, for example, and be respectful and sensitive to cultural context in clinical interactions (Telfer et al., 2018). Many factors may be relevant to culture and gender, including religious beliefs, gender-related expectations, and the degree to which gender diversity is accepted (Oliphant et al., 2018). Intersections between gender diversity, sociocultural diversity, and minority statuses can be sources of strength, social stress, or both (Brown & Mar, 2018; Oliphant et al., 2018; Riggs & Treharne, 2016).

Each child, family member, and family dynamic is unique and potentially encompasses multiple cultures and belief patterns. Thus, HCPs of all disciplines should avoid stereotyping based on preconceived ideas that may be incorrect or biased (e.g., that a family who belongs to a religious organization that is opposed to appreciating gender diversity will necessarily be unsupportive of their child's gender diversity) (Brown & Mar, 2018). Instead, it is essential to approach each family openly and understand each family member and family pattern as distinct.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 7.1

We recommend the health care professionals working with gender diverse children receive training and have expertise in gender development and gender diversity in children and possess general knowledge of gender diversity across the life span.

HCPs working with gender diverse children should acquire and maintain the necessary training and credentials relevant to the scope of their role as professionals. This includes licensure, certification, or both by appropriate national and/or regional accrediting bodies. We recognize the specifics of credentialing and regulation of professionals vary globally. Importantly, basic licensure, certification, or both may be insufficient in and of itself to ensure competency working with gender diverse children, as HCPs specifically require in-depth training and supervised experience in childhood gender development and gender diversity to provide appropriate care.

Statement 7. 2

We recommend health care professionals working with gender diverse children receive theoretical and evidenced-based training and develop expertise in general child and family mental health across the developmental spectrum.

HCPs should receive training and supervised expertise in general child and family mental health across the developmental spectrum from toddlerhood through adolescence, including evidence-based assessment and intervention approaches. Gender diversity is not a mental health disorder; however, as cited above, we know mental health can be adversely impacted for gender diverse children (e.g., through gender minority stress) (Hendricks & Testa, 2012) that may benefit from exploration and support; therefore, mental health expertise is highly recommended. Working with children is a complex endeavor, involving an understanding of a child's developmental needs at various ages, the ability to comprehend the forces impacting a child's well-being both inside and outside the family (Kaufman & Tishelman, 2018), and an ability to fully assess when a child is unhappy or experiencing significant mental health difficulties, related or unrelated to gender. Research has indicated high levels of adverse experiences and trauma in the gender diverse community of children, including susceptibility to rejection or even maltreatment (APA, 2015; Barrow & Apostle, 2018; Giovanardi et al., 2018; Reisner, Greytak et al., 2015; Roberts et al., 2012; Tishelman & Neumann-Mascis, 2018). HCPs need to be cognizant of the potential for adverse experiences and be able to initiate effective interventions to prevent harm and promote positive well-being.

Statement 7.3

We recommend health care professionals working with gender diverse children receive training and develop expertise in autism spectrum disorders and other neurodiversity or collaborate with an expert with relevant expertise when working with autistic/neurodivergent, gender diverse children.

The experience of gender diversity in autistic children as well as in children with other forms of neurodivergence may present extra clinical complexities (de Vries et al., 2010; Strang, Meagher et al., 2018). For example, autistic children may find it difficult to self-advocate for their gender-related needs and may communicate in highly individualistic ways (Kuvalanka et al., 2018; Strang, Powers et al., 2018). They may have varied interpretations of gender-related experiences given common differences in communication and thinking style. Because of the unique needs of gender diverse neurodivergent children, they may be at high risk for being misunderstood (i.e., for their communications to be misinterpreted). Therefore, professionals providing support to these children can best serve them by receiving training and developing expertise in autism and related neurodevelopmental presentations and/or collaborating with autism specialists (Strang, Meagher et al., 2018). Such training is especially relevant as research has documented

higher rates of autism among gender diverse youth than in the general population (de Vries et al., 2010; Hisle-Gorman et al., 2019; Shumer et al., 2015).

Statement 7.4

We recommend health care professionals working with gender diverse children engage in continuing education related to gender diverse children and families.

Continuing professional development regarding gender diverse children and families may be acquired through various means, including through readings (journal articles, books, websites associated with gender knowledgeable organizations), attending on-line and in person trainings, and joining peer supervision/consultation groups (Bartholomaeus et al., 2021).

Continuing education includes 1) maintaining up-to-date knowledge of available and relevant research on gender development and gender diversity in prepubescent children and gender diversity across the life span; 2) maintaining current knowledge regarding best practices for assessment, support, and treatment approaches with gender diverse children and families. This is a relatively new area of practice and health care professionals need to adapt as new information emerges through research and other avenues (Bartholomaeus et al., 2021).

Statement 7.5

We recommend health care professionals conducting an assessment with gender diverse children access and integrate information from multiple sources as part of the assessment.

A comprehensive assessment, when requested by a family and/or an HCP can be useful for developing intervention recommendations, as needed, to benefit the well-being of the child and other family members. Such an assessment can be beneficial in a variety of situations when a child and/or their family/guardians, in coordination with providers, feel some type of intervention would be helpful. Neither assessments nor interventions should ever be used as a means of covertly or overtly discouraging a child's gender diverse expressions or identity. Instead, with appropriately trained providers, assessment can be an effective means of better understanding how to support a child and their family without privileging any particular gender identity or expression. An assessment can be especially important for some children and their families by collaborating to promote a child's gender health, well-being, and self-fulfillment.

A comprehensive assessment can facilitate the formation of an individualized plan to assist a gender diverse prepubescent children and family members (de Vries & Cohen-Kettenis, 2012; Malpas et al., 2018; Steensma & Wensing-Kruger, 2019; Telfer et al., 2018; Tishelman & Kaufman, 2018). In such an assessment, integrating information from multiple sources is important to 1) best understand the child's gender needs and make recommendations; and 2) identify areas of child, family/caregiver, and community strengths and supports specific to the child's gender status and development as well as risks and concerns for the child, their family/caregivers and environment. Multiple informants for both evaluation and support/intervention planning purposes may include the child, parents/caregivers, extended family members, siblings, school personnel, HCPs, the community, broader cultural and legal contexts and other sources as indicated (Berg & Edwards-Leeper, 2018; Srinath, 2019).

An HCP conducting an assessment of gender diverse children needs to explore gender-related issues but must also take a broad view of the child and the environment, consistent with the ecological model described above (Bronfenbrenner, 1979) to fully understand the factors impacting a child's well-being and areas of gender support and risk (Berg & Edwards-Leeper, 2018; Hendricks & Testa, 2012; Kaufman & Tishelman, 2018; Tishelman & Neumann-Mascis, 2018). This includes understanding the strengths and challenges experienced by the child/family and that are present in the environment. We advise HCPs conducting an assessment with gender diverse children to consider incorporating multiple assessment domains, depending on the child and the family's needs and circumstances. Although some of the latter listed domains below do not directly address the child's gender (see items 7–12 below), they need to be accounted for in a gender assessment, as indicated by clinical judgment, to understand the complex web of factors

that may be affecting the child's well-being in an integrated fashion, including gender health, consistent with evaluation best practices a (APA, 2015; Berg & Edwards-Leeper, 2018; Malpas et al., 2018) and develop a multi-pronged intervention when needed.

Summarizing from relevant research and clinical expertise, assessment domains often include 1) a child's asserted gender identity and gender expression, currently and historically; 2) evidence of dysphoria, gender incongruence, or both; 3) strengths and challenges related to the child, family, peer and others' beliefs and attitudes about gender diversity, acceptance and support for child; 4) child and family experiences of gender minority stress and rejection, hostility, or both due to the child's gender diversity; 5) level of support related to gender diversity in social contexts (e.g., school, faith community, extended family); 6) evaluation of conflict regarding the child's gender and/or parental/caregiver/sibling concerning behavior related to the child's gender diversity; 7) child mental health, communication and/or cognitive strengths and challenges, neurodivergence, and/or behavioral challenges causing significant functional difficulty; 8) relevant medical and developmental history; 9) areas that may pose risks (e.g., exposure to domestic and/or community violence, any form of child maltreatment; history of trauma; safety and/or victimization with peers or in any other setting; suicidality); 10) co-occurring significant family stressors, such as chronic or terminal illness, homelessness or poverty; 11) parent/caregiver and/or sibling mental health and/or behavioral challenges causing significant functional difficulty; and 12) child's and family's strengths and challenges.

A thorough assessment incorporating multiple forms of information gathering is helpful for understanding the needs, strengths, protective factors, and risks for a specific child and family across environments (e.g., home/school). Methods of information gathering often include 1) interviews with the child, family members and others (e.g., teachers), structured and unstructured; 2) caregiver and child completed standardized measures related to gender; general child well-being; child cognitive and communication skills and developmental disorders/disabilities; support and acceptance by parent/caregiver, sibling, extended family and peers; parental stress; history of childhood adversities; and/or other issues as appropriate (APA, 2020; Berg & Edwards-Leeper, 2018; Kaufman & Tishelman, 2018; Srinath, 2019).

Depending on the family characteristics, the developmental profile of the child, or both, methods of information gathering also may also benefit from including the following 1) child and/or family observation, structured and unstructured; and 2) structured and visually supported assessment techniques (worksheets; self-portraits; family drawings, etc.) (Berg & Edwards-Leeper, 2018).

Statement 7.6

We recommend that health care professionals conducting an assessment with gender diverse children consider relevant developmental factors, neurocognitive functioning and language skills.

Given the complexities of assessing young children who, unlike adults, are in the process of development across a range of domains (cognitive, social, emotional, physiological), it is important to consider the developmental status of a child and gear assessment modalities and interactions to the individualized abilities of the child. This includes tailoring the assessment to a child's developmental stage and abilities (preschoolers, school age, early puberty prior to adolescence), including using language and assessment approaches that prioritize a child's comfort, language skills, and means of self-expression (Berg & Edwards-Leeper, 2018; Srinath, 2019). For example, relevant developmental factors, such as neurocognitive differences (e.g., autism spectrum conditions), and receptive and expressive language skills should be considered in conducting the assessment. Health care professionals may need to consult with specialists for guidance in cases in which they do not possess the specialized skills themselves (Strang et al., 2021).

Statement 7.7

We recommend health care professionals conducting an assessment with gender diverse children consider factors that may constrain accurate reporting of gender identity/gender expression by the child and/or family/caregiver(s).

HCPs conducting an assessment with gender diverse children and families need to account for developmental, emotional, and environmental factors that may constrain a child's, caregiver's, sibling or other's report or influence their belief systems related to gender (Riggs & Bartholomaeus, 2018). As with all child psychological assessments, environmental and family/caregiver reactions (e.g., punishment), and/or cognitive and social factors may influence a child's comfort and/or ability to directly discuss certain factors, including gender identity and related issues (Srinath, 2019). Similarly, family members may feel constrained in freely expressing their concerns and ideas depending on family conflicts or dynamics and/or other influences (e.g., cultural/religious; extended family pressure) (Riggs & Bartholomaeus, 2018).

Statement 7.8

We recommend health care professionals consider consultation, psychotherapy, or both for a gender diverse child and family/caregivers when families and health care professionals believe this would benefit the well-being and development of a child and/or family.

The goal of psychotherapy should never be aimed at modifying a child's gender identity (APA, 2021; Ashley, 2019b; Paré, 2020; SAMHSA, 2015; UN Human Rights Council, 2020), either covertly or overtly. Not all gender diverse children or their families need input from MHPs as gender diversity is not a mental health disorder (Pediatric Endocrine Society, 2020; Telfer et al., 2018). Nevertheless, it is often appropriate and helpful to seek psychotherapy when there is distress or concerns are expressed by parents to improve psychosocial health and prevent further distress (APA, 2015). Some of the common reasons for considering psychotherapy for a gender diverse child and family include the following 1) A child is demonstrating significant conflicts, confusion, stress or distress about their gender identity or needs a protected space to explore their gender (Ehrensaft, 2018; Spivey and Edwards-Leeper, 2019); 2) A child is experiencing external pressure to express their gender in a way that conflicts with their self-knowledge, desires, and beliefs (APA, 2015); 3) A child is struggling with mental health concerns, related to or independent of their gender (Barrow & Apostle, 2018); 4) A child would benefit from strengthening their resilience in the face of negative environmental responses to their gender identity or presentation (Craig & Auston, 2018; Malpas et al., 2018); 5) A child may be experiencing mental health and/or environmental concerns, including family system problems that can be misinterpreted as gender congruence or incongruence (Berg & Edwards-Leeper, 2018); and 6) A child expresses a desire to meet with an MHP to get gender-related support. In these situations, the psychotherapy will focus on supporting the child with the understanding that the child's parent(s)/caregiver(s) and potentially other family members will be included as necessary (APA, 2015; Ehrensaft, 2018; McLaughlin & Sharp, 2018). Unless contraindicated, it is extremely helpful for parents/guardians to participate in some capacity in the psychotherapy process involving prepubescent children as family factors are often central to a child's well-being. Although relatively unexplored in research involving gender diverse children, it may be important to attend to the relationship between siblings and the gender diverse child (Pariseau et al., 2019; Parker & Davis-McCabe, 2021).

HCPs should employ interventions tailor-made to the individual needs of the child that are designed to 1) foster protective social and emotional coping skills to promote resilience in the face of potential negative reactions to the child's gender identity, expressions, or both (Craig & Austin, 2016; Malpas et al., 2018; Spencer, Berg et al., 2021); 2) collaboratively problem-solve social challenges to reduce gender minority stress (Barrow & Apostle, 2018; Tishelman & Neumann-Mascis, 2018); 3) strengthen environmental supports for the child and/or members of the immediate and extended family (Kaufman & Tishelman, 2018); and 4) provide the child an opportunity to further understand their internal gender experiences (APA, 2015; Barrow& Apostle, 2018; Ehrensaft, 2018; Malpas et al., 2018; McLaughlin & Sharp, 2018). It is helpful for HCPs to develop a relationship with a gender diverse child and family that can endure over time as needed. This enables the child/family to establish a long-term trusting relationship throughout childhood whereby the HCP can offer support and guidance as a child matures and as potentially

different challenges or needs emerge for the child/family (Spencer, Berg et al., 2021; Murchison et al., 2016). In addition to the above and within the limits of available resources, when a child is neurodivergent, an HCP who has the skill set to address both neurodevelopmental differences and gender is most appropriate (Strang et al., 2021).

As outlined in the literature, there are numerous reasons parents/caregivers, siblings, and extended family members of a prepubescent child may find it useful to seek psychotherapy for themselves (Ehrensaft, 2018; Malpas et al., 2018; McLaughlin & Sharp, 2018). As summarized below, some of these common catalysts for seeking such treatment occur when one or more *family members* 1) desire education around gender development (Spivey & Edwards-Leeper, 2019); 2) are experiencing significant confusion or stress about the child's gender identity, expression, or both (Ashley, 2019c; Ehrensaft, 2018); 3) need guidance related to emotional and behavioral concerns regarding the gender diverse child (Barrow & Apostle, 2018; 4) need support to promote affirming environments outside of the home (e.g., school, sports, camps) (Kaufman & Tishelman, 2018); 5) are seeking assistance to make informed decisions about social transition, including how to do so in a way that is optimal for a child's gender development and health (Lev & Wolf-Gould, 2018); 6) are seeking guidance for dealing with condemnation from others, including political entities and accompanying legislation, regarding their support for their gender diverse child (negative reactions directed toward parents/caregivers can sometimes include rejection and/or harassment/abuse from the social environment arising from affirming decisions (Hidalgo & Chen, 2019); 7) are seeking to process their own emotional reactions and needs about their child's gender identity, including grief about their child's gender diversity and/or potential fears or anxieties for their child's current and future well-being (Pullen Sansfaçon et al., 2019); and 8) are emotionally distressed and/or in conflict with other family members regarding the child's gender diversity (as needed, HCPs can provide separate sessions for parents/caregivers, siblings and extended family members for support, guidance, and/or psychoeducation) (McLaughlin & Sharp, 2018; Pullen Sansfaçon et al., 2019; Spivey & Edwards-Leeper, 2019).

Statement 7.9

We recommend health care professionals offering consultation, psychotherapy, or both to gender diverse children and families/caregivers work with other settings and individuals important to the child to promote the child's resilience and emotional well-being.

Consistent with the ecological model described above and, as appropriate, based on individual/family circumstances, it can be extremely helpful for HCPs to prioritize coordination with important others (e.g., teachers, coaches, religious leaders) in a child's life to promote emotional and physical safety across settings (e.g., school settings, sports and other recreational activities, faith-based involvement) (Kaufman & Tishelman, 2018). Therapeutic and/or support groups are often recommended as a valuable resource for families/caregivers and/or gender diverse children themselves (Coolhart, 2018; Horton et al., 2021; Malpas et al., 2018; Murchison et al., 2016).

Statement 7.10

We recommend HCPs offering consultation, psychotherapy, or both to gender diverse children and families/caregivers provide both parties with age appropriate psycho-education about gender development.

Parents/caregivers and their gender diverse child should have the opportunity to develop knowledge regarding ways in which families/caregivers can best support their child to maximize resilience, self-awareness, and functioning (APA, 2015; Ehrensaft, 2018; Malpas, 2018; Spivey & Edwards-Leeper, 2019). It is neither possible nor is it the role of the HCP to predict with certainty the child's ultimate gender identity; instead, the HCP's task is to provide a safe space for the child's identity to develop and evolve over time without attempts to prioritize any particular developmental trajectory with regard to gender (APA, 2015; Spivey & Edwards-Leeper, 2019). Gender diverse children and early adolescents have different needs and experiences than older adolescents, socially and physiologically, and those differences should be reflected in the individualized approach HCPs

provide to each child/family (Keo-Meir & Ehrensaft, 2018; Spencer, Berg et al., 2021).

Parents/caregivers and their children should also have the opportunity to develop knowledge about gender development and gender literacy through age-appropriate psychoeducation (Berg & Edwards-Leeper, 2018; Rider, Vencill et al., 2019; Spencer, Berg et al., 2021). Gender literacy involves understanding the distinctions between sex designated at birth, gender identity, and gender expression, including the ways in which these three factors uniquely come together for a child (Berg & Edwards-Leeper, 2018; Rider, Vencill et al., 2019; Spencer, Berg et al., 2021). As a child gains gender literacy, they begin to understand their body parts do not necessarily define their gender identity and/or their gender expression (Berg & Edwards-Leeper, 2018; Rider, Vencill et al., 2019; Spencer, Berg et al., 2021). Gender literacy also involves learning to identify messages and experiences related to gender within society. As a child gains gender literacy, they may view their developing gender identity and gender expression more positively, promoting resilience and self-esteem, and diminishing risk of shame in the face of negative messages from the environment. Gaining gender literacy through psychoeducation may also be important for siblings and/or extended family members who are important to the child (Rider, Vencill et al., 2019; Spencer, Berg et al., 2021).

Statement 7.11

We recommend health care professionals provide information to gender diverse children and their families/caregivers as the child approaches puberty about potential gender-affirming medical interventions, the effects of these treatments on future fertility, and options for fertility preservation.

As a child matures and approaches puberty, HCPs should prioritize working with children and their parents/caregivers to integrate psychoeducation about puberty, engage in shared decision-making about potential gender-affirming medical interventions, and discuss fertility-related and other reproductive health implications of medical treatments (Nahata, Quinn et al., 2018; Spencer, Berg et al., 2021). Although only limited empirical research exists to evaluate such interventions, expert consensus and developmental psychological literature generally support the notion that open communication with children about their bodies and preparation for physiological changes of puberty, combined with gender-affirming acceptance, will promote resilience and help to foster positive sexuality as a child matures into adolescence (Spencer, Berg et al., 2019). All these discussions may be extended (e.g., starting earlier) to include neurodivergent children, to ensure there is enough time for reflection and understanding, especially as choices regarding future gender- affirming medical care potentially arise (Strang, Jarin et al., 2018). These discussions could include the following topics:

- Review of body parts and their different functions;
- The ways in which a child's body may change over time with and without medical intervention;
- The impact of medical interventions on later sexual functioning and fertility;
- The impact of puberty suppression on potential later medical interventions;
- Acknowledgment of the current lack of clinical data in certain areas related to the impacts of puberty suppression;
- The importance of appropriate sex education prior to puberty.

These discussions should employ developmentally appropriate language and teaching styles, and be geared to the specific needs of each individual child (Spencer, Berg et al., 2021).

Statement 7.12

We recommend parents/caregivers and health care professionals respond supportively to children who desire to be acknowledged as the gender that matches their internal sense of gender identity.

Gender social transition refers to a process by which a child is acknowledged by others and has the opportunity to live publicly, either in all situations or in certain situations, in the gender identity they affirm and has no singular set of parameters or actions (Ehrensaft et al., 2018).

Gender social transition has often been conceived in the past as binary—a girl transitions to a boy, a boy to a girl. The concept has expanded to include children who shift to a nonbinary or individually shaped iteration of gender identity (Chew et al., 2020; Clark et al., 2018). Newer research indicates the social transition process may serve a protective function for some prepubescent children and serve to foster positive mental health and well-being (Durwood et al., 2017; Gibson et al., 2021; Olson et al., 2016). Thus, recognition that a child's gender may be fluid and develop over time (Edwards-Leeper et al., 2016; Ehrensaft, 2018; Steensma, Kreukels et al., 2013) is not sufficient justification to negate or deter social transition for a prepubescent child when it would be beneficial. Gender identity evolution may continue even after a partial or complete social transition process has taken place (Ashley, 2019e; Edwards-Leeper et al., 2018; Ehrensaft, 2020; Ehrensaft et al., 2018; Spivey & Edwards-Leeper, 2019). Although empirical data remains limited, existing research has indicated children who are most assertive about their gender diversity are most likely to persist in a diverse gender identity across time, including children who socially transition prior to puberty (Olson et al., 2022; Rae et al., 2019; Steensma, McGuire et al., 2013). Thus, when considering a social transition, we suggest parents/caregivers and HCPs pay particular attention to children who consistently and often persistently articulate a gender identity that does not match the sex designated at birth. This includes those children who may explicitly request or desire a social acknowledgement of the gender that better matches the child's articulated gender identity and/or children who exhibit distress when their gender as they know it is experienced as incongruent with the sex designated at birth (Rae et al., 2019; Steensma, Kreukels et al., 2013).

Although there is a dearth of empirical literature regarding best practices related to the social transition process, clinical literature and expertise provides the following guidance that prioritizes a child's best interests (Ashley, 2019e; Ehrensaft, 2018; Ehrensaft et al, 2018; Murchison et al., 2016; Telfer et al., 2018): 1) social transition should originate from the child and reflect the child's wishes in the process of making the decision to initiate a social transition process; 2) an HCP may assist exploring the advantages/benefits, plus potential challenges of social transition; 3) social transition may best occur in all or in specific contexts/settings only (e.g., school, home); and 4) a child may or may not choose to disclose to others that they have socially transitioned, or may designate, typically with the help of their parents/caregivers, a select group of people with whom they share the information.

In summary, social transition, when it takes place, is likely to best serve a child's well-being when it takes place thoughtfully and individually for each child. A child's social transition (and gender as well) may evolve over time and is not necessarily static, but best reflects the cross-section of the child's established self-knowledge of their present gender identity and desired actions to express that identity (Ehrensaft et al., 2018).

A social transition process can include one or more of a number of different actions consistent with a child's affirmed gender (Ehrensaft et al., 2018), including:

- Name change;
- Pronoun change;
- Change in sex/gender markers (e.g., birth certificate; identification cards; passport; school and medical documentation; etc.);
- Participation in gender-segregated programs (e.g., sports teams; recreational clubs and camps; schools; etc.);
- Bathroom and locker room use;
- Personal expression (e.g., hair style; clothing choice; etc.);
- Communication of affirmed gender to others (e.g., social media; classroom or school announcements; letters to extended families or social contacts; etc.).

Statement 7.13

We recommend health care professionals and parents/caregivers support children to continue to explore their gender throughout the pre-pubescent years, regardless of social transition.

It is important children who have engaged in social transition be afforded the same opportunities as other children to continue considering

meanings and expressions of gender throughout their childhood years (Ashley 2019e; Spencer, Berg et al., 2021). Some research has found children may experience gender fluidity or even detransition after an initial social transition. Research has not been conclusive about when in the life span such detransition is most likely to occur, or what percentage of youth will eventually experience gender fluidity and/or a desire to detransition—due to gender evolution, or potentially other reasons (e.g., safety concerns; gender minority stress) (Olson et al., 2022; Steensma, Kreukels et al., 2013). A recent research report indicates in the US, detransition occurs with only a small percentage of youth five years after a binary social transition (Olson et al., 2022); further follow-up of these young people would be helpful. Replication of these findings is important as well since this study was conducted with a limited and self-selected participant pool in the US and thus may not be applicable to all gender diverse children. In summary, we have limited ability to know in advance the ways in which a child's gender identity and expressions may evolve over time and whether or why detransition may take place for some. In addition, not all gender diverse children wish to explore their gender (Telfer et al., 2018). Cisgender children are not expected to undertake this exploration, and therefore attempts to force this with a gender diverse child, if not indicated or welcomed, can be experienced as pathologizing, intrusive and/or cisnormative (Ansara & Hegarty, 2012; Bartholomaeus et al., 2021; Oliphant et al., 2018).

Statement 7.14

We recommend health care professionals discuss the potential benefits and risks of a social transition with families who are considering it.

Social transition in prepubescent children consists of a variety of choices, can occur as a process over time, is individualized based on both a child's wishes and other psychosocial considerations (Ehrensaft, 2018), and is a decision for which possible benefits and challenges should be weighted and discussed.

A social transition may have potential benefits as outlined in clinical literature (e.g., Ehrensaft et al., 2018) and supported by research (Fast & Olson, 2018; Rae et al., 2019). These include facilitating gender congruence while reducing gender dysphoria and enhancing psychosocial adjustment and well-being (Ehrensaft et al., 2018). Studies have indicated socially transitioned gender diverse children largely mirror the mental health characteristics of age matched cisgender siblings and peers (Durwood et al., 2017). These findings differ markedly from the mental health challenges consistently noted in prior research with gender diverse children and adolescents (Barrow & Apostle, 2018) and suggest the impact of social transition may be positive. Additionally, social transition for children typically can only take place with the support and acceptance of parents/caregivers, which has also been demonstrated to facilitate well-being in gender diverse children (Durwood et al., 2021; Malpas et al., 2018; Pariseau et al., 2019), although other forms of support, such as school-based support, have also been identified as important (Durwood et al., 2021; Turban, King et al., 2021). HCPs should discuss the potential benefits of a social transition with children and families in situations in which 1) there is a consistent, stable articulation of a gender identity that is incongruent with the sex assigned at birth (Fast & Olson, 2018). This should be differentiated from gender diverse expressions/behaviors/interests (e.g., playing with toys, expressing oneself through clothing or appearance choices, and/or engaging in activities socially defined and typically associated with the other gender in a binary model of gender) (Ehrensaft, 2018; Ehrensaft et al., 2018); 2) the child is expressing a strong desire or need to transition to the gender they have articulated as being their authentic gender (Ehrensaft et al., 2018; Fast & Olson, 2018; Rae et al., 2019); and 3) the child will be emotionally and physically safe during and following transition (Brown & Mar, 2018). Prejudice and discrimination should be considerations, especially in localities where acceptance of gender diversity is limited or prohibited (Brown & Mar, 2018; Hendricks & Testa, 2012; Turban, King et al., 2021). Of note, there can also be possible risks to a gender diverse child who does not socially transition, including 1) being ostracized or bullied for being perceived as not conforming to prescribed community

gender roles and/or socially expected patterns of behavior; and 2) living with the internal stress or distress that the gender they know themselves to be is incongruent with the gender they are being asked to present to the world.

To promote gender health, the HCP should discuss the potential challenges of a social transition. One concern often expressed relates to fear that a child will preclude considering the possible evolution of their gender identity as they mature or be reluctant to initiate another gender transition even if they no longer feel their social transition matches their current gender identity (Edwards-Leeper et al., 2016; Ristori & Steensma, 2016). Although limited, recent research has found some parents/caregivers of children who have socially transitioned may discuss with their children the option of new gender iterations (for example, reverting to an earlier expression of gender) and are comfortable about this possibility (Olson et al., 2019). Another often identified social transition concern is that a child may suffer negative sequelae if they revert to the former gender identity that matches their sex designated at birth (Chen et al., 2018; Edwards-Leeper et al., 2019; Steensma & Cohen-Kettenis, 2011). From this point of view, parents/caregivers should be aware of the potential developmental effect of a social transition on a child.

HCPs should provide guidance to parents/caregivers and supports to a child when a social gender transition is being considered or taking place by 1) providing consultation, assessment, and gender supports when needed and sought by the parents/caregivers; 2) aiding family members, as needed, to understand the child's desires for a social transition and the family members' own feelings about the child's expressed desires; 3) exploring with, and learning from, the parents/caregivers whether and how they believe a social transition would benefit their child both now and in their ongoing development; 4) providing guidance when parents/caregivers are not in agreement about a social transition and offering the opportunity to work together toward a consistent understanding of their child's gender status and needs; 5) providing guidance about safe and supportive ways to disclose their child's social transition to others and to facilitate their child transitioning in their various social environments (e.g., schools, extended family); 6) facilitating communication, when desired by the child, with peers about gender and social transition as well as fortifying positive peer relationships; 7) providing guidance when social transition may not be socially accepted or safe, either everywhere or in specific situations, or when a child has reservations about initiating a transition despite their wish to do so; there may be multiple reasons for reservations, including fears and anxieties; 8) working collaboratively with family members and MHPs to facilitate a social transition in a way that is optimal for the child's unfolding gender development, overall well-being, and physical and emotional safety; and 9) providing psychoeducation about the many different trajectories the child's gender may take over time, leaving pathways open to future iterations of gender for the child, and emphasizing there is no need to predict an individual child's gender identity in the future (Malpas et al., 2018).

All of these tasks incorporate enhancing the quality of communication between the child and family members and providing an opportunity for the child to be heard and listened to by all family members involved. These relational processes in turn facilitate the parents/caregivers' success in making informed decisions about the advisability and/or parameters of a social transition for their child (Malpas et al., 2018).

One role of HCPs is to provide guidance and support in situations in which children and parents/caregivers wish to proceed with a social transition but conclude that the social environment would not be accepting of those choices, by 1) helping parents/caregivers define and extend safe spaces in which the child can express their authentic gender freely; 2) discussing with parents/caregivers ways to advocate that increase the likelihood of the social environment being supportive in the future, if this is a realistic goal; 3) intervening as needed to help the child/family with any associated distress and/or shame brought about by the continued suppression of authentic gender identity and the need for secrecy; and 4) building both the child's and the family's resilience, instilling the understanding that if the social environment is having difficulty accepting a child's social transition and affirmed gender identity, it is not because of some shortcoming in the child but because of

insufficient gender literacy in the social environment (Ehrensaft et al., 2018).

Statement 7.15

We suggest health care professionals consider working collaboratively with other professionals and organizations to promote the well-being of gender diverse children and minimize the adversities they may face.

All children have the right to be supported and respected in their gender identities (Human Rights Campaign, 2018; Paré, 2020; SAMHSA, 2015). As noted above, gender diverse children are a particularly vulnerable group (Barrow & Apostle, 2018; Cohen-Kettenis et al., 2003; Giovanardi et al., 2018; Gower, Rider, Coleman et al., 2018; Grossman & D'Augelli, 2007; Hendricks & Testa, 2012; Reisner, Greytak et al., 2015; Ristori & Steensma, 2016; Roberts et al., 2012; Tishelman & Neumann-Mascis, 2018). The responsibilities of HCPs as advocates encompass acknowledging social determinants of health are critical for marginalized minorities (Barrow & Mar, 2018; Hendricks & Testa, 2012). Advocacy is taken up by all HCPs in the form of child and family support (APA, 2015; Malpas et al., 2018). Some HCPs may be called on to move beyond their individual offices or programs to advocate for gender diverse children in the larger community, often in partnership with stakeholders, including parents/caregivers, allies, and youth (Kaufman & Tishelman, 2018; Lopez et al., 2017; Vanderburgh, 2009). These efforts may be instrumental in enhancing children's gender health and promoting their civil rights (Lopez et al., 2017).

HCP's voices may be essential in schools, in parliamentary bodies, in courts of law, and in the media (Kuvalanka et al., 2019; Lopez et al., 2017; Whyatt-Sames, 2017; Vanderburgh, 2009). In addition, HCPs may have a more generalized advocacy role in acknowledging and addressing the frequent intentional or unintentional negating of the experience of gender diverse children that may be transmitted or communicated by adults, peers, and in media (Rafferty et al., 2018). Professionals who possess the skill sets and find themselves in appropriate situations can provide clear de-pathologizing statements on the needs and rights of gender diverse children and on the damage caused by discriminatory and transphobic rules, laws, and norms (Rafferty et al., 2018).

CHAPTER 8 Nonbinary

Nonbinary is used as an umbrella term referring to individuals who experience their gender as outside of the gender binary. The term nonbinary is predominantly but not exclusively associated with global north contexts and may sometimes be used to describe indigenous and non-Western genders. The term nonbinary includes people whose genders are comprised of more than one gender identity simultaneously or at different times (e.g., bigender), who do not have a gender identity or have a neutral gender identity (e.g., agender or neutrois), have gender identities that encompass or blend elements of other genders (e.g., polygender, demiboy, demigirl), and/or who have a gender that changes over time (e.g., genderfluid) (Kuper et al., 2014; Richards et al., 2016; Richards et al., 2017; Vincent, 2019). Nonbinary people may identify to varying degrees with binary-associated genders, e.g., nonbinary man/woman, or with multiple gender terms, e.g., nonbinary and genderfluid (James et al., 2016; Kuper et al., 2012). Nonbinary also functions as a gender identity in its own right (Vincent, 2020). It is important to acknowledge this is not an exhaustive list, the same identities can have different meanings for different people, and the use of terms can vary over time and by location.

Genderqueer, first used in the 1990s, is an identity category somewhat older than nonbinary—which first emerged in approximately the late 2000s (Nestle et al., 2002; Wilchins, 1995). Genderqueer may sometimes be used synonymously with nonbinary or may communicate a specific consciously politicized dimension to a person's gender. While transgender is used in many cultural contexts as an umbrella term inclusive of nonbinary people, not all nonbinary people consider themselves to be transgender for a range of reasons, including because they consider being transgender to be exclusively within the gender binary or because they do not feel "trans enough" to describe themselves as transgender (Garrison, 2018). Some nonbinary people are unsure or ambivalent about whether they would describe themselves as transgender (Darwin, 2020; Vincent, 2019).

In the context of the English language, nonbinary people may use the pronouns they/them/theirs, or neopronouns which include e/em/eir, ze/zir/hir, er/ers/erself among others (Moser & Devereux, 2019; Vincent, 2018). Some nonbinary people use a combination of pronouns (either deliberately mixing usage, allowing free choice, or changing with social context), or prefer to avoid gendered pronouns entirely, instead using their name. Additionally, some nonbinary people use she/her/hers, or he/him/his, sometimes or exclusively, whilst in some regions in the world descriptive language for nonbinary people does not (yet) exist. In contexts outside of English, a wide range of culturally specific linguistic adaptations and evolutions can be observed (Attig, 2022; Kirey-Sitnikova, 2021; Zimman, 2020). Also of note, some languages use one pronoun that is not associated with sex or gender while others gender all nouns. These variations in language are likely to influence nonbinary people's experience of gender and how they interact with others.

Recent studies suggest nonbinary people comprise roughly 25% to over 50% of the larger transgender population, with samples of youth reporting the highest percentage of nonbinary people (Burgwal et al., 2019; James et al., 2016; Watson, 2020). In recent studies of transgender adults, nonbinary people tend to be younger than transgender men and transgender women and in studies of both youth and adults, nonbinary people are more likely to have been assigned female at birth (AFAB). However, these findings should be interpreted with caution as there are likely a number of complex, sociocultural factors influencing the quality, representativeness, and accuracy of this data (Burgwal et al., 2019; James et al., 2016; Watson, 2020; Wilson & Meyer, 2021) (see also Chapter 3—Population Estimates).

Understanding gender identities and gender expressions as a non-linear spectrum

Nonbinary genders have long been recognized historically and cross-culturally (Herdt, 1994; McNabb, 2017; Vincent & Manzano, 2017). Many gender identity categories are culturally specific and cannot be easily translated from their context, either linguistically or in relation to the Western paradigm of gender. Historical settler colonial interactions with indigenous people with

non-Western genders remain highly relevant as cultural erasure and the intersections of racism and cisnormativity may detrimentally inform the social determinants of health of indigenous gender diverse people. From the 1950s, gender was used to reference the socially constructed categorization of behaviors, activities, appearance, etc. in relation to a binary model of male/man/masculine, and female/woman/feminine within contemporary Western contexts. However, gender now has a wider range of possible meanings, appreciating interrelated yet distinguishable concepts, including gendered biology (sex), gender roles, gender expression, and gender identity (Vincent, 2020). Aspects of gender expression that might traditionally be understood culturally as "masculine", "feminine", or "androgynous" may be legitimately expressed among people of any and all gender identities, whether nonbinary or not. For example, a nonbinary individual presenting in a feminine manner cannot be taken to imply they will necessarily later identify as a woman or access interventions associated with transgender women, such as vaginoplasty. A person's gender nonconformity in relation to cultural expectations should neither be viewed as a cause for concern nor assumed to be indicative of clinical complexity—for example, a nonbinary person assigned male at birth (AMAB) wearing feminine-coded clothing, using she/her pronouns, but keeping a masculine-coded first name.

Modeling gender as a spectrum offers greater nuance than a binary model. However, there remain significant limitations in a linear spectrum model that can lead to uncritical generalizations about gender. For example, while it is intuitive to position the "binary options" (man/male, woman/female) at either end of such a continuum, doing so situates masculinity as oppositional to femininity, failing to accommodate gender neutrality, the expression of masculinity and femininity simultaneously, and genderqueer or non-Western concepts of gender. It is essential HCPs do not view nonbinary genders as "partial" articulations of transgender manhood (in nonbinary people AFAB) or transgender womanhood (in nonbinary people AMAB), or definitively as "somewhere along the spectrum of masculinity/femininity"; some nonbinary individuals consider themselves outside male/female dichotomization altogether. A *non-linear* spectrum indicates differences of gender expression, identity, or needs around gender affirmation between clients should not be compared for the purposes of situating them along a linear spectrum. Additionally, the interpretation of gender expression is subjective and culturally defined, and what may be experienced or viewed as highly feminine by one person may not be viewed as such by another (Vincent, 2020). HCPs benefit from avoiding assumptions about how each client conceptualizes their gender and by being prepared to be led by a given client's personal understanding of gender as it relates to the client's gender identity, expression, and any need for medical care.

The gender development process experienced by all transgender and gender diverse (TGD) people regardless of their relationship to a gender binary appear to share similar themes (e.g., awareness, exploration, meaning making, integration), but the timing, progression, and personal experiences associated with each of these processes vary both within and across groups of transgender and nonbinary people (Kuper, Wright et al., 2018; Kuper, Lindley et al., 2019; Tatum et al., 2020). Sociocultural and intersectional perspectives can be helpful at contextualizing gender development and social transition, including how individual experiences are shaped by the social and cultural context and how they interact with additional domains of identity and personal experience.

The need for access to gender-affirming care

Some nonbinary people seek gender-affirming care to alleviate gender dysphoria or incongruence and increase body satisfaction through medically necessary interventions (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1). Some nonbinary people may feel a certain treatment is necessary for them—see also Chapter 5—Assessment of Adults (Beek et al., 2015; Jones et al., 2019; Köhler et al., 2018), whilst others do not (Burgwal & Motmans, 2021; Nieder, Eyssel et al., 2020), and the proportion of nonbinary people who seek gender-affirming care and the specific goals of

that care, remains unclear. It is the role of the health care professional to provide information about existing medical options (and their availability) that might help alleviate gender dysphoria or incongruence and increase body satisfaction without making assumptions about which treatment options may best fit each individual person.

Motivations for accessing (or not accessing) gender-affirming medical interventions, including hormone treatment, surgeries, or both are heterogeneous and potentially complex (Burgwal & Motmans, 2021; Vincent, 2019, 2020) and should be explored collaboratively before making decisions about physical interventions. The need of an individual to access gender-affirming medical procedures cannot be predicted by their gender role, expression, or identity. For example, some transgender women have no need of vaginoplasty, while some nonbinary individuals AMAB may need and benefit from that same intervention. Further, nonbinary people seeking gender-affirming care associated closely with a transition pathway from their assigned sex/gender to the other binarily-recognized category (i.e., estrogen therapy and vaginoplasty for someone AMAB) does not undermine the validity of their nonbinary identity.

While barriers to care remain widespread for many transgender people, nonbinary people appear to experience particularly high rates of difficulty accessing both mental health and gender-affirming medical care (Clark et al., 2018; James, 2016). Many nonbinary people report having experiences with health care professionals who were not affirming of their nonbinary gender, including experiences where health care professionals convey beliefs that their gender is not valid, or they are fundamentally more difficult to provide care for (Valentine, 2016; Vincent, 2020). Nonbinary people may face provider assumptions that they do not need or want gender-affirming treatment (Kcomt et al., 2020; Vincent, 2020) and have described experiencing pressure to present themselves as transgender men or transgender women (within a binary framework of gender) in order to access treatment (Bradford et al., 2019; Taylor et al., 2019). At times, nonbinary people find themselves educating the provider from whom they are seeking services despite the inappropriateness of providers relying primarily on their patients for education (Kcomt et al., 2020). In comparison to transgender men and transgender women, Burgwal and Motmans (2021) found that nonbinary people experienced more fear of prejudice from health care providers, less confidence in the services provided, and greater difficulty knowing where to go to for care. Studies in both Europe and US have shown that nonbinary individuals tend to delay care more often than binary transgender men or transgender women, with fear of insensitive or incompetent treatment being the most cited reason (Burgwal & Motmans, 2021; Grant et al., 2011). Nonbinary people also appear less likely to disclose their gender identity to their health care providers than other transgender people (Kcomt et al., 2020).

The need for an appropriate level of support

Providing gender-affirming care to nonbinary people goes beyond the provision of specific gender-affirming interventions such as hormone therapy or surgery and involves supporting the overall health and development of nonbinary people. Minority stress models have been adapted to conceptualize how the gender-related stressors experienced by transgender people are associated with physical and mental health disparities (Delozier et al., 2020; Testa et al., 2017). Nonbinary people appear to experience minority stressors that are both similar to and unique from those experienced by transgender men and transgender women. Johnson (2020) reported that experiences of invalidation are particularly high among nonbinary people, e.g., statements or actions conveying a belief that nonbinary identities are not "real" or are the result of a "fad" or "phase," and nonbinary people appear less likely than transgender men and transgender women to have their correct pronouns used by others. Similarly, nonbinary people have described feeling "invisible" to others (Conlin, 2019; Taylor, 2018) and one study found that nonbinary youth reported lower levels of self-esteem in comparison to young transgender men and transgender women (Thorne, Witcomb et al., 2019).

While many TGD people report experiences of discrimination, victimization, and interpersonal rejection (James, 2016) including bullying within

samples of youth (Human Rights Campaign, 2018; Witcomb et al., 2019), the prevalence of these experiences may vary across groups and appears influenced by additional intersecting characteristics. For example, Newcomb (2020) found transgender women and nonbinary youth AMAB experienced higher levels of victimization than transgender men and nonbinary youth AFAB, with nonbinary youth AMAB reporting the highest levels of traumatic stress. In a second study, Poquiz (2021) found transgender men and transgender women experienced higher levels of discrimination than nonbinary people. This intersectional complexity is also likely contributing to the variability in findings from studies comparing the physical and mental health of nonbinary and transgender men and transgender women, with some studies indicating more physical and mental health concerns among nonbinary people, some reporting less concerns, and some reporting no difference between groups (Scandurra, 2019).

Given nonbinary identity narratives may be less widely available than more binary-oriented identity narratives, nonbinary people may have less resources available to explore and articulate their gender-related sense of self. For example, this might include access to community spaces and interpersonal relationships where nonbinary identity can be explored, or access to language and concepts that allow more nuanced consideration of nonbinary experiences (Bradford et al., 2018; Fiani & Han, 2019; Galupo et al., 2019). Clinical guidance is now developing to assist providers in adapting gender-affirming therapeutic care to meet these unique experiences of nonbinary people (Matsuno, 2019; Rider, Vencill et al., 2019).

Gender-affirming medical interventions for nonbinary people

In contexts where a particular medical intervention does not have established precedent, it is important that before the intervention is considered, the individual is provided with an overview of the available information, including recognition of potential knowledge limits. It is equally important to undertake and document a comprehensive discussion of the physical changes needed and the potential limitations in achieving those attributes, as well as the implication that any given intervention may or may not enhance an individual's ability to express their gender.

With regards to estrogen therapy for nonbinary people AMAB, it is important to note the possibility of breast growth cannot be avoided (Seal, 2017). Although the extent of growth is highly variable, this should be made clear if a nonbinary person seeks some of the other changes associated with estrogen therapy (such as softening of skin and reduction in facial hair growth) but does not want or is ambivalent about breast growth. Likewise, for nonbinary people AFAB who may wish to access testosterone to acquire some changes but not others, it should be recognized that if facial hair development is needed, genital growth is inevitable (Seal, 2017). The time frame for taking testosterone means these changes are likely also to be accompanied by an irreversible vocal pitch drop, although the extent of each is individual (Vincent, 2019; Ziegler et al., 2018). A vocal pitch drop without the development of body hair is another such challenge. For some nonbinary people, hair removal is a very important part of their gender affirmation (Cocchetti, Ristori, Romani et al., 2020).

If hormonal therapy is discontinued and gonads are retained, many physical changes will revert to pre-hormone therapy status as gonadal hormones once again take effect, including reversal of amenorrhea and body hair development in nonbinary people AFAB and reduction in muscular definition and erectile dysfunction in nonbinary people AMAB. Other changes will be permanent such as "male-pattern" baldness, genital growth, and facial hair growth in nonbinary people AFAB or breast development in nonbinary people AMAB (Hembree et al., 2017). These will require further interventions to reverse, such as electrolysis or mastectomy and are sometimes described as "partially reversible" (Coleman et al., 2012). As the implications of using low-dose hormone therapy are not documented in this patient population, it is important to consider monitoring for cardiovascular risk and bone health if low-dose hormone therapy is used. For more detailed information see Chapter 12—Hormone Therapy.

If neither testosterone nor estrogen expression is needed, inhibition of estrogen and/or testosterone

Statements of Recommendations

8.1- We recommend health care professionals provide nonbinary people with individualized assessment and treatment that affirms their experience of gender.
8.2- We recommend health care professionals consider gender-affirming medical interventions (hormonal treatment or surgery) for nonbinary people in the absence of "social gender transition."
8.3- We recommend health care professionals consider gender-affirming surgical interventions in the absence of hormonal treatment, unless hormone therapy is required to achieve the desired surgical result.
8.4- We recommend health care professionals provide information to nonbinary people about the effects of hormonal therapies/surgery on future fertility and discuss the options for fertility preservation prior to starting hormonal treatment or undergoing surgery.

production is possible. The implications of this with regards to increased cardiovascular risk, reduced bone mineralization, and risk of depression should be discussed and measures taken to mitigate risk (Brett et al., 2007; Vale et al., 2010; Wassersug & Johnson, 2007). For more information see also Chapter 9—Eunuchs and Chapter 12—Hormone Therapy. Exploration of medical and/or social transition independently of each other and options to explore hormones, surgery, or both independently of each other should be available to everyone, whether the person is a transgender man, transgender woman, or a nonbinary person.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 8.1

We recommend health care professionals provide nonbinary people with individualized assessment and treatment that affirms their nonbinary experiences of gender.

An individualized assessment with a nonbinary person starts with an understanding of how they experience their own gender and how this impacts their goals for the care they are seeking. How individuals conceptualize their gender-related experiences are likely to vary across groups and cultures and may incorporate experiences associated with other intersecting aspects of identity (e.g., age, sexuality, race, ethnicity, socioeconomic status, disability status) (Kuper et al., 2014; Subramanian et al., 2016).

HCPs should avoid making a priori assumptions about any client's gender identity, expression, or needs for care. They should also be mindful that a client's nonbinary experience of gender may or may not be relevant to the assessment and treatment-related goals. The extent to which the client's gender is relevant to their treatment goals should determine the level of detail at which their gender identity is explored. For example, when seeking care for a presenting concern wholly unrelated to gender, simply determining the correct name and pronouns may be sufficient (Knutson et al., 2019). When addressing a concern for which current or past hormonal or surgical status is relevant, more detail may be needed, even if the concern is not specifically gender-related.

Clinical settings need to be welcoming, reflective of the diversity of genders, and affirm the experiences of gender of nonbinary people to be culturally competent. Ensuring clinic and provider information (e.g., websites), forms (e.g., intake surveys), and other materials are inclusive of nonbinary identities and experiences conveys that nonbinary people are welcome and recognized (Hagen & Galupo, 2014). Using free text fields for gender identity and pronouns is more inclusive than using a list of response options. Ensuring privacy at the reception desk, setting up alternatives for listing legal names in digital databases (in cultural contexts where this is necessary), installing gender-neutral toilets, and setting up alternatives to calling out the legal name in the waiting room are additional examples of transgender and gender diverse (TGD) cultural competency (Burgwal et al., 2021). In care settings, it is important preferences for names, pronouns, and other gender-related terms are asked and used both initially and on a regular basis as they may vary over time and circumstance.

HCPs are encouraged to adopt an approach that focuses on strengths and resilience.

Increasingly, critiques are emerging regarding HCPs over-focus on gender-related distress as it is also important to consider experiences of increased comfort, joy, and self-fulfilment that can result from self-affirmation and access to care (Ashley, 2019a; Benestad, 2010). In addition to utilizing diagnoses when/where required to facilitate access to care, HCPs are encouraged to collaboratively explore with clients this broader range of potential gender-related experiences and how they may fit with treatment options (Motmans et al., 2019). For all TGD people, resiliency factors such as supportive relationships, participation in communities that include similar others, and identity pride are essential to consider as they are associated with a range of positive health outcomes (Bowling et al., 2019; Budge, 2015; Johns et al., 2018).

Awareness of the limitations that exist in the tools providers have historically used to assess transgender people's experience of dysphoria is important as they may be particularly pronounced for many nonbinary people. Most gender-related measures assume clients experience their gender in a binary way, among other concerns (e.g., Recalled Gender Identity Scale, Utrecht Gender Dysphoria Scale). While several newer measures have been developed in an attempt to better capture the experiences of nonbinary people (McGuire et al., 2018; McGuire et al., 2020), open-ended discussion is likely to provide a deeper and more accurate understanding of each individual's unique experiences of dysphoria and their associated care needs. Similarly, while more recent iterations of diagnostic categories (i.e., "gender dysphoria" in the DSM 5 and "gender incongruence" in ICD-11) were intended to be inclusive of people with nonbinary experiences of gender, they may not adequately capture the full diversity and scope of experiences of gender-related distress, particularly for nonbinary people. In addition to distress associated with aspects of one's physical body and presentation (including features that may be existing or absent), distress may arise from how one experiences their own gender, how one's gender is perceived within social situations, and from experiences of minority stress associated with one's gender (Winters & Ehrbar, 2010). Nonbinary peoples' experiences in each of these areas may or may not be similar to those of transgender men or women.

A person-centered approach for affirming care includes specific discussion of how different interventions may or may not shift the client's comfort with their own experience of gender, and how their gender is perceived by others. Nonbinary people can face challenges in reconciling their personal identities with the limits of the medical treatments available and can also encounter confusion and intolerance from society regarding their gender presentations (Taylor et al., 2019). Emerging research suggests the medical treatment needs of nonbinary people are particularly diverse, with some reporting needs for treatments that have typically been associated with transition trajectories historically associated with transgender men and women and some reporting alternative approaches (e.g., low dose hormone therapy, surgery without hormone therapy), some reporting a lack of interest in medical treatment, and some reporting feeling unsure about their needs (Burgwal & Motmans, 2021; James et al., 2016). Conceptualizing assessment as an ongoing process is particularly important given gender-related experiences and associated needs may shift throughout the lifespan. Given the ongoing evolution in treatment options and knowledge of treatment effects, particularly for nonbinary people, clients will benefit from providers who regularly seek up-to-date knowledge and convey these updates to their clients.

Statement 8.2

We recommend health care professionals consider medical interventions (hormonal treatment or surgery) for nonbinary people in the absence of "social gender transition."

Previous requirements for accessing hormonal treatment and surgery, such as "living in a gender role that is congruent with one's gender identity," do not reflect the lived experiences of many TGD people (Coleman et al., 2012). Due to the entrenched nature of the gender binary in most contemporary Western cultures, one can typically only be understood by others as a man or woman within most settings (Butler, 1993). Hence, the visibility and understanding of nonbinary embodiments and expressions is limited. This is due to gendered cues

being almost always understood in reference to a gender binary (Butler, 1993). Presently, it can be difficult for nonbinary people to be reliably recognized as their gender via visual cues associated with their gender expression (e.g., clothing, hair). However, androgyny or gender nonconformity may be communicated by the mixing or combining of cultural markers with traditionally masculine or feminine connotations. Because there is no commonly recognized "nonbinary category" within most contemporary Western, global north cultural contexts, nonbinary visibility often necessitates explicit sharing of one's gender with others or the use of cues that may be interpreted as gender nonconformity (but not necessarily nonbinary).

For these reasons, framing access to medical care in the context of someone experiencing a "social gender transition" where they are "living in a gender role that is congruent with one's gender identity" is not in line with the way many TGD people understand themselves and their personal transition process. For some, "living in a gender role that is congruent with one's gender identity" does not involve changes in name, pronouns, or gender expression even as medical intervention may be necessary. Even if a person is able to live in ways that are congruent with their gender identity, it may be difficult for an outside observer to assess this without learning directly from that person how they understand their own experience in this regard. Expectation of "social gender transition" may be unhelpful when considering eligibility for gender- affirming care, such as hormones and surgery, and rigid expectations of what a "social gender role transition" "should" look like can be a barrier to care for nonbinary people. There is no logical requirement gender-affirming medical interventions can only be done once a person legally changes their name, changes the gender marker on their identity documents, or wears or refrains from wearing particular items of clothing. Nonbinary people may struggle to access recognition of their genders on formal documentation, which may negatively affect their mental health or well-being (Goetz & Arcomano, 2021). TGD people may benefit from specific support in accessing (or retaining) their gender marker of preference. A requirement that someone disclose their gender identity in all circles of their lives (family, work, school, etc.) in order to access medical care may not be consistent with their goals and can place them at risk if it is not safe to do so.

Statement 8.3

We recommend health care professionals consider gender-affirming surgical interventions in the absence of hormonal treatment unless hormone therapy is required to achieve the desired surgical result.

The trajectory of "hormones before surgery" is an option across a range of surgical interventions. Some nonbinary people will seek gender-affirming surgical treatment to alleviate gender incongruence and increase body satisfaction (Beek et al., 2015; Burgwal & Motmans, 2021; Jones et al., 2019; Koehler et al., 2018), but do not want hormonal treatment or are unable to undergo hormonal therapy due to other medical reasons (Nieder, Eyssel et al., 2020). Currently, it is unknown for which proportion of nonbinary people these options apply.

Perhaps the surgery which has some specific association with nonbinary people (rather than sought by transgender men or undergone by some cisgender women) is mastectomy in nonbinary people AFAB who have not taken testosterone—although testosterone is not a requirement for this type of surgery—and some nonbinary people AFAB may need breast reduction (McTernan et al., 2020). An example of a surgery for which at least a period of hormone therapy may be necessary is metoidioplasty that enhances the enlarged clitoris produced by testosterone therapy. See Chapter 13—Surgery and Postoperative Care for more detail on whether hormone therapy is necessary for various surgeries. Procedures addressing the internal reproductive system include hysterectomy, unilateral or bilateral salpingo-oophorectomy, and vaginectomy. Hormone therapy is not required for any of these procedures, but hormone replacement therapy (either with estrogens, testosterone, or both) is advisable in those individuals undergoing a total gonadectomy to prevent adverse effects on their cardiovascular and musculoskeletal systems (Hembree et al., 2017; Seal, 2017). For phalloplasty, while there is no surgical requirement per se for a minimum period of testosterone

treatment, virilization (or the absence of virilization) of the clitoris and labia minora may impact the choice of surgical technique and influence surgical options. For more information see Chapter 13—Surgery and Postoperative Care.

Nonbinary AMAB clients should be informed commencing estrogen therapy post-surgically with no prior history of estrogen therapy may influence (perhaps adversely) the surgical result (Kanhai, Hage, Asscheman et al., 1999; Kanhai, Hage, Karim et al., 1999). Nonbinary people AMAB requesting a bilateral orchiedectomy do not require estrogen therapy to achieve a better outcome (Hembree et al., 2017). In these contexts, it is good practice to inform clients of the risks and benefits of hormone replacement therapy (estrogens, testosterone, or both) in preventing adverse effects on the cardiovascular and musculoskeletal system as well as alternative treatment options, such as calcium plus vitamin D supplementation to prevent osteoporosis (Hembree et al., 2017; Seal, 2017; Weaver et al., 2016). See also Chapter 9—Eunuchs for those who choose to forgo hormone replacement therapy. In the case of vaginoplasty, individuals should be advised lack of testosterone-blocking therapy may cause postoperative hair growth in the vagina when hair-bearing skin graft and flaps have been used (Giltay & Gooren, 2000).

Additional surgical requests for nonbinary people AMAB include penile-preserving vaginoplasty, vaginoplasty with preservation of the testicle(s), and procedures resulting in an absence of external primary sexual characteristics (i.e., penectomy, scrotectomy, orchiectomy, etc.). The surgeon and individual seeking treatment are advised to engage in discussions so as to understand the individual's goals and expectations as well as the benefits and limitations of the intended (or requested) procedure, to make decisions on an individualized basis and collaborate with other health care providers who are involved (if any).

Statement 8.4.

We recommend health care professionals provide information to nonbinary people about the effects of hormonal therapies/surgery on future fertility and discuss the options for fertility preservation prior to starting hormonal treatment or undergoing surgery.

All nonbinary individuals who seek gender-affirming hormonal therapies should be offered information and guidance about fertility options (Hembree et al., 2017; De Roo et al., 2016; Defreyne, Elaut et al., 2020; Defreyne, van Schuvlenbergh et al., 2020; Nahata et al., 2017; Quinn et al., 2021). It is important to discuss the potential impact of hormone therapy on fertility prior to initiation. This discussion should include fertility preservation options, the extent to which fertility may or may not be regained if hormone therapy is ceased, and the fact that hormone therapy per se is not birth control. For more information see Chapter 16—Reproductive Health.

Recent studies suggest that nonbinary individuals are less likely to access care and make their needs for potential interventions heard (Beek et al., 2015; Taylor et al., 2019). As such, it stands to reason that any gender diverse individual should be offered information on current options and techniques for fertility preservation, ideally prior to commencing hormonal treatment as the quality of the sperm or eggs may be impacted by exposure to hormones (Hamada et al., 2015; Payer et al., 1979). However, this should in no way preclude making inquiries and seeking more information at a later time, as there is evidence that fertility is still possible for individuals taking estrogen and testosterone (Light et al., 2014). A decision by a nonbinary or gender diverse person that fertility preservation or counseling is not needed should not be used as a basis for denying or delaying access to hormonal treatment.

CHAPTER 9 Eunuchs

Among the many people who benefit from gender-affirming medical care, those who identify as eunuchs are among the least visible. The 8th version of the Standards of Care (SOC) includes a discussion of eunuch individuals because of their unique presentation and their need for medically necessary gender-affirming care (see Chapter 2—Global Applicability, Statement 2.1).

Eunuch individuals are those assigned male at birth (AMAB) and wish to eliminate masculine physical features, masculine genitals, or genital functioning. They also include those whose testicles have been surgically removed or rendered nonfunctional by chemical or physical means and who identify as eunuch. This identity-based definition for those who embrace the term eunuch does not include others, such as men who have been treated for advanced prostate cancer and reject the designation of eunuch. We focus here on those who identify as eunuchs as part of the gender diverse umbrella.

As with other gender diverse individuals, eunuchs may also seek castration to better align their bodies with their gender identity. As such, eunuch individuals are gender nonconforming individuals who have needs requiring medically necessary gender-affirming care (Brett et al., 2007; Johnson et al., 2007; Roberts et al., 2008).

Eunuch individuals identify their gender identities in various ways. Many eunuch individuals see their status as eunuch as their distinct gender identity with no other gender or transgender affiliation. The focus of this chapter is on the treatment and care for those who identify as eunuchs. Health care professionals (HCPs) will encounter eunuchs requesting hormonal interventions, castration, or both to become eunuchs. These individuals may also benefit from a eunuch community because of the identification—with or without actual castration.

While there is a 4000-year history of eunuchs in society, the greatest wealth of information about contemporary eunuch-identified people is found within the large online peer-support community that congregates on sites such as the Eunuch Archive (www.eunuch.org), which was established in 1998. The moderators of this site attempt to maintain both medical and historical accuracy in its discussion forums, although there is certainly misinformation as well. According to the website, as of January 2022, there have been over 130,000 registered members from various parts of the world and frequently over 90% of those reading the site are "guests" rather than members. The website lists over 23,000 threads and nearly 220,000 posts. For example, two threads giving instructions for self-castration by injection of different toxins directly into the testicles have about 2,500 posts each, and each has been read well over one million times. Beginning in 2001, there have been 20 annual international gatherings of the Eunuch Archive community in Minneapolis in addition to many regional gatherings elsewhere. While the topic of castration is of interest to the great majority of people who participate in the discussions, it is a minority of the membership who seriously seek or have undergone castration. Many former Eunuch Archive members have achieved their goals and no longer participate.

Because of misconceptions and prejudice about historic eunuchs, the invisibility of contemporary eunuchs, and the social stigma that affects all gender and sexual minorities, few eunuch individuals come out publicly as eunuch and many will tell no one and will share only with like-minded people in an online community or are known as such only to close family and friends (Wassersug & Lieberman, 2010). The stereotypes of eunuchs are often highly negative (Lieberman 2018), and eunuchs may suffer the same minority stress as other stigmatized groups (Wassersug & Lieberman, 2010). Research into minority stress affecting gender diverse people should therefore include eunuchs.

The current set of recommendations is directed at professionals working with individuals who identify as eunuchs (Johnson & Wassersug, 2016; Vale et al., 2010) requesting medically necessary gender-affirming medical and/or surgical treatments (GAMSTs). Although not a specific diagnostic category in the ICD or DSM, eunuch is a useful construct as it speaks to the specifics of eunuch experience while also connecting it to the experience of gender incongruence more broadly. Eunuch individuals will present themselves clinically in various ways. They wish for

Statements of Recommendations

9.1- We recommend health care professionals and other users of the Standards of Care 8th guidelines should apply the recommendations in ways that meet the needs of eunuch individuals
9.2- We recommend health care professionals should consider medical intervention, surgical intervention, or both for eunuch individuals when there is a high risk that withholding treatment will cause individuals harm through self-surgery, surgery by unqualified practitioners, or unsupervised use of medications that affect hormones.
9.3- We recommend health care professionals who are assessing eunuch individuals for treatment have demonstrated competency in assessing them.
9.4- We suggest health care professionals providing care to eunuch individuals include sexuality education and counseling.

a body that is compatible with their eunuch identity—a body that does not have fully functional male genitalia. Some other eunuch individuals feel acute discomfort with their male genitals and need to have them removed to feel comfortable in their bodies (Johnson et al., 2007; Roberts et al., 2008). Others are indifferent to having male external genitalia as long as they are only physically present and do not function to produce androgens and male secondary sexual features (Brett et al., 2007). Hormonal means may be used to suppress the production of androgens, although orchiectomy provides a permanent solution for those not wishing genital functioning (Wibowo et al., 2016). Some eunuch individuals desire lower testosterone levels achieved with orchiectomy, but many will elect some form of hormone replacement to prevent adverse effects associated with hypogonadism. Most who elect hormone therapy choose either a full or partial replacement dose of testosterone. A smaller number elect estrogen.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 9.1.

We recommend health care professionals and other users of the Standards of Care, Version 8 guidelines should apply the recommendations in ways that meet the needs of eunuch individuals.

Eunuch individuals are part of the population of gender diverse people who experience gender incongruence and may also seek gender-affirming care. Like other transgender and gender diverse (TGD) individuals, eunuchs require access to affirming care to gain comfort with their gendered self. Each section of the SOC addresses the needs of diverse individuals, and eunuchs can be included within that group. They may have commonality with some nonbinary individuals in that social transition may not be a desired option, and hormone therapy may not play the same role as it might in a social transition or transition within the binary (Wassersug & Lieberman, 2010).

Like other gender diverse individuals, eunuch individuals may be aware of their identity in childhood or adolescence. Due to the lack of research into the treatment of children who may identify as eunuchs, we refrain from making specific suggestions.

Eunuch individuals may seek medical or surgical care (hormone suppression, orchiectomy, and, in some cases, penectomy) to achieve physical, psychological, or sexual changes (Wassersug & Johnson, 2007). It is important all patients, including both eunuchs and those seeking castration, establish and maintain a relationship with an HCP that is built upon trust and mutual understanding. Given a lack of awareness of eunuchs within the general medical community and the fear among many individuals seeking castration they will not be accepted, many do not receive appropriate primary care and screening tests (Jäggi et al., 2018). Increased awareness and education among medical providers will help address the need to be informed about the need to include eunuchs in discussions of gender diversity (Deutsch, 2016a). It goes without saying that eunuchs require and deserve the same primary care services as the general population. The topic of screening tests for cancers, such as prostate and breast, is an important area for

discussion as the risks of hormone-related cancers are likely different among male-assigned people whose testosterone and estrogen levels are not in the male range. Due to a lack of studies looking at the prevalence and incidence of hormone-related cancers in the eunuch population, there is no evidence to guide how often to screen for hormone-related cancers with prostate exams, PSA measurements, mammograms, etcetera.

The large literature on prostate cancer patients who have been medically or surgically castrated provides information about some of the effects of post-pubertal castration (such as potential osteoporosis, depression, or metabolic syndrome), but voluntary eunuchs may interpret the results very differently from those castrated for medical reasons. Chemical or surgical castration may be experienced as a source of distress to cis men with prostate cancer, while the same treatment may be affirming and a source of comfort for eunuch individuals. Similarly, transmasculine people who have a mastectomy to gain comfort with their bodies experience that surgery differently from ciswomen who undergo mastectomy to treat breast cancer (Koçan & Gürsoy, 2016; van de Grift et al., 2016). The prostate cancer information is well summarized by Wassersug et al. (2021) who provide references that explore the large literature on the subject. Such information on the effects of castration should be made available to those seeking castration.

Following an assessment as per the SOC-8, medical options requested by the patient can be considered and prescribed, if appropriate. These options can be tailored to the individual to create a plan that reflects their specific needs and preferences. The number and type of interventions applied and the order in which these take place may differ from person to person. These options are consistent with both the assessment and surgery chapters of the SOC-8. Treatment options for eunuchs to consider include:

- Hormone suppression to explore the effects of androgen deficiency for eunuch individuals wishing to become asexual, nonsexual, or androgynous;
- Orchiectomy to stop testicular production of testosterone;
- Orchiectomy with or without penectomy to alter their body to match their self-image;
- Orchiectomy followed by hormone replacement with testosterone or estrogen.

Per statement 5.6 in Chapter 5—Assessment of Adults, eunuch individuals seeking gonadectomy consider a minimum of 6 months of hormone therapy as appropriate to the TGD person's gender goals before the TGD person undergoes irreversible surgical intervention (unless hormones are not clinically indicated for the individual).

Statement 9.2.

We recommend health care professionals consider medical intervention, surgical intervention, or both for eunuch individuals when there is a high risk that withholding treatment will cause individuals harm through self-surgery, surgery by unqualified practitioners, or unsupervised use of medications that affect hormones.

The same assessment process recommended in the SOC-8 ought to apply to eunuchs (see Chapter 5—Assessment of Adults). The Eunuch Archive has a large number of posts from individuals finding great difficulty in seeking medical providers who will perform castration surgery. There are a large number of eunuch individuals who have performed self-surgery or have had surgery performed by people who are not credentialed medical providers (Johnson & Irwig, 2014). There are also clinical reports of eunuch individuals who have self-castrated and accounts of patients who have misled medical providers to obtain castration (Hermann & Thorstenson, 2015; Mukhopadhyay & Chowdhury, 2009). There is no doubt when members of this population are denied access to quality medical treatment, they will take actions that may cause them great harm, such as bleeding and infection that may require hospital admission (Hay, 2021; Jackowich et al., 2014; Johnson & Irwig, 2014). Because of these serious problems and harm caused through self-surgery, surgery by unqualified practitioners or the unsupervised use of medications that affect hormones, it is important health care providers create a welcoming environment and consider various treatment options after careful assessment

to avoid the problems that lack of access to treatment and withholding treatment will cause.

When desired, castration can be achieved either chemically or surgically. For some, chemical castration can be an appropriate trial prior to undergoing surgical castration to determine how the individual feels when hypogonadal (Vale et al., 2010). Chemical castration is usually reversible if the medications are discontinued (Wassersug et al., 2021). The most common types of medications used to lower testosterone levels are antiandrogens and estrogen.

The two most commonly used antiandrogens, cyproterone acetate and spironolactone, are oral. Estrogen is sometimes prescribed for prostate cancer patients to lower serum testosterone levels via negative feedback at the hypothalamus and pituitary gland. Estrogens and antiandrogens may not fully suppress testosterone levels into the female or castrate range, and oral estrogens increase the risk of venous thromboembolism. Although not commonly used due to cost, gonadotropin releasing hormone (GnRH) agonists are a very effective method for suppressing the production of sex steroids and fertility (Hembree et al., 2017). When selecting a medication, we advise using those which have been studied in multiple transgender populations (i.e., estrogen, cyproterone acetate, GnRH agonists) rather than medications with little to no peer-reviewed scientific studies (i.e., bicalutamide, rectal progesterone, etc.) (Angus et al., 2021; Butler et al., 2017; Efstathiou et al., 2019; Tosun et al., 2019).

Many eunuch individuals pursue hormone replacement therapy following castration as they do not desire the complete suppression of hormone levels and consequent problems, such as the increased risk of osteoporosis. The two main options for replacement of sex steroids are testosterone and estrogen that may be used in full or partial replacement doses. The majority elect testosterone as they present as male and are not interested in feminization. A minority elect estrogen at a high enough dose to prevent osteoporosis, but low enough avoid most feminization. They may identify as nonbinary, agender, or other (Johnson et al., 2007; Johnson & Wassersug, 2016).

Although studies on hormone replacement therapy in eunuchs are lacking, findings from cisgender men treated for prostate cancer can be informative regarding the effects of hormone therapy. In a randomized controlled trial of 1,694 cisgender men treated for locally advanced or metastatic prostate cancer, one group received a GnRH agonist and the other received transdermal estrogen (Langley et al., 2021). Cisgender men who received the GnRH agonist developed signs and symptoms of both androgen and estrogen deficiency, whereas men who received the estrogen patch only developed androgen-depleting symptoms. Both groups had high rates of sexual side effects (91%), and weight gain was similar among the groups. Compared with cisgender men receiving the GnRH agonist, cisgender men treated with estrogen patches had a higher self-reported quality of life, lower rates of hot flushes (35% vs. 86%), and higher rates of gynecomastia (86% vs. 38%). Metabolically, cisgender men receiving estrogen patches had favorable changes with a lower mean fasting glucose, fasting total cholesterol, systolic and diastolic blood pressure. Conversely, cisgender men receiving the GnRH agonist experienced the opposite effects. Based on this study, eunuchs may consider a low dose of transdermal estrogen therapy to avoid adverse estrogen-depleting effects, which include hot flashes, fatigue, metabolic effects, and loss of bone mineral density (Hembree et al., 2017; Langley et al., 2021). For further information see Chapter 12—Hormone Therapy.

Statement 9.3.

We recommend health care professionals who are assessing eunuch individuals for treatment have demonstrated competency in assessing them.

A frequent topic on the discussion boards of the Eunuch Archive is the difficulty of finding practitioners who are able to understand their needs. Eunuchs and those seeking castration usually are less visible than other gender minorities (Wassersug & Lieberman, 2010). Due to stigma and fear of rejection by the medical community, they may not voluntarily disclose their identity and desires to their medical or mental health providers. In some environments, medical providers may not be aware eunuchs exist and may not even know they have treated eunuch-identified patients.

The SOC section on assessment is applicable to eunuch individuals. Like other gender diverse individuals, those seeking castration can engage in an informed consent process in which qualified providers conduct assessments to ensure individuals are capable of providing informed consent prior to medical interventions and to ensure a mental health problem is not the etiology of the desire. As with other sexual and gender minorities, working with eunuchs requires an understanding that they are a diverse population, and that each person is eunuch in their own way (Johnson et al., 2007). The person seeking services benefits from the professional's accepting stance, open inquiry, suspension of judgment, and flexible expectations, combined with professional competency and expertise.

To provide appropriate treatment, providers must establish trust and respect by creating an inclusive environment for eunuch-identified people. For eunuch-identified individuals, the ideal intake form would ask the assigned sex and identified gender and offer multiple gender options, including "eunuch" and "other." Individuals may identify with more than one option and should be able to select more than one.

HCPs may be involved in the assessment, psychotherapy (if desired), preparation, and follow-up for medical and surgical gender-affirming interventions. They may also provide support for partners and families. Eunuch-identified individuals who want the support of a qualified mental health provider will benefit from a therapist who meets the experience and criteria set out in Chapter 4—Education.

While some individuals seeking or considering castration come to counseling or therapy because they want emotional support or help with decision-making, many come to providers for an assessment in preparation for specific medical interventions (Vale et al., 2010).

Statement 9.4.

We suggest health care professionals providing care to eunuch individuals include sexuality education and counseling.

Several research studies have contributed to our knowledge of contemporary eunuch-identified people and have explored demographic characteristics and sexuality (Handy et al., 2015; Vale et al., 2013; Wibowo et al., 2012, 2016). Medical and MHPs should assume eunuchs are sexual people capable of sexual activity, pleasure, and relationships, unless they report otherwise (Wibowo et al., 2021). Research has shown there is great diversity among eunuchs regarding the level of desire, type of preferred physical or sexual contact, and nature of preferred relationships (Brett et al., 2007; Johnson et al., 2007; Roberts et al., 2008). While some enjoy active sex lives with or without romantic relationships, others identify as asexual or aromantic and are relieved by the loss of libido achieved through surgical or chemical castration (Brett et al., 2007). Each person is different, and one's genital status does not determine sexual or romantic attraction (Walton et al., 2016; Yule et al., 2015).

Regardless of the type of chemical suppression or surgery a person has undergone, they may be capable of sexual pleasure and sexual activity. Contrary to popular belief, eunuchs are not necessarily asexual or nonsexual (Aucoin & Wassersug, 2006). Safe sex education is necessary for all people who engage in sexual activity that could involve an exchange of body fluids. See Chapter 17—Sexual Health for information regarding sex education and safe sex options for people with diverse genders and sexualities. In addition, fertility preservation should be discussed when considering medical interventions that might impact the possibilities for future parenthood. For more considerations see Chapter 16—Reproductive Health.

CHAPTER 10 Intersex

The Standards of Care, Version 7 included a chapter on the applicability of the standards to people with physical intersexuality who become gender-dysphoric and/or change their gender because they differ from transgender individuals without intersexuality in phenomenological presentation, life trajectories, prevalence, etiology, and stigma risks. The current chapter provides an update and adds recommendations on the medically necessary clinical approach to the management of individuals with intersexuality in general (see medical necessity statement in Chapter 2—Global Applicability, Statement 2.1). Because a newborn with an atypical sexual differentiation may already present with clinical challenges, including the need for family education and support from early on, the decision-making on gender assignment, subsequent clinical gender management, components of which—especially genital surgery—may be controversial, and a later risk of gender dysphoria development and gender change that is markedly increased (Sandberg & Gardner, 2022).

Terminology

"Intersex" (from Latin, literal translation "between the sexes") is a term grounded in the binary system of sex underlying mammalian (including human) reproduction. In medicine, the term is colloquially applied to individuals with markedly atypical, congenital variations in the reproductive tract. Some variations, often labeled "genital ambiguity," preclude the simple recognition of somatic sex as male or female and, in resource-rich societies, may require a comprehensive physical, endocrine, and genetic work-up, before a sex/gender is "assigned." In recent years "intersex" has also become an identity label adopted by some individuals with intersex conditions and a subset of (non-intersex) individuals with a nonbinary gender identity (Tamar-Mattis et al., 2018).

At a 2005 international consensus conference on intersex management, intersex conditions were subsumed under a new standard medical term, "Disorders of Sex Development" (DSD), defined as "congenital conditions in which development of chromosomal, gonadal, or anatomical sex is atypical" (Hughes et al., 2006). DSD covers a much wider range of conditions than those traditionally included under intersexuality and comprises conditions such as Turner syndrome and Klinefelter syndrome, which are much more prevalent. In addition, many affected individuals dislike the term "disorder," viewing it as inherently stigmatizing (Carpenter, 2018; Griffiths, 2018; Johnson et al., 2017; Lin-Su, et al., 2015; Lundberg et al., 2018; Tiryaki et al., 2018). Health care professionals (HCPs) also vary in their acceptance of the term (Miller et al., 2018). The wide-spread alternative reading of DSD as "Differences in Sex Development" can be seen as less pathologizing, but is semantically unsatisfactory as this term does not distinguish the typical genital differences between males and females from atypical sexual differentiation. Other recent attempts to come up with less obviously stigmatizing terms such as "Conditions Affecting Reproductive Development" (CARD; Delimata et al., 2018) or "Variations of/in Sex Characteristics" (VSC; Crocetti, et al., 2021) are also not specific to intersexuality.

Given these definitional issues, in this chapter we are using the term "intersexuality" (or "intersex") to refer to congenital physical manifestations only. This is done for both descriptive clarity and historical continuity. This choice is not meant to indicate an intention on our part to take sides in the ongoing discussion regarding the concept of sex/gender as a bipolar system or as a continuum, which may vary with considerations of context and utility (Meyer-Bahlburg, 2019). In 21st century societies, the concepts of sex and gender are in a process of evolution.

Prevalence

The prevalence of intersex conditions depends on the definition used. Obvious genital atypicality ("ambiguous genitalia") occurs with an estimated frequency ranging from approximately 1:2000—1:4500 people (Hughes et al., 2007). The most inclusive definitions of DSD estimate a prevalence of up to 1.7% (Blackless et al., 2000). Although these numbers are high in aggregate, the individual conditions associated with the intersex variations tend to be much rarer. For instance, androgen insensitivity syndrome (AIS) occurs in approximately 1 in 100,000 46,XY births (Mendoza & Motos, 2013), and classic congenital adrenal

hyperplasia (CAH) in approximately 1 in 15,000 46,XX births (Therrell, 2001). Prevalence figures for individual syndromes may vary dramatically between countries and ethnic groups.

Presentation

The presentation of individuals with intersex traits varies widely. Intersexuality can be recognized during prenatal ultrasound imaging, although most individuals will be identified during genital examinations at birth. In resource-rich societies, such children will undergo extensive medical diagnostic procedures within the first weeks of life. Taking into consideration the specific medical diagnosis, physical and hormonal findings, and information from long-term follow-up studies about gender outcome, joint decision-making between the health-care team and the parents generally leads to the newborn being assigned to the male or female sex/gender. Some individuals with intersexuality come to the attention of specialists only around the age of puberty, for instance, when female-raised adolescents are evaluated for primary amenorrhea.

HCPs assisting individuals with both intersexuality and gender uncertainty need to be aware that the medical context in which such individuals have grown up is typically very different from that of non-intersex TGD people. There are many different syndromes of intersexuality, and each syndrome can vary in its degree of severity. Thus, hormonal and surgical treatment approaches vary accordingly.

Some physical manifestations of intersexuality may require early urgent intervention, as in cases of urinary obstruction or of adrenal crisis in CAH. Most physical variations among individuals with intersexuality neither impair function, at least in the early years, nor risk safety for the individual. Yet, the psychosocial stigma associated with atypical genital appearance often motivates early genital surgery (commonly labeled 'corrective' or 'normalizing') long before the individual reaches the age of consent. This approach is highly controversial because it conflicts with ethical principles supporting a person's autonomy (Carpenter, 2021; Kon, 2015; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). In addition, among the manifestations without immediate safety concerns, some individuals, when older, may opt for a range of medical interventions to optimize function and appearance. The specifics of medical treatments are far beyond the scope of what can be addressed in this chapter, and the interested reader should consult the respective endocrine and surgical literature.

Some intersex conditions are associated with a greater variability in long-term gender identity outcome than others (Dessens et al., 2005). For instance, the incidence of a non-cisgender gender identity in 46,XX individuals with CAH assigned female may be as high as 5–10% (Furtado et al., 2012). The substantial biological component underlying gender identity is a critical factor that must be considered when offering psychosocial, medical, and surgical interventions for individuals with intersex conditions.

There is also ample evidence people with intersexuality and their families may experience psychosocial distress (de Vries et al., 2019; Rosenwohl-Mack et al., 2020; Wolfe-Christensen et al., 2017), in part related to psychosocial stigma (Meyer-Bahlburg, Khuri et al., 2017; Meyer-Bahlburg, Reyes-Portillo et al., 2017; Meyer-Bahlburg et al., 2018).

Intersexuality in the psychiatric nomenclature

Since 1980, the American psychiatric nomenclature recognized individuals with intersexuality who meet the criteria for gender identity variants; however, their diagnostic categorization changed with successive DSM editions. For instance, in DSM-III (American Psychiatric Association, 1980), the Axis-I category of "transsexualism" could not be applied to such individuals in adulthood, but such children were labeled "gender identity disorder of childhood," with the medical intersex condition to be specified in Axis III. In DSM-IV-TR (American Psychiatric Association, 2000), individuals with intersexuality were excluded from the Axis-I category of "gender identity disorder" regardless of age and, instead, grouped with other conditions under the category "gender identity disorder not otherwise specified." In DSM-5 (American Psychiatric Association, 2013), which moved away from the multiaxial

Statements of Recommendations

10.1- We suggest a multidisciplinary team, knowledgeable in diversity of gender identity and expression as well as in intersexuality, provide care to individuals with intersexuality and their families.
10.2- We recommend health care professionals providing care for transgender youth and adults seek training and education in the aspects of intersex care relevant to their professional discipline.
10.3- We suggest health care professionals educate and counsel families of children with intersexuality from the time of diagnosis onward about the child's specific intersex condition and its psychosocial implications.
10.4- We suggest both providers and parents engage children/individuals with intersexuality in ongoing, developmentally appropriate communications about their intersex condition and its psychosocial implications.
10.5- We suggest health care professionals and parents support children/individuals with intersexuality in exploring their gender identity throughout their life.
10.6- We suggest health care professionals promote well-being and minimize the potential stigma of having an intersex condition by working collaboratively with both medical and non-medical individuals/organizations.
10.7- We suggest health care professionals refer children/individuals with intersexuality and their families to mental-health providers as well as peer and other psychosocial supports as indicated.
10.8- We recommend health care professionals counsel individuals with intersexuality and their families about puberty suppression and/or hormonal treatment options within the context of the individual's gender identity, age, and unique medical circumstances.
10.9- We suggest health care professionals counsel parents and children with intersexuality (when cognitively sufficiently developed) to delay gender-affirming genital surgery, gonadal surgery, or both, so as to optimize the children's self-determination and ability to participate in the decision based on informed consent.
10.10- We suggest only surgeons experienced in intersex genital or gonadal surgery operate on individuals with intersexuality.
10.11- We recommend health care professionals who are prescribing or referring for hormonal therapies/surgeries counsel individuals with intersexuality and fertility potential and their families about a) known effects of hormonal therapies/surgery on future fertility; b) potential effects of therapies that are not well studied and are of unknown reversibility; c) fertility preservation options; and d) psychosocial implications of infertility.
10.12- We suggest health care professionals caring for individuals with intersexuality and congenital infertility introduce them and their families, early and gradually, to the various alternative options of parenthood.

system, "gender identity disorder" was re-defined as "gender dysphoria" and applied regardless of age and intersex status, but individuals with intersexuality received the added specification "with a disorder of sex development" (Zucker et al., 2013). The just published text revision of DSM-5 (American Psychiatric Association, 2022) keeps the term gender dysphoria. Note, however, the recent revision of the International Classification of Diseases [ICD-11; World Health Organization, 2019a] has moved "gender incongruence" from the chapter "Mental, Behavioral, or Neurodevelopmental Disorders" to a new chapter "Conditions Related to Sexual Health."

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 10.1

We suggest a multidisciplinary team, knowledgeable in diversity of gender identity and expression as well as in intersexuality, provide care to individuals with intersexuality and their families.

Intersexuality, a subcategory of DSD, is a complex congenital condition that requires the involvement of experts from various medical and behavioral disciplines (Hughes et al., 2006). Team composition and function can vary depending on team location, local resources, diagnosis, and the needs of the individual with intersexuality and her/his/their family. The ideal team includes pediatric subspecialists in endocrinology, surgery and/or urology, psychology/psychiatry, gynecology, genetics, and, if available, personnel trained in social work, nursing, and medical ethics (Lee et al., 2006). The structure of the team can be in line with 1) the traditional multidisciplinary medical model; 2) the interprofessional model; or 3) the transdisciplinary model. Although these structures can appear similar, they are in fact very different and can exert varying influences on how the team functions (Sandberg & Mazur, 2014). The 2006 Consensus Statement makes no decision about which model is best—multidisciplinary, interdisciplinary, or transdisciplinary—and only states the models "imply different degrees of collaboration and professional

autonomy" (Lee, Nordenström et al., 2016). Since the publication of the Consensus Statement in 2006, such teams have been created both in Europe and in the US. A listing of teams in the US can be found on the DSD-Translational Network (DSD-TRN) website. There are also teams in a number of European countries (Thyen et al., 2018). While there are barriers to the creation of teams as noted by Sandberg and Mazur (2014), multidisciplinary teams help address a number of problems that have undermined the successful care of individuals with an intersex diagnosis and their families, such as the scattered nature of services, the limited or absent communication between professionals, and the resulting fragmented nature of the explanations individuals receive that cause more confusion than clarity.

Most individuals born with intersexuality will be identified at birth or shortly thereafter, while others will be identified at later times in the life cycle, for example at puberty (see Brain et al., 2010, Table 1). When this happens the team approach will be modified based on the diagnosis and the age of the person. In some circumstances, the composition of the team can be expanded to include other specialists as needed.

It has been reported children seen by a multidisciplinary team were significantly more likely to receive nearly the full range of services rather than only those services offered by a single provider (Crerand et al., 2019). Parents who received such care positively endorsed psychosocial services and the team approach and reported receiving more information than those who did not interact with such a team (Crerand et al., 2019).

Statement 10.2

We recommend health care professionals providing care for transgender youth and adults seek training and education in the aspects of intersex care relevant to their professional discipline.

Results from interviews with medical trainees (Liang et al., 2017; Zelin et al., 2018) and from programmatic self-audits and surveys (DeVita et al., 2018; Khalili et al., 2015) suggest medical training programs are not adequately preparing practitioners to provide competent care to individuals presenting with gender dysphoria and intersexuality. Professional and stakeholder attendees of intersex-specific events have identified ongoing education and collaboration as an important professional development need (Bertalan et al., 2018; Mazur et al., 2007). This may be especially true for adult care providers who may have less clinical guidance or support in assisting those individuals who are transitioning from pediatric to adult care (Crouch & Creighton, 2014).

However, there are few guidelines for training or assessing practitioner competency in managing these topics, and those that are available primarily apply to mental health professionals (MHPs) (Hollenbach et al., 2014), with the exception of a primary care guide (National LGBTQIA + Health Education Center, 2020).

For HCPs wanting to improve their competency, seeking consultation from experts may be an option when formal education or empirical guidelines are otherwise unavailable. Given the relative widespread adoption of multidisciplinary expert teams in the treatment of intersexuality (Pasterski et al., 2010), individuals serving on these teams are well positioned to consult with and educate other health care staff who may not have received adequate training (Hughes et al., 2006). Therefore, it is recommended the training of other professionals be a central component of team development (Auchus et al., 2010) and members of multidisciplinary teams receive training specific to team-based work, including strategies for engaging in interprofessional learning (Bisbey, et al., 2019; Interprofessional Education Collaborative Expert Panel, 2011).

Statement 10.3

We suggest health care professionals educate and counsel families of children with intersexuality from the time of diagnosis onward about the child's specific intersex condition and its psychosocial implications.

Full disclosure of medical information to families of children with intersex conditions through education and counseling should begin at the time of diagnosis and should be consistent with guidance from multiple international consensus guidelines. One of the most challenging issues presented by a newborn with intersexuality, particularly

when associated with noticeable genital ambiguity, is sex assignment and from the parents' perspective, the gender of rearing (Fisher, Ristori et al., 2016). Given this is a very stressful situation for most parents, it is generally recommended the decisions about sex/gender should be made as quickly as a thorough diagnostic evaluation permits (Houk & Lee, 2010). However, the criteria for sex/gender decisions have changed over time. In the second half of the 20th century, the decisions were biased towards female assignment, because feminizing genital surgery was seen as easier and less side-effect prone than masculinizing surgery. Yet, in certain intersex conditions, for instance 46,XY 5α-RD-2 deficiency, female sex/gender assignment was found to be associated with high rates of later gender dysphoria and gender change (Yang et al., 2010). Therefore, since the International Consensus Conference on Intersex Management in 2005, sex/gender assignment takes into consideration the gradually accumulating data on long-term gender outcome in the diverse conditions of intersexuality.

The practice of disclosure seeks to enable more fully informed decision-making about care. Additionally, while shame and stigma surrounding intersexuality is associated with poorer psychosocial outcomes, open and proactive communication of health information has been proposed as a strategy to reduce those risks (de Vries et al., 2019). Depending on the person's diagnosis and developmental stage, intersex conditions may differentially impact individuals and their health care needs. Intersex-health-related communication must therefore be continuous and tailored to the individual. Research on decision-making in intersex care suggests families are influenced by how clinical teams communicate (Timmermans et al., 2018). In keeping with the SOC, we encourage providers to adopt normalizing, affirming language and attitudes across education and counseling functions. For example, describing genital atypia as a "variation" or "difference" is more affirming than using the terms "birth defect" or "abnormality."

All HCPs involved in an individual's care can provide essential education and information to families. In multidisciplinary teams, the type of education may align with an HCP's area of expertise, for example, a surgeon educating the individual on their anatomy, an endocrinologist teaching the specifics of hormonal development, or an MHP conveying the spectrums of gender and sexual identity. Other HCPs may need to provide comprehensive education. Families should receive information that is pertinent to the individual's specific intersex variation, when known. All HCPs can supplement this information with patient-centered resources available from support groups. People with intersexuality have also been hired as team members to provide education using their lived experience.

Consensus guidelines also recommend families be offered ongoing peer and professional psychosocial support (Hughes et al., 2006) that may involve counseling with a focus on problem-solving and anticipatory guidance (Hughes et al., 2006). For example, families may seek guidance in educating other people—siblings, extended family, and caregivers—about the specific intersex condition of an individual. Other families may need support or mental health care to manage the stress of intersex treatment. Adolescents may benefit from guidance on how to disclose information to peers as well as from support when navigating dating and sex. Providing counseling may also involve guiding families and individuals of all ages through a shared decision-making process around medical or surgical care. Providers may employ decision aids to support this process (Sandberg et al., 2019; Weidler et al., 2019).

Statement 10.4

We suggest both providers and parents engage children/individuals with intersexuality in ongoing, developmentally appropriate communications about their intersex condition and its psychosocial implications.

Communicating health information is a multi-directional process that includes the transfer of information from providers to patients, from parents to patients, as well as from patients back to their providers (Weidler & Peterson, 2019). While much emphasis has been placed on communicating to parents around issues of diagnosis and surgical decision-making, youth with DSD have reported barriers to engaging with health care providers and may not always turn

to their parents for support (Callens et al., 2021). To prepare individuals to be fully engaged and autonomous in their treatment, it is critical both providers and parents communicate continuously with children/individuals.

Providers must set an expectation as soon as possible for ongoing, open communication between all parties, especially since parents may experience distress due to the uncertainty associated with DSD and may seek quick fixes (Crissman et al., 2011; Roberts et al., 2020). Models of shared decision-making as well as related decisional tools have been developed to support ongoing communication between HCPs and families/individuals (Karkazis et al., 2010; Sandberg et al., 2019; Siminoff & Sandberg, 2015; Weidler et al., 2019). In addition to setting an expectation for dialogue, providers can also set the tone of communication. Providers can help parents and individuals tolerate diagnostic uncertainty while simultaneously providing education on anatomic variations, modeling openness to gender and sexual identity, and welcoming the child's/individual's questions. As they age, children/individuals may have questions or need age-appropriate information on issues of sex, menstruation, fertility, the need for hormone treatment (adrenal/sex), bone health, and cancer risk.

Parents also play a critical role in educating their children and may be the first people to disclose health information to their child (Callens et al., 2021). As part of expectation-setting around communication, providers should prepare parents to educate their child and members of their support system about the intersex diagnosis and treatment history. Some parents report difficulties in knowing how much to disclose to others as well as to their own children (Crissman et al., 2011; Danon & Kramer, 2017). The stress parents experience while raising children with an intersex condition is increased when parents adopt an approach that minimizes disclosure/discussion of their child's diagnosis (Crissman et al., 2011). The level of stress also varies by developmental stage, with parents of adolescents reporting higher rates of stress (Hullman et al., 2011). Therefore, HCPs should assist parents in developing strategies specific to their child's developmental stage that address their psychosocial or cultural concerns and values (Danon & Kramer, 2017; Weidler & Peterson, 2019). Finally, broader research on sexuality and gender variance has found—counter to the associations between shame/stigma and negative health outcomes—supportive family behaviors (including talking with children about their identity and connecting them with peers) predicted greater self-esteem and better health outcomes in individuals (Ryan et al., 2010).

Statement 10.5

We suggest health care professionals and parents support children/individuals with intersexuality in exploring their gender identity throughout their life.

Psychological, social, and cultural constructs all intersect with biological factors to form an individual's gender identity. As a group, individuals with intersexuality show increased rates of gender nonconforming behavior, gender-questioning, and cross-gender wishes in childhood, dependent in part on the discrepancy between the prenatal sex-hormonal milieu in which the fetal brain has differentiated and the sex assigned at birth (Callens et al., 2016; Hines, et al., 2015; Meyer-Bahlburg et al., 2016; Pasterski et al., 2015). Gender identity problems are observed at different rates in individuals with different intersex conditions (de Vries et al., 2007). More recently, some individuals have been documented to develop a nonbinary identity, at least privately (Kreukels et al., 2018). Although the majority of people with intersexuality may not experience gender dysphoria or wishes for gender transition, they may still have feelings of uncertainty and unanswered questions regarding their gender (Kreukels et al., 2018). Questions about gender identity may arise from such factors as genital appearance, pubertal development, and knowledge of items such as the diagnostic term of the medical condition, gonadal status, sex chromosome status, and a history of genital surgery. Therefore, HCPs need to be accessible for clients to discuss such questions and feelings, openly converse about gender diversity, and adopt a less binary approach to gender. HCPs are advised to guide parents as well in supporting their children in exploring gender.

Furthermore, such support should not be confined to the childhood years. Rather, individuals should be given the opportunity to explore their gender identity throughout their lifetime, because different phases may come with new questions regarding gender (for example, puberty/adolescence, childbearing age). Children in general may have questions regarding their gender identity at salient points during their maturation and evolution. When faced with additional stressors, for example, genital ambiguity, genital examinations and procedures, as well as the intersectionality of cultural bias and influences, individuals with intersexuality may need support and should be encouraged to seek educated professional assistance and guidance when needed. Also, HCPs should inquire regularly to determine if their clients with intersexuality need such support. When people experience gender incongruence, gender-affirming interventions may be considered. Procedures that should be applied in such interventions are described in other chapters.

Statement 10.6

We suggest health care professionals promote well-being and minimize the potential stigma of having an intersex condition by working collaboratively with both medical and non-medical individuals/organizations.

Individuals with intersexuality are reported to experience stigma, feelings of shame, guilt, anger, sadness and depression (Carroll et al., 2020; Joseph et al., 2017; Schützmann et al., 2009). Higher levels of psychological problems are observed in this population than in the general population (Liao & Simmonds, 2014; de Vries et al., 2019). In addition, parental fear of stigmatization and adjustment to their child's diagnosis must not be overlooked by the clinical team. Parents may benefit from supportive counseling to assist them both in managing clinical decision-making (Fleming et al., 2017; Rolston et al., 2015; Timmermans et al., 2019) as well as understanding the impact of clinical decisions on their view of their child (Crissman et al., 2011; Fedele et al., 2010).

Thyen et al. (2005) found repeated genital examinations appear to be correlated with shame, fear and pain and may increase the likelihood of developing post-traumatic stress disorder (PTSD) later in life (Alexander et al., 1997; Money & Lamacz, 1987). Exposure to repeated genital examinations, fear of medical interventions, and parental and physician secrecy about being intersex ultimately undermine the self-empowerment and self-esteem of the person with intersexuality (Meyer-Bahlburg et al., 2018; Thyen et al., 2005; Tishelman et al., 2017; van de Grift, Cohen-Kettenis et al., 2018). For recommendations on how to conduct genital examinations to minimize adverse psychological side effects see Tishelman et al. (2017).

There is an active movement within the intersex community to alleviate stigma and to return human rights and dignity to intersex people rather than viewing them as medical anomalies and curiosities (Yogyakarta Principles, 2007, 2017). Chase (2003) summarizes the major reasons for the intersex advocacy movement and outlines how stigma and emotional trauma are the outcome of ignorance and the perceived need for secrecy. Public awareness of intersex conditions is very limited, and images and histories of individuals with intersexuality are still presented as "abnormalities of nature". We, therefore, advise HCPs to actively educate their colleagues, individuals with intersexuality, their families, and communities, raise public awareness, and increase knowledge about intersexuality. Societal awareness and knowledge regarding intersexuality may help reduce discrimination and stigmatization. Tools and education/information materials may also help individuals with intersexuality disclose their condition, if desired (Ernst et al., 2016).

HCPs should be able to recognize and address stigmatization in their clients (Meyer-Bahlburg et al., 2018) and should encourage people with intersexuality of various ages to connect via support groups. There is a need for developing specific techniques/methods for assisting clients to cope with stigma related to intersex.

Statement 10.7

We suggest health care professionals refer children/individuals with intersexuality and their families to mental health professionals as well as peer and other psychosocial supports as indicated.

For almost all parents, the birth of a child with intersexuality is entirely unexpected and comes as a shock. Their inability to respond immediately to the ubiquitous question, "Is your baby a boy or a girl?", their lack of knowledge about the child's condition, the uncertainty regarding the child's future, and the pervasive intersex stigma are likely to cause distress, sometimes to the level of PTSD and may lead to prolonged anxiety and depression (Pasterski et al., 2014; Roberts et al., 2020; Wisniewski & Sandberg, 2015). This situation may affect parental care and long-term outcome of their child with intersexuality (Schweizer et al., 2017). As these children grow up, they are also at risk of experiencing intersex stigma in its three major forms (enacted, anticipated, internalized) in all spheres of life (Meyer-Bahlburg et al., 2018), along with other potential difficulties such as body image problems, gender-atypical behavior, and gender identity questioning. Many may face the additional challenge presented by the awareness of the incongruence between their assigned gender and biological characteristics such as sexual karyotype, gonads, past and/or current sex-hormonal milieu, and reproductive tract configuration. This situation may also adversely affect the individuals' mental health (Godfrey, 2021; Meyer-Bahlburg, 2022). A recent online study of a very large sample of LGBTQ youth indicated that LGBTQ youth who categorized themselves as having a physical intersex variation had a rate of mental health problems that was higher than the rate in LGBTQ youth without intersexuality (Trevor Project, 2021). As intersex conditions are rare, parents of such children and later the individuals themselves may experience their situation as unique and very difficult for others to understand. Thus, based on clinical experience, there is a consensus among HCPs who are experienced in intersex care, that social support is a crucial component of intersex care, not only through professional support by MHPs (Pasterski et al., 2010), but also, importantly, through support groups of individuals with intersex conditions (Baratz et al., 2014; Cull & Simmonds, 2010; Hughes et al., 2006; Lampalzer et al., 2021). A detailed international listing of DSD and intersex peer support and advocacy groups with their websites has been provided by Lee, Nordenström et al. (2016). Given the heterogeneity of intersex conditions and treatment regimens, an individual with intersexuality may find it most helpful to associate with a support group that includes members with the same or similar condition as that of the individual. It is important HCPs specializing in intersex care also collaborate closely with such support groups so that occasional differences in opinions regarding specific aspects of care can be resolved through detailed discussions. Close contacts between HCPs and support groups also facilitate community-based participatory research that benefits both sides.

Statement 10.8

We recommend health care professionals counsel individuals with intersexuality and their families about puberty suppression and/or hormonal treatment options within the context of the individual's gender identity, age, and unique medical circumstances.

While many people with intersexuality have a gender identity in line with their XX or XY karyotype, there is sufficient heterogeneity that HCPs should be able to provide customized approaches. For example, among XX individuals with virilizing CAH, a larger than expected minority have a male gender identity (Dessens et al., 2005). Among XY individuals with partial androgen insensitivity syndrome, gender identity can vary significantly (Babu & Shah, 2021). Furthermore, among XY individuals with 5α-reductase-2 (5α-RD-2) deficiency and with 17-beta-hydroxysteroid dehydrogenase-3 deficiency who are assigned the female sex at birth, a large fraction (56–63% and 39–64%, respectively) change from a typical female gender role to a typical male gender role as they age (Cohen-Kettenis, 2005).

People with intersexuality have a wide range of medical options open to them depending on their gender identity and its alignment with anatomy. These options include puberty suppression medication, hormonal treatment, and surgeries, all customized to the unique circumstances of the individual (Weinand & Safer, 2015; Safer & Tangpricha, 2019) (for further information see Chapter 6—Adolescents and Chapter 12—Hormone Therapy). Specifically, when functional gonads are present, puberty may be temporarily suspended by using gonadotropin-releasing hormone (GnRH) analogues. Such intervention can

facilitate the necessary passage of time needed by the individual to explore gender identity and to actively participate in sex designation, especially for conditions in which sex role change is common (i.e., in female-raised individuals with 5α-RD-2 deficiency; Cocchetti, Ristori, Mazzoli et al., 2020; Fisher, Castellini et al., 2016).

HCPs can counsel individuals and their families directly if the providers have sufficient expertise and can leverage expertise needed to determine both a course of treatment appropriate for the individual and the logistics involved in implementing the chosen therapeutic option.

Statement 10.9

We suggest health care professionals counsel parents and children with intersexuality (when cognitively sufficiently developed) to delay gender-affirming genital surgery, gonadal surgery, or both, so as to optimize the children's self-determination and ability to participate in the decision based on informed consent.

International human rights organizations have increasingly expressed their concerns that surgeries performed before a child can participate meaningfully in decision-making may endanger the child's human rights to autonomy, self-determination, and an open future (e.g., Human Rights Watch, 2017). Numerous medical and intersex advocacy organizations as well as several countries have joined these international human rights groups in recommending the delay of surgery when medically feasible (Dalke et al., 2020; National Academies of Sciences, Engineering, and Medicine, 2020). However, it is important to note some anatomic variations, such as obstruction of urinary flow or exposure of pelvic organs, pose an imminent risk to physical health (Mouriquand et al., 2016). Others, such as menstrual obstruction or long-term malignancy risk in undescended testes, have eventual physical consequences. A third group of variations, i.e., variations in the appearance of external genitals or vaginal depth, pose no immediate or long-term physical risk. The above recommendation addresses only those anatomic variations that, if left untreated, have no immediate adverse physical consequences and where delaying surgical treatment poses no physical health risk.

Non-urgent surgical care for individuals with these variations is complex and often contested, particularly when an individual is an infant or a young child and cannot yet participate in the decision-making process. Older people with intersexuality have reported psychosocial and sexual health problems, including depression, anxiety, and sexual and social stigma (de Vries et al., 2019; Rosenwohl-Mack et al., 2020). Some studies have suggested individuals with a specific variation (e.g., 46,XX CAH) agree with surgery being performed before adolescence (Bennecke et al., 2021). Recent studies suggest some adolescents and adults are satisfied with the appearance and function of the genitals after childhood surgery (Rapp et al., 2021). A child's genital difference can also become a source of stress for parents, and there is research that reports a correlation of surgery to create binary genitals with a limited amount of reduction in parental distress (Wolfe-Christensen et al., 2017), although a minority of parents may report decisional regret (Ellens et al., 2017). Consequently, some organizations recommend surgery be offered to very young children (American Urological Association, 2019; Pediatric Endocrine Society, 2020).

This shows the division within the medical field regarding its management guidelines for early genital surgery. The authors of this chapter also did not reach complete consensus. Some intersex specialists consider it potentially harmful to insist on a universal deferral of early genital surgery for genital variations without immediate medical risks. Reasons supporting this view include 1) intersex conditions are highly heterogeneous with respect to type and severity as well as associated gonadal structure, function, and malignancy risk; 2) societies and families vary tremendously in gender norms and intersex stigma potential; 3) early surgery may present certain technical advantages; and 4) a review of surveys of individuals with intersexuality (most of whom had previously undergone genital surgery) show the majority endorse surgery before the age of consent, especially in the case of individuals with 46,XX CAH and less strongly for individuals with XY intersex conditions (Meyer-Bahlburg, 2022). Experts supporting this view call for an individualized approach to

decisions regarding genital surgery and its timing. This approach has been adopted by medical societies with high rates of intersex specialists (Bangalore Krishna et al., 2021; Pediatric Endocrine Society, 2020; Speiser et al., 2018; Stark et al., 2019) and by certain support organizations (CARES Foundation; Krege et al., 2019).

Nonetheless, long-term outcome studies are limited and most studies reporting positive outcomes lack a non-surgical comparison group (Dalke, et al., 2020; National Academies of Sciences, Engineering, and Medicine, 2020). There is also no evidence surgery protects children with intersex conditions from stigma (Roen, 2019). Adults with intersexuality do experience stigma, depression, and anxiety related to their genitalia, but can also experience stigma whether or not they have surgery (Ediati et al., 2017; Meyer-Bahlburg, Khuri et al., 2017; Meyer-Bahlburg et al., 2018). There is also evidence surgeries may lead to significant cosmetic, urinary, and sexual complications extending into adulthood (Gong & Cheng, 2017; National Academies of Sciences, Engineering, and Medicine, 2020). Recent studies suggest some groups of individuals may have particularly negative experiences with gonadectomy, although this risk has to be weighed against that of gonadal malignancy (Duranteau et al., 2020; Rapp et al., 2021). People with intersex conditions are also far more likely than the general population to be transgender, to be gender diverse, or to have gender dysphoria (Almasri et al., 2018; Pasterski et al., 2015). Genital surgeries of young children may therefore irreversibly reinforce a binary sex assignment that is not aligned with the persons' future. These findings, together with human rights perspectives, support the call for the delay in the decision for surgery until the individual can decide for him/her/themselves.

Systematic long-term follow-up studies are urgently needed to compare individuals with the same intersex conditions who differ in the age at surgery or have had no surgery with regard to gender identity, mental health, and general quality of life.

Statement 10.10

We suggest only surgeons experienced in intersex genital or gonadal surgery operate on individuals with intersexuality.

Intersex conditions are rare, and intersex genital and gonadal anatomy are heterogeneous. Surgeries have been associated with a risk of significant long-term complications (e.g., National Academies of Sciences, Engineering, and Medicine, 2020), and most surgical training programs do not prepare trainees to provide this specialized care (Grimstad, Kremen et al., 2021). In recognition of the complexity of surgical care across the lifespan, standards produced by expert and international consensus recommend this care be provided by multidisciplinary teams of experts (Krege et al, 2019; Lee, Nordenström et al., 2016; Pediatric Endocrine Society, 2020). Therefore, we advise surgical care be limited to intersex-specialized, multidisciplinary settings that include surgeons experienced in intersex care.

Statement 10.11

We recommend health care professionals who are prescribing or referring for hormonal therapies/surgeries counsel individuals with intersexuality and fertility potential and their families about a) known effects of hormonal therapies/surgery on future fertility; b) potential effects of therapies that are not well studied and are of unknown reversibility; c) fertility preservation options; and d) psychosocial implications of infertility.

Individuals with certain intersex conditions may have reproductively functional genitalia but experience infertility due to atypical gonadal development. Others may have functioning gonads with viable germ cells but an inability to achieve natural fertility secondary to incongruent internal or external genitalia (van Batavia & Kolon, 2016). Pubertal suppression, hormonal treatment with sex steroid hormones, and gender affirming surgeries may all have an adverse impact on future fertility. The potential consequences of the treatment and fertility preservation options should therefore be reviewed and discussed.

Individuals with functioning testes should be advised prolonged treatment with estrogen and suppression of testosterone, as studied in TGD people without intersexuality, may cause testicular atrophy and a reduction in sperm count (Mattawanon et al., 2018). Although interruption

of such gender affirming hormonal treatment may improve sperm quality, a complete reversal of semen impairment cannot be guaranteed (Sermondade et al., 2021). The principal fertility preservation option for individuals with functioning testes is cryopreservation of sperm collected through masturbation or vibratory stimulation (de Roo et al., 2016). Although there are no data for success in humans, there is a proposal to offer direct testicular extraction and cryopreservation of immature testicular tissue to adolescents who have not yet undergone spermarche (Mattawanon et al., 2018).

Individuals with functioning ovaries should be advised testosterone therapy usually results in cessation of both menses and ovulation, often within a few months of initiating therapy. There are major gaps in knowledge regarding the potential effects of testosterone on oocytes and subsequent fertility. In transgender people, one study reported testosterone treatment may be associated with the development of polycystic ovarian morphology (Grynberg et al., 2010). However, other researchers have not found evidence of polycystic ovarian syndrome (PCOS) among transgender men receiving gender affirming hormone therapy based on metabolic (Chan et al., 2018) or histologic parameters (de Roo et al., 2017). Individuals with an intact uterus and functioning ovaries may regain their fertility potential if testosterone therapy is discontinued.

Fertility preservation options in post-pubertal people with intersexuality and functioning ovaries include hormonal stimulation for mature oocyte cryopreservation or ovarian tissue cryopreservation. Alternatively, stimulated oocyte extraction has been reported even for a transgender man continuing testosterone therapy (Greenwald, 2021). Similarly, oocyte cryopreservation after ovarian stimulation has been reported in a transgender boy receiving GnRHa therapy (Rothenberg et al., 2019). It should be noted ovarian stimulation, temporary cessation of GnRHa, testosterone treatment, or both, as well as gynecological procedures, can all be psychologically distressing to individuals, with the stress reaction being influenced by mental health, gender identity, and other medical experience. Applicability of certain interventions may depend on the support of other people in the individual's social network, including potential partners.

Statement 10.12

We suggest health care professionals caring for individuals with intersexuality and congenital infertility introduce them and their families, early and gradually, to the various alternative options of parenthood.

For people with intersex characteristics, the likelihood of infertility may be recognized in infancy, childhood, adolescence as well as in adulthood, without first engaging in attempts to conceive. For many individuals, a diagnosis of infertility accompanies the intersex diagnosis (Jones, 2019). For some individuals, assisted heterologous fertilization (e.g., oocyte or sperm donation) may be an option. Multiple adoption pathways exist. Some may require commitment and a considerable investment of time. Individuals who are either not interested in engaging in the efforts to achieve fertility previously described or for whom fertility is not possible can benefit from early exposure to the options available for adoption and alternative parenthood. While uterus transplantation has had preliminary success in people with Mullerian agenesis (Richards et al., 2021), there is no protocol to date that avoids exposure of the developing fetus to the risks associated with the medications used to avoid transplant rejection.

CHAPTER 11 Institutional Environments

This chapter addresses care for transgender and gender diverse (TGD) individuals who reside in institutions. By definition, institutions are facilities or establishments in which people live and receive care in a congregate or large group setting, where individuals may or may not have freedom of movement, individual consent, or agency. Carceral facilities (correctional facilities, immigration detention centers, jails, juvenile detention centers) and noncarceral facilities (long-term care facilities, in-patient psychiatric facilities, domiciliaries, hospice/palliative care, assisted living facilities) are residential institutions where health care access for transgender persons may be provided. Much of the evidence in support of proper care of TGD persons comes from carceral settings. However, the recommendations put forth here apply to all institutions that house TGD individuals, both carceral and noncarceral (Porter et al., 2016). All of the recommendations of the Standards of Care apply equally to people living in both types of institutions. People should have access to these medically necessary treatments irrespective of their housing situation within an institution (Brown, 2009). Care for an institutionalized person must consider the individual does not have the access that non-institutionalized persons have to securing care on their own. For that reason, institutionalized persons must be supported in being able to receive the Standards of Care established by the World Professional Association for Transgender Health (WPATH).

TGD residents in carceral facilities report the lack of access to medically necessary transgender-specific health care (see Chapter 2—Global Applicability, Statement 2.1), which is ranked as their number one concern while incarcerated (Brown, 2014; Emmer et al., 2011). The systemic racial inequities inherent in many carceral environments (Sawyer, 2020), racial disparities in health outcomes (Nowotny et al., 2017), and the overrepresentation of TGD people of color in some facilities (Reisner et al., 2014) punctuate a need for facility leadership to attend to transitional care access issues. Controlled studies show clinically significant health and mental health disparities for justice-involved transgender people compared to matched groups of transgender people who have not been incarcerated or jailed (Brown and Jones, 2015). Too often the agencies, structures, and personnel that provide care are lacking in knowledge, training, and capacity to care for gender diverse people (Clark et al., 2017). Discrimination against TGD residents in palliative care settings, including hospice, is common, and the needs of TGD patients or their surrogates have been ignored in these settings (Stein et al., 2020). This is one reason why lesbian, gay, bisexual and transgender (LGBT)

Statements of Recommendations

11.1- We recommend health care professionals responsible for providing gender-affirming care to individuals residing in institutions (or associated with institutions or agencies) recognize the entire list of recommendations of the SOC-8 apply equally to people living in institutions.
11.2- We suggest institutions provide all staff with training on gender diversity.
11.3- We recommend medical professionals charged with prescribing and monitoring hormones for TGD individuals living in institutions who need gender-affirming hormone therapy do so without undue delay and in accordance with the SOC-8.
11.4- We recommend staff and professionals charged with providing health care to TGD individuals living in institutions recommend and support gender-affirming surgical treatments in accordance with the SOC-8 when sought by the individual, without undue delay.
11.5- We recommend administrators, health care professionals, and all others working in institutions charged with the responsibility of caring for TGD individuals allow those individuals who request appropriate clothing and grooming items to obtain such items concordant with their gender expression.
11.6- We recommend all institutional staff address TGD individuals by their chosen names and pronouns at all times.
11.7- We recommend institutional administrators, health care professionals, and other officials responsible for making housing decisions for TGD residents consider the individual's housing preference, gender identity and expression, and safety considerations rather than solely their anatomy or sex assignment at birth.
11.8- We recommend institutional personnel establish housing policies that ensure the safety of TGD residents without segregating or isolating these individuals.
11.9- We recommend institutional personnel allow TGD residents the private use of shower and toilet facilities upon request.

patients may choose to hide their sexual and/or gender identity when they enter a nursing home, despite the fact that prior to their admission to the facility they had been living publicly as a LGBT-identified person (Carroll, 2017; Serafin et al., 2013).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable. The majority of the available literature related to institutions focuses on those who are incarcerated in jails, prisons, or other carceral environments. Literature about other institutional types were also considered and referenced where available. We hope future investigations will address this relative lack of data from noncarceral institutions. The recommendations summarized above are generalizable to a variety of institutional settings that have characteristics in common, including extended periods of stay, loss of or limited agency, and reliance on institutional staff for some or all of the basic necessities of life.

Statement 11.1

We recommend health care professionals responsible for providing gender-affirming care to individuals residing in institutions (or associated with institutions or agencies) recognize the entire list of recommendations of the SOC-8, apply equally to TGD people living in institutions.

Just as people living in institutions require and deserve mental and medical health care in general and in specialty areas, we recognize TGD people are in these institutions and thus need care specific to TGD concerns. We recommend the application of the Standards of Care (SOC) to people living in institutions as basic principles of health care and ethics (Beauchamp & Childress, 2019; Pope & Vasquez, 2016). Additionally, numerous courts have long upheld the need to provide TGD-informed care based in the WPATH SOC to people living in institutions as well (e.g., Koselik v. Massachusetts, 2002; Edmo v. Idaho Department of Corrections, 2020). Agencies that provide staffing for long-term, in-home services should also be aware of the applicability of the Standards of Care.

Statement 11.2

We suggest institutions provide all staff with training on gender diversity.

Because TGD care affects a small percentage of the population, it requires specialized training as outlined in this SOC Version 8. While the level of training will vary based on the staff member's role within the institutional setting, all staff will need training in addressing residents appropriately while other clinical staff may need more intensive training and/or consultation. These training recommendations also apply to agencies that supply staffing for in-home, long-term care. Misgendering institutionalized residents, not allowing for gender appropriate clothing, shower facilities, or housing, and not using chosen names communicates a lack of respect for TGD residents who may experience repeated indignities as emotionally traumatic, depressing, and anxiety-producing. By providing all institutional staff with training on gender diversity and basic competence in transgender-related health care issues, these harms can be prevented (Hafford-Letchfield et al., 2017). Surveys indicate individuals working with incarcerated individuals as well as in workers in noncarceral settings like palliative care have significant knowledge gaps (Stein et al., 2020; White et al., 2016). Hafford-Letchfied et al. (2017) showed benefit to training residential long-term care staff when such training began with "recognizing LBGT issues" and existed in "care homes". If the assigned health care providers lack the expertise to assess and/or treat gender diverse persons under their charge, outside consultation should be sought from professionals with expertise in the provision of gender-affirming health care (Brömdal et al., 2019; Sevelius and Jenness, 2017).

Statement 11.3

We recommend medical professionals charged with prescribing and monitoring hormones for TGD individuals living in institutions who need gender-affirming hormone therapy do so

without undue delay and in accordance with the SOC-8.

TGD persons may be admitted to institutions in need of evaluation for gender-affirming hormonal care or may develop this need after they have resided in an institutional setting for varying degrees of time. It is not uncommon for TGD persons to be denied access to hormonal care for months or years after making such needs known or to be undertreated and poorly monitored, delaying the necessary titration of medications for safety and efficacy (Keohane, 2018; Kosilek v. Massachusetts, 2002; Monroe v. Baldwin et al., 2019). This can result in significant negative mental health outcomes to include depression, anxiety, suicidality, and surgical self-treatment risks (Brown, 2010). As with all medically necessary health care, access to gender-affirming hormone therapies should be provided in a timely fashion when indicated for a TGD resident, in both carceral and noncarceral institutional environments. Medical professionals shall appropriately titrate hormones based on laboratory results and clinical outcomes to ensure results are within the range of recommended standards within the field of endocrinology. Such labs shall be taken at a frequency so as not to delay appropriate titration.

TGD elderly people living in long-term care facilities have unique needs (Boyd, 2019; Caroll, 2017; Porter, 2016). When elderly individuals request hormonal treatment, while physicians should assess pre-existing conditions, rarely do such conditions absolutely contraindicate administering hormones in this population (Ettner, 2013). People with gender incongruence in institutions may also have coexisting mental health conditions (Brown and Jones, 2015; Cole et al., 1997). These conditions should be evaluated and treated appropriately as part of the overall assessment. Persons receiving hormones must be closely medically monitored to avoid potential drug interactions and polypharmacy (Hembree et al., 2017).

TGD persons who enter an institution on an appropriate regimen of gender-affirming hormone therapy should be continued on the same or similar therapies and monitored according to the SOC Version 8. A "freeze frame" approach is inappropriate and dangerous (Kosilek v. Massachusetts, 2002). A "freeze frame" approach is the outmoded practice of denying hormones to people who are not already on them or keeping TGD persons on the same dose of hormones throughout their institutionalization that they were receiving upon admission, even if that dose was an initiation (low) dose. TGD persons who are deemed appropriate for de novo gender-affirming hormone therapy should be started on such therapy just as they would be outside of an institution (Adams v. Federal Bureau of Prisons, No. 09-10272 [D. MO June 7, 2010]; Brown 2009). The consequences of abrupt withdrawal of hormones or lack of initiation of hormone therapy when medically necessary include a significant likelihood of negative outcomes (Brown, 2010; Sundstrom and Fields v. Frank, 2011), such as surgical self-treatment by autocastration, depressed mood, increased gender dysphoria, and/or suicidality (Brown, 2010; Maruri, 2011).

If an individual in an institution does receive gender-affirming hormones and/or surgeries, decisions regarding housing in sex-segregated facilities may need to be reassessed for the safety and well-being of the TGD person (Ministry of Justice [UK], 2016).

Statement 11.4

We recommend staff and professionals charged with providing health care to TGD individuals living in institutions recommend and support gender-affirming surgical treatments in accordance with SOC-8, when sought by the individual, without undue delay.

TGD people with gender dysphoria should have an appropriate treatment plan to provide medically necessary surgical treatments that contain similar elements provided to persons who reside outside institutions (Adams v. Federal Bureau of Prisons, No. 09-10272 [D. MO June 7, 2010]; Brown 2009; Edmo v. Idaho Department of Corrections, 2020). The consequences of denial or lack of access to gender- affirming surgeries for residents of institutions who cannot access such care outside of their institutions may be serious, including substantial worsening of gender dysphoria symptoms, depression, anxiety, suicidality, and the possibility of surgical self-treatment

(e.g., autocastration or autopenectomy; Brown, 2010; Edmo v. Idaho Department of Corrections, 2020; Maruri, 2011). It is not uncommon for residents of institutions to be denied access to evaluation for gender-affirming surgery as well as denial of the treatment itself, even when medically necessary (Kosilek v. Massachusetts/Dennehy, 2012; Edmo v. Idaho Department of Corrections, 2020). The denial of medically necessary evaluations for and the provision of gender-affirming surgical treatments and necessary aftercare is inappropriate and inconsistent with these Standards of Care.

Statement 11.5

We recommend administrators, health care professionals, and all others working in institutions charged with the responsibility of caring for TGD individuals allow those individuals who request appropriate clothing and grooming items to obtain such items concordant with their gender expression.

Gender expression refers to people having hairstyles, grooming products, clothing, names, and pronouns associated with their gender identity in their culture and/or community (American Psychological Association, 2015; Hembree et al., 2017). Gender expression is the norm among most people within a culture or a community. Social transition is the process of TGD persons beginning and continuing to express their gender identity in ways that are authentic and socially perceptible. Often, social transition involves behavior and public presentation differing from what is usually expected for people assigned a given legal gender marker at birth. A gender marker is the legal label for a person's sex that is typically assigned or designated at birth on official documents (American Psychological Association, 2015). This is most commonly recorded as male or female but also intersex or "X" in some nations and jurisdictions. TGD individuals need the same rights to gender expression afforded cisgender people living both outside and inside institutional settings. Staff acceptance of social transition also sets a tone of respect and affirmation that may enhance respect and affirmation with others residing in the institution, thereby increasing safety and reducing some aspects of gender incongruence.

Research indicates social transition and congruent gender expression have a significant beneficial effect on the mental health of TGD people (Bockting & Coleman, 2007; Boedecker, 2018; Devor, 2004; Glynn et al., 2016; Russell et al., 2018). To allow for expressing gender identity, these recommendations include being allowed to wear gender congruent clothing and hairstyles, to obtain and use gender-appropriate hygiene and grooming products, to be addressed by a chosen name or legal last name (even if unable to change the assigned name legally yet), and to be addressed by a pronoun consistent with one's identity. These elements of gender expression and social transition, individually or collectively as indicated by the individual's needs, reduce gender dysphoria/incongruence, depression, anxiety, self-harm ideation and behavior, suicidal ideation and attempts (Russell et al., 2018). Furthermore, these elements of congruent gender expression enhance well-being and functioning (Glynn et al., 2016).

Statement 11.6

We recommend all institutional staff address TGD individuals by their chosen names and pronouns at all times.

Given that an increasing percentage of people openly identify as gender diverse, there is a need to develop and implement practices and policies that meet the needs of these people irrespective of where they live (McCauley et al., 2017). For example, institutions should utilize medical and administrative records systems for their residents that track gender markers consistent with gender identity and not solely sex assigned at birth. In developing these recommendations, there was recognition that gender expansiveness can challenge some institutional norms where TGD people live. However, all institutions have the responsibility to provide for the safety and well-being of all persons living therein (Australia, 2015; Corrective Services New South Wales, 2015; Edmo v. Idaho Department of Corrections, 2020; Kosilek v. Massachusetts, 2002; NCCHC, 2015). Sevelius and colleagues (2020) demonstrated correct pronoun usage is gender-affirming for

transgender women and correlates with positive mental health and HIV-related health outcomes. If a resident of an institution has legally changed names, the institutional records should be changed to reflect those changes.

Statement 11.7

We recommend institutional administrators, health care professionals, and other officials responsible for making housing decisions for TGD residents consider the individual's housing preference, gender identity and expression, and safety considerations, rather than solely their anatomy or sex assignment at birth.

The separation of people based on sex assigned at birth, a policy almost universally implemented in institutional settings (Brown and McDuffie, 2009; Routh et al., 2017), can create an inherently dangerous environment (Ledesma & Ford, 2020). Gender diverse people are extremely vulnerable to stigmatization, victimization, neglect, violence, and sexual abuse (Banbury, 2004; Beck, 2014; Jenness and Fenstermaker, 2016; Malkin & DeJong, 2018; Oparah, 2012; Stein et al., 2020). This systemic sex-segregated rigidity often fails to keep TGD people safe and may impede access to gender-affirming health care (Stohr, 2015). As a result, institutions should follow procedures that routinely evaluate the housing needs and preferences of TGD inmates (e.g., Federal Bureau of Prisons, 2016). Likewise, the Prison Rape Elimination Act specifically cites TGD individuals as a vulnerable population and directs prisons nationwide in the US to consider the housing preferences of these inmates (Bureau of Justice Assistance, 2017).

Statement 11.8

We recommend institutional personnel establish housing policies that ensure the safety of transgender and gender diverse residents without segregating or isolating these individuals.

Assigning placement for a TGD resident solely on the basis of their genital anatomy or sex assigned at birth is misguided and places people at risk for physical and/or psychological harm (Scott, 2013; Simopoulos & Khin, 2014; Yona & Katri, 2020). It is well established within carceral settings, transgender individuals are far more likely than other prisoners to be sexually harassed, assaulted, or both (James et al., 2016; Jenness & Fenstermaker, 2016; Malkin & DeJong, 2019). While placement decisions need to address security concerns, shared decision-making that includes the input of the individual should be made on a case-by-case basis (Federal Bureau of Prisons, 2016; Jenness and Smyth, 2011). Some transgender women prefer to reside in a male facility while others feel safer in a female facility. Given the range of gender identities, expression and transition status is so heterogeneous among gender diverse people, keeping residents safe requires flexible decision-making processes (Yona & Katri, 2020). One of the fears older LBGT individuals have living in long-term care is mistreatment by roommates (Jablonski et al., 2013). Consequently, housing in nursing homes and assisted living facilities should consider assigning rooms to elders based on their self-identified gender without regard to birth assignment or surgical history and in collaboration with the TGD patient.

Solitary confinement, sometimes referred to as administrative segregation in carceral facilities, refers to physical isolation of individuals during which they are confined in their cells for approximately twenty-three hours each day. The use of isolation is employed in some carceral facilities as a disciplinary measure as well as a means of protecting prisoners who are considered a risk to themselves or others or who are at risk of sexual assault by other inmates. However, isolating prisoners for safety concerns, if necessary, should be brief, as isolation can cause severe psychological harm and gross disturbances of functioning (Ahalt et al., 2017; Scharff Smith, 2006). National prison standards organizations as well as The United Nations consider isolation longer than 15 days to be torture (NCCHC, 2016; United Nations, 2015).

Statement 11.9

We recommend institutional personnel allow transgender and gender diverse residents the private use of shower and toilet facilities, upon request.

The necessity and importance of privacy is universal irrespective of gender identity. TGD

individuals report avoiding public restrooms, limiting the amount they eat and drink so as not to have to use a public facility, often leading to urinary tract infections and kidney-related problems (James et al., 2016). TGD individuals in institutions are often deprived of privacy in bathroom and shower use, which can result in psychological harm and/or physical and sexual abuse (Bartels and Lynch, 2017; Brown, 2014; Cook-Daniels, 2016; Mann, 2006). Similarly, in carceral environments, pat downs, strip searches and body cavity searches should be conducted by staff members of the same sex with the understanding this may not be possible in extreme emergencies. The incidental viewing of searches by other employees should be avoided (Bureau of Justice Assistance, 2017). Private use of shower and toilet facilities for incarcerated transgender people is also required by some laws, including for instance the United States' federal Prison Rape Elimination Act in the US.

The population of aging/older TGD persons who need to be served by institutions is increasing (Carroll, 2017; Witten & Eyler, 2016). Many long-term care and other facilities catering to the needs of the aging need to take into consideration the needs of their non-cisgender residents (Ettner, 2016; Ettner & Wiley, 2016). Surveys of HCPs working with elders in hospice and palliative care settings as well as other long-term care facilities report patients who identify as TGD often do not get their basic needs met, are discriminated against in their medical care access, or are physically and/or emotionally abused (Stein et al., 2020) A survey of retirement and residential care providers in Australia found little experience with or understanding of the issues facing this population. Indeed, many elderly TGD residents admitted to concealing their gender identity, bowing to the fear of insensitive treatment or frank discrimination (Cartwright et al., 2012; Cook-Daniels, 2016; Grant et al., 2012; Horner et al., 2012; Orel & Fruhauf, 2015).

CHAPTER 12 Hormone Therapy

Transgender and gender diverse (TGD) persons may require medically necessary gender-affirming hormone therapy (GAHT) to achieve changes consistent with their embodiment goals, gender identity, or both (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1). This chapter describes hormone therapy recommendations for TGD adults and adolescents. Please refer to Chapter 5—Assessment of Adults and Chapter 6—Adolescents for the assessment criteria related to initiation of hormone therapy for adults and adolescents, respectively. A summary of the recommendations and assessment criteria can be found in Appendix D.

Ever since the first World Professional Association for Transgender Health (WPATH) Standards of Care (SOC) was published in 1979 and in subsequent updates of the SOC, including SOC version 7, GAHT has been accepted as medically necessary (Coleman et al., 2012). WPATH endorsed the Endocrine Society's guidelines for GAHT for TGD persons in 2009 and 2017 (Hembree et al., 2009; Hembree et al., 2017). The European Society for Sexual Medicine has also published a position statement on hormone management in adolescent and adult TGD people (T'Sjoen et al., 2020). When provided under medical supervision, GAHT in adults is safe (Tangpricha & den Heijer, 2017; Safer & Tangpricha, 2019). However, there are some potential long-term risks, and careful monitoring and screening are required to reduce adverse events (Hembree et al., 2017; Rosenthal, 2021).

In general, the goal is to target serum levels of the sex steroids to match the levels associated with the individual's gender identity, although optimal target ranges have not been established (Hembree et al., 2017). Health care professionals (HCPs) can use serum testosterone and/or estradiol levels to monitor most sex steroid treatments. However, conjugated estrogens or synthetic estrogen use cannot be monitored. The assumption that the estrone/estradiol ratio should be monitored was not supported in a recent cohort study as there was no relationship between estrone concentration and change in body fat or breast development seen in a European cohort of 212 adult transgender women during a 1-year follow-up of hormone treatment (Tebbens et al., 2021). This study demonstrated higher estrone concentrations or higher estrone/estradiol ratios are not associated with antagonistic effects on feminization (fat percentage and breast development) (Tebbens et al., 2021). Thus, monitoring of the estrone to estradiol ratio is not supported by the current published evidence. Previously used conjugated estrogens have been abandoned in favor of bioidentical estrogens. Even if several studies have shown a significantly greater risk of thromboembolic and cardiovascular complications with the use of oral conjugated estrogens compared with oral estradiol in postmenopausal women, no randomized controlled trials have taken place, either in postmenopausal women or in transgender people undergoing estrogen treatment (Smith et al., 2014).

The approach to GAHT differs and depends on the developmental stage of the individual at the time of initiation of hormone therapy as well as their treatment goals. Hormone therapy is not recommended for children who have not begun endogenous puberty. In eligible youth (as per Chapter 6—Adolescents) who have reached the early stages of puberty, the focus is usually to delay further pubertal progression with gonadotropin releasing hormone agonists (GnRHas) until an appropriate time when GAHT can be introduced. In these cases, pubertal suppression is considered medically necessary. Eligible adults may initiate GAHT if they fulfill the criteria as per Chapter 5—Assessment for Adults. In addition, health care providers should discuss fertility goals and fertility preservation procedures prior to initiating GAHT. See Chapter 16—Reproductive Health.

GAHT with feminine embodiment goals typically consists of estrogen and an androgen-lowering medication (Hembree et al., 2017). Although there are anecdotal reports of progesterone use for breast development and mood management, there is currently insufficient evidence the potential benefits of progesterone administration outweigh the potential risks (Iwamoto, T'Sjoen et al., 2019). Masculinizing GAHT typically consists of testosterone. Both WPATH and the Endocrine Society recommend monitoring levels of sex

hormones. While GAHT is customized to meet the individual needs of the TGD person, typically hormone levels are maintained at a concentration sufficient to support good bone health and are not supraphysiologic (Hembree et al., 2017; Rosen et al., 2019).

Statements of Recommendations

12.1- We recommend health care professionals begin pubertal hormone suppression in eligible* transgender and gender diverse adolescents after they first exhibit physical changes of puberty (Tanner stage 2).
12.2- We recommend health care professionals use gonadotropin releasing hormone (GnRH) agonists to suppress endogenous sex hormones in eligible* transgender and gender diverse people for whom puberty blocking is indicated.
12.3- We suggest health care professionals prescribe progestins (oral or injectable depot) for pubertal suspension in eligible* transgender and gender diverse youth when GnRH agonists are either not available or are cost prohibitive.
12.4- We suggest health care professionals prescribe GnRH agonists for suppression of sex steroids without concomitant sex steroid hormone replacement in eligible* transgender and gender diverse adolescents seeking such intervention and who are well into or have completed pubertal development (past Tanner stage 3) but are either unsure about or do not want to begin sex steroid hormone therapy.
12.5- We recommend health care professionals prescribe sex hormone treatment regimens as part of gender-affirming treatment for eligible* transgender and gender diverse adolescents who are at least Tanner stage 2, with parental/guardian involvement unless their involvement is determined to be harmful or unnecessary to the adolescent.
12.6- We recommend health care professionals measure hormone levels during gender-affirming treatment to ensure endogenous sex steroids are lowered and administered sex steroids are maintained at levels appropriate for the treatment goals of transgender and gender diverse people according to the Tanner stage.
12.7- We recommend health care professionals prescribe progestogens or a GnRH agonist for eligible* transgender and gender diverse adolescents with a uterus to reduce dysphoria caused by their menstrual cycle when gender-affirming testosterone use is not yet indicated.
12.8- We recommend health care providers involve professionals from multiple disciplines who are experts in transgender health and in the management of the care required for transgender and gender diverse adolescents.
12.9- We recommend health care professionals institute regular clinical evaluations for physical changes and potential adverse reactions to sex steroid hormones, including laboratory monitoring of sex steroid hormones every 3 months during the first year of hormone therapy or with dose changes until stable adult dosing is reached followed by clinical and laboratory testing once or twice a year once an adult maintenance dose is attained.
12.10- We recommend health care professionals inform and counsel all individuals seeking gender-affirming medical treatment about the options available for fertility preservation prior to initiating puberty suppression and prior to treating with hormone therapy.
12.11- We recommend health care professionals evaluate and address medical conditions that can be exacerbated by lowered endogenous sex hormone concentrations and treatment with exogenous sex hormones before beginning treatment for transgender and gender diverse people.
12.12- We recommend health care professionals educate transgender and gender diverse people undergoing gender-affirming treatment about the onset and time course of the physical changes induced by sex hormonal treatment.
12.13- We recommend health care professionals not prescribe ethinyl estradiol for transgender and gender diverse people as part of a gender-affirming hormonal treatment.
12.14- We suggest health care professionals prescribe transdermal estrogen for eligible* transgender and gender diverse people at higher risk of developing venous thromboembolism based on age > 45 years or a previous history of venous thromboembolism, when gender-affirming estrogen treatment is recommended.
12.15- We suggest health care professionals not prescribe conjugated estrogens in transgender and gender diverse people when estradiol is available as a component of gender-affirming hormonal treatment.
12.16- We recommend health care professionals prescribe testosterone-lowering medications (either cyproterone acetate, spironolactone, or GnRH agonists) for eligible* transgender and gender diverse people with testes who are taking estrogen as part of a hormonal treatment plan if the individual's goal is to approximate circulating sex hormone concentrations in cisgender women.
12.17- We recommend health care professionals monitor hematocrit (or hemoglobin) in transgender and gender diverse people treated with testosterone.
12.18- We suggest health care professionals collaborate with surgeons regarding hormone use before and after gender-affirmation surgery.
12.19- We suggest health care professionals counsel transgender and gender diverse people about the various options available for gender-affirmation surgery unless surgery is not indicated or is medically contraindicated.
12.20- We recommend health care professionals initiate and continue gender-affirming hormone therapy for eligible* transgender and gender diverse people who require this treatment due to demonstrated improvement in psychosocial functioning and quality of life.
12.21- We recommend health care professionals maintain existing hormone therapy if the transgender and gender diverse individual's mental health deteriorates and assess the reason for the deterioration, unless contraindicated.

** For eligibility criteria for adolescents and adults, please refer to Chapter 5—Assessment for Adults and Chapter 6—Adolescents and Appendix D.*

In most cases, GAHT is maintained throughout life. It is not known if doses of GAHT should be reduced in older TGD people. Discontinuation of hormone therapy may result in bone loss in TGD individuals and will definitely do so in individuals whose gonads have been removed (Wiepjes et al., 2020). Routine primary care should also be performed (see Chapter 15—Primary Care). Epidemiology studies have reported an increased incidence of cardiovascular disease and venous thromboembolism (VTE) in TGD people receiving estrogen, most notably in older people and with different preparations of GAHT (Irwig, 2018; Maraka et al., 2017). TGD individuals treated with testosterone may also have increased adverse cardiovascular risks and events, such as increased myocardial infarction, blood pressure, decreased HDL-cholesterol, and excess weight (Alzahrani et al., 2019; Irwig, 2018; Kyinn et al., 2021). Health care professionals (HCPs) should discuss lifestyle and pharmacologic therapy with patients who are at the highest risk of developing cardiovascular disease (see Chapter 15—Primary Care). Polycythemia is another disorder that may present in TGD people taking testosterone (Antun et al., 2020). Therefore, it is important to continuously monitor for the development of conditions that can be exacerbated by GAHT throughout life (Hembree et al., 2017).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Gender-Affirming Hormone Therapy in Youth

The following sections will discuss hormone therapy in TGD youth. Depending on the developmental stage of the youth, this hormone therapy generally comprises two phases, namely pubertal suppression followed by the addition of GAHT. During the first phase, pubertal development is halted to allow the youth to explore their gender identity and embodiment goals to prepare for the next phase, which may include GAHT. This section will discuss the recommendations for the use of gonadotropin releasing hormone agonists (GnRHas) as well as alternate approaches to pubertal suppression and will be followed by recommendations for GAHT. Sections that are applicable to youth and adults will follow in the next section.

Statement 12.1

We recommend health care professionals begin pubertal hormone suppression in eligible* transgender and gender diverse adolescents only after they first exhibit physical changes of puberty (Tanner stage 2).

In general, the goal of GnRHa administration in TGD adolescents is to prevent further development of the endogenous secondary sex characteristics corresponding to the sex designated at birth. Since this treatment is fully reversible, it is regarded as an extended time for adolescents to explore their gender identity by means of an early social transition (Ashley, 2019e). Treatment with GnRHas also has therapeutic benefit since it often results in a vast reduction in the level of distress stemming from physical changes that occur when endogenous puberty begins (Rosenthal, 2014; Turban, King et al., 2020).

For those prepubertal TGD children who have been persistent in their gender identity, any amount of permanent development of secondary sex characteristics could result in significant distress. While one might consider use of a GnRHa to prevent initiation of puberty in such individuals who remain at Tanner Stage 1, this use of GnRHa has not been recommended (Hembree et al., 2017). When a child reaches an age where pubertal development would normally begin (typically from 7-8 to 13 years for those with ovaries and from 9 to 14 years for those with testes), it would be appropriate to screen the child more frequently, perhaps at 4-month intervals, for signs of pubertal development (breast budding or testicular volume > 4 cc). Given the typical tempo of pubertal development (3.5–4 years for completion), it would be very unlikely for permanent pubertal changes to develop if one is only in puberty for 4 months or less. Thus, with frequent follow-up, the initiation of puberty can easily be detected before there are irreversible physical changes, and GnRHa can be started at that time with great efficacy. Of note, following initiation of a GnRHa, there is typically

a regression of one Tanner stage. Thus, if there is only Tanner stage 2 breast development, it typically fully regresses to the prepubertal Tanner stage 1; the same is typically true with Tanner stage 2 testes (often not even discernable to the patient and is not associated with development of secondary sex characteristics).

Given GnRHas work through GnRH receptor desensitization, if there's no uptick in endogenous GnRH stimulation of the pituitary (the first biochemical sign of puberty), there's no need for GnRH receptor desensitization. In addition, because of the wide variability in the timing of the start of puberty (as noted above), it is hard to justify using a GnRHa that might have some unknown risk if there's no physiological benefit before pubertal onset. Using a GnRHa with a child at Tanner stage 1 would only be indicated in cases of constitutional delay in growth and puberty, likely alongside the start of GAHT.

However, the use of a GnRHa could be considered in a child who, due to a constitutional delay in growth and puberty, starts GAHT while still in Tanner Stage 1. Initiating GAHT may activate the hypothalamic-pituitary gonadal axis in the beginning but may also mask the effects on the body of this activation. To avoid body changes with the potential to exacerbate an individual's gender incongruence, the GnRHa can be started as an adjunctive therapy to the GAHT shortly after the initiation of the GAHT to provide for pubertal development of the identified phenotype.

In addition, the suppression of the development of secondary sex characteristics is most effective when sex hormonal treatment is initiated in early to mid-puberty when compared with the initiation of sex hormonal treatment after puberty is completed (Bangalore-Krisha et al., 2019). Correspondingly, for adolescents who have already completed endogenous puberty and are considering starting GAHT, GnRHas can be used to inhibit physical functions, such as menses or erections, and can serve as a bridge until the adolescent, guardian(s) (if the adolescent is not able to consent independently), and treatment team reach a decision (Bangalore-Krishna et al., 2019; Rosenthal, 2021).

The onset of puberty occurs through reactivation of the hypothalamic-pituitary-gonadal axis. Clinical assessment of the stages of puberty is based on physical features that reflect that reactivation. In individuals with functioning ovaries, Tanner stage 2 is characterized by the budding of the mammary gland. The development of the mammary gland occurs from exposure to estrogen produced by the ovaries. In individuals with functioning testes, Tanner stage 2 is characterized by an increase in testicular volume (typically greater than 4 ml). The growth of the testes is mediated through the gonadotropins luteinizing hormone (LH) and follicle stimulating hormone (FSH). In the later stages, the testes produce enough testosterone to induce masculinization of the body.

Statement 12.2

We recommend health care professionals use GnRH agonists to suppress endogenous sex hormones in eligible* transgender and gender diverse people for whom puberty blocking is indicated. For supporting text, see Statement 12.4.

Statement 12.3

We suggest health care professionals prescribe progestins (oral or injectable depot) for pubertal suspension in eligible* transgender and gender diverse youth when GnRH agonists are not available or are cost prohibitive. For supporting text, see Statement 12.4.

Statement 12.4.

We suggest health care professionals prescribe GnRH agonists to suppress sex steroids without concomitant sex steroid hormone replacement in eligible transgender and gender diverse adolescents seeking such intervention who are well into or have completed pubertal development (past Tanner stage 3) but are unsure about or do not wish to begin sex steroid hormone therapy.

GnRHas reduce gonadotrophin and sex steroid concentrations in TGD adolescents and thus halt the further development of secondary sex characteristics (Schagen et al., 2016). Their use is generally safe with the development of hypertension being the only short-term adverse event reported in the literature (Delemarre-van de Waal & Cohen-Kettenis, 2006; Klink, Bokenkamp et al., 2015). GnRHas prevent the pituitary gland from

secreting LH and FSH (Gava et al., 2020). When the gonadotropins decrease, the gonad is no longer stimulated to produce sex hormones (estrogens or androgens), and the sex hormone levels in the blood decrease to prepubertal levels. GnRHa treatment leads to partial regression of the initial stages of the already developed secondary sex characteristics (Bangalore et al., 2019). TGD adolescents with functioning ovaries will experience diminished growth of breast tissue, and if treatment is started at Tanner stage 2, the breast tissue may disappear completely (Shumer et al., 2016). Menarche can be prevented or discontinued following the administration of GnRHas in adolescents with a uterus. In TGD adolescents with functioning testes, testicular volume will regress to a lower volume.

When GnRHa treatment is started in adolescents at the later phases of pubertal development, some physical changes of pubertal development, such as late-stage breast development in TGD adolescents with functioning ovaries and a lower voice and growth of facial hair in TGD adolescents with functioning testes, will not regress completely, although any further progression will be stopped (Delemarre-van de Waal & Cohen-Kettenis, 2006). GnRHas have been used since 1981 for the treatment of central precocious puberty (Comite et al., 1981; Laron et al., 1981), and their benefits are well established (please also see the statements in Chapter 6—Adolescents). The use of GnRHas in individuals with central precocious puberty is regarded as both safe and effective, with no known long-term adverse effects (Carel et al., 2009). However, the use of GnRHas in TGD adolescents is considered off-label because they were not initially developed for this purpose. Nonetheless, data from adolescents prescribed GnRHas in a similar dose and fashion demonstrate effectiveness in delaying the onset of puberty although the long-term effects on bone mass have not been well established (Klink, Caris et al., 2015). Although long-term data are more limited in TGD adolescents than in adolescents with precocious puberty, data collection specifically in this population are ongoing (Klaver et al., 2020; Lee, Finlayson et al., 2020; Millington et al., 2020; Olson-Kennedy, Garofalo et al., 2019).

We recognize even though GnRHas are a medically necessary treatment, they may not be available for eligible adolescents because it is not covered by health insurance plans in some countries or may be cost-prohibitive. Therefore, other approaches should be considered in these cases, such as oral or injectable progestin formulations. In addition, for adolescents older than 14 years, there are currently no data to inform HCPs whether GnRHas can be administered as monotherapy (and for what duration) without posing a significant risk to skeletal health. This is because the skeleton will not have any exposure to adequate levels of sex steroid hormones (Rosenthal, 2021).

A prolonged hypogonadal state in adolescence, whether due to medical conditions such as hypergonadotropic hypogonadism, iatrogenic causes such as GnRHa monotherapy or physiological conditions such as conditional delay of growth and development, is often associated with an increased risk of poor bone health later in life (Bertelloni et al., 1998; Finkelstein et al., 1996). However, bone mass accrual is a multifactorial process that involves a complex interplay between endocrine, genetic, and lifestyle factors (Anai et al., 2001). When deciding on the duration of GnRHa monotherapy, all contributing factors should be considered, including factors such as pretreatment bone mass, bone age, and pubertal stage from an endocrine perspective and height gain, as well as psychosocial factors such as mental maturity and developmental stage relative to one's adolescent cohort and the adolescent's individual treatment goals (Rosenthal, 2021). For these reasons, a multidisciplinary team and an ongoing clinical relationship with the adolescent and the family should be maintained when initiating GnRHa treatment (see Statements 6.8, 6.9, and 6.12 in Chapter 6—Adolescents). The clinical course of the treatment, e.g., the development of bone mass during GnRHa treatment and the adolescent's response to treatment, can help to determine the length of GnRHa monotherapy.

Statement 12.5

We recommend health care professionals prescribe sex hormone treatment regimens as part of gender-affirming treatment in eligible*

transgender and gender diverse adolescents who are at least Tanner stage 2, with parental/guardian involvement unless their involvement is determined to be harmful or unnecessary to the adolescent. For supporting text, see Statement 12.6.

Statement 12.6

We recommend health care professionals measure hormone levels during gender-affirming treatment to ensure endogenous sex steroids are lowered and administered sex steroids are maintained at a level appropriate for the treatment goals of transgender and gender diverse people according to the Tanner stage.

Sex steroid hormone therapy generally comprises two treatment regimens, depending on the timing of the GnRHa treatment. When GnRHa treatment is started in the early stages of endogenous pubertal development, puberty corresponding with gender identity or embodiment goals is induced with doses of sex steroid hormones similar to those used in peripubertal hypogonadal adolescents. In this context, adult doses of sex steroid hormones are typically reached over approximately a 2-year period (Chantrapanichkul et al., 2021). When GnRHa treatment is started in late- or postpubertal transgender adolescents, sex steroid hormones can be given at a higher starting dose and increased more rapidly until a maintenance dose is achieved, resembling treatment protocols used in transgender adults (Hembree et al., 2017). An additional advantage of GnRHa treatment is sex steroid hormones do not have to be administered in supraphysiological doses, which would otherwise be needed to suppress endogenous sex steroid production (Safer & Tangpricha, 2019). For TGD individuals with functioning testes, GnRHa treatment (or another testosterone-blocking medication) should be continued until such time as the TGD adolescent/young adult ultimately undergoes gonadectomy, if this surgical procedure is pursued as a medically necessary part of their gender-affirming care. Once adult levels of testosterone are reached in TGD individuals with functioning ovaries who have been initially suppressed with GnRHa's, testosterone alone at physiological doses is typically sufficient to lower ovarian estrogen secretion, and GnRHas can be discontinued as discussed below (Hembree et al., 2017). For TGD adolescents with functioning ovaries who are new to care, GAHT can be accomplished with physiological doses of testosterone alone without the need for concomitant GnRHa administration (Hembree et al., 2017).

Gender-affirming sex steroid hormone therapy induces the development of secondary sex characteristics of the gender identity. Also, the rate of bone mineralization, which decreases during treatment with GnRHa's, rapidly recovers (Klink, Caris et al., 2015). During GnRHa treatment in early-pubertal TGD adolescents, the bone epiphyseal plates are still unfused (Kvist et al., 2020; Schagen et al., 2020). Following the initiation of sex steroid hormone treatment, a growth spurt can occur, and bone maturation continues (Vlot et al., 2017). In postpubertal TGD adolescents, sex steroid hormone treatment will not affect height since the epiphyseal plates have fused, and bone maturation is complete (Vlot et al., 2017).

In TGD adolescents with functioning testes, the use of 17-ß-estradiol for pubertal induction is preferred over that of synthetic estrogens, such as the more thrombogenic ethinyl estradiol (see Appendix D (Asscheman et al., 2015). It is still necessary to either continue GnRHa's to suppress endogenous testosterone production or transition to another medication that suppresses endogenous testosterone production (Rosenthal et al., 2016). Breast development and a female-typical fat distribution are among a number of physical changes that occur in response to estrogen treatment. See Appendix C—Table 1.

For TGD adolescents seeking masculinizing treatment, androgens are available as injectable preparations, transdermal formulations, and subcutaneous pellets. For pubertal induction, the use of testosterone-ester injection is generally recommended by most experts initially because of cost, availability, and experience (Shumer et al., 2016). It is advised to continue GnRHas at least until a maintenance level of testosterone is reached. In response to androgen treatment, virilization of the body occurs, including a lowering of the voice, more muscular development particularly in the upper body, growth of facial and body hair, and clitoral enlargement (Rosenthal et al., 2016). See Appendix C—Table 1.

In almost all situations, parental/caregiver consent should be obtained. Exceptions to this recommendation, in particular when caregiver or parental involvement is determined to be harmful to the adolescent, are described in more detail in Chapter 6—Adolescents (see Statement 6.11) where the rationale for involving parents/caregivers in the consent process is also described.

Statement 12.7

We recommend health care professionals prescribe progestogens or a GnRH agonist for eligible* transgender and gender diverse adolescents with a uterus to reduce dysphoria caused by their menstrual cycle when gender-affirming testosterone use is not yet indicated.

Menstrual suppression is a treatment option commonly needed by TGD individuals who experience distress related to menses or the anticipation of menarche. Statement 6.7 in Chapter 6—Adolescents describes this in more detail. To achieve amenorrhea, menstrual suppression can be initiated as a solo option before initiating testosterone or alongside testosterone therapy (Carswell & Roberts, 2017). Some youth, who are not ready for testosterone therapy or are not yet at an appropriate pubertal/developmental stage to begin such treatment, will benefit from the induction of amenorrhea (Olson-Kennedy, Rosenthal et al., 2018). Adolescents who experience an exacerbation of dysphoria related to the onset of puberty may elect to be treated with GnRHas for pubertal suppression (also see the Adolescents chapter).

Progestogens may be effective in adolescents whose goal is solely menstrual suppression. Continuous administration of progestin-only oral pills (including the contraceptive and noncontraceptive options), medroxyprogesterone injections, or levonorgestrel intrauterine device can be used for induction of amenorrhea (Pradhan & Gomez-Lobo, 2019). TGD individuals with functioning ovaries who start testosterone therapy may have 1–5 menstrual cycles before amenorrhea is achieved (Taub et al., 2020). Once amenorrhea is achieved, some TGD individuals with functioning ovaries may also choose to continue progestin treatment for birth control if relevant to their sexual practices.

TGD individuals with functioning ovaries and a uterus should be counseled about the potential for breakthrough menstrual bleeding in the first few months after initiating menstrual suppression. With GnRHa therapy, breakthrough bleeding may occur 2–3 weeks after initiation of the medication. For individuals seeking contraception or for those who continue to experience menstrual bleeding on progestin therapy, an estrogen combination with progestin may be considered for the maintenance of amenorrhea, yet they should be counseled on the possible side effect of breast development (Schwartz et al., 2019).

Statement 12.8

We recommend health care providers involve professionals from multiple disciplines who are experts in transgender health and in the management of the care of transgender and gender diverse adolescents.

As with the care of adolescents, we suggest where possible a multidisciplinary expert team of medical and mental health professionals (MHPs) be assembled to manage this treatment. In adolescents who pursue GAHT (given this is a partly irreversible treatment), we suggest initiating treatment using a schedule of gradually increasing doses after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and has established the individual possesses the mental capacity to give informed consent (Hembree et al., 2017). Specific aspects concerning the assessment of adolescents and the involvement of their caregivers and a multidisciplinary team are described in more detail in Chapter 6—Adolescents.

If possible, TGD adolescents should have access to experts in pediatric transgender health from multiple disciplines including primary care, endocrinology, fertility, mental health, voice, social work, spiritual support, and surgery (Chen, Hidalgo et al., 2016; Eisenberg et al., 2020; Keo-Meier & Ehrensaft, 2018). Individual providers are encouraged to form collaborative working relationships with providers from other disciplines to facilitate referrals as needed for the individual youth and their family (Tishelman et al., 2015). However, the lack of available

experts and resources should not constitute a barrier to care (Rider, McMorris et al., 2019). Helpful support for adolescents includes access to accurate, culturally informed information related to gender and sexual identities, transition options, the impact of family support, and connections to others with similar experiences and with TGD adults through online and in person support groups for adolescents and their family members (Rider, McMorris et al., 2019).

Many TGD adolescents have been found to experience mental health disparities and initial mental health screening (e.g., PHQ-2, GAD) can be employed as indicated (Rider, McMorris et al., 2019). Providers should keep in mind being transgender or questioning one's gender does not constitute pathology or a disorder. Therefore, individuals should not be referred for mental health treatment exclusively on the basis of a transgender identity. HCPs and MHPs who treat these youths and make referrals should, at a minimum, be familiar with the impact of trauma, gender dysphoria, and gender minority stressors on any potential mental health symptomatology, such as disordered eating, suicidal ideation, social anxiety. These health care providers should also be knowledgeable about the level of readiness of inpatient mental health services in their region to provide competent, gender-affirming care to TGD youth (Barrow & Apostle, 2018; Kuper, Wright et al., 2018; Kuper, Mathews et al., 2019; Tishelman & Neumann-Mascis, 2018). Statements 6.3, 6.4, and 6.12d in Chapter 6—Adolescents address this in more detail. Because parents of these youth commonly experience high levels of anxiety immediately after learning their youth is TGD, and their response to their child predicts that child's long-term physical and mental health outcomes, appropriate referrals for mental health support of the parents can be of great utility (Coolhart et al., 2017; Pullen Sansfaçon et al., 2015; Taliaferro et al., 2019).

Statement 12.9

We recommend health care professionals organize regular clinical evaluations for physical changes and potential adverse reactions to sex steroid hormones, including laboratory monitoring of sex steroid hormones every 3 months during the first year of hormone therapy or with dose changes until a stable adult dosing is reached followed by clinical and laboratory testing once or twice a year once an adult maintenance dose is attained.

Sex steroid hormone therapy is associated with a broad array of physical and psychological changes (Irwig, 2017; Tangpricha & den Heijer, 2017) (see Appendix C—Table 1). After sex steroid hormone therapy has been initiated, the HCP should regularly assess the progress and response of the individual to the treatment (also see Chapter 6—Adolescents). This evaluation should assess the presence of any physical changes as well as the impact of treatment on gender dysphoria (if present) and psychological well-being (see Appendix C—Table 1). Clinical visits provide important opportunities for HCPs to educate patients about the typical time course required for physical changes to manifest and encourage realistic expectations. During the first year of hormone therapy, sex steroid hormone doses are often increased. A major factor guiding the dose is the serum level of the corresponding sex steroid hormone. In general, the goal is to target serum levels of the sex steroids to match the levels associated with the individual's gender identity, although optimal target ranges have not been established (Hembree et al., 2017).

In addition to assessing the positive changes associated with sex steroid hormone therapy, the HCP should regularly assess whether the treatment has caused any adverse effects (see Appendix C—Table 2**).** Examples of adverse signs and symptoms include androgenic acne or bothersome sexual dysfunction (Braun et al., 2021; Kerckhof et al., 2019). GAHT also has the potential to adversely influence several laboratory tests. For example, spironolactone may cause hyperkalemia, although it is an uncommon and transient phenomenon (Millington et al., 2019). Testosterone increases the red blood cell count (hematocrit), which may occasionally cause erythrocytosis (Antun et al., 2020) (see Statement 12.17) (Hembree et al., 2017). Both estrogen and testosterone can alter lipid parameters, such as high-density protein lipoprotein (HDL) cholesterol and triglycerides (Maraka et al., 2017). See Appendix C—Tables 3 and 4.

The frequency of clinical evaluations should be individualized and guided by the individual's response to treatment. We suggest clinical assessments be performed approximately every 3 months during the first year of hormone therapy in patients who are stable and are not experiencing significant adverse effects (Appendix C—Table 5). We suggest rather than recommend testing be carried out every 3 months in the first year to allow some flexibility on the timing of these tests as there is no strong evidence or evidence from published studies supporting specific testing intervals. If an individual does experience an adverse effect, more frequent laboratory testing and/or clinical visits are often needed. Given the potential harm associated with sex hormone levels that exceed expected ranges in humans, we strongly recommend regular testing be performed as a standard practice when initiating GAHT in TGD individuals. Once a person has reached a stable adult dose of sex steroid hormone with no significant adverse effects, the frequency of clinic visits can be reduced to one to two per year (Hembree et al., 2017).

Statement 12.10

We recommend health care professionals inform and counsel all individuals seeking gender-affirming medical treatment about options for fertility preservation prior to initiating puberty suppression and prior to administering hormone therapy.

Pubertal suppression and hormone treatment with sex steroid hormones may have potential adverse effects on a person's future fertility (Cheng et al., 2019) (see also Chapter 6—Adolescents and Chapter 16—Reproductive Health). Although some TGD people may not have given much thought to their future reproductive potential at the time of their initial assessment to begin medical therapy, the potential implications of the treatment and fertility preservation options should be reviewed by the hormone prescriber and discussed with the person seeking these therapies (Ethics Committee of the American Society for Reproductive Medicine et al., 2015; De Roo et al., 2016).

Individuals with testes should be advised prolonged treatment with estrogen often causes testicular atrophy and a reduction in sperm count and other semen parameters (Adeleye et al., 2018). Nonetheless, there are major gaps in knowledge, and findings regarding the fertility of trans feminine people who take estrogen and antiandrogens are inconsistent (Cheng et al., 2019). In one study, heterogeneity in testicular histology was evident whether patients discontinued or continued therapy prior to orchiectomies (Schneider et al., 2015). For example, the discontinuation of estrogen and antiandrogens for six weeks resulted in complete spermatogenesis in 45% of individuals with the remainder showing meiotic arrest or spermatogonial arrest (Schneider et al., 2015). However, serum testosterone levels confirmed to be within female reference ranges leads to complete suppression of spermatogenesis in most transgender women (Vereecke et al., 2020). The principal fertility preservation option for patients with functioning testes is sperm cryopreservation, also known as sperm banking (Mattawanon et al., 2018). For prepubertal patients, suppression of puberty with GnRHs pauses the maturation of sperm (Finlayson et al., 2016).

Individuals with functioning ovaries should be advised testosterone therapy usually results in the cessation of menses and ovulation, often within a few months of initiation (Taub et al., 2020). There are also major gaps in knowledge regarding the potential effects of testosterone on oocytes and subsequent fertility of TGD patients (Eisenberg et al., 2020; Stuyver et al., 2020). One study found testosterone treatment may be associated with polycystic ovarian morphology, whereas other studies reported no metabolic (Chan et al., 2018) or histologic (De Roo et al., 2017; Grynberg et al., 2010) evidence of polycystic ovary syndrome (PCOS) following treatment with testosterone, and some studies have found a pre-existing higher prevalence of PCOS in transgender patients with ovaries (Baba, 2007; Gezer et al., 2021). TGD patients with an intact uterus and ovaries often regain their fertility potential if testosterone therapy is discontinued (Light et al., 2014). Indeed, a live birth after assisted reproductive technology has been reported following hormone-stimulated egg retrieval from a TGD

individual who did not discontinue testosterone therapy (Greenwald et al., 2021; Safer and Tangpricha, 2019). Other fertility preservation options for TGD patients with ovaries are oocyte cryopreservation and embryo cryopreservation with sperm from a partner or donor. The above options require hormonal stimulation for egg retrieval and the use of assisted reproductive technology.

For early pubertal transgender youth, suppression of puberty with GnRHa's pauses the maturation of germ cells, although a recent report noted ovarian stimulation of a TGD adolescent treated with a GnRHa's in early puberty (and continued during ovarian stimulation) resulted in a small number of mature oocytes that were cryopreserved (Rothenberg et al., 2019). Treating an TGD adolescent with functioning testes in the early stages of puberty with a GnRHa not only pauses maturation of germ cells but will also maintains the penis in a prepubertal size. This will likely impact surgical considerations if that person eventually undergoes a penile-inversion vaginoplasty as there will be less penile tissue to work with. In these cases, there is an increased likelihood a vaginoplasty will require a more complex surgical procedure, e.g., intestinal vaginoplasty (Dy et al., 2021; van de Grift et al., 2020). Such considerations should be included in any discussions with patients and families considering use of pubertal blockers in early pubertal adolescents with functioning testes.

Statement 12.11

We recommend health care professionals evaluate and address medical conditions that can be exacerbated by lowered endogenous sex hormone concentrations and treatment with exogenous sex hormones before beginning treatment in transgender and gender diverse people.

TGD people seeking masculinization must be informed about the possibilities, consequences, limitations, and risks associated with testosterone treatment. Testosterone therapy is contraindicated during pregnancy or while attempting to become pregnant given its potential iatrogenic effects on the fetus. Relative contraindications to testosterone therapy include severe hypertension, sleep apnea, and polycythemia since these conditions can be exacerbated by testosterone. Monitoring blood pressure and lipid profiles should be performed before and after the onset of testosterone therapy. The increase in blood pressure typically occurs within 2 to 4 months following the initiation of testosterone therapy (Banks et al., 2021). Patients who develop hypercholesterolemia and/or hypertriglyceridemia may require treatment with dietary modifications, medication, or both.

TGD people seeking feminizing treatment with a history of thromboembolic events, such as deep vein thrombosis and pulmonary embolism, should undergo evaluation and treatment prior to the initiation of hormone therapy. This is because estrogen therapy is strongly associated with an increased risk of thromboembolism, a potentially life-threatening complication. In addition, risk factors that can increase the risk of thromboembolic conditions, such as smoking, obesity, and sedentary lifestyle, should be modified. In patients with nonmodifiable risk factors, such as a known history of thrombophilia, a past history of thrombosis, or a strong family history of thromboembolism, treatment with transdermal estrogen concomitant with anticoagulants may decrease the risk of thromboembolism. However, there are limited data to guide treatment decisions. The presence of a disease at baseline such as a hormone sensitive cancer, coronary artery disease, cerebrovascular disease, hyperprolactinemia, hypertriglyceridemia, and cholelithiasis should be evaluated prior to the initiation of gender-affirming hormone therapy as relative risks may be shifted in association with exogenous hormone treatment (Hembree et al., 2017).

Statement 12.12

We recommend health care professionals educate transgender and gender diverse people undergoing gender-affirming treatment about the onset and time course of physical changes induced by sex hormone treatment.

The effects of testosterone treatment are multiple and may include the appearance of increased body and facial hair, male pattern baldness, increased muscle mass and strength, decreased fat mass, deepening of the voice, interruption of

menses (if still present), increased prevalence and severity of acne, clitoral enlargement, and increased sexual desire (Defreyne, Elaut et al., 2020; Fisher, Castellini et al., 2016; Giltay & Gooren, 2000; T'Sjoen et al., 2019; Yeung et al., 2020). Other testosterone-associated changes include increased lean body mass, skin oiliness, (de Blok et al., 2020; Hembree et al., 2017; Kuper, Mathews et al., 2019; Taliaferro et al., 2019; Tishelman & Neumann-Mascis, 2018) (see Appendix C—Table 1).

Estrogen treatment induces breast development. However, fewer than 20% of individuals reach Tanner breast stages 4–5 after 2 years of treatment (de Blok et al., 2021). Additional changes include decreases in testicular volume, lean body mass, skin oiliness, sexual desire, spontaneous erections, facial hair, and body hair along with increased subcutaneous body fat) (see Appendix C—Table 1). In adult patients, estrogen does not alter a person's voice or height (Iwamoto, Defreyne et al., 2019; Wiepjes et al., 2019).

The time course and extent of physical changes vary among individuals and are related to factors such as genetics, age of initiation, and overall state of health (Deutsch, Bhakri et al., 2015; van Dijk et al., 2019). Knowledge of the extent and timing of sex hormone–induced changes, if available, may prevent the potential harm and expense of unnecessary treatment changes, dosage increases, and premature surgical procedures (Dekker et al., 2016).

Statement 12.13

We recommend health care professionals not prescribe ethinyl estradiol for transgender and gender diverse people as part of a gender-affirming hormonal treatment. For supporting text, see Statement 12.15.

Statement 12.14

We suggest health care professionals prescribe transdermal estrogen for eligible* transgender and gender diverse people at higher risk of developing venous thromboembolism based on age >45 years or a previous history of venous thromboembolism, when gender-affirming estrogen treatment is recommended. For supporting text, see Statement 12.15).

Statement 12.15

We suggest health care professionals not prescribe conjugated estrogens in transgender and gender diverse people when estradiol is available as part of a gender- affirming hormonal treatment.

Determining the safest and most efficacious estrogen compound and route of administration for TGD people is an important topic. The recommended estrogen-based regimens are presented in Appendix C—Table 4. The Amsterdam Medical Center (AMC) first reported 45 events of VTE occurring in 816 transgender women, notably an expected incidence ratio of VTE 20-fold higher than that reported in a reference population (van Kesteren et al., 1997). Following this report, the AMC clinic recommended the use of transdermal estradiol for transgender women older than 40 years of age, which subsequently lowered the incidence of VTE (Nota et al., 2019; Toorians et al., 2003). Other studies suggested ethinyl estradiol is associated with a higher risk of blood clotting due to an increased resistance to the anticoagulating effects of activated protein C (APC) and elevated concentrations of the clotting factors protein C and protein S (Toorians et al., 2013). Other studies published within the past 15 years from other clinics reported transgender women taking other forms of estrogen had lower rates of VTE than transgender women taking ethinyl estradiol (Asscheman et al., 2013). Furthermore, a 2019 systematic review concluded ethinyl estradiol administration was associated with the highest risk of VTE in transgender women, while an association between progesterone use and VTE was also identified (Goldstein et al., 2019).

The 2017 Endocrine Society guidelines did not recommend conjugated equine estrogens (CEEs) as a treatment option because blood levels of conjugated estrogens cannot be measured in transgender women making it difficult to prevent supraphysiologic dosing of estrogen and thereby increasing the potential risk of VTE (Hembree et al., 2017). A retrospective study from the UK examined the risks of oral CEE versus oral estradiol valerate versus oral ethinyl estradiol and found up to a 7-fold increase in the percentage of transgender women in the oral CEE group

who developed VTE compared with transgender women using other forms of estrogen (Seal et al., 2012). In a nested, case-control study, over 80,000 cisgender women aged 40–79 who developed a VTE were matched to approximately 390,000 cisgender women without VTE; the results showed oral estradiol use had a lower risk of VTE than conjugated estrogens, and transdermal estrogen was not associated with an increased risk of VTE (Vinogradova et al., 2019).

A systematic review evaluated several formulations of estrogen and identified a retrospective and a cross-sectional study that made head-to-head comparisons of the risks associated with different formulations (Wierckx, Mueller et al., 2012; Wierckx et al., 2013). No identified studies evaluating the risk of different formulations of estrogen employed a prospective interventional design. The retrospective study examined 214 transgender women taking transdermal estradiol (17β-estradiol gel 1.5 mg/d or estradiol patch 50 mcg/d) or a daily intake of oral estrogens (estradiol 2 mg/d, estriol 2 mg/d, ethinyl estradiol 50 mcg/day, or ethinyl estradiol 30–50 mcg in an oral contraceptive) (Wierckx et al., 2013). Within a 10-year observation period, 5% of the cohort developed a VTE, 1.4% (3 of 214) experienced a myocardial infarction (MI), and 2.3% (5 of 214) a transient ischemic attack or cerebrovascular accident (TIA/CVA). The prevalence of VTE, MI and TIA/CVA was increased following the initiation of estrogen therapy. However, the authors did not report differences between regimens of estrogen in terms of these endpoints.

The same group of investigators conducted a cross-sectional study that examined 50 transgender women (mean age 43 ± 10) taking oral estrogen (estradiol valerate 2 mg/d, estriol 2 mg/d or ethinyl estradiol 50–120 mcg/day) or using transdermal estradiol (17β-estradiol 1.5 mg/day or estradiol 50 mcg/day) over a follow-up duration of 9.2 years (Wierckx, Mueller et al., 2012). Twelve percent (n = 6) developed either a VTE, MI, or a TIA/CVA. Two of the participants were taking conjugated estrogen 0.625 mg/d (one person in combination with cyproterone acetate), 2 participants were taking ethinyl estradiol 20–50 mcg/d, 1 was taking cyproterone acetate 50 mg/d, while the estrogen regimen used by the sixth participant was not defined. None of the subjects taking oral estradiol or transdermal estradiol developed a VTE, MI, or TIA/CVA.

One prospective study examined the route of estrogen administration in 53 transgender women in a multicenter study carried out throughout Europe. Transgender women younger than 45 years of age (n = 40) received estradiol valerate 4 mg/d in combination with cyproterone acetate (CPA) 50 mg/d and transgender women older than 45 years of age (n = 13) received transdermal 17β-estradiol, also with CPA. No VTE, MI, or TIA/CVA was reported after a 1-year follow-up in either the oral or transdermal estrogen group. An additional retrospective study from Vienna found no occurrences of VTE among 162 transgender women using transdermal estradiol who were followed for a mean of 5 years (Ott et al., 2010).

We are strongly confident in our recommendation against the use of ethinyl estradiol based on historical data from the Amsterdam clinic demonstrating a reduction in the incidence of VTE after discontinuing the use of ethinyl estradiol and the recent systematic review demonstrating an increased risk of VTE in transgender women taking ethinyl estradiol (Weinand & Safer, 2015). We are confident in our recommendation against the use of CEE based on the 2012 study by Seal et al. demonstrating an increased risk of VTE in transgender women taking CEE compared with other formulations of estrogen and with data from cisgender women on hormone replacement therapy (Canonico et al., 2007; Seal et al., 2012). Prospective and retrospective studies in transgender women have reported occurrences of VTE/MI/CVA only in those taking CEE or ethinyl estradiol. Since estradiol is inexpensive, more widely available, and appears safer than CEE in limited studies, the committee recommends against using CEE when estradiol is an available treatment option. The quality of studies may be limited to prospective, cohort or cross-sectional study designs; however, the stronger level of recommendation is based on the consistent evidence supporting the association between the use of ethinyl estradiol and CEE and a greater risk of VTE/MI/CVA in transgender women.

We are also confident in our recommendation for the administration of transdermal preparations of estrogen in older transgender women

(age > 45 years) or those with a previous history of VTE. The confidence in our recommendation is based on the decreased incidence of VTE reported from the Amsterdam clinic when transgender women are switched to using transdermal preparations after age 40 (van Kesteren et al., 1997). Furthermore, the prospective, multicenter cohort study ENIGI found no incidence of VTE/MI/CVA in transgender women who are routinely switched to transdermal estrogen at age 45 (Dekker et al., 2016). In addition, a study by Ott et al. demonstrated no incidence of VTE in 162 transgender women treated with estradiol patches (Ott et al., 2010).

With the exception of cyproterone acetate (note this is not approved for use in the US because of concerns of potential hepatotoxicity), the use of progestins in hormone therapy regimens remains controversial. To date, there have been no quality studies evaluating the role of progesterones in hormone therapy for transgender patients.

We are aware some practitioners who prescribe progestins, including micronized progesterone, are under the impression there may be improvements in breast and/or areolar development, mood, libido, and overall shape for those seeking it along with other benefits yet to be demonstrated (Deutsch, 2016a; Wierckx, van Caenegem et al., 2014). However, these improvements remain anecdotal, and there are no quality data to support such progestin use. An attempted systematic review we commissioned for this version of the SOC failed to identify enough data to make a recommendation in favor of any progestins. Instead, existing data suggest harm is associated with extended progestin exposure (Safer, 2021).

For cisgender women who have a uterus, progestins in combination with estrogens are necessary to avoid the endometrial cancer risk associated with the administration of unopposed estrogen. For cisgender women who do not have a uterus, progestins are not used. The best data for the concerns related to progestin use come from comparisons between the above two cisgender populations, which we acknowledge is not necessarily generalizable to this population. Although not definitive of a class effect for all progestins, medroxyprogesterone added to combined equine estrogens is associated with greater breast cancer and cardiac risks (Chlebowski 2020; Manson, 2013). It is important to note data from the Women's Health Initiative (WHI) studies may not be generalizable to transgender populations. Compared with the cisgender women in the studies, transgender populations seeking hormone therapy tend to be younger, do not use equine estrogen, and hormone therapy in these cases address current mental health and quality of life and not solely risk prevention (Deutsch, 2016a).

Potential adverse effects of progestins include weight gain, depression, and lipid changes. Micronized progesterone may be better tolerated and may have a more favorable impact on the lipid profile than medroxyprogesterone (Fitzpatrick et al., 2000). When paired with estrogens for transgender women, the progestin cyproterone acetate is associated with elevated prolactin, decreased HDL cholesterol, and rare meningiomas—none of which are seen when estrogens are paired with GnRH agonists or spironolactone (Bisson, 2018; Borghei-Razavi, 2014; Defreyne, Nota et al., 2017; Sofer et al., 2020).

Thus, data to date do not include quality evidence supporting a benefit of progestin therapy for transgender women. However, the literature does suggest a potential harm of some progestins, at least in the setting of multi-year exposure. If, after a discussion of the risks and benefits of progesterone treatment, there is a collaborative decision to begin a trial of progesterone therapy, the prescriber should evaluate the patient within a year to review the patient's response to this treatment.

Statement 12.16

We recommend health care professionals prescribe testosterone-lowering medications (either cyproterone acetate, spironolactone, or GnRH agonists) for eligible* transgender and gendered diverse people with testes taking estrogen as part of a hormonal treatment plan if their individual goal is to approximate levels of circulating sex hormone in cisgender women.

Most gender clinics in the US and Europe prescribe estrogen combined with a testosterone-lowering medication (Mamoojee et al., 2017) (see Appendix C—Table 5). In the

US, spironolactone is the most commonly prescribed testosterone-lowering medication, while GnRHas are commonly used in the UK, and cyproterone acetate are most often prescribed in the rest of Europe (Angus et al., 2021; Kuijpers et al., 2021). The rationale for adding a testosterone-lowering medication is two-fold 1) to lower testosterone levels to within the reference range of cisgender women; and 2) to reduce the amount of estrogen needed to achieve adequate physical effects. Each testosterone-lowering medication has a different side effect profile. Spironolactone is an antihypertensive and potassium-sparing diuretic, and thus may lead to hyperkalemia, increased frequency of urination, and a reduction in blood pressure (Lin et al., 2021). Cyproterone acetate has been associated with the development of meningioma and hyperprolactinemia (Nota et al., 2018). GnRHa's, while very effective in lowering testosterone levels, can result in osteoporosis if doses of estrogen given concurrently are insufficient (Klink, Caris et al., 2015).

One systematic review identified one study that reported findings from a head-to-head comparison of the testosterone-lowering medications cyproterone acetate and leuprolide (Gava et al., 2016). Two studies compared a group of transgender women taking estrogen plus testosterone-lowering medications with a group who received only estrogen. The systematic review did not provide sufficient evidence to suggest any of the three testosterone-lowering medications had a better safety profile in terms of improved outcomes in bone health, testosterone levels, potassium levels, or in the incidence of hyperprolactinemia or meningiomas (Wilson et al., 2020). Therefore, no recommendation can be given. The review did report spironolactone-based regimens were associated with a 45% increase in prolactin levels, whereas cyproterone-based regimens increased prolactin levels by more than 100%. However, the clinical significance of elevated prolactin levels is not clear because the rates of prolactinomas were not significantly elevated in either the spironolactone- or CPA-treated groups (Wilson et al., 2020). One retrospective, cohort study from a single center in the US reported no clinically significant increases in prolactin levels in 100 transgender women treated with estrogen plus spironolactone (Bisson et al., 2018). A retrospective study from the Netherlands of 2,555 transgender women taking primarily CPA with various formulations of estrogen reported an increased standardized incidence ratio of meningiomas in patients who used cyproterone acetate after gonadectomy for many years when compared with the general Dutch population (Nota et al., 2018). Furthermore, in a shorter study in Belgium, 107 transgender women had transient elevations in prolactin levels following treatment with cyproterone acetate, which declined to normal after discontinuation (Defreyne, Nota et al., 2017). A recent publication, not included in the systematic review, examined 126 transgender women taking spironolactone, GnRHas, or cyproterone and concluded cyproterone was associated with higher prolactin levels and a worse lipid profile than spironolactone or GnRHas (Sofer et al., 2020). After balancing the costs and accessibility of measuring prolactin levels against the clinical significance of an elevated level, a decision was made not to make a recommendation for or against monitoring prolactin levels at this time. HCPs should therefore make individualized clinical decisions about the necessity to measure prolactin levels based on the type of hormone regimen and/or the presence of symptoms of hyperprolactinemia or a pituitary tumor (e.g., galactorrhea, visual field changes).

Cyproterone has also been linked to meningiomas. Nine cases of meningioma have been reported in the literature among transgender women primarily taking cyproterone acetate (Mancini et al., 2018). This increased risk has also been identified in cisgender populations. In 2020, the European Medicines Agency published a report recommending cyproterone products with daily doses of 10 mg or more should be restricted because of the risk of developing meningioma (European Medicines Agency, 2020). Most likely this association is a specific effect of cyproterone acetate and has not been extrapolated to include other testosterone-lowering drugs. In the US, where cyproterone acetate is not available, the North American Association of Central Cancer Registries (NAACCRs) database did not identify an increased risk of brain tumors (not specific to

meningiomas) among transgender women (Nash et al., 2018). Furthermore, there was not an increase in the hazard ratio of brain tumors in the Kaiser cohort of 2,791 transgender women compared with cisgender controls (Silverberg et al., 2017). No long-term studies have reported on the risk of meningiomas and prolactinomas in transgender women taking GnRHas.

Our strong recommendation for the use of testosterone-lowering medications as part of a hormone regimen for transgender individuals with testes is based on the global practice of using these medications in addition to estrogen therapies as well as the relatively minimal risk associated with these therapies. However, we are not able to make a recommendation favoring one testosterone-lowering medication over another at this time. The published data thus far raises some concerns about the risk of meningiomas with the prolonged use (>2 years) and higher doses (>10mg daily) of cyproterone acetate (Nota et al., 2018; Ter Wengel et al., 2016; Weill et al., 2021).

Bicalutamide is an antiandrogen that has been used in the treatment of prostate cancer. It competitively binds to the androgen receptor to block the binding of androgens. Data on the use of bicalutamide in trans feminine populations is very sparse and safety data is lacking. One small study looked at the use of bicalutamide 50 mg daily as a puberty blocker in 23 trans feminine adolescents who could not obtain treatment with a GnRH analogue (Neyman et al., 2019). All adolescents experienced breast development which is also commonly seen in men with prostate cancer who are treated with bicalutamide. Although rare, fulminant hepatotoxicity resulting in death has been described with bicalutamide (O'Bryant et al., 2008). Given that bicalutamide has not been adequately studied in trans feminine populations, we do not recommend its routine use.

The administration of 5α-reductase inhibitors block the conversion of testosterone to the more potent androgen dihydrotestosterone. The Food & Drug Administration (FDA) approved indications of finasteride administration include benign prostatic hypertrophy and androgenetic alopecia. Data on the use of 5α-reductase inhibitors in trans feminine populations is very sparse (Irwig, 2021). It is unclear whether this class of medication could have any clinical benefit in trans feminine individuals whose testosterone and dihydrotestosterone levels have already been lowered with estrogen and an antiandrogen. We therefore do not recommend their routine use in trans feminine populations. Finasteride may be an appropriate treatment option in trans masculine individuals experiencing bothersome alopecia resulting from higher dihydrotestosterone levels. Nonetheless, treatment with a 5α-reductase inhibitor may impair clitoral growth and the development of facial and body hair in trans masculine individuals. Studies are needed to assess the efficacy and safety of 5α-reductase inhibitors in transgender populations.

Statement 12.17

We recommend health care professionals monitor hematocrit (or hemoglobin) levels in transgender and gender diverse people treated with testosterone.

There are good quality data suggesting a rise in hematocrit (or hemoglobin) is associated with TGD persons treated with testosterone (Defreyne et al., 2018). The testosterone regimens in the systematic review included testosterone esters ranging from the equivalent of 25–250 mg SC/IM weekly, testosterone undecanoate 1000 mg every 12 weeks, or testosterone gel 50 mg applied daily to the skin (Defreyne et al., 2018; Gava et al., 2018; Giltay et al., 2000; Meriggiola et al., 2008; Pelusi et al., 2014; T'Sjoen et al., 2005; Wierckx, van Caenegem et al., 2014; Wierckx, van de Peer et al., 2014). The expected rise should be consistent with reference ranges in cisgender males.

Statement 12.18

We suggest health care professionals collaborate with surgeons regarding hormone use before and after gender-affirmation surgery. For supporting text, see Statement 12.19.

Statement 12.19

We suggest health care professionals counsel eligible* transgender and gender diverse people about the various options for gender-affirmation surgery unless surgery is either not indicated or is medically contraindicated.

Despite the absence of evidence, perioperative clinical standards for gender-affirmation surgeries have included cessation of hormone therapy for 1–4 weeks before and after surgery, most commonly genital surgeries (Hembree et al., 2009). Such practice was meant to mitigate the risk of VTE associated with exogenous estrogen administration (Hembree et al., 2009). Estrogen and testosterone could then be resumed at some point postoperatively.

After careful examination, investigators have found no perioperative increase in the rate of VTE among transgender individuals undergoing surgery, while being maintained on sex steroid treatment throughout when compared with that among patients whose sex steroid treatment was discontinued preoperatively (Gaither et al., 2018; Hembree et al., 2009; Kozato et al., 2021; Prince & Safer, 2020). Sex steroid treatment is especially important after gonadectomy to avoid the sequelae of hypogonadism, the risk of developing osteoporosis, and for the maintenance of mental health and quality of life (Fisher, Castellini et al., 2016; Rosen et al., 2019). Thus, hormone providers and surgeons should educate patients about the necessity for continuous exogenous hormone therapy after gonadectomy.

To be able to educate patients and serve as clinical advocates, HCPs should be knowledgeable about the risks and benefits of gender-affirmation surgeries and should also be cognizant of the performance measures and surgical outcomes of the surgeons to whom they might refer patients (Beek, Kreukels et al., 2015; Colebunders et al., 2017; Wiepjes et al., 2018). In general, most medically necessary surgeries can be thought of as involving three regions: the face, chest/breasts, and genitalia (internal and external). Additional medically necessary procedures include body contouring and voice surgery. See medical necessity statement in Chapter 2—Global Applicability, Statement 2.1).

Multiple procedures are available for facial gender-affirming surgeries including, but not limited to chondrolanryngoplasty, rhinoplasty, contouring or augmentation of the jaw, chin, and forehead, facelift, hair removal and hair transplantation (see Chapter 13—Surgery and Postoperative Care). Procedures available for chest/breast surgery include breast augmentation, double mastectomy with nipple grafts, periareolar mastectomy, and liposuction. The most common gender-affirmation surgery for TGD individuals with endogenous breast development is masculinizing chest surgery (mastectomy) (Horbach et al., 2015; Kailas et al., 2017).

Internal genital surgery procedures include but are not limited to orchiectomy, hysterectomy, salpingo-oophorectomy, vaginoplasty, and colpectomy/vaginectomy (Horbach et al., 2015; Jiang et al., 2018). The inner lining in vaginoplasty is typically constructed from penile skin, skin grafts, a combination of both, or a bowel segment. Removal of the uterus/ovaries can be performed individually or all at once (hysterectomy, salpingo-oophorectomy, and colpectomy). If colpectomy is performed, a hysterectomy must also be performed. The ovaries may remain in situ, upon patient request. A potential benefit of leaving one or both ovaries is fertility preservation, while the downside is the potential for the development of ovarian pathology, including cancer (De Roo et al., 2017).

External genital surgery procedures include but are not limited to vulvoplasty, metoidioplasty, and phalloplasty (Djordjevic et al., 2008; Frey et al., 2016). Hair removal is generally necessary before performing external genital procedures (Marks et al., 2019). Vulvoplasty can include the creation of the mons, labia, clitoris, and urethral opening. Urethral lengthening is an option for both metoidioplasty and phalloplasty, but is associated with a greatly increased complication rate (Schechter & Safa, 2018). Wound care and physical therapy are necessary for managing wounds resulting from the donor sites for phalloplasty (van Caenegem, Verhaeghe et al., 2013). Pelvic physical therapy can also be an important adjunct intervention after surgery for managing voiding and sexual function (Jiang et al., 2019). Dialogue, mutual understanding, and clear communication in a common language between patients, HCPs, and surgeons will contribute to well-considered decisions about the available surgical procedures.

Statement 12.20

We recommend health care professionals initiate and continue gender-affirming hormone

therapy for eligible* transgender and gender diverse people who wish this treatment due to demonstrated improvement in psychosocial functioning and quality of life. For supporting text, see Statement 12.21.

Statement 12.21

We recommend health care professionals maintain existing hormone therapy if the transgender and gender diverse individual's mental health deteriorates and assess the reason for the deterioration, unless contraindicated.

Several mental health disparities have been documented in the transgender population including depression, suicidality, anxiety, decreased self-esteem, and post-traumatic stress disorder (Arcelus et al., 2016; Becerra-Culqui et al, 2018; Bouman et al., 2017; Eisenberg et al., 2017; Heylens, Elaut et al., 2014; Witcomb et al., 2018). The gender minority stress model provides evidence of several mediators and moderators of these disparities (Hendricks & Testa, 2012; Meyer, 2003). Mediators and moderators of mental health disparities unique to transgender people include experiences of discrimination, victimization, misgendering, family rejection, and internalized transphobia (Hendricks & Testa, 2012). Factors that have a positive effect on mental health include family acceptance, supportive social and romantic relationships, transgender community connectedness, protection by affirming and inclusive policies, policies of affirmation and inclusion, possession of updated legal name/gender documentation, and achievement of physical gender transition based on individualized embodiment goals (Bauer et al., 2015; Bockting et al., 2013; Bouman et al., 2016; Davey et al., 2014; de Vries et al., 2014; Du Bois et al., 2018; Gower, Rider, Brown et al., 2018; Hendricks & Testa, 2012; Keo-Meier et al., 2015; Meier et al., 2013; Pflum et al., 2015; Ryan et al., 2010; Smith et al., 2018).

Hormone therapy has been found to positively impact the mental health and quality of life of TGD youth and adults who embark on this treatment (Aldridge et al., 2020; Allen et al., 2019; Bauer et al., 2015; Nobili et al., 2018; Russell et al., 2018; Ryan, 2009). In many cases, hormone therapy is considered a lifesaving intervention (Allen et al., 2019; Grossman & D'Augelli, 2006; Moody et al., 2015). Several studies have found associations between the initiation of hormone therapy and improved mental health in youth and adults (Aldridge et al., 2020; Costa et al., 2016; de Vries et al., 2014; Kuper et al., 2020; Nguyen et al., 2018; White Hughto & Reisner, 2016), including improvements in quality of life (Gorin-Lazard et al., 2012; Gorin-Lazard et al., 2013; Murad et al., 2010; Newfield et al., 2006; Nobili et al., 2018; White Hughto & Reisner, 2016), a reduction in anxiety and depression (Aldridge et al., 2020; Colizzi et al., 2014; Davis & Meier, 2014; de Vries, Steensma et al., 2011; Gómez-Gil et al., 2012; Rowniak et al., 2019), decreased stress, and decreased paranoia (Keo-Meier & Fitzgerald, 2017). A prospective, controlled trial using the Minnesota Multiphasic Personality Inventory-2 (MMPI-2) demonstrated significant improvement in multiple domains of psychological functioning in transgender men after only 3 months of testosterone treatment (Keo-Meier et al., 2015). Although there are higher rates of autism symptoms in the transgender population, these symptoms have not been found to increase after the initiation of hormone therapy (Nobili et al., 2020).

As a reduction in depressive symptoms may correlate with a decrease in the risk of suicide, withholding hormone therapy based on the presence of depression or suicidality may cause harm (Keo-Meier et al., 2015; Levy et al., 2003). Turban, King et al. (2020) found a decrease in the odds of lifetime suicidal ideation in adolescents who required pubertal suppression and had access to this treatment compared with those with a similar desire with no such access (Turban, King et al., 2020). A recent systematic review found pubertal suppression in TGD adolescents was associated with an improved social life, decreased suicidality in adulthood, improved psychological functioning and quality of life (Rew et al., 2020). Because evidence suggests hormone therapy is directly linked to decreased symptoms of depression and anxiety, the practice of withholding hormone therapy until these symptoms are treated with traditional psychiatry is considered to have iatrogenic effects

(Keo-Meier et al., 2015). If psychiatric treatment is indicated, it can be started or adjusted concurrently without discontinuing hormone therapy.

**For eligibility criteria for adolescents and adults, please refer to Chapter 5—Assessment for Adults and Chapter 6—Adolescents as well as Appendix D.*

CHAPTER 13 Surgery and Postoperative Care

Medically necessary gender-affirmation surgery (GAS) refers to a constellation of procedures designed to align a person's body with their gender identity (see Chapter 2—Global Applicability for medical necessity, Statement 2.1). This chapter describes surgery and postoperative care recommendations for TGD adults and adolescents. Please refer to Chapter 5—Assessment of Adults and Chapter 6—Adolescents for the assessment criteria related to surgery for adults and adolescents, respectively. A summary of the recommendations and assessment criteria can be found in Appendix D.

Recognizing the diverse and heterogeneous community of individuals who identify as transgender and gender diverse (TGD), gender-affirming surgical interventions may be categorized along a spectrum of procedures for individuals assigned male at birth (AMAB) and assigned female at birth (AFAB).

In appropriately selected TGD individuals, the current literature supports the benefits of GAS. While complications following GAS occur, many are either minor or can be treated with local care on an outpatient basis (Canner et al., 2018; Gaither et al., 2018; Morrison et al., 2016). In addition, complication rates are consistent with those of similar procedures performed for different diagnoses (i.e., non-gender-affirming procedures).

In individuals AFAB, gender-affirming chest surgery or "top surgery" (i.e. "subcutaneous mastectomy") has been studied in prospective (Agarwal et al., 2018; Frederick et al., 2017; Top & Balta, 2017; van de Grift, Elaut et al., 2017; van de Grift et al., 2016), retrospective (Bertrand et al., 2017; Claes et al., 2018; Esmonde et al., 2019; Lo Russo et al., 2017; Marinkovic & Newfield, 2017; Poudrier et al., 2019; Wolter et al., 2015; Wolter et al., 2018), and cross-sectional cohort studies (Olson-Kennedy, Warus et al., 2018; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018; van de Grift, Elfering et al., 2018). The efficacy of top surgery has been demonstrated in multiple domains, including a consistent and direct increase in health-related quality of life, a significant decrease in gender dysphoria, and a consistent increase in satisfaction with body and appearance. Additionally, rates of regret remain very low, varying from 0 to 4%. While the effect of top surgery on additional outcome measures such as depression, anxiety, and sexual function also demonstrated a benefit, the studies were of insufficient strength to draw definitive conclusions. Although further investigation is needed to draw more robust conclusions, the evidence demonstrates top surgery to be a safe and effective intervention.

In individuals AMAB, fewer studies have been published regarding gender-affirming breast surgery ("breast augmentation") and include 2 prospective (Weigert et al., 2013; Zavlin et al., 2018), 1 retrospective cohort (Fakin et al., 2019), and 3 cross-sectional cohort studies (Kanhai et al., 2000; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018). All the studies reported a consistent and direct improvement in patient satisfaction, including general satisfaction, body image satisfaction, and body image following surgery. Owen-Smith et al. (2018) demonstrated a positive trend toward improvement in both depression and anxiety scores with increasing levels of gender-affirming interventions. However, there was no statistical comparison between individuals who underwent top surgery and any other group.

Gender-affirming vaginoplasty is one of the most frequently reported gender-affirming surgical interventions; 8 prospective (Buncamper et al., 2017; Cardoso da Silva et al., 2016; Kanhai, 2016; Manero Vazquez et al., 2018; Papadopulos, Zavlin et al., 2017; Tavakkoli Tabassi et al., 2015; Wei et al., 2018; Zavlin et al., 2018), 15 retrospective cohort (Bouman, van der Sluis et al., 2016; Buncamper et al., 2015; Hess et al., 2016; Jiang et al., 2018; LeBreton et al., 2017; Manrique et al., 2018; Massie et al., 2018; Morrison et al., 2015; Papadopulos, Lelle et al., 2017; Raigosa et al., 2015; Salgado et al., 2018; Seyed-Forootan et al., 2018; Sigurjonsson et al., 2017; Simonsen et al., 2016; Thalaivirithan et al., 2018), and 3 cross-sectional cohort studies have recently been reported (Castellano et al., 2015; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018).

Although different assessment measurements were used, the results from all studies consistently reported both a high level of patient satisfaction (78–100%) as well as satisfaction with sexual function (75–100%). This was especially evident

Statements of Recommendations

13.1- We recommend surgeons who perform gender-affirming surgical procedures have the following credentials:
13.1.a- Training and documented supervision in gender-affirming procedures;
13.1.b- Maintenance of an active practice in gender-affirming surgical procedures;
13.1.c- Knowledge about gender diverse identities and expressions;
13.1.d- Continuing education in the field of gender-affirmation surgery
13.1.e- Tracking of surgical outcomes.
13.2- We recommend surgeons assess transgender and gender diverse people for risk factors associated with breast cancer prior to breast augmentation or mastectomy.
13.3- We recommend surgeons inform transgender and gender diverse people undergoing gender-affirming surgical procedures about aftercare requirements, travel and accommodations, and the importance of postoperative follow-up during the preoperative process.
13.4- We recommend surgeons confirm reproductive options have been discussed prior to gonadectomy in transgender and gender diverse people.
13.5- We suggest surgeons consider offering gonadectomy to eligible* transgender and gender diverse adults when there is evidence they have tolerated a minimum of 6 months of hormone therapy (unless hormone replacement therapy or gonadal suppression is not clinically indicated or the procedure is inconsistent with the patient's desires, goals, or expressions of individual gender identity).
13.6- We suggest health care professionals consider gender-affirming genital procedures for eligible* transgender and gender diverse adults seeking these interventions when there is evidence the individual has been stable on their current treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated).
13.7- We recommend surgeons consider gender-affirming surgical interventions for eligible* transgender and gender diverse adolescents when there is evidence a multidisciplinary approach that includes mental health and medical professionals has been involved in the decision-making process.
13.8- We recommend surgeons consult a comprehensive, multidisciplinary team of professionals in the field of transgender health when eligible* transgender and gender diverse people request individually customized (previously termed "non-standard") surgeries as part of a gender-affirming surgical intervention.
13.9- We suggest surgeons caring for transgender men and gender diverse people who have undergone metoidioplasty/phalloplasty encourage lifelong urological follow-up.
13.10- We recommend surgeons caring for transgender women and gender diverse people who have undergone vaginoplasty encourage follow-up with their primary surgeon, primary care physician, or gynecologist.
13.11- We recommend patients who regret their gender-related surgical intervention be managed by an expert multidisciplinary team.

** For eligibility criteria for adolescents and adults, please refer to the Assessment for Adults and Adolescents chapters and Appendix D.*

when using more recent surgical techniques. Gender-affirming vaginoplasty was also associated with a low rate of complications and a low incidence of regret (0–8%).

Recent literature reflects the increased clinical interest in metoidioplasty and phalloplasty as reflected by 3 prospective cohort (Garaffa et al., 2010; Stojanovic et al., 2017; Vukadinovic et al., 2014), 6 retrospective cohort (Cohanzad, 2016; Garcia et al., 2014; Simonsen et al., 2016; van de Grift, Pigot et al., 2017; van der Sluis et al., 2017; Zhang et al., 2015), and 4 cross-sectional studies (Castellano et al., 2015; Owen-Smith et al., 2018; van de Grift, Elaut et al., 2018; Wierckx, Van Caenegem et al., 2011), which reviewed the risks and benefits of these procedures.

In terms of urinary function, between 75 and 100% of study participants were able to void while standing. In terms of sexual function, between 77 and 95% of study participants reported satisfaction with their sexual function. Most of these studies report high overall levels of postoperative satisfaction (range 83–100%), with higher rates of satisfaction in studies involving newer surgical techniques. Two prospective and two retrospective cohort studies specifically assessed regret following surgery and found no transgender men experienced regret. While study limitations were identified, the reported results were consistent and direct.

In recent years, facial GAS (FGAS) has received increased attention, and current literature supports its benefits. Eight recent publications include 1 prospective cohort (Morrison et al., 2020), 5 retrospective cohort (Bellinga et al., 2017; Capitán et al., 2014; Noureai et al., 2007; Raffaini et al., 2016; Simon et al., 2022), and 2 cross-sectional studies (Ainsworth & Spiegel, 2010; van de Grift, Elaut

et al., 2018). All 8 studies clearly demonstrated individuals were very satisfied with their surgical results (between 72% and 100% of individuals). Additionally, individuals were significantly more satisfied with the appearance of their face compared with individuals who had not undergone surgery. One prospective, international, multicenter, cohort study found facial GAS significantly improves both mid- and long-term quality of life (Morrison et al., 2020). The results were direct and consistent, but somewhat imprecise because of certain study limitations. While gender-affirming facial surgery for AFAB individuals is an emerging field, current limited data points toward equal benefits in select patients. Future studies are recommended.

Additional procedures and/or interventions such as hair removal (prior to facial and/or genital surgery) may be required as part of the preoperative process. See Chapter 15—Primary Care. Furthermore, consultation with pelvic floor physical therapy may be important (or required) both before and after surgery.

Representative surgical interventions include (for complete list, see appendix E and the end of this chapter):

AMAB: facial feminization surgery (including chondrolaryngoplasty/vocal cord surgery), gender-affirming breast surgery, body contouring procedures, orchiectomy, vagino/vulvoplasty (with/without depth), aesthetic procedures, and procedures designed to prepare individuals for surgery (i.e., hair removal).

AFAB: facial masculinization surgery, gender-affirming chest surgery, hysterectomy/oophorectomy, metoidioplasty (including placement of testicular prosthesis), phalloplasty (including placement of testicular/penile prostheses), body contouring procedures, aesthetic procedures, and procedures designed to prepare individuals for surgery (i.e., hair removal).

It is important surgeons understand the indication(s) and the timing for GAS. This is especially important when caring for adolescents (see Chapter 6—Adolescents).

It is important the surgeon and the patient participate in a shared decision-making approach that includes 1) a multidisciplinary approach; 2) an understanding of the patient's goals and expectations; 3) a discussion regarding the surgical options and associated risks and benefits; and 4) an informed plan for aftercare (see Chapter 5—Assessment for Adults). These recommendations are designed to facilitate an individualized approach to care.

Appropriate aftercare is essential for optimizing outcomes (Buncamper et al., 2015; Lawrence, 2003), and it is important patients are informed about postoperative needs (including local wound care, activity restrictions, time off from work or school, etc.). In addition, it is important the surgeon is available to provide and facilitate postoperative care, refer to specialty services, or both as needed. This may include the need for ongoing support (i.e., both from the caregiver as well as the primary care provider, mental health professionals (MHPs), or both), as well as the need for routine primary care (i.e., breast/chest cancer screening, urologic/gynecologic care, etc.).

With the increase both in public interest and in the number of gender-affirming surgical procedures (Canner et al., 2018; Ross, 2017; Shen et al., 2019), additional training, tracking of outcomes, and continuing medical education for surgeons are necessary (Schechter et al., 2017).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 13.1

We recommend surgeons who perform gender-affirming surgical procedures have the following credentials:

a. **Training and documented supervision in gender-affirming procedures;**
b. **Maintenance of an active practice in gender-affirming surgical procedures;**
c. **Knowledge about gender diverse identities and expressions;**
d. **Continuing education in the field of gender-affirmation surgery;**
e. **Tracking of surgical outcomes.**

Surgeons offering GAS may have a variety of surgical specialty training and backgrounds. The most common surgical specialties include plastic surgery, urology, gynecology, otolaryngology and oro-maxillofacial surgery (Jazayeri et al., 2021). Consistent with other surgical domains, we recommend only surgeons who are certified or eligible to be certified by their respective national professional boards offer GAS. Furthermore, it is recommended surgeons offering care for TGD people have received documented training in gender-affirming procedures and principles of gender-affirming care (Schechter et al., 2017; Schechter & Schechter, 2019). The latter includes, but is not limited, to knowledge about gender diverse identities and expressions, and how those affect patient goals, expectations, and outcomes. It is important surgeons offering GAS be familiar with the available procedures and can provide informed consent. If surgeons do not offer a requested procedure, they may offer a referral for a second opinion. Surgeons offering GAS are expected to participate in continuing education activities in the field of GAS (i.e., meetings, conferences, seminars, etc.) to maintain current knowledge. We further recommend surgical outcomes be tracked and communicated to the patients as part of the informed consent (Schechter et al., 2017).

In addition, hospitals, institutions, and physician offices that offer GAS need to be knowledgeable regarding cultural competencies (i.e., language, terminology, etc.). This may require ongoing and regular staff education.

Statement 13.2

We recommend surgeons assess transgender and gender diverse people for risk factors associated with breast cancer prior to breast augmentation or mastectomy.

Prior to breast augmentation or mastectomy, individuals need to be informed about and assessed for breast cancer risk factors, including genetic mutations (i.e., BRCA1, BRCA2), family history, age, radiation, exposure to estrogen, and the amount of breast tissue anticipated to remain after surgery (Brown, Lourenco et al., 2021; Brown & Jones, 2015; Colebunders et al., 2014; Gooren et al., 2013; Salibian et al., 2021; Weyers et al., 2010). Breast cancer screening balances the identification of cancer with the selection of appropriate imaging, tests, and procedures. Currently, evidence-based screening guidelines specific for TGD individuals do not exist (Salibian et al., 2021), however, recent guidelines have been proposed by the American College of Radiology (Brown, Lourenco et al., 2021). Because the risk of cancer in individuals seeking gender-affirming breast augmentation or mastectomy is similar to that in the general population (even in the setting of hormone use), existing cancer screening guidelines need to be followed (Brown & Jones, 2015; Gooren et al., 2013; Salibian et al., 2021; Weyers et al., 2010). Professionals need to be familiar with updates to these guidelines as they are subject to change. Individuals who undergo gender-affirming surgery of the chest should have ongoing breast cancer surveillance, which should be overseen by their primary care providers.

Statement 13.3

We recommend surgeons inform transgender and gender diverse people undergoing gender-affirming surgical procedures about aftercare requirements, travel and accommodations, and the importance of postoperative follow-up during the preoperative process.

Details about the timing, technique, and duration of the aftercare requirements are shared with patients in the preoperative period such that appropriate planning may be undertaken. This includes a discussion regarding the anticipated staging of surgical procedures (and associated travel requirements). Given the small number of surgeons who specialize in GAS, it is common for patients to travel for their procedures. Prior to surgery, surgeons should provide patients with a postoperative follow-up schedule. The surgeon should discuss the duration of the patient's travel dates, the anticipated inpatient versus outpatient stay, and the potential need for flexibility in travel arrangements (especially if complications occur). Given the complexity and cost of travel and lodging, changes in the care plan should be shared with the patient as early as possible. Surgeons should facilitate continuity of care with a local provider upon returning home.

Aftercare and postsurgical follow-up are important. Gender-affirming surgical procedures

often have specific aftercare requirements, such as postsurgery resources (stable, safe housing; resources for travel and follow-up care), instructions in health-positive habits (e.g., personal hygiene, healthy living, prevention of urinary tract infections (UTIs) and sexually-transmitted infections (STIs) (Wierckx, Van Caenegem et al., 2011)), postsurgery precautions or limitations on activities of daily life (e.g., bathing, physical activity, exercise, nutritional guidance, resumption of sexual activity) (Capitán et al., 2020), postsurgery resumption of medications (i.e., anticoagulants, hormones, etc.), and detailed postsurgery self-care activities (e.g., postvaginoplasty dilation and douching regimens, activation of a penile prosthesis, strategies to optimize postphalloplasty urination, recommendations for hair transplant care) (Capitán et al., 2017; Falcone et al., 2018; Garcia, 2018; Hoebeke et al., 2005). Some aspects of postsurgery self-care activities may be introduced prior to surgery and are reinforced after surgery (Falcone et al., 2018). As issues such as wound disruptions, difficulty with dilation, and UTIs may occur (Dy et al., 2019), the follow-up period provides an opportunity to intervene, mitigate, and prevent complications (Buncamper et al., 2016; Garcia, 2021).

Statement 13.4

We recommend surgeons confirm reproductive options have been discussed prior to gonadectomy in transgender and gender diverse people.

Infertility is often a consequence of both gender-affirming hormone therapy (temporary) and GAS (permanent), and fertility preservation is discussed prior to medical interventions, surgical interventions, or both (Defreyne, van Schuylenbergh et al., 2020; Jahromi et al., 2021; Jones et al., 2021). Surgical interventions that alter reproductive anatomy or function may limit future reproductive options to varying degrees (Nahata et al., 2019). It is thus critical to discuss infertility risk and fertility preservation (FP) options with transgender individuals and their families prior to initiating any of these interventions and on an ongoing basis thereafter (Hembree et al., 2017).

For specific recommendations regarding reproductive options, see Chapter 16—Reproductive Health.

Statement 13.5

We suggest surgeons consider offering gonadectomy to eligible* transgender and gender diverse adults when there is evidence they have tolerated a minimum of 6 months of hormone therapy (unless hormone replacement therapy or gonadal suppression is not clinically indicated or the procedure is inconsistent with the patient's desires, goals, or expressions of individual gender identity). For supporting text, see Statement 13.6.

Statement 13.6

We suggest health care professionals consider gender-affirming genital procedures in eligible* transgender and gender diverse adults seeking these interventions when there is evidence the individual has been stable on their current treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result unless hormone therapy is either not desired or is medically contraindicated).

GAHT leads to anatomical, physiological, and psychological changes. The onset of the anatomic effects (e.g., clitoral growth, vaginal mucosal atrophy) may begin early after the initiation of therapy, and the peak effect is expected at 1–2 years (T'Sjoen et al., 2019). Depending upon the surgical result required, a period of hormone treatment may be required (e.g., sufficient clitoral virilization prior to metoidioplasty/phalloplasty) or preferred for psychological reasons, anatomical reasons, or both (breast growth and skin expansion prior to breast augmentation, softening of skin and changes in facial fat distribution prior to facial GAS) (de Blok et al., 2021).

For individuals who are not taking hormones prior to surgical interventions, it is important surgeons review the impact of this on the proposed surgery.

For individuals undergoing gonadectomy who are not taking hormones, a plan for hormone replacement can be developed with their prescribing professional prior to surgery.

Statement 13.7

We recommend surgeons consider gender-affirming surgical interventions for eligible* transgender and gender diverse adolescents when there is evidence a multidisciplinary approach that includes mental health and medical professionals has been involved in the decision-making process.

Substantial evidence (i.e., observational studies (Monstrey et al., 2001; Stojanovic et al., 2017), literature reviews and expert opinions (Esteva de Antonio et al., 2013; Frey et al., 2017; Hadj-Moussa et al., 2019; Pan & Honig, 2018), established guidelines (Byne et al., 2018; Chen, Fuqua et al., 2016; Hembree et al., 2017; Karasic & Fraser, 2018; Klein, Paradise et al., 2018; Weissler et al., 2018), and a thematic content analysis (Gerritse et al., 2018), support the importance of a multidisciplinary (i.e., medical, mental health, and surgery) approach to transgender health care.

A multidisciplinary approach is especially important in managing mental health issues if these are experienced by a TGD person undergoing GAS (de Freitas et al., 2020; Dhejne et al., 2016; van der Miesen et al., 2016). In addition, primary care providers and medical specialists can help support decisions regarding the timing of surgery, surgical outcomes and expectations, perioperative hormone management, and optimization of medical conditions (Elamin et al., 2010; Hembree et al., 2017).

For specific recommendations regarding presurgical assessment in adolescents, see Chapter 6—Adolescents.

Statement 13.8

We recommend surgeons consult a comprehensive, multidisciplinary team of professionals in the field of transgender health when eligible* transgender and gender diverse people request individually customized (previously termed "non-standard") surgeries as part of a gender-affirming surgical intervention.

Gender identities may present along a spectrum, and the expression of a person's identity may vary quite widely amongst individuals (Beek et al., 2015; Koehler et al., 2018). While the overall goal of a particular procedure usually includes reduction of gender dysphoria (van de Grift, Elaut et al., 2017) or achieving gender congruence, gender diverse presentations may lead to individually customized surgical requests some may consider "non-standard" (Beek et al., 2015; Bizic et al., 2018). Individually customized surgical requests can be defined as 1) a procedure that alters an individual's gender expression without necessarily aiming to express an alternative, binary gender; 2) the "non-standard" combination of well-established procedures; or 3) both.

This is designed to help counsel and inform the patient as well as to ensure their goals can be achieved. The patient and their surgeon need to work together to ensure the patient's expectations are realistic and achievable, and the proposed interventions are safe and technically feasible. The patient and their surgical team need to engage in a shared decision-making process (Cavanaugh et al., 2016). This informed consent process needs to address the irreversibility of some procedures, the newer nature of some procedures, and the limited information available about the long-term outcomes of some procedures.

Statement 13.9

We suggest surgeons caring for transgender men and gender diverse people who have undergone metoidioplasty/phalloplasty encourage lifelong urological follow-up.

Postoperative complications following metoidioplasty/phalloplasty comprise the urinary tract and sexual function (Kang et al., 2019; Monstrey et al., 2009; Santucci, 2018; Schardein et al., 2019). Reported urethral complications (related to urethral lengthening) include urethral strictures 35–58%, urethral fistulae 15–70% (Monstrey et al., 2009; Santucci, 2018; Schardein et al., 2019), diverticulae, mucocele due to vaginal remnant, and hair growth within the neourethra (Berli et al., 2021; Veerman et al., 2020). Complications related to sexual function include limited to absent tactile and/or erogenous sensation, difficulties with orgasm function, and complications with penile prosthetics (Kang et al., 2019; Santucci, 2018). Penile prosthesis-related complications are estimated to involve infection (incidence 8–12%),

malfunction, urethral erosion, skin extrusion, and dislocation of its bone fixation (Falcone et al., 2018; Kang et al., 2019; Morrison et al., 2016). Although most urethral and prosthetic complications occur in the immediate and intermediate postoperative period, complications can occur at any time. Early detection may reduce morbidity (e.g., urethral strictures resulting in fistulae, pending erosion of a penile prosthetic leading to infection and requiring total explant) (Blecher et al., 2019).

Routine follow-up to assess for early evidence of urethral stricture (or other urinary issues) includes bladder ultrasound measurement of postvoid residual volume (to screen for and stage neourethral stricture), fluoroscopic urethrography (to identify and stage neourethral strictures, fistulae, and diverticulae), and cystourethroscopy to examine the urethra and bladder. TGD men may also have routine urologic issues that need not be related to gender transition (urinary calculi, hematuria, and genitourinary malignancies; fertility preservation) (Sterling & Garcia, 2020a, 2020b).

Statement 13.10

We recommend surgeons caring for transgender women and gender diverse people who have undergone vaginoplasty encourage follow-up with their primary surgeon, primary care physician, or gynecologist.

Vaginoplasty is a safe procedure (Hontscharuk, Alba, Hamidian Jahromi et al., 2021). While complications may occur, most are self-limited or can be treated with minor interventions (Hontscharuk, Alba, Hamidian Jahromi et al., 2021). Minor complications include issues such as the formation of granulation tissue, intravaginal hair growth, delayed wound healing or wound disruption (or both), aesthetic concerns, and introital stenosis (Ferrando, 2020; Kloer et al., 2021). While these complications are usually self-limited, they may impact patient well-being after surgery. Additionally, these issues may go either undiagnosed or may be misdiagnosed if patients are not able to access care provided by professionals with expertise in the field of transgender health. We recommend patients be followed by their primary surgeon in person and at regular intervals—for example at two weeks, three months, six months, and one year after surgery—although more follow-up may be indicated for some individuals.

Additional gynecologic care is conducted throughout the TGD person's lifetime and can be managed in many settings. A speculum exam to check for granulation tissue, hair, and lesions can be performed by the primary care provider, gynecologist, or GAS surgeon and may be necessary outside of the immediate postoperative period (Grimstad, McLaren et al., 2021; Suchak et al., 2015; van der Sluis et al., 2020). After confirmation by laboratory testing, UTIs, STIs, and other fluctuations in the vaginal microbiome may be treated following relevant guidelines formulated for cisgender populations (Hooton, 2012; Sherrard et al., 2018). Manual prostate checks are performed based on relevant guidelines formulated for cisgender populations via the vaginal canal, as the prostate is located on the anterior wall of the vagina (Carter et al., 2013).

Other complications include issues such as stenosis of the neovaginal canal, rectovaginal fistulae, and inflammation (intestinal vaginoplasty) (Bustos et al., 2021). These require a combination of nonsurgical and surgical treatment with consultation and possible referral back to the primary surgeon with other surgical consultants (i.e., colorectal surgeon), if required. In addition, as pelvic floor dysfunction may affect 30–40% of patients both prior to and following vaginoplasty, the availability of pelvic floor physical therapists is an important adjunct in the postoperative period (Jiang et al., 2019).

Statement 13.11

We recommend patients who regret their gender-related surgical intervention be managed by an expert multidisciplinary team.

The percentage of individuals who regret their GAS is very low (between 0.3% and 3.8%) (De Cuypere & Vercruysse, 2009; Defreyne, Motmans et al., 2017; Hadj-Moussa et al., 2019; Hadj-Moussa, Agarwal et al., 2018; Hadj-Moussa, Ohl et al., 2018; Landén et al., 1998; Narayan et al., 2021; van de Grift, Elaut et al., 2018; Wiepjes et al., 2018). The highest incidence of

regret was reported at a time when surgical techniques were less refined, the role of multidisciplinary care was less established, and the *Standards of Care* did not exist or were not widely known (Landén et al., 1998). Regret can be temporarily or permanent and may be classified as (Narayan et al., 2021) social regret (caused by difficulties in familial, religious, social, or professional life), medical regret (due to long-term medical complications, disappointment in surgical results or inadequate preoperative decision-making), and true gender-related regret (mostly based on patient experienced misdiagnosis, insufficient exploration of gender identity, or both). This classification is in accordance with previously discussed positive and negative predictive factors (De Cuypere & Vercruysse, 2009; Gils & Brewaeys, 2007; Pfäfflin & Junge, 1998).

A multidisciplinary team can help identify the etiology of regret as well as the temporal stability of the surgical request (Narayan et al., 2021). Following this evaluation and in consideration of the individual's circumstances, medical and/or surgical interventions with the intent of either continuing transition or performing surgical procedures to return anatomy to that of the sex assigned at birth may be indicated. For further information see Chapter 5—Assessment of Adults.

**For eligibility criteria for adolescents and adults, please refer to the Assessment for Adults and Adolescent chapters and Appendix D*

GENDER-AFFIRMING SURGICAL PROCEDURES

As the field's understanding of the many facets of gender incongruence expands, and as technology develops which allows for additional treatments, it is imperative to understand this list is not intended to be exhaustive. This is particularly important given the often lengthy time periods between updates to the SOC, during which evolutions in understanding and treatment modalities may occur.

FACIAL SURGERY	
Brow	• Brow reduction • Brow augmentation • Brow lift
Hair line advancement and/or hair transplant	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	• Platysmaplasty
Blepharoplasty	• Lipofilling
Rhinoplasty (+/- fillers)	
Cheek	• Implant • Lipofilling
Lip	• Upper lip shortening • Lip augmentation (includes autologous and non-autologous)
Lower jaw	• Reduction of mandibular angle • Augmentation
Chin reshaping	• Osteoplastic • Alloplastic (implant-based)
Chondrolaryngoplasty	• Vocal cord surgery (see voice chapter)
BREAST/CHEST SURGERY	
Mastectomy	• Mastectomy with nipple-areola preservation/reconstruction as determined medically necessary for the specific patient • Mastectomy without nipple-areola preservation/reconstruction as determined medically necessary for the specific patient
Liposuction	
Breast reconstruction (augmentation)	• Implant and/or tissue expander • Autologous (includes flap-based and lipofilling)
GENITAL SURGERY	
Phalloplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Metoidioplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Vaginoplasty (inversion, peritoneal, intestinal)	• May include retention of penis and/or testicle
Vulvoplasty	• May include procedures described as "flat front"
GONADECTOMY	
Orchiectomy	
Hysterectomy and/or salpingo-oophorectomy	
BODY CONTOURING	
Liposuction	
Lipofilling	
Implants	• Pectoral, hip, gluteal, calf
Monsplasty/mons reduction	
ADDITIONAL PROCEDURES	
Hair removal: Hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process. (see Statement 15.14 regarding hair removal)	• Electrolysis • Laser epilation
Tattoo (i.e., nipple-areola)	
Uterine transplantation	
Penile transplantation	

CHAPTER 14 Voice and Communication

Human beings engage in communication practices not only to exchange ideas about the outside world, but also to present themselves as sociocultural beings and to negotiate forms of address, referral and treatment by others that allow them to feel safe and respected (Azul et al., 2022). The human voice is widely regarded as one of the key modalities that contributes to the communication of gender as one of the dimensions of human diversity. However, other aspects and ways of communicating (e.g., articulation, word choice, gesture, listener perceptions and attributions) need to be considered as well (Azul, 2015; Azul & Hancock, 2020). Throughout this chapter "voice and communication" is used as a phrase encompassing the meaning-making practices in which each of the participants of a social encounter engage according to their own needs, wishes, identifications, and capacities.

While a binary understanding of gender has dominated the research literature in this area, the approach recommended in this chapter implies a broadly inclusive view of gender identification (e.g., trans feminine, trans masculine, gender fluid, nonbinary, genderqueer, agender) and the understanding that gender does not exist in isolation, but intersects with other aspects of human diversity (e.g., First Nation status, ethnicity/race, sexuality, dis/ability, faith/religion/spirituality). The recommendations in this chapter apply to all transgender and gender diverse (TGD) people who are seeking professional voice and communication support, including children, adolescents, younger and older adults, and people who wish to transition or detransition, irrespective of their intervention choices.

Not every TGD person experiences challenges with or wants professional support for their voice and communication, but those who do often encounter barriers in accessing care. Although the percentages vary by country and TGD subpopulation, the statistics support the concern TGD people are not able to access voice and communication services when and how they desire (Eyssel et al., 2017; James et al., 2016; Oğuz et al., 2021; Södersten et al., 2015; Veale et al., 2019). In these studies, the percentage of TGD people wishing to receive voice and communication training or voice surgery is generally higher than the percentage of people who have undergone these interventions. With few exceptions, access to voice training is usually greater than access to voice surgery. Groups of TGD people who are further marginalized in their societies, such as TGD people of marginalized race/ethnicity, experience discrimination and limited access to care at even greater rates (James et al., 2016; Xavier et al., 2005).

Cost, not knowing where to access services, and services not being available are amongst the most common barriers cited by research participants. According to studies in the US (Hancock & Downs, 2021; Kennedy & Thibeault, 2020), Turkey (Oğuz et al., 2021), and Aotearoa/New Zealand (Veale et al., 2019), lack of accurate information about options for voice and communication services among TGD people is a significant and ubiquitous barrier to care. Notably, in Sweden, all TGD people are offered support for their voice and communication when a diagnosis of gender incongruence is made (Södersten et al., 2015). Additionally, cultural responsiveness of providers is only slowly improving (Hancock & Haskin, 2015; Jakomin et al., 2020; Matthews et al., 2020; Sawyer et al., 2014). Hancock and Downs (2021) have conducted preliminary work to identify specific barriers to voice and communication services and develop effective means for eliminating them.

This chapter is intended to provide guidance for health care professionals (HCPs) to support and foster well-being in all TGD people who are experiencing challenges or distress regarding their own voice and communication practices and/or regarding responses and attributions they receive from others (Azul et al., 2022).

A number of different approaches TGD people can use to modify their voice and communication, either individually or in combination include self-initiated change, which may be supported by resources TGD people use to guide their voice use and communication practice; behavioral change supported by voice and communication specialists (hereafter referred to as "voice and communication training"); and change as a result of androgen hormonal treatment and/or laryngeal surgery. The currently existing research evidence

does not include self-initiated change, but is focused on the latter three approaches.

A "voice and communication specialist" is someone who has knowledge regarding the ongoing and dynamic agency of speaker and listener practices, relevant professional interventions including behavioral, hormonal, and surgical, and relevant processes related to biophysiology, sociocultural meaning-making, and external material forces (Azul & Hancock, 2020). This specialist is capable of conducting appropriate assessments to inform the TGD person's choice and support the exploration of goals and intervention options by providing guidance in a culturally responsive, person-centered approach. This specialist has knowledge and skills in behavioral voice and communication intervention approaches.

Practices amenable to behavioral change include: speaking and singing voice, mindfulness, relaxation, respiration, pitch and pitch range, voice quality, resonance/timbre, loudness, projection, facial expression, gesture, posture, movement, introducing self to others, describing identifications and requesting culturally responsive treatment and forms of address by others, assertive and resilient responses to misattributions, practicing implementation of voice use and communication practices with different people and in different everyday settings (e.g., Hancock & Siegfriedt, 2020; Mills & Stoneham, 2017).

Voice and communication services are offered as part of a complete and coordinated approach to health, including support for medical, psychological, and social needs (Södersten et al., 2015); however, there are no prerequisites (e.g., hormone use, pursuit of surgeries, or duration living in a gender role). The overall purposes of voice and communication support for TGD people are:

- To educate clients about the factors that influence functional voice and communication practices and the communication of the speaker's identity (speaker, listener, professional practices, external material, biophysiological, and sociocultural factors);
- To enable clients to communicate their sense of sociocultural belonging (e.g., in terms of gender) in everyday encounters in a manner that matches the client's desired self-presentation and to develop, maintain and habituate voices, vocal qualities, and communication practices that support the clients' goals in a manner that does not harm the voice production mechanism;
- To provide training in functional voice production for clients who present with restrictions of voice function (e.g., as a result of overextending their voice production mechanism);
- To support clients with developing the capacity to assertively negotiate desired forms of address and referral from others (e.g., names, pronouns, titles) and to respond to misattributions in a skillful manner that contributes to increasing and maintaining the client's well-being;
- To support clients to develop the problem-solving skills needed to manage anxiety, stress, and dysphoria in collaboration with mental health providers; and to navigate barriers to practice or real-life use of one's preferred voice and communication.
- To provide, or refer clients to, supportive resources that facilitate developing voice and communication skills, vocal awareness, and well-being.
- To refer clients to, or collaborate with, other specialists such as mental health practitioners, laryngeal surgeons, and endocrinologists, who may be more equipped to meet the specific needs of that client. This may be especially relevant in cases where clients face unique challenges due to multiple barriers to their health and well-being or when the client wishes to pursue laryngeal surgery or hormone therapy.

Two types of laryngeal surgeries are relevant for TGD populations: those for raising voice pitch (e.g., glottoplasty with retro-displacement of the anterior commissure, cricothyroid approximation (CTA), feminization laryngoplasty, laser-assisted voice adjustment (LAVA)) (Anderson, 2007; Anderson, 2014; Brown, 2000; Casado, 2017; Geneid, 2015; Gross, 1999; Kelly et al., 2018; Kanagalingam, 2005; Kim, 2017; Kim, 2020; Kocak, 2010; Kunachak, 2000; Mastronikolis, 2013; Mastronikolis et al., 2013; Matai, 2003; Meister,

Statements of Recommendations

14.1- We recommend voice and communication specialists assess current and desired vocal and communication function of transgender and gender diverse people and develop appropriate intervention plans for those dissatisfied with their voice and communication.
14.2- We recommend voice and communication specialists working with transgender and gender diverse people receive specific education to develop expertise in supporting vocal functioning, communication, and well-being in this population.
14.3- We recommend health care professionals in transgender health working with transgender and gender diverse people who are dissatisfied with their voice or communication consider offering a referral to voice and communication specialists for voice-related support, assessment, and training.
14.4- We recommend health care professionals consider working with transgender and gender diverse people who are considering undergoing voice surgery consider offering a referral to a voice and communication specialist who can provide pre- and/or postoperative support.
14.5- We recommend health care professionals in transgender health inform transgender and gender diverse people commencing testosterone therapy of the potential and variable effects of this treatment on voice and communication.

2017; Mora, 2018; Neumann, 2004; Nuyen et al., 2022; Orloff, 2006; Pickuth, 2000; Remacle, 2011; Thomas & MacMillan, 2013; Tschan, 2016; Van Borsel, 2008; Wagner, 2003; Wendler, 1990; Yang, 2002) and for lowering voice pitch (e.g., thyroplasty type III, vocal fold injection augmentation) (Bultynck et al, 2020; Isshiki et al., 1983; Kojima, et al. 2008; Webb et al., 2021). Reported acoustic benefits of pitch-raising surgery include increased voice pitch (average frequency (f_o)) and increased Min f_o(the lowest frequency in physiological voice range). TGD people's self-rating ratings show general satisfaction with voice postsurgery, although individuals who are interested in more comprehensive changes to vocal self-presentation may need to engage in behavioral interventions with a voice and communication specialist in addition to laryngeal surgery (Brown, Chang et al. 2021; Kelly et al., 2018; Nuyen et al., 2022). Potential harms of pitch-raising surgery can be assessed and addressed in voice training by a voice and communication specialist. Reported harms of pitch-raising surgery include voice problems such as dysphonia, weak voice, restricted speaking voice range especially upper range (lowered Max f_o, in the physiological voice range), hoarseness, vocal instability, and lowering of frequency values over time (Kelly et al., 2018; Song & Jiang, 2017), although the rate of these outcomes is inconsistent.

Research on pitch-lowering surgeries is limited. However, studies including eight TGD people who elected to undergo thyroplasty type III after continued dissatisfaction with hormonal treatment (Bultynck et al., 2020) and one person who received injection augmentation after testosterone therapy and voice training (Webb et al., 2020), reported statistically significant lowering of fundamental frequency, perceived as pitch.

Estrogen treatment in TGD people has not been associated with measurable voice changes (Mészáros et al., 2005), while testosterone treatment in TGD people has been found to result in both desired and undesired changes in gender- and function-related aspects of voice production (Azul, 2015; Azul et al., 2017, 2018, 2020; Azul & Neuschaefer-Rube, 2019; Cosyns et al., 2014; Damrose, 2008; Deuster, Di Vicenzo et al., 2016; Deuster, Matulat et al. 2016; Hancock et al., 2017; Irwig et al., 2017; Nygren et al., 2016; Van Borsel et al., 2000; Yanagi et al., 2015; Ziegler et al., 2018). Desired changes associated with testosterone treatment include lowered voice pitch, increased male attributions to voice, and increased satisfaction with voice. Reported dissatisfaction with testosterone treatment include lack of or insufficient lowering of voice pitch, dysphonia, weak voice, restricted singing pitch range, and vocal instability. These areas can be assessed and addressed in voice training by a voice and communication specialist.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 14.1.

We recommend voice and communication specialists assess current and desired vocal and

communication function of transgender and gender diverse people and develop appropriate intervention plans for those dissatisfied with their voice and communication.

Voice and communication specialists may assess satisfaction with the presentation of sociocultural positionings in communicative encounters, including gender and other intersecting identifications, taking into consideration that these may or may not be static over time; attributions received from others, and how these relate to the individual's identifications, wishes, and well-being; ratings of voice and speech naturalness; and voice and communication function in relation to vocal demands. Assessments may vary in nature (e.g., client-reported outcome measures, perceptual, acoustic, aerodynamic, endoscopic) according to their purpose (Davies et al., 2015; Leyns et al., 2021; Oates & Dacakis, 1983). For example, laryngeal visualization is used when individuals present with a concomitant voice problem, (e.g., muscle tension dysphonia) (Palmer et al., 2011) or experience voice difficulties, which may or may not be secondary to medical gender-affirming interventions of androgen therapy or laryngeal surgery (Azul et al., 2017).

Voice and communication specialists inform intervention-seeking TGD people who are dissatisfied with their voice and communication about available interventions that support TGD people with their voice, communication, and well-being. The nature of each option, including potential outcomes and permanence, is presented objectively to provide the TGD person respect and autonomy in decision-making. Appropriate intervention plans are individualized and feasible and should be inclusive of any professional services available. Goals may evolve over the course of the support period as the TGD person explores modifications to voice and communication, assesses their satisfaction with achieved change and refines their goals.

Statement 14.2.

We recommend voice and communication specialists working with transgender and gender diverse people receive specific education to develop expertise in supporting vocal functioning, communication, and well-being in this population.

Academic and licensing credentials of voice and communication specialists (e.g., speech-language pathologists, speech therapists, singing voice teachers, voice coaches) vary by location but typically do not specify criteria for working with specific populations. Standard curricula in formal education for these professions often do not include specific or adequate training for working with TGD populations (Jakomin et al., 2020; Matthews et al., 2020). General knowledge and skills related to the vocal mechanism and interpersonal communication are foundational but insufficient for conducting culturally responsive, person-centered care for TGD people that is effective, efficient, inclusive, and accessible (Hancock, 2017; Russell & Abrams, 2019).

Professionals in this area should receive comprehensive education that invites them to develop self-awareness, cultural humility, and cultural responsiveness in order to be respectful of and attentive to gender diversity and other aspects of a client's identifications that can take a variety of forms and imply a range of different support needs (Azul, 2015; Azul et al., 2022). Client preferences for use of names, formal forms of address, gender entry, and pronouns need to be respected in all communication with and about the client (including medical records, reports, emails). Education also needs to inform the setting up of a training space or clinic and administrative practices that are designed to be welcoming to TGD people and allow TGD people to feel safe and respected when raising concerns or issues with the voice and communication support team.

Voice and communication specialists working with TGD people will need working knowledge of applicable intervention principles, mechanisms, and effectiveness, competence in teaching and modeling voice and communication modification skills, and a basic understanding of transgender health, including hormonal and surgical treatments and trans-specific psychosocial issues. Education needs to include methodologies and practices that have been developed within TGD communities and shown to be effective and should ideally be presented by or in collaboration with TGD people with lived experience of voice and communication support.

Statement 14.3.

We recommend health care professionals in transgender health working with transgender and gender diverse people who are dissatisfied with their voice or communication consider offering a referral to voice and communication specialists for voice-related support, assessment, and training.

A voice and communication specialist is well positioned to provide information and guidance to the TGD person expressing dissatisfaction with their voice or communication when available. There is evidence voice and communication specialists provide support in such a way that a client's satisfaction with voice and communication can be achieved, thereby reducing gender dysphoria and improving communication-related quality of life (Azul, 2016; Block, 2017; Deuster, Di Vincenzo et al., 2016; Hancock, 2017; Hancock et al., 2011; Hardy et al., 2013; Kelly et al., 2018; McNamara, 2007; McNeill et al., 2008; Owen & Hancock, 2010; Pasricha et al., 2008; Söderpalm et al., 2004; Watt et al., 2018).

There is empirical evidence that behavioral voice support for TGD AMAB people is effective with regard to achieving the targeted voice changes (Oates, 2019). Seven studies prior to 2020 provide empirical evidence for the effectiveness of voice training, although it is somewhat weak (Carew et al., 2007; Dacakis, 2000; Gelfer & Tice, 2013; Hancock et al., 2011;Hancock & Garabedian, 2013; McNeill et al., 2008; Mészáros et al., 2005). Voice training methods across these seven studies were similar and indicated voice training can be effective at increasing average fundamental frequency (average pitch), fundamental frequency range (pitch range), satisfaction with voice, self-perception and listener perception of vocal femininity, voice-related quality of life, and social and vocational participation. Weaknesses of the identified studies include lack of randomized controlled trials evaluating voice training, small sample sizes, inadequate long-term follow-up, and lack of control of confounding variables. In 2021, another systematic review of the effects of behavioral speech training for AMAB people reached similar conclusions (Leyns et al., 2021).

Until recently, there was almost no research exploring the effectiveness of voice training with TGD AFAB people. There is, however, some promising, although weak evidence of effectiveness from a case study (Buckley et al., 2020) and one uncontrolled prospective study of group voice training (Mills et al., 2019).

Statement 14.4.

We recommend health care professionals working with transgender and gender diverse people who are considering undergoing voice surgery consider offering a referral to a voice and communication specialist who can provide pre- and/or postoperative support.

This statement does not intend to require TGD people receive presurgical voice training. Rather, it is recommended that every available support be offered to provide individualized informational counseling critical to person-centered care. The recommendation is for the TGD person's consideration to be informed as necessary by individualized informational counseling based on voice assessment, trial voice training, and discussion of expected voice outcomes and risks of surgery with a voice and communication specialist.

For most types of laryngeal surgery, voice training is recommended both prior to surgery to ensure preparation of the vocal mechanism for the surgical intervention and postsurgery to ensure a return to functional voice production (Branski et al., 2006; Park et al., 2021). For pitch-raising surgery in particular, another reason a trial of voice training is recommended is because there are indications certain measures improve with training but not with pitch-raising surgery (e.g., factors relevant to intonation and naturalness, such as maximum *f0* pitch in speech range; Kelly et al., 2018).

The number and quality of research studies evaluating pitch-lowering surgeries are currently insufficient, particularly with regard to comparing outcomes with and without other interventions (i.e., testosterone) (Bultynck et al., 2020). There are more techniques and studies of pitch-raising surgeries, but the quality of the evidence is still low. Outcomes from pitch-raising surgeries have been compared to outcomes from having no surgery (Anderson, 2007, 2014; Brown et al., 2000;

Geneid et al., 2015; Gross, 1999; Kim, 2017; Kocak et al., 2010; Kunachak et al., 2000; Matai et al., 2003; Meister et al., 2017; Neumann & Welzel, 2004; Orloff et al., 2006; Pickuth et al., 2000; Remacle et al., 2011; Thomas & Macmillan, 2013; Tschan et al., 2016; Van Borsel et al., 2008; Yang et al., 2002), another type of surgical technique (Mora, 2018), voice training alone (Kanagalingam, 2005; Mastronikolis, 2013; Wagner, 2003) and surgery in conjunction with voice training (Casado, 2017; Kelly et al., 2018).

In the 11 studies reporting whether participants had voice training prior to pitch-raising surgery, most participants had prior voice training, but remained dissatisfied with voice and sought surgical intervention. Thus, most studies of surgical outcomes reflect the combined effects of voice training and surgical intervention. Attributes predicting which clients will pursue surgery after training are unknown.

Statement 14.5.

We recommend health care professionals in transgender health inform transgender and gender diverse people commencing testosterone therapy of the potential and variable effects of this treatment on voice and communication.

The research on the effects of androgen treatment on voice and communication of TGD people points to diverse and unpredictable effects on individual clients. While a number of studies have revealed effects on voice that matched TGD people's expectations and wishes, there is high quality evidence demonstrating TGD people are not always satisfied with the vocal outcomes of testosterone therapy, and many experience difficulties such as inadequate pitch lowering, compromised voice quality, vocal loudness, vocal endurance, pitch range, and flexibility (Azul, 2015, 2016, 2017, 2018; Cosyns et al., 2014; Nygren et al., 2016; Ziegler et al., 2018). A recent meta-analysis of 19 studies examining the effects of at least 1 year of testosterone therapy estimated 21% of participants did not achieve cisgender male normative frequencies, 21% of participants reported incomplete voice-gender congruence and voice problems, and 16% were not completely satisfied with their voice (Ziegler, 2018).

For people who wish to be treated with androgens, accurate informational counseling prior to commencing treatment should enable the development of realistic expectations to avoid disappointment regarding the permanent impact of hormone treatment on voice and communication. In addition, TGD people who do not have access to or do not wish to be treated with testosterone, but want to change their voice and those who are dissatisfied with the outcomes of testosterone treatment can be advised by a voice and communication specialist of alternative and additional support options (e.g., behavioral voice and communication training; pitch-lowering surgery).

CHAPTER 15 Primary Care

Primary care is the broadest of health care disciplines and is defined as the "provision of integrated, accessible health care services by health care professionals who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community." (Institute of Medicine, 1996).

Primary care providers (PCPs) encompass a wide range of health care professionals (HCPs) who deliver this care, including general and family medical practitioners, nurse practitioners, advanced practice nurses, physician associates/assistants, and internists. PCPs are represented by a variety of educational backgrounds, training, and specialties. Given the type of degree and the nature of the specialty, the scope of practice varies, and not all providers may be trained or qualified to directly provide the full breadth of transgender health care, such as mental health, genital/pelvic care, or postoperative care, following gender-affirming procedures. Physicians and other providers receive little education in transgender and gender-diverse (TGD) health at any time during their training (Dubin et al., 2018), and thus most skills are currently acquired in practice, either informally or through brief continuing education opportunities, see also Chapter 4—Education. However, if providers are competent to deliver similar care for cisgender patients, they should develop competency in caring for TGD patients. The competencies outlined below are all to be understood as being within the provider's scope of licensure and practice. However, all PCPs should be able to manage the comprehensive health of TGD patients either directly or by appropriate referral to other HCPs, including other specialists, for evaluation and treatment. There is no evidence competency in caring for TGD patients can only be achieved through a formal or certification process. In explicitly stating recommended competencies, however, PCP's and TGD persons across all settings can share a standard set of expectations of the knowledge, skills, and cultural competence required for the care of TGD persons.

Due to the unique medical, surgical, and social conditions faced by TGD people, PCPs need distinct competencies in the care of TGD persons, apart from what is expected of all PCP's who may otherwise care for a diverse population that includes ethnic, racial, or sexual minorities. Professional bodies from a range of generalist disciplines have issued position statements and guidelines specific to the care of TGD people (American College of Obstetricians and Gynecology, 2021; Italian Society of Gender, Identity and Health (SIGIS); the Italian Society of Andrology and Sexual Medicine (SIAMS); the Italian Society of Endocrinology (SIE), 2021; Polish Sexological Society, 2021; the Southern African HIV Clinicians' Society, 2021). Wylie et al. (2016) state "For the most part, the general health and well-being of transgender people should be attended to within the primary care setting, without differentiation from services offered to cisgender (non-transgender) people for physical, psychological, and sexual health issues. Specific care for gender transition is also possible in primary care." There are many examples of these services being provided safely and effectively outside of specialist care in diverse cities such as Toronto and Vancouver in Canada, New York and Boston in the US, and in Sydney, Australia, (Radix & Eisfeld, 2014; Reisner, Radix et al., 2016; Spanos et al., 2021).

Hormone therapy

Whether TGD patients receive medically necessary gender-affirming hormone therapy (GAHT) from a specialist, e.g., an endocrinologist, or a PCP may depend on the availability of knowledgeable and welcoming providers and country-level factors, such as health care regulations and health services funding (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1). In much of the world, specialty services for TGD people are partly or wholly unavailable, which reinforces the need for all health providers to undertake

training in the provision of gender-affirming care. In some countries, PCPs may be required to refer TGD patients to specialist services (e.g., gender identity clinics) resulting in unacceptable delays to access GAHT (Royal College of General Practitioners, 2019).

Hormone-related therapy encompasses a range of interventions, such as puberty suppression and hormone initiation or hormone maintenance. With training, gender-affirming hormone therapy can be managed by most PCPs. Regardless of whether they serve as the primary hormone prescriber, all PCPs should be familiar with the medications, suggested monitoring, and potential side effects associated with GAHT (see Chapter 12—Hormone Therapy). PCPs should be able to make appropriate referrals to appropriate providers for all transition-related services they do not themselves provide.

This chapter supports the argument GAHT can be prescribed by PCPs or other non-specialists—"Considering barriers to health care access and the importance of GAHT to this population, it is imperative that PCPs are able and willing to provide GAHT for TGD patients." (Shires, 2017).

PCPs are commonly called upon to provide care for a broad range of conditions and needs, including those with which they may have had limited or no prior experience. Often this involves accessing commonly used and readily available reference sources, such as professional society guidelines or obtaining a subscription to online knowledge bases. PCPs are advised to use a similar approach when asked to provide basic GAHT care by using the Standards of Care as well as other readily accessed resources (Cheung et al., 2019; Hembree et al., 2017; Oliphant et al., 2018; T'Sjoen et al., 2020). It should be noted most of the commonly used medications in gender-affirming regimens are familiar to everyday primary care practice, including, but not limited to, testosterone, estradiol, progesterone and other progestagens, and spironolactone.

Mental health

PCPs should be able and willing to assess and provide mental health support for TGD people and GAHT that can alleviate gender dysphoria and allow gender expression. At the very least, they should be aware of these needs and consult additional specialty support if needed.

Preventive care

General practitioners are versed to provide comprehensive primary and secondary cancer prevention as a part of routine primary care. Evidence-based cancer prevention guidelines vary globally due to differences in national guidelines and levels of access to screening modalities at the local level. To date, research on the long-term impact of GAHT on cancer risk is limited (Blondeel et al., 2016; Braun et al., 2017). We have insufficient evidence to estimate the prevalence of cancer of the breast or reproductive organs among TGD populations (Joint et al., 2018). However, cancer screening should commence, in general, according to local guidelines. Several modifications are discussed in detail, below, depending on the type and duration of hormone use, surgical intervention, or both. In caring for transgender patients, the PCP should maintain an updated record of which organs are present in TGD patients so that appropriate, routine screening can be offered.

This organ inventory should be updated based on the surgical history or any development that has occurred due to taking gender-affirming hormones. Not all PCP's provide care across the lifespan. However, if providers routinely care for children, adolescents, or elder cisgender persons, they should develop competency in transgender care that is applicable to these age groups. If they are unable to do so, then PCPs should be able to make appropriate referrals to other HCPs who care for these populations.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statements of Recommendations

15.1- We recommend health care professionals obtain a detailed medical history from transgender and gender diverse people that includes past and present use of hormones, gonadal surgeries, as well as the presence of traditional cardiovascular and cerebrovascular risk factors with the aim of providing regular cardiovascular risk assessment according to established, locally used guidelines.
15.2- We recommend health care professionals assess and manage cardiovascular health in transgender and gender diverse people using a tailored risk factor assessment and cardiovascular/cerebrovascular management methods.
15.3- We recommend health care professionals tailor sex-based risk calculators used for assessing medical conditions to the needs of transgender and gender diverse people, taking into consideration the length of hormone use, dosing, serum hormone levels, current age, and the age at which hormone therapy was initiated.
15.4- We recommend health care professionals counsel transgender and gender diverse people about their tobacco use and advise tobacco/nicotine abstinence prior to gender-affirming surgery.
15.5- We recommend health care professionals discuss and address aging-related psychological, medical, and social concerns with transgender and gender diverse people.
15.6- We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people who have received estrogens, taking into consideration the length of time of hormone use, dosing, current age, and the age at which hormones were initiated.
15.7- We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people with breasts from natal puberty who have not had gender-affirming chest surgery.
15.8- We recommend health care professionals apply the same respective local screening guidelines (including the recommendation not to screen) developed for cisgender women at average and elevated risk for developing ovarian or endometrial cancer in their care of transgender and gender diverse people who have the same risks.
15.9- We recommend against routine oophorectomy or hysterectomy solely for the purpose of preventing ovarian or uterine cancer for transgender and gender diverse people undergoing testosterone treatment and who have an otherwise average risk of malignancy.
15.10- We recommend health care professionals offer cervical cancer screening to transgender and gender diverse people who currently have or previously had a cervix following local guidelines for cisgender women.
15.11- We recommend health care professionals counsel transgender and gender diverse people that the use of antiretroviral medications is not a contraindication to gender-affirming hormone therapy.
15.12- We recommend health care professionals obtain a detailed medical history from transgender and gender diverse people that includes past and present use of hormones, gonadal surgeries as well as the presence of traditional osteoporosis risk factors to assess the optimal age and necessity for osteoporosis screening.
15.13- We recommend health care professionals discuss bone health with transgender and gender diverse people including the need for active weight bearing exercise, healthy diet, calcium, and vitamin D supplementation.
15.14- We recommend health care professionals offer transgender and gender diverse people referrals for hair removal from the face, body, and genital areas for gender-affirmation or as part of a preoperative preparation process.

Statement 15.1

We recommend health care professionals obtain a detailed medical history from transgender and gender diverse people, that includes past and present use of hormones, gonadal surgeries, as well as the presence of traditional cardiovascular and cerebrovascular risk factors with the aim of providing regular cardiovascular risk assessment according to established, locally used guidelines. For supporting text, see Statement 15.3.

Statement 15.2

We recommend health care professionals assess and manage cardiovascular health in transgender and gender diverse people using a tailored risk factor assessment and cardiovascular/cerebrovascular management methods. For supporting text, see Statement 15.3.

Statement 15.3

We recommend health care professionals tailor sex-based risk calculators used for assessing medical conditions to the needs of transgender and gender diverse people, taking into consideration the length of hormone use, dosing, serum hormone levels, current age, and the age at which hormone therapy was initiated.

Cardiovascular disease (CVD) and stroke are the leading causes of mortality worldwide (World Health Organization, 2018). Extensive data among racial, ethnic, and sexual minorities in multiple settings demonstrate significant disparities in the prevalence of CVD and its risk factors as well as in the outcomes to medical interventions. Structural factors such as access to care, socioeconomic status, and allostatic load related to minority stress contribute to these disparities (Flentje et al., 2020; Havranek et al., 2015; Streed et al., 2021). TGD people often experience social, economic, and discriminatory conditions similar to other minority populations with known increased cardiovascular risk (Carpenter et al., 2020; James et al., 2016; Reisner, Radix et al., 2016). TGD persons of racial, ethnic, and sexual

minorities have been shown to experience increased impact related to intersectional stress. Conversely, access to gender-affirming care, including GAHT, may buffer against the elevation of CVD risk due to the improvement in quality of life and reduction in gender dysphoria and incongruence (Defreyne et al., 2019; Martinez et al., 2018). PCPs can significantly improve TGD health through screening and prevention of CVD and its associated risk conditions—such as tobacco use, diabetes mellitus, hypertension, dyslipidemia, and obesity.

The few, primarily US based, studies evaluating the prevalence of CVD, stroke, or CVD risk in TGD persons independent of GAHT indicate an elevated CV risk, including high rates of undiagnosed and untreated CV risk factors with inadequate CV prevention when compared with cisgender populations (Denby et al., 2021; Malhotra et al., 2022; Nokoff et al., 2018). In one population-based study, TGD people had greater odds of discrimination, psychological distress, and adverse childhood experience, and these were associated with increased odds of having a cardiovascular condition (Poteat et al., 2021).

In US studies that are based on data from the Behavioral Risk Factor Surveillance System, both transgender men and transgender women show a higher prevalence of myocardial infarction (MI), stroke, or any CVD compared with cisgender men, cisgender women or both. Results vary based on the adjustment of data for additional variables, including race, income, or cardiovascular risk factors (Alzahrani et al., 2019; Caceres et al., 2020; Nokoff et al., 2018). Gender nonbinary persons also have higher odds of CVD (Downing & Przedworski, 2018). Data on hormone use was not collected in these studies, which are also limited by the use of self-reported health histories. In the US, TGD individuals presenting for GAHT may have higher rates of undiagnosed and untreated CVD risk factors compared with the cisgender population (Denby et al., 2021), although this may not be applicable globally.

A large 2018 case control study from several US centers that used 10:1 cisgender matched controls found no statistically significant difference in rates of MI or stroke between transgender women and cisgender men, and no difference in rates of MI, stroke, or venous thromboembolism (VTE) between transgender men and cisgender men or women. There was a statistically significant hazard ratio of 1.9 for VTE among transgender women when compared with cisgender men. A subcohort of transgender women who initiated GAHT during (versus prior to) the 6-year study window did show an increased risk of stroke. Increases in rates of VTE in the overall cohort of transgender women and in rates of stroke in the initiation subcohort of transgender women demonstrated calculated numbers-needed-to-harm (not reported in the paper) between 71-123 (Getahun et al., 2018). Other studies have demonstrated no increase in CV events or stroke among transgender men undergoing testosterone therapy, although studies are limited by their small sample size, relatively short follow-up, and the younger age of the sample population (Martinez et al., 2020; Nota et al., 2019).

European and US studies in transgender women who have accessed feminizing GAHT increasingly indicate a higher risk of CVD, stroke, or both, compared with cisgender women and, in some studies, cisgender men (Getahun et al., 2018; Nota et al., 2019; Wierckx et al., 2013). Many of these studies had significant limitations, such as variably adjusting for CV-related risk factors, small sample sizes—especially involving older transgender women—and variable duration and types of GAHT (Connelly et al., 2019; Defreyne et al., 2019, Martinez et al., 2020). Furthermore, the overall increased risk was small. In many of these studies, the majority of transgender women who experienced cardiac events or stroke were over 50 years old, had one or more CVD risk factors, and were taking a variety of hormone regimens, including, but not limited, to ethinyl estradiol, a synthetic estrogen that confers significant elevations in thrombotic risk and is not recommended for use in feminizing regimens (Gooren et al., 2014; Martinez et al., 2020). Current limited evidence suggests estrogen-based GAHT is associated with an increased risk of myocardial infarction and stroke, but whether this small risk is a result of GAHT or an effect of pre-existing CV risk is unclear. There are no known studies that specifically address CVD and

related conditions in nonbinary individuals, individuals who use subphysiologic doses of gender-affirming hormones, or in adults previously treated with puberty suppression.

PCPs can best address CVD risk during GAHT by assessing TGD people for CVD and modifiable CVD risk factors, such as diabetes mellitus, hypertension, hyperlipidemia, obesity, and smoking, as well as by addressing the impact of minority stress on cardiovascular risk (Streed et al., 2021). In addition, PCPs can mitigate transgender cardiovascular health disparities by providing a timely diagnosis and treatment of risk conditions and by tailoring their management in a way that supports ongoing gender-affirming interventions.

Risk assessment guidelines vary based on the national or international context and scientific affiliation of guideline developers. CVD prevention guidelines also vary in terms of the nature and frequency of the risk assessment for otherwise healthy adults under age 40 (Arnett et al., 2019; Piepoli et al., 2020; Précoma et al., 2019; Streed et al., 2021; WHO, 2007). Over age 40, when cardiovascular risk increases, guidelines clearly recommend scheduled risk assessments using a calculated prediction of ten-year total CVD risk based on risk prediction equations from large population samples. Examples of risk calculators include SCORE (recommended by the European Guidelines on CVD Prevention), Pooled Cohort Studies Equations (2013 AHA ACC Guideline on the Assessment of CVD risk), Framingham Risk scores, and the World Health Organization (WHO) Risk Prediction Charts. The WHO charts were developed based on information from the countries in each WHO subregion. In many low resource settings, facilities are not available to measure cholesterol or serum glucose, and alternative predication charts are available without these measures.

Of note, all current cardiovascular risk calculators are gendered, using sex as a significant risk variable. There is currently insufficient data on cardiovascular risk interventions across the lifespan in TGD persons with medical and surgical interventions to adjust these predictive equations. Nonetheless, it is clear both sex assigned at birth and medical transition can affect the parameters used to calculate cardiovascular risk (Connelly et al., 2019; Defreyne et al., 2019; Maraka et al., 2017; Martinez et al., 2020). Providers can take a variety of approaches to using cardiovascular risk calculators in TGD persons, including employing the risk calculator for the sex assigned at birth, affirmed gender, or a weighted average of the two, taking into consideration total lifetime exposure to GAHT. Although data are lacking, using the affirmed gender for transgender adults with a history of pubertal-age GAHT initiations is likely to be most appropriate. Patients with a history of submaximal GAHT use or prolonged periods of time postgonadectomy without hormone replacement before roughly age 50 may require an even more nuanced approach. Providers should be aware of the characteristics and limitations of the risk calculator in use and should engage patients in shared decision-making regarding these specific considerations.

There are currently no studies comparing the prevalence of dyslipidemia between transgender and cisgender samples, while controlling for hormone use. As noted previously, data in other populations demonstrate the presence of psychosocial stress during childhood and remote adulthood favor adiposity and abnormal lipid metabolism. Both testosterone- and estrogen-based GAHT affect lipid metabolism, although evidence is limited by the variety of hormone regimens and additional variables (Connelly et al., 2019; Defreyne et al., 2019; Deutsch, Glidden et al., 2015; Maraka et al., 2017; Martinez et al., 2020;). On balance, estrogen tends to increase high-density lipoprotein (HDL) cholesterol and triglycerides with variable effects on low density lipoprotein (LDL) cholesterol, while testosterone variably affects triglycerides, decreases HDL cholesterol and increases LDL cholesterol. The method of administration may also affect this pattern, particularly in relation to oral versus transdermal estrogen and their impact on triglycerides (Maraka et al., 2017). In general, the effect sizes of these differences are minimal, and the overall impact on cardio- and cerebrovascular outcomes is unclear. There are no studies examining hormone effects in TGD people with pre-existing dyslipidemia with hormone use starting over age 50, or investigating effects beyond 2-5 years of therapy.

Studies comparing the prevalence of hypertension between TGD and cisgender samples that controlled for hormone use are lacking. Data in other populations demonstrate chronic and acute psychosocial stress, including experiences of discrimination can mediate hypertension (Din-Dzietham et al., 2004; Spruill, 2010). In US studies that were based on the Behavioral Risk Factor Surveillance System, a large national US health survey, there were no differences in reported hypertension between transgender men or women compared with cisgender samples (Alzahrani et al., 2019; Nokoff et al., 2018).

Studies of testosterone—and estrogen-based GAHT have shown inconsistent effects on systolic and diastolic blood pressure. A retrospective study of the effects of estrogen- and testosterone-based GAHT regimens on blood pressure found a slight reduction in systolic blood pressure with the initiation of estrogen-based regimens; while there was a slight elevation (4 mm Hg) in mean systolic blood pressure on long term follow-up of testosterone-based regimens, this difference was at the margin of statistical significance and of limited clinical relevance (Banks et al., 2021). A systematic review concluded, given the limited quality of the studies, there is insufficient data to reach conclusions on the effects of gender-affirming hormone therapy on blood pressure (Connelly et al., 2021). Spironolactone, often used as an androgen blocker in feminizing GAHT, is a potassium sparing diuretic and may increase potassium when used in conjunction with ACE inhibitors or angiotensin receptor blocker medications, as well as salt substitutes. There are no studies examining hormone effects in TGD people with pre-existing hypertension with hormone use starting over age 50, or investigating effects beyond 2–5 years of therapy. Transgender persons receiving GAHT should undergo any additional blood pressure screening or monitoring indicated by WPATH guidelines for GAHT.

There are limited data comparing the prevalence of diabetes mellitus between TGD and cisgender samples independent of hormone use. Recent data from the STRONG cohort study (Islam et al., 2021) found the prevalence and incidence of type 2 diabetes was more common in the trans feminine cohort compared with cisgender females but not cisgender male controls. No significant differences in the prevalence or incidence of type 2 diabetes were observed in the trans masculine cohort and in TGD persons overall after starting hormone therapy. However, the mean follow-up for both cohorts was 2.8 and 3.1 years, respectively (Islam et al., 2021). Data in other populations, including sexual minorities, indicates chronic and acute psychosocial stress can mediate the development and control of type 2 diabetes (Beach et al., 2018; Kelly & Mubarak, 2015).

US studies based on the Behavioral Risk Factor Surveillance System found no differences in reported diabetes between transgender men, transgender women and nonbinary persons compared with cisgender persons (Alzahrani et al., 2019; Caceres et al., 2020; Nokoff et al., 2018). Several small studies have shown a higher-than-expected prevalence of polycystic ovarian syndrome or hyperandrogenemia among transgender men (Feldman et al., 2016), conditions associated with insulin resistance and diabetes risk. While studies of both testosterone- and estrogen-based GAHT show varying effects on weight/body fat, glucose metabolism, and insulin resistance (Defreyne et al., 2019), most do not demonstrate any increase in prediabetes or diabetes (Chan et al., 2018; Connelly et al., 2019). There are no studies examining hormone effects in TGD people with pre-existing diabetes, with hormone use starting over age 50, or investigating effects beyond 2–5 years of therapy. There are currently no studies specifically addressing diabetes in adults previously treated with puberty suppression.

While intermediate-outcome studies of the effects of GAHT on blood pressure and lipids are helpful for hypothesis generation and for studying etiology, future studies should focus on cardiovascular outcomes of interest, with a specific focus on individual predictors such as age, route and dose of hormones used, and total lifetime exposure to GAHT. Interpretation of data should always consider whether cisgender controls were of the same natal sex or identified gender.

Statement 15.4

We recommend health care professionals counsel transgender and gender diverse people about

their tobacco use and advise tobacco/nicotine abstinence prior to gender-affirming surgery.

Tobacco use is a leading contributor to cardiovascular disease, pulmonary disease, and cancer worldwide (World Health Organization, 2020). TGD persons have a higher prevalence of tobacco use compared with cisgender individuals, which varies across the gender spectrum (Azagba et al., 2019; Buchting et al., 2017). This pattern is consistent with other populations experiencing minority stress (Gordon et al., 2021). PCPs can promote protective factors against tobacco use, including reducing exposure to personal or structural discrimination, having gender-affirming identification, and having health insurance (Kidd et al., 2018; Shires & Jafee, 2016).

The health risks of tobacco use affect TGD persons disproportionately, primarily due to decreased access to culturally competent, affordable screening, and treatment of tobacco-related diseases (Shires & Jafee, 2016). Smoking may further increase cardiovascular and VTE risk for TGD individuals taking feminizing GAHT (Hontscharuk, Alba, Manno et al., 2021). Smoking also doubles or triples the risk of general surgery complications, such as wound healing, scarring, and infection (Yoong et al., 2020) and increases these risks for those accessing gender-affirming surgeries. Data in cisgender populations show quitting smoking prior to surgery and maintaining abstinence for six weeks postoperatively significantly reduces complications (Yoong et al., 2020).

There are currently few studies of smoking cessation programs specifically focused on TGD persons (Berger & Mooney-Somers, 2017). However, limited evidence suggests PCPs can enhance smoking cessation efforts by addressing the effects of minority stress (Gamarel et al., 2015) and incorporating gender-affirming interventions, such as GAHT (Myers & Safer, 2016).

HCPs should take into consideration the significant barriers people habituated to nicotine encounter when attempting cessation. Nicotine replacement therapy and/or other cessation adjuncts should be made available, with an emphasis on individual preferences and a recognition of underlying behavioral health factors that contribute to continued nicotine use. Decision-making regarding approaches to GAHT or surgery should include consideration of the "first do no harm" principle of medical practice, with the realities of an individual patient's abilities and needs.

Statement 15.5

We recommend health care professionals discuss and address aging-related psychological, medical, and social concerns with transgender and gender diverse people.

Aging presents specific social, physical, and mental health challenges for TGD persons. While the literature on aging and transgender elders is limited, many older TGD adults have experienced a lifetime of stigma, discrimination, and repression of identified gender (Fabbre & Gaveras, 2020; Witten, 2017). This experience affects TGD elders' interactions with health care systems (Fredriksen-Goldsen et al., 2014; Kattari & Hasche, 2016; Walker et al., 2017). Transgender elders are more likely than cisgender LGB peers to report poor physical health, even when controlling for socio-demographic factors (Fredriksen-Goldsen 2011; Fredriksen-Goldsen et al., 2014). Reduced access to culturally competent care and the sequelae of minority stress often result in delayed care, potentially exacerbating chronic conditions common with aging (Bakko & Kattari, 2021; Fredriksen-Goldsen et al., 2014).

Although there are few studies on gender-affirming medical interventions among TGD elders, evidence suggests older adults experience a significantly higher quality of life with medical transition even when compared with younger TGD adults (Cai et al., 2019). Although age itself is not an absolute contraindication or limitation to gender-affirming medical or surgical interventions, TGD elders may not be aware of the current range of social, medical or surgical options available that can help them meet their individual needs (Hardacker et al., 2019; Houlberg, 2019).

While studies on mental health among TGD elders are limited, those over age fifty experience significantly higher rates of depressive symptoms and perceived stress compared with cisgender LGB and heterosexual older adults (Fredriksen-Goldsen 2011, Fredriksen-

Goldsen et al., 2014). Risk factors specific to TGD elders include gender- and age-related discrimination, general stress, identity concealment, victimization, and internalized stigma, while social support and community belonging appear protective (Fredriksen-Goldsen et al., 2014; Hoy-Ellis & Fredriksen-Goldsen, 2017; White Hughto & Reisner, 2018). PCPs can assist patients by encouraging spirituality, self-acceptance and self-advocacy, and an active healthy lifestyle, all of which are associated with resilience and successful aging (McFadden et al., 2013; Witten, 2014).

TGD elders often face social isolation, loss of support systems, and disconnection from close friends and children (Fredriksen-Goldsen 2011; Witten, 2017). The most common aging concerns among TGD persons are losing the ability to care for themselves followed by having to go into a nursing home or assisted living facility (Henry et al., 2020). While long-term care settings offer the helpful needed assistance, they also have the potential for physical or emotional abuse, for denial of GAHT and routine care, for being "outed," and being prevented from living and dressing according to one's affirmed gender (Auldridge et al., 2012; Pang et al., 2019; Porter et al., 2016). TGD elders identify senior housing, transportation, social events, support groups as being the most needed services (Auldridge et al., 2012; Witten, 2014).

Despite barriers, most TGD persons engage in successful aging strengthened by self-acceptance, caring relationships, and advocacy (Fredriksen-Goldsen 2011; Witten, 2014). PCPs should address core health issues facing TGD elders, including mental health, gender-affirming medical interventions, social support, and end of life/long-term care.

Beyond the independent impact of factors such as minority stress and social determinants of health in later years, data are lacking on specific health issues facing transgender people who use GAHT later in life, individuals who began GAHT at a younger age, and those seeking to continue or begin GAHT in their sixth, seventh, eighth, or later decades. With an increasing proportion of transgender people beginning GAHT at younger ages, including some who begin at the time of puberty, studies to examine the impact of decades of such treatment on long-term health are ever more important.

Statement 15.6

We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people who have received estrogens, taking into consideration length of time of hormone use, dosing, current age, and the age at which hormones were initiated.

TGD individuals taking estrogen-based GAHT will develop breasts, and therefore warrant consideration for breast cancer screening. Exogenous estrogen may be one of multiple factors that contribute to breast cancer risk in cisgender people. Two cohort studies have been published evaluating breast cancer prevalence among transgender women in the Netherlands (Gooren et al., 2013) and the US (Brown & Jones, 2015). Both were retrospective cohorts of clinical samples using a diagnosis of breast cancer as the outcome of interest and cisgender controls as a comparison group. Neither study involved prospective screening for breast cancer, and both had significant methodological limitations. Numerous guidelines have been published (Deutsch, 2016a) recommending some combination of "age plus length of estrogen exposure" as the determinant of need to commence screening. These recommendations are based on expert consensus only and are evidentiarily weak.

BRCA1 and 2 mutations increase the risk of breast cancer, however the role sex hormone exposure plays, if any, in this increased risk is unclear (Rebbeck et al., 2005) The degree of increase in risk, if any, from gender-affirming estrogen therapy is unknown. Patients with a known BRCA1 mutation should be counseled about the unknowns and shared decision-making with informed consent should occur between the patient and provider, recognizing the numerous benefits of GAHT.

Breast cancer screening among transgender women should also take into consideration the likelihood that a transgender woman's breasts may be denser on mammography. Dense breasts, a history of injecting breasts with fillers such as silicone, and breast implants may complicate the interpretation of mammographic findings (Sonnenblick et al., 2018). Therefore, special

techniques should be used accordingly. People who have injected particles such as silicone or other fillers for breast augmentation may also develop complications, such as sclerosing lipogranulomas, which obscure normal tissue on mammography or ultrasound.

Statement 15.7

We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people with breasts from natal puberty who have not had gender-affirming chest surgery.

For TGD people assigned female at birth and who developed breasts via natal puberty, there are theoretical concerns about whether direct exposure to testosterone and exposure to aromatized estrogen resulting from testosterone therapy are risk factors for the development of breast cancer. Limited retrospective data has not demonstrated increased risk for breast cancer among transgender men (Gooren et al., 2013; Grynberg et al., 2010), however prospective and comparison data are lacking. Most people in this group will have some breast tissue remaining, and therefore it is important for providers to be aware breast cancer risk is not zero in this population. The timing and approach to breast cancer screening in this group who have had chest surgery is currently not established, and, similar to cisgender men with significant family history or BRCA gene mutation, screening via MRI or ultrasound may be appropriate. Because the utility and performance of these approaches have not been studied and because self- and HCP-led chest/breast screening exams are not recommended in cisgender women due to potential harms of both false-positive results and over-detection (detection of a cancer which would have regressed on its own with no need for intervention), any approach to screening in this group should occur in the context of shared decision-making between patients and providers regarding the potential harms, benefits, and unknowns of these approaches.

Statement 15.8

We recommend health care professionals apply the same respective local screening guidelines (including the recommendation not to screen) developed for cisgender women at average and elevated risk for developing ovarian or endometrial cancer in their care of transgender and gender diverse people who have the same risks.

Current consensus guidelines do not recommend routine ovarian cancer screening for cisgender women. Case reports of ovarian cancer among transgender men have been reported (Dizon et al., 2006; Hage et al., 2000). There is currently no evidence testosterone therapy leads to an increased risk of ovarian cancer, although long-term prospective studies are lacking (Joint et al., 2018).

Statement 15.9

We recommend against routine oophorectomy or hysterectomy solely for the purpose of preventing ovarian or uterine cancer for transgender and gender diverse people undergoing testosterone treatment and who have an otherwise average risk of malignancy.

TGD people with ovaries who are taking testosterone-based GAHT are often in an oligo- or anovulatory state, or otherwise experience shifts in luteal phase function and progesterone production. This condition combined with the possible increased estrogen exposure from aromatization of exogenous testosterone raises the concern for excessive or unopposed endometrial estrogen exposure, although the clinical significance is unknown. Histologic studies of the endometrium in TGD people taking testosterone have found atrophy rather than hyperplasia (Grimstad et al., 2018; Grynberg et al., 2010; Perrone et al., 2009). In a large cohort of trans masculine people who underwent a hysterectomy with oophorectomy, benign ovarian histopathology was noted in all cases (n = 85) (Grimstad et al., 2020). While prospective outcome data are lacking, there is insufficient evidence at this time to support a recommendation transgender men undergo routine hysterectomy or oophorectomy solely to prevent endometrial or ovarian cancer. Certainly, unexplained signs/symptoms of endometrial or ovarian cancer should be evaluated appropriately.

Statement 15.10

We recommend health care professionals offer cervical cancer screening to transgender and

gender diverse people who currently have or previously had a cervix, following local guidelines for cisgender women.

Individuals with a cervix should undergo routine cervical cancer screening and prevention according to age-based regional practices and guidelines. This includes vaccination against the human papilloma virus (HPV) and screening according to local guidelines, including cytologic, high-HPV co-testing if available. It is important HCPs be mindful of performing pelvic speculum examinations in a manner that minimizes pain and distress for transgender masculine people.

TGD people with a cervix are less likely to have had conventional cervical cancer screening, either because the exam can cause worsening of dysphoria and/or because general practitioners and patients are misinformed about the need for this screening (Agenor et al., 2016; Potter et al., 2015). In addition, testosterone therapy can result in atrophic changes of the genital tract, and the duration of testosterone use has been associated with a greater likelihood of obtaining an inadequate sample for cytologic screening of cervical cancer (Peitzmeier et al., 2014). Alternatives to speculum exams and cervical cytology, such as provider- or self-collected high-risk HPV swabs, may be of particular benefit for screening people with a cervix. Research underway in the US is investigating the use of self-collected vaginal high-risk HPV testing among transgender masculine populations. HPV swabs were found to be highly acceptable among transgender men with a sensitivity to high-risk HPV of 71.4% (negative predictive value of 94.7%) and a specificity of 98.2% (Reisner et al., 2018). Further study is needed to evaluate the harms of HPV primary screening in transgender men in terms of the potential increased harms associated with invasive examinations and colposcopies.

Statement 15.11

We recommend health care professionals counsel transgender and gender diverse people that the use of antiretroviral medications is not a contraindication to gender-affirming hormone therapy.

Human immunodeficiency virus (HIV) prevalence is disproportionately high in TGD populations. A recent large metanalysis found a global odds ratio for HIV infection of sixty-six for trans feminine individuals and 6.8 for trans masculine individuals (Stutterheim et al., 2021). PCPs have unique opportunities to provide crucial education and implement prevention strategies, especially related to decreasing HIV burden among TGD people. Mistrust of health care providers due to past experiences of discrimination and transphobia impacts HIV prevention and disrupts the linkage to care efforts (Sevelius et al., 2016). Stigma, lack of adequate training, and innate power hierarchies within medical establishments, all contribute to ambivalence and uncertainty among HCPs when caring for TGD people (Poteat et al., 2013). Finally, a lack of inclusiveness and gender-affirming practices in the health care setting may lead to TGD people feeling unsafe discussing sensitive topics, such as HIV diagnosis and avoiding care out of fear (Bauer et al., 2014; Gibson et al., 2016; Seelman et al., 2017).

HCPs should be aware of this broader context within which many TGD people are seeking care for either gender-affirming hormones, HIV pre-exposure chemoprophylaxis/treatment (PrEP), or both. There may be various misconceptions about the safety of taking gender-affirming hormones concurrently with antiretroviral therapy for HIV chemoprophylaxis or treatment.

Direct study of antiretroviral/gender-affirming hormone therapy (ART/GAHT) interactions has been limited. A subanalysis of transgender women and trans feminine persons in the multinational iPrEx trial found poor effectiveness in this group in the intention-to-treat analysis, although effectiveness was similar to that in cisgender gay men among those transgender participants who adhered to the medication as prescribed, suggesting that uptake and adherence to PrEP remain challenging in this population. Two studies of the effects of GAHT on tenofovir diphosphate (Grant et al., 2021) and tenofovir diphosphate and emtricitabine (Shieh et al., 2019) found the significantly lowered ART drug levels were unlikely to be of clinical significance. Overall, data on the interactions between hormonal contraceptives and antiretrovirals are reassuring in terms of the impact of hormones on ART (Nanda

et al., 2017). Because estradiol is partially metabolized by cytochrome P450 (CYP) 3A4 and 1A2 enzymes, potential drug interactions with other medications that induce or inhibit these pathways, such as non-nucleoside reverse transcriptase inhibitors (NNRTIs, e.g., efavirenz (EFV) and nevirapine (NVP)), may exist (Badowski et al., 2021). However, the preferred first-line ART regimens in most countries include integrase inhibitors, which have minimal to no drug interactions with gender-affirming hormones and can be used safely (Badowski, 2021; Department of Health and Human Services. Panel on Antiretroviral Guidelines for Adults and Adolescents, 2021). If concerns exist about potential interactions, HCPs should monitor blood hormone levels as needed. Therefore, TGD people living with HIV and taking antiretroviral medications should be counseled that taking antiretrovirals alongside GAHT is safe.

Statement 15.12

We recommend health care professionals obtain a detailed medical history from transgender and gender diverse people that includes past and present use of hormones, gonadal surgeries as well as the presence of traditional osteoporosis risk factors, to assess the optimal age and necessity for osteoporosis screening. For supporting text, see Statement 15.13.

Statement 15.13

We recommend health care professionals discuss bone health with transgender and gender diverse people including the need for active weight bearing exercise, healthy diet, calcium, and vitamin D supplementation.

Estrogen and testosterone both support bone formation and turnover. Decreased sex hormone levels are associated with a greater risk of osteoporosis in older age (Almeida et al., 2017). TGD individuals may receive medical and/or surgical interventions that have the potential to influence bone health, such as sex hormone treatment, androgen blockade, and gonadectomy. Therefore, a detailed medical history, including past and present use of hormones along with gonadal surgeries, is necessary to establish the need for osteoporosis screening.

Several observational studies have compared bone mineral density (BMD) of TGD adults before and after gender-affirming hormone therapy along with in TGD individuals compared with sex-at-birth matched cisgender controls.

Low BMD may exist before the initiation of hormones. One study showed a lower mean areal BMD at the femoral neck, total hip, and spine in transgender women than in age-matched cisgender male controls (Van Caenegem, Taes et al., 2013). Another study revealed a high prevalence of low BMD scores among TGD youth before starting puberty blockers (Lee, Finlayson et al., 2020). The authors of both studies concluded low rates of physical activity may be an important contributor to these findings.

Acceleration of bone loss can occur after gonadectomy if hormones are stopped or if hormones levels are suboptimal. In one study, thirty percent of transgender women who had undergone gonadectomy had low bone mass, and this correlated with lower 17-ß estradiol levels and adherence to GAHT (Motta et al., 2020).

Investigation of the effects of GAHT on BMD have revealed TGD women receiving estrogen therapy show improvements in BMD. A systematic review and meta-analysis on the impact of sex hormones on bone health of transgender individuals included 9 eligible studies in transgender women (n = 392) and 8 eligible studies in transgender men (n = 247) published between 2008 and 2015. The meta-analysis revealed transgender women showed a statistically significant increase in lumbar spine BMD (but not femoral neck BMD) compared with baseline measures. Among transgender men, there were no statistically significant changes in the lumbar spine, femoral neck, and total hip BMD at 12 and 24 months after starting testosterone compared with baseline measures (Singh-Ospina et al., 2017). Since the publication of this study, the European Network for Investigation of Gender Incongruence (ENIGI) study, a multicenter prospective observational study (Belgium, Norway, Italy, and the Netherlands) published results on BMD outcomes for 231 transgender women and 199 transgender men one year after initiating GAH (Wiepjes et al., 2017). Transgender women had an increase in BMD of the lumbar spine, total hip and

femoral neck, and increased BMD of the total hip occurred in transgender men. One study reported no fractures in transgender individuals at 12 months following initiation of hormones in 53 transgender men and 53 transgender women (Wierckx, van Caenegem et al., 2014). No studies suggest GAHT should be an indication for enhanced osteoporosis screening. Rather, gaps in GAHT in those who have undergone prior gonadectomy would be a consideration for such screening.

Clinical practice guidelines include recommendations for osteoporosis screening in TGD individuals (Deutsch, 2016a; Hembree et al., 2017; Rosen et al., 2019). For TGD people, both the International Society for Clinical Densitometry and the Endocrine Society suggest consideration of baseline BMD screening before initiation of hormones. Further recommendations for BMD screening are based on several factors including sex reported at birth and age along with the presence of traditional risk factors for osteoporosis, such as prior fracture, high risk medication use, conditions associated with bone loss, and low body weight (Rosen et al., 2019). Specifically, the ISCD guidelines state BMD testing is indicated for TGD individuals if they have a history of gonadectomy or therapy that lowers endogenous gonadal steroid levels prior to the initiation of GAHT, hypogonadism with no plan to take GAHT or known indications for BMD testing (Rosen et al., 2019). However, the evidentiary basis for these recommendations is weak.

The recommended screening modality for osteoporosis is dual energy x-ray absorptiometry (DXA) of the lumbar spine, total hip, and femoral neck (Kanis, 1994). However in many low- and middle-income countries, BMD tests using DXA are not available, and routine DXA-based screening is conducted in few countries, the US being an exception.

PCPs should discuss ways to optimize bone health with TGD people. In addition, PCPs should provide information about the importance of nutrition and exercise on maintaining bone health. TGD individuals with (or at risk) for osteoporosis should be informed about the benefits of weight bearing exercise along with strength and resistance exercises in limiting bone loss (Benedetti et al., 2018). Nutrition is integral to bone health. Nutritional deficiencies, including insufficient calcium intake and low vitamin D, can result in low bone mineralization. Vitamin D and calcium supplementation have been shown to reduce hip as well as total fracture incidence (Weaver et al., 2016). Although relevant to all populations, this discussion is pertinent as a high prevalence of hypovitaminosis D has been observed in TGD populations (Motta et al., 2020; Van Caenegem, Taes et al., 2013).

Statement 15.14

We recommend health care professionals offer transgender and gender diverse people referrals for hair removal from the face, body, and genital areas for gender-affirmation or as part of a preoperative preparation process.

Hair removal is necessary both for the elimination of facial hair (Marks et al., 2019) as well as in preparation for certain gender-affirming surgeries (GAS) such as vaginoplasty, phalloplasty, and metoidioplasty (Zhang et al., 2016). Preoperative permanent hair removal is required for any skin area that will either be brought into contact with urine (e.g., used to construct a neourethra) or be moved to reside within a partially closed cavity within the body (e.g., used to line the neovagina) (Zhang et al., 2016). Hair removal techniques used in gender-affirming care are electrolysis hair removal (EHR) and laser hair removal (LHR) (Fernandez et al., 2013). EHR is currently the only US Food and Drug Administration–approved method of permanent hair removal, whereas LHR is approved for permanent hair reduction (Thoreson et al., 2020).

EHR involves the use of an electric current with a very fine probe that is manually inserted sequentially into individual hair follicles (Martin et al., 2018). Since this method uses direct mechanical destruction of the blood supply to the hair, it can be used on all hair colors and skin types (Martin et al., 2018). EHR is time consuming and costly as it requires each hair follicle to be treated individually, but is effective for permanent hair removal. For genital permanent hair removal prior to GAS, this treatment needs to be performed by a practitioner competent in genital hair removal as this method differs

from that of the face and body. EHR is more painful than LHR, with possible side effects of erythema, crusting, and swelling (Harris et al., 2014). Postinflammatory hyperpigmentation is a risk for dark-skinned individuals (Richards & Meharg, 1995). Pain can be controlled with topical local anesthetic and cooling techniques, and tolerance to EHR does develop to some degree with many persons able to tolerate longer sessions (Richards & Meharg, 1995).

LHR uses laser energy to target hair follicles. It is beneficial for larger surface areas. The mechanism is photo-thermolysis, whereby light from a laser selectively targets melanin in the hair shaft (Gao et al., 2018). This energy is converted to heat, which damages the follicles within the skin that produce hairs and results in the destruction of hair growth. Further treatments are needed to achieve best results and are typically spaced six weeks apart to allow for hair cycling (Zhang et al., 2016). Because LHR targets melanin, results may be limited for those with grey, blonde, or red hair.

There are specific considerations for using LHR in dark-skinned individuals (Fitzpatrick skin types IV to VI) (Fayne et al., 2018)). The higher melanin content of the epidermis can compete with the target chromophore of the light or laser, which is the melanin in the hair shaft of the hair follicle. For selective thermolysis to occur, heat diffuses from the hair shaft to the follicular stem cells to cause damage. In darker skin types, rather than reaching the target melanin in the hair shaft, light is absorbed in the epidermis where it is then converted to heat. This may result in poorer clinical outcomes and a higher rate of thermally induced adverse effects, such as hypo- or hyperpigmentation, blistering, and crust formation (Fayne et al., 2018). The selection of laser wavelength is critical in reducing this risk, with longer wavelength recommended to minimize the absorption of light in epidermal melanin and thus maximize efficacy and minimize adverse effects in patients with dark skin (Zhang et al., 2016). Side effects from LHR can include the feeling of sunburnt after treatment, as well as inflammation, redness, hyperpigmentation, and swelling. Flashing lights have been known to induce seizures in susceptible patients, so patients should be screened for this risk. Pain and discomfort during the procedure can also represent a significant barrier, and PCPs should be prepared to prescribe topical or systemic analgesics, such as a eutectic mixture of local anesthetics (EMLA) or a low dose systemic opioid. For genital GAS, some have recommended a 3-month wait after the last planned hair removal treatment before proceeding with surgery to confirm that no further hair regrowth will occur (Zhang et al., 2016).

CHAPTER 16 Reproductive Health

All humans, including transgender individuals, have the reproductive right to decide whether or not to have children (United Nations Population Fund, 2014). Medically necessary gender-affirming hormonal treatments (GAHTs) and surgical interventions (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1) that alter reproductive anatomy or function may limit future reproductive options to varying degrees (Hembree et al., 2017; Nahata et al., 2019). It is thus critical to discuss infertility risk and fertility preservation (FP) options with transgender individuals and their families prior to initiating any of these treatments and to continue these conversations on an ongoing basis thereafter (Hembree et al., 2017). Established FP options, such as embryo, oocyte, and sperm cryopreservation, may be available for postpubertal transgender individuals (Nahata et al., 2019). Research protocols for ovarian and testicular tissue cryopreservation have also been developed and studied (Borgström et al., 2020; Nahata et al., 2019; Rodriguez-Wallberg, et al., 2019). Whereas the use of embryos, mature oocytes, and sperm have all proven to be efficacious when employed within clinical treatments, cryopreserved gonadal tissues would require either future retransplantation aimed at obtaining fully functional gametes or the application of laboratory methods for culture, which are still under development in basic science research settings. Of note, recent American Society for Reproductive Medicine guidelines have lifted the experimental label on ovarian tissue cryopreservation, but evidence remains limited in prepubertal children (Practice Committee of the American Society for Reproductive Medicine, 2019).

Individualized care should be provided in the context of each person's parenthood goals. Some research suggests transgender and gender diverse (TGD) people may be less likely to desire genetically related children or children at all when compared with cisgender peers (Defreyne, van Schuvlenbergh et al., 2020; Russell et al., 2016; von Doussa et al., 2015). Yet, several other studies have shown many TGD individuals 1) desire genetically related children; 2) regret missed opportunities for FP; and 3) are willing to delay or interrupt hormone therapy to preserve fertility and/or conceive (Armuand, Dhejne et al., 2017; Auer et al., 2018; De Sutter et al., 2002; Defreyne, van Schuylenbergh et al., 2020; Tornello & Bos, 2017).

Many barriers to FP have been reported, such as cost (which is exacerbated when insurance coverage is lacking), urgency to start treatment, inability to make future-oriented decisions, inadequate provider knowledge/provider biases that affect offering FP, and difficulties accessing FP (Baram et al., 2019; Defreyne, van Schuylenbergh et al., 2020). Additionally, transgender individuals may have worsening dysphoria due to various steps in the FP process that are inseparably connected with the gender assigned at birth (Armuand, Dhejne, et al., 2017; Baram et al., 2019). When available, a multidisciplinary team approach, where both medical and mental health providers collaborate with gender-affirming fertility specialists, can help overcome some of these barriers (Tishelman et al., 2019). TGD individuals should be educated about the distinction between fertility (utilizing one's own gametes/reproductive tissues) and pregnancy. In addition to fertility considerations, efforts to ensure equitable high-quality care for all forms of family planning and building throughout the full reproductive continuum must be maintained. This includes procreative options such as perinatal care, pregnancy, delivery, and postpartum care, as well as family planning and contraceptive options to prevent unplanned pregnancies, and pregnancy termination if sanctioned (Bonnington et al., 2020; Cipres et al., 2017; Krempasky et al., 2020; Light et al., 2018; Moseson, Fix et al., 2020). TGD people who wish to carry a pregnancy should undergo standard of care preconception care and prenatal counseling and should receive counseling about breast/chest feeding in environments supportive of people with diverse gender identities and experiences (MacDonald et al., 2016; Obedin-Maliver & Makadon, 2016).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and

Statements of Recommendations

16.1- We recommend health care professionals who are treating transgender and gender diverse people and prescribing or referring patients for hormone therapies/surgeries advise their patients about:
16.1.a- Known effects of hormone therapies/surgery on future fertility;
16.1.b- Potential effects of therapies that are not well studied and are of unknown reversibility;
16.1.c- Fertility preservation (FP) options (both established and experimental);
16.1.d- Psychosocial implications of infertility.
16.2- We recommend health care professionals refer transgender and gender diverse people interested in fertility preservation to providers with expertise in fertility preservation for further discussion.
16.3- We recommend transgender care teams partner with local reproductive specialists and facilities to provide specific and timely information and fertility preservation services prior to offering medical and surgical interventions that may impact fertility.
16.4- We recommend health care professionals counsel pre- or early-pubertal transgender and gender diverse youth seeking gender-affirming therapy and their families that currently evidence-based/established fertility preservation options are limited.
16.5- We recommend transgender and gender diverse people with a uterus who wish to carry a pregnancy undergo preconception care, prenatal counseling regarding use and cessation of gender-affirming hormones, pregnancy care, labor and delivery, chest/breast feeding supportive services, and postpartum support according to local standards of care in a gender-affirming way.
16.6. We recommend medical providers discuss contraception methods with transgender and gender diverse people who engage in sexual activity that can result in pregnancy.
16.7. We recommend providers who offer pregnancy termination services ensure procedural options are gender-affirming and serve transgender people and those of diverse genders.

harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 16.1

We recommend health care professionals who are treating transgender and gender diverse people and prescribing or referring patients for hormone therapies/surgeries advise their patients about:

a. **Known effects of hormone therapies/surgeries on future fertility;**
b. **Potential effects of therapies that are not well studied and are of unknown reversibility;**
c. **Fertility preservation (FP) options (both established and experimental;**
d. **Psychosocial implications of infertility.**

TGD individuals assigned female at birth

GAHT may negatively impact future reproductive capacity (Hembree et al., 2017). Based on current evidence in transgender men and gender diverse people assigned female at birth, these risks are as follows:

Gonadotropin-releasing hormone agonists (GnRHas) may be used for pubertal suppression to prevent further pubertal progression until adolescents are ready for masculinizing treatment. GnRHas may also be used for menstrual suppression. GnRHas impact the maturation of gametes but do not cause permanent damage to gonadal function. Thus, if GnRHas are discontinued, oocyte maturation would be expected to resume.

There are few studies detailing the effects of testosterone therapy on reproductive function in transgender men (Moravek et al., 2020). Restoration of normal ovarian function with oocyte maturation after testosterone interruption has been demonstrated in transgender men who have achieved natural conception. A retrospective study on oocyte cryopreservation showed no differences in the total number of oocytes retrieved or in the number of mature oocytes between transgender men and age- and BMI-matched cisgender women (Adeleye et al., 2018, 2019). The first results have recently been published evaluating live birth rates after controlled ovarian stimulation in transgender men compared with cisgender women (Leung et al., 2019). Testosterone was discontinued prior to ovarian stimulation. Overall, the results concerning the influence of testosterone on reproductive organs and their function appear to be reassuring. However, there have been no prospective studies to date evaluating the effect of long-term hormone therapy on fertility (i.e., started in adolescence) or in those treated with GnRHas in early puberty followed by testosterone therapy. It is important to take into consideration that required medications and procedures for cryopreserving oocytes (a

pelvic examination, vaginal ultrasound monitoring, and oocyte retrievals) may lead to increasing gender dysphoria in transgender men (Armuand, Dhejne et al., 2017).

Surgical interventions among transgender men will have obvious implications for reproductive capacity. If patients desire a hysterectomy, the option should be offered of preserving the ovaries to retain the possibility of having a genetically related child. Alternatively, if the ovaries are removed either separately or concurrently with the hysterectomy, egg freezing should be offered prior to surgery and/or ovarian tissue cryopreservation can be done at the time of oophorectomy. Although this procedure is no longer considered experimental, many transgender men may desire *in vitro* maturation of primordial follicles, which is still investigational. Studies evaluating oocyte function have shown oocytes isolated from transgender men with testosterone exposure at the time of oophorectomy can be matured *in vitro* to develop normal metaphase II meiotic spindle structure (De Roo et al., 2017; Lierman et al., 2017).

TGD individuals assigned male at birth

Based on current evidence in transgender women and gender diverse people assigned male at birth (AMAB), the influence of medical treatment is as follows:

GnRHas inhibit spermatogenesis. Data suggest discontinuation of treatment results in a re-initiation of spermatogenesis, although this may take at least 3 months and most likely longer (Bertelloni et al., 2000). Furthermore, the psychological burden of re-exposure to testosterone should be considered.

Anti-androgens and estrogens result in an impaired sperm production (de Nie et al., 2020; Jindarak et al., 2018; Kent et al., 2018). Spermatogenesis might resume after discontinuation of prolonged treatment with anti-androgens and estrogens, but data are limited (Adeleye et al., 2019; Alford et al., 2020; Schneider et al., 2017). Testicular volumes diminish under the influence of gender-affirming hormone treatment (Matoso et al., 2018). Semen quality in transgender women may also be negatively affected by specific life-style factors, such as a low frequency of masturbation, wearing the genitals tight against the body (e.g., with use of tight undergarments for tucking) (Jung & Schuppe, 2007; Mieusset et al., 1985, 1987; Rodriguez-Wallberg, Häljestig et al., 2021).

Statement 16.2

We recommend health care professionals refer transgender and gender diverse people interested in fertility preservation to providers with expertise in fertility preservation for further discussion.

Research shows many transgender adults desire biological children (De Sutter et al., 2002; Defreyne, van Schuylenbergh et al., 2020; Wierckx, Van Caenegem et al., 2012), yet FP rates remain widely variable, particularly in youth (< 5%–40%) (Brik et al., 2019; Chen et al., 2017; Chiniara et al., 2019; Nahata et al., 2017; Segev-Becker et al., 2020). In a recent survey, many youth acknowledged their feelings about having a biological child might change in the future (Strang, Jarin et al., 2018). Non-elective sterilization is a violation of human rights (Ethics Committee of the American Society for Reproductive Medicine, 2015; Equality and Human Rights Commission, 2021; Meyer III et al., 2001) and due to advances in social attitudes, fertility medicine, and affirmative transgender health care, opportunities for biological parenthood during transition should be supported for transgender people. Due to the influence clinical opinion may have on transgender or nonbinary people's FP and on parenting decisions, FP options should be explored by health care providers alongside options such as fostering, adoption, coparenting, and other parenting alternatives (Bartholomaeus & Riggs, 2019). Transgender patients who have been offered this type of discussion and have been given the choice to undergo procedures for FP have reported the experience to be an overall positive one (Armuand, Dhejne et al., 2017; De Sutter et al., 2002; James-Abra et al., 2015).

In other patient populations, fertility referrals and formal fertility programs have been shown to increase FP rates and improve patient satisfaction (Kelvin et al., 2016; Klosky, Anderson et al., 2017; Klosky, Wang et al., 2017;

Shnorhavorian et al., 2012) Physician attitudes have been investigated, and recent studies indicate both an awareness and a desire to provide fertility-related information to children and their families (Armuand et al., 2020). However, barriers have also been identified, including lack of knowledge, comfort, and resources (Armuand, Nilsson et al., 2017; Frederick et al., 2018). Thus, the need for appropriate training of health care providers has been highlighted, with emphasis placed on fertility counseling and offering FP options to all at-risk individuals in an unbiased way (Armuand, Nilsson et al., 2017). Parents' recommendations have also been shown to significantly influence FP rates in adolescent and young adult males with cancer (Klosky, Flynn et al., 2017). While there are clear clinical differences in these populations, these findings can help inform best practices for fertility counseling and FP referrals for transgender individuals.

Statement 16.3

We recommend transgender care teams partner with local reproductive specialists and facilities to provide specific and timely information and fertility preservation services prior to offering medical and surgical interventions that may impact fertility.

Cryopreservation of sperm and oocytes are established FP techniques and can be offered to pubertal, late pubertal, and adult birth assigned males and birth assigned females, respectively, preferably prior to the initiation of GAHT (Hembree et al., 2017; Practice Committee of the American Society for Reproductive Medicine, 2019). Cryopreservation of embryos can be offered to adult (post-pubertal) TGD people who wish to have a child and have an available partner. The future use of cryopreserved gametes is also dependent on the gametes and reproductive organs of the future partner (Fischer, 2021; Maxwell et al., 2017)

Although semen parameters have been shown to be compromised when FP is performed after initiation of GAH medication (Adeleye et al., 2019), one small study showed when the treatment was discontinued, semen parameters were comparable to those in TGD patients who had never undergone GAH treatment. With regard to ovarian stimulation, oocyte vitrification yield and subsequent use of the oocytes in in-vitro fertilization (IVF), there is no reason to anticipate a different outcome in assisted reproductive technology (ART) treatments for TGD patients than that obtained in cisgender patients undergoing ART—other than individual confounding factors related to (in)fertility—when gametes are banked prior to any medical treatment (Adeleye et al., 2019). The use of oocytes in ART treatment resulted in similarly successful outcomes in TGD compared with controlled, matched cisgender patients (Adeleye et al., 2019; Leung et al., 2019; Maxwell et al., 2017).

Although these are established options, few pubertal, late pubertal or adult TGD people undergo FP (Nahata et al., 2017), and many experience challenges while undergoing FP interventions. Not only is access and cost of these methods a barrier (particularly in regions without insurance coverage), but these procedures are often physically and emotionally uncomfortable, and many express concerns about postponing the transitioning process (Chen et al., 2017; De Sutter et al., 2002; Nahata et al., 2017; Wierckx, Stuyver et al., 2012). Especially for the birth assigned females, the invasiveness of endovaginal ultrasound follow-up of the ovarian stimulation and oocyte retrieval procedures (and associated psychological distress) have been cited as a barrier (Armuand, Dhejne et al., 2017; Chen et al., 2017). There is also the concern young adults going through transitioning may not have a clear vision of parenting and are therefore likely to decline the opportunity to use FP at that time—while as adults, they may have different opinions about parenthood (Cauffman & Steinberg, 2000). The reduction of gender dysphoria during transitioning could also influence the decision-making process surrounding FP (Nahata et al., 2017). Based on research showing TGD youths' fertility perspectives may change over time (Nahata et al., 2019; Strang, Jarin et al., 2018), FP options should be discussed on an ongoing basis.

Statement 16.4

We recommend health care professionals counsel pre- or early-pubertal transgender and

gender diverse youth seeking gender-affirming therapy and their families that currently evidence-based/established fertility preservation options are limited.

For prepubertal and early-pubertal children, FP options are limited to the storage of gonadal tissue. Although this option is available for TGD children in the same way that it is available for cisgender prepubertal and early-pubertal oncological patients, there is no literature describing the utilization of this approach in the transgender population. Ovarian tissue autotransplantation has resulted in over 130 live births in cisgender women. Most of these patients conceived naturally without ART (Donnez & Dolmans, 2015; Jadoul et al., 2017), and the majority stored their ovarian tissue either as adults or during puberty. Although the recent American Society for Reproductive Medicine guideline has lifted the experimental label from ovarian tissue cryopreservation (Practice Committee of the American Society for Reproductive Medicine, 2019), there are very few case reports describing a successful pregnancy in a woman following the transplantation of ovarian tissue cryopreserved before puberty. Demeestere et al. (2015) and Rodriguez-Wallberg, Milenkovic et al. (2021) described cases of successful pregnancies following transplantation of tissue procured at the age of 14, and recently Matthews et al. (2018) described the case of a girl diagnosed with thalassemia who had ovarian tissue stored at the age of 9 and transplantation 14 years late. She subsequently conceived through IVF and delivered a healthy baby.

Currently, the only future clinical application for storing ovarian tissue is autotransplantation, which might be undesirable in a transgender man (due to the potentially undesirable effects of estrogen). A laboratory procedure that would make it possible to mature oocytes *in vitro* starting with ovarian tissue would be the ideal future application of stored ovarian tissue for transgender people, but this technique is currently only being investigated and optimized in basic science research settings (Ladanyi et al., 2017; Oktay et al., 2010).

Prepubertal procurement of testicular tissue has been documented as a low-risk procedure (Borgström et al., 2020; Ming et al., 2018). Some authors have also described this approach as a theoretical option in transgender people (De Roo et al., 2016; Martinez et al., 2017; Nahata, Curci et al., 2018). However, there are no reports in the literature describing the clinical or investigational utilization of this FP option for TGD patients. Moreover, the viability of the clinical application of autotransplantation of testicular tissue remains unknown in humans, and *in vitro* maturation techniques are still in the realm of basic science research. Thus, specialists currently consider this technique experimental (Picton et al., 2015). The possibility of storing gonadal tissue should be discussed prior to any genital surgery that would result in sterilization, although the probability of being able to use this tissue must be clearly addressed.

Statement 16.5

We recommend transgender and gender diverse people with a uterus who wish to carry a pregnancy undergo preconception care and prenatal counseling regarding the use and cessation of gender-affirming hormones, pregnancy care, labor and delivery, chest/breast feeding supportive services, and postpartum support according to local standards of care in a gender-affirming way.

Most transgender men and gender diverse people (AFAB) retain their uterus and ovaries and thus can conceive and carry a pregnancy even after long-term testosterone use (Light et al., 2014). Many transgender men desire children (Light et al., 2018; Wierckx, van Caenegem et al., 2012) and are willing to carry a pregnancy (Moseson, Fix, Hastings et al., 2021; Moseson, Fix, Ragosta et al., 2021). ART has expanded the opportunity for many transgender men to conceive and fulfill their family planning wishes (De Roo et al., 2017; Ellis et al., 2015; Maxwell et al., 2017). Some transgender men report psychological isolation, dysphoria related to the gravid uterus and chest changes, and depression (Charter, 2018; Ellis et al., 2015; Hoffkling et al., 2017; Obedin-Maliver & Makadon, 2016). Conversely, other studies have reported some positive experiences during pregnancy as well (Fischer, 2021; Light et al., 2014). Mental health providers should be involved to provide support, and counseling should be

provided addressing when to stop and when to resume gender-affirming hormones, what options are available for the mode of delivery and for chest/breast feeding (Hoffkling et al., 2017). Finally, system-level and interpersonal-level interventions should be implemented to ensure person-centered reproductive health care for all people (Hahn et al., 2019; Hoffkling et al., 2017; Moseson, Zazanis et al., 2020; Snowden et al., 2018).

Given the potential harmful effects of testosterone on the developing embryo, discontinuing testosterone or masculinizing hormone therapy prior to conception and during the entire pregnancy is recommended. However, the optimal time for both the discontinuation of testosterone prior to pregnancy and its resumption after pregnancy is unknown. Since stopping gender-affirming hormones may cause distress and exacerbate dysphoria in transgender men, when and how to stop this therapy should be discussed during prenatal counseling (Hahn et al., 2019). Because information about the duration of testosterone exposure and the risk of teratogenicity is lacking, testosterone use should be discontinued prior to attempting pregnancy and before stopping contraception. Moreover, there is limited information regarding health outcomes of infants born to transgender men. Small case series attempting to evaluate this question have revealed no adverse physical or psychosocial differences between infants born to transgender men and infants in the general population (Chiland et al., 2013).

Chest/Breast feeding

In the limited studies evaluating lactation and chest/breast feeding, the majority of transgender men and TGD individuals AFAB who chose to chest/breast feed postpartum were successful, with research suggesting induction of lactation is in part dependent on preconception counseling and experienced lactation nursing support (MacDonald et al., 2016; Wolfe-Roubatis & Spatz, 2015). Specifically, transgender men and TGD people who use testosterone should be informed 1) although quantities are small, testosterone does pass through chest/breast milk; and 2) the impact on the developing neonate/child is unknown, and therefore gender-affirming testosterone use is not recommended during lactation but may be resumed after discontinuation of chest/breast feeding (Glaser et al., 2009). Transgender men and other TGD individuals AFAB should be made aware some patients who carry a pregnancy may experience undesired chest growth and/or lactation even after chest reconstruction and should therefore be supported if they desire to suppress lactation (MacDonald et al., 2016).

There is limited information concerning lactation in transgender women as well as other TGD AMAB but many also express the desire to chest/breast feed. While there is a case report of a transgender woman successfully lactating and chest/breast feeding her infant after hormonal support using a combination of estrogen, progesterone, domperidone, and breast pumping (Reisman & Goldstein, 2018), the nutritional and immunological profile of chest/breast milk under these conditions has not been studied. Therefore, patients need to be informed about the risks and benefits of this approach to child feeding (Reisman & Goldstein, 2018).

Statement 16.6

We recommend medical providers discuss contraception methods with transgender and gender diverse people who engage in sexual activity that can result in pregnancy.

Many TGD individuals may retain reproductive capacity, and they (if they retain a uterus, ovaries, and tubes) or their sexual partners (for sperm producing individuals) may experience unplanned pregnancies (James et al., 2016; Light et al., 2014; Moseson, Fix et al., 2020). Therefore, intentional family planning counseling, including contraception and abortion conducted in gender-expansive ways is needed (Klein, Berry-Bibee et al., 2018; Obedin-Maliver, 2015; Stroumsa & Wu, 2018). TGD people AFAB may not use contraception due to an erroneous assumption that testosterone is a reliable form of contraception (Abern & Maguire, 2018; Ingraham et al., 2018; Jones, Wood et al., 2017; Potter et al., 2015). However, based on current understanding, testosterone should not be considered a reliable form of contraception because of its incomplete suppression of the hypothalamic-pituitary-adrenal axis (Krempasky et al., 2020). Furthermore, pregnancies have occurred while individuals are amenorrheic due

to testosterone use, which may outlast active periods of administration (Light et al., 2014). Pregnancy can also occur in TGD people after long-term testosterone use (at least up to 10 years), although the effect on oocytes and baseline fertility is still unknown (Light et al., 2014).

TGD people AFAB may use a variety of contraceptive methods (Abern & Maguire, 2018; Bentsianov et al., 2018; Bonnington et al., 2020; Chrisler et al., 2016; Cipres et al., 2017; Jones, Wood et al., 2017; Krempasky et al., 2020; Light et al., 2018).These methods may be used explicitly for pregnancy prevention, menstrual suppression, abnormal bleeding, or other gynecological needs (Bonnington et al., 2020; Chrisler et al., 2016; Krempasky et al., 2020; Schwartz et al., 2019). Contraceptive research gaps within this population are profound. No studies have examined how the use of exogenous androgens (e.g., testosterone) may modify the efficacy or safety profile of hormonal contraceptive methods (e.g., combined estrogen and progestin hormonal contraceptives, progestin-only based contraceptives) or non-hormonal and barrier contraceptive methods (e.g., internal and external condoms, non-hormonal intrauterine devices, diaphragms, sponges, etc.).

Gender diverse individuals who currently have a penis and testicles may engage in sexual activity with individuals who have a uterus, ovaries, and tubes of any gender. Gender diverse people who have a penis and testicles can produce sperm even while on gender-affirming hormones (i.e., estrogen), and although semen parameters are diminished among those who are currently using or who have previously used gender-affirming hormones, azoospermia is not complete and sperm activity is not totally suppressed (Adeleye et al., 2019; Jindarak et al., 2018; Kent et al., 2018). Therefore, contraception needs to be considered if pregnancy is to be avoided in penis-in-vagina sexual activity between a person with a uterus, ovaries, and tubes and one with a penis and testicles, irrespective of the use of gender-affirming hormones by either partner. Currently, contraceptive methods available for use by the sperm-producing partner are primarily mechanical barriers (i.e., external condoms, internal condoms), permanent sterilization (i.e., vasectomy), and gender-affirming surgery (e.g., orchiectomy, which also results in sterilization). Contraceptive counseling that considers sperm producing, egg producing, and gestating partners (as relevant) is recommended.

Statement 16.7

We recommend providers who offer pregnancy termination services ensure procedural approaches are gender-affirming and serve transgender people and those of diverse genders.

Unplanned pregnancies and abortions have been reported among TGD individuals with a uterus (Abern & Maguire, 2018; Light et al., 2014; Light et al., 2018; Moseson, Fix et al., 2020) and documented through surveys of abortion-providing facilities (Jones et al., 2020). However, the population-based epidemiology of abortion provision and the experiences and preferences of TGD individuals AFAB undergoing abortion still represents a critical gap in research (Fix et al., 2020; Moseson, Fix et al., 2020; Moseson, Lunn et al., 2020). Nonetheless, given that pregnancy capacity exists among many TGD people and pregnancies may not always be planned or desired, access to safe, legal, and gender-affirming pregnancy medical and surgical termination services is necessary.

CHAPTER 17 Sexual Health

Sexual health has a profound impact on physical and psychological well-being, regardless of one's sex, gender, or sexual orientation. However, stigma about sex, gender and sexual orientation influences individual's opportunities to live out their sexuality and to receive appropriate sexual health care. Specifically, in most societies, cisnormativity and heteronormativity lead to the assumption that all people are cisgender and heterosexual (Bauer et al., 2009), and that this combination is superior to all other genders and sexual orientations (Nieder, Güldenring et al., 2020; Rider, Vencill et al., 2019). Hetero-cisnormativity negates the complexity of gender, sexual orientation, and sexuality and disregards diversity and fluidity. This is all the more important since sexual identities, orientations, and practices of transgender and gender diverse (TGD) people are characterized by an enormous diversity (Galupo et al., 2016; Jessen et al., 2021; Thurston & Allan, 2018; T'Sjoen et al., 2020). Likewise, a strong cross-cultural tendency toward allonormativity—the assumption that all people experience sexual attraction or interest in sexual activity—negates the diverse experiences of TGD people, especially those who locate themselves on the asexual spectrum (McInroy et al., 2021; Mollet, 2021; Rothblum et al., 2020).

The World Health Organization (WHO, 2010) emphasizes sexual health depends on respect for the sexual rights of all people, including the right to express diverse sexualities and to be treated respectfully, safely, and with freedom from discrimination and violence. Sexual health discourses have focused on agency and body autonomy, which include consent, sexual pleasure, sexual satisfaction, partnerships, and family life (Cornwall & Jolly, 2006; Lindley et al., 2021). In light of this, the WHO defines sexual health as "a state of physical, emotional, mental, and social well-being in relation to sexuality and not merely the absence of disease, dysfunction, or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected, and fulfilled" (WHO, 2006, p. 5). This includes individuals on the asexual spectrum, who may not experience sexual attraction to others but may still choose to be sexual at times (e.g., via self-stimulation) and/or experience interest in forming and building romantic relationships (de Oliveira et al., 2021).

Scientific attention to the sexual experiences and behaviors of TGD people has grown in recent years (Gieles et al., 2022; Holmberg et al., 2019; Klein & Gorzalka, 2009; Kloer et al., 2021; Mattawanon et al., 2021; Stephenson et al., 2017; Tirapegui et al., 2020; Thurston & Allan, 2018). This expansion within the literature reflects a sex-positive framework (Harden, 2014), a framework that recognizes both the positive aspects such as sexual pleasure (Laan et al., 2021) and potential risks associated with sexuality (Goldhammer et al., 2022; Mujugira et al., 2021). Studies of TGD people's sexuality, however, often lack validated measures, an appropriate control group, or a prospective design (Holmberg et al., 2019). Additionally, most focus exclusively on sexual functioning (Kennis et al., 2022), and thus neglecting sexual satisfaction and broader operationalizations of sexual pleasure beyond functioning. The effects of current TGD-related medical treatments on sexuality are heterogeneous (Özer et al., 2022; T'Sjoen et al., 2020), and there has been little research on the sexuality of TGD adolescents (Bungener et al., 2017; Maheux et al., 2021; Ristori et al., 2021; Stübler & Becker-Hebly, 2019; Warwick et al., 2022). While sex-positive approaches to counseling and treatment for sexual difficulties experienced by TGD individuals have been proposed (Fielding, 2021; Jacobson et al., 2019; Richards, 2021), to date there is insufficient research on the effectiveness of such interventions. Focusing on the promotion of sexual health, the World Association for Sexual Health (WAS) asserts the importance of sexual pleasure and considers self-determination, consent, safety, privacy, confidence, and the ability to communicate and negotiate sexual relations as major facilitators (Kismödi et al., 2017). WAS asserts sexual pleasure is integral to sexual rights and human rights (Kismödi et al., 2017). To contribute to

Statements of Recommendations

17.1- We recommend health care professionals who provide care to transgender and gender diverse people acquire the knowledge and skills needed to address sexual health issues (relevant to their care provision).
17.2- We recommend health care professionals who provide care to transgender and gender diverse people discuss the impact of gender-affirming treatments on sexual function, pleasure, and satisfaction.
17.3- We recommend health care professionals who provide care to transgender and gender diverse people offer the possibility of including the partner(s) in sexuality-related care, if appropriate.
17.4- We recommend health care professionals counsel transgender and gender diverse people about the potential impact of stigma and trauma on sexual risk behavior, sexual avoidance, and sexual functioning.
17.5- We recommend any health care professional who offers care that may impact sexual health provide information, ask about the expectations of the transgender and gender diverse individual and assess their level of understanding of possible changes.
17.6.-We recommend health care professionals who provide care to transgender and gender diverse people counsel adolescents and adults regarding prevention of sexually transmitted infections.
17.7- We recommend health care professionals who provide care to transgender and gender diverse people follow local and World Health Organization guidelines for human immunodeficiency virus/sexual transmitted infections (HIV/STIs) screening, prevention, and treatment.
17.8- We recommend health care professionals who provide care to transgender and gender diverse people address concerns about potential interactions between antiretroviral medications and hormones.

the sexual health of TGD people, health care professionals (HCPs) need both transgender-related expertise and sensitivity (Nieder, Güldenring et al., 2020). With the goal of improving sexual health care for TGD people to an ethically-sound, evidence-based and high-quality level, HCPs must provide their health services with the same care (i.e., with transgender-related expertise), respect (i.e., with transgender-related sensitivity), and investment in sexual pleasure and sexual satisfaction as they provide for cisgender people (Holmberg et al., 2019).

In many societies, nonconforming gender expressions can elicit strong (emotional) reactions, including in HCPs. Thus, when initiating a health-related contact or establishing a therapeutic relationship, a nonjudgmental, open and welcoming manner is most likely ensured when HCPs reflect on their emotional, cognitive, and interactional reactions to the person (Nieder, Güldenring et al., 2020). In addition, transgender-related expertise refers to identifying the impact the TGD person's intersectional identities and experiences of marginalization and stigma may have had on their whole self (Rider, Vencill et al., 2019). To adequately address the specific physical, psychological, and social conditions of TGD people, HCPs must be aware these conditions are generally overlooked due to hetero-cis-normativity, lack of knowledge, and lack of skills (Rees et al., 2021). It is also important to consider cultural norms in relation to sexuality. For example, in some African cultures, the idea of sex as taboo restricts the number of acceptable terms to be used when taking a sexual history (Netshandama et al., 2017). Culturally respectful language can facilitate talking openly about one's sexual history and reduce ambiguity or shame (Duby et al., 2016). In addition, HCPs must be sensitive to the history of (mis)use of sexual identity and orientation as a gatekeeping function to exclude transgender people from gender-affirming health care (Nieder & Richter-Appelt, 2011; Richards et al., 2014). The following recommendations aim to improve sexual health care for TGD people.

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 17.1

We recommend health care professionals who provide care to transgender and gender diverse people acquire the knowledge and skills to address sexual health issues (relevant to their care provision).

It is important HCPs addressing the sexual health of TGD people be familiar with commonly used terminology (see Chapter 1—Terminology) and invite those seeking care to explain terms with which the provider may not be familiar. In this context, it is also important HCPs (are

prepared to) take a sexual history and offer treatment (according to their competencies) in a gender-affirming way with a sex-positive approach (Centers for Disease Control, 2020; Tomson et al., 2021). However, HCP's should apply greater importance to the terminology that the TGD person uses for their own body over more traditionally accepted or used medical terminology (Wesp, 2016). When talking about sexual practices, it is advisable to focus on body parts (e.g., "Do you have sex with people with a penis, people with a vagina, or both?"; ACON, 2022) and what role they play in their sexuality (e.g., "During Sex, do any parts of your body enter your partners body, such as their genitals, anus, or mouth?"; ACON, 2022).

Statement 17.2

We recommend health care professionals who provide care to transgender and gender diverse people discuss the impact of gender-affirming treatments on sexual function, pleasure, and satisfaction.

To achieve gender-affirming care, it is crucial HCPs providing transition-related medical interventions be sufficiently informed about the possible effects on sexual function, pleasure, and satisfaction (T'Sjoen et al., 2020). Since clinical data indicate that TGD people score significantly lower in sexual pleasure compared to cisgender individuals, this is even more important (Gieles et al., 2022). If the HCP cannot provide information about the effects of their treatment on sexual function, pleasure, and satisfaction, they are at least expected to refer the individual to someone qualified to do so. If the sexuality-related effects of their treatment are unknown, HCPs should inform their patients accordingly. As introduced above, the sexuality of TGD people often challenges heteronormative views. Nevertheless, there is a large amount of literature (e.g., Bauer, 2018; Laube et al., 2020; Hamm & Nieder, 2021; Stephenson et al., 2017) highlighting the spectrum character of sexuality that does not fit into expectations of what male and female sexuality entails (neither cis- nor transgender), let alone that of gender diverse people (e.g., nonbinary, agender, genderqueer). Thus, these aspects should be carefully considered by HCPs as cisnormativity, heteronormativity, and transition-related medical interventions, all have a strong impact on sexual health.

Sexual pleasure has been well documented as a factor in improving sexual, mental, and physical health outcomes (Anderson, 2013). Next to sexual function, HCPs providing sexual health care must address sexual pleasure and satisfaction as a key factor within sexual health. Historically sexual health care has been disease focused, and this is particularly true for research and clinical practice in working with TGD patients. Although competent sexual health care regarding HIV and STIs is necessary, integration of valuing sexual pleasure of TGD patients is also necessary. Calls for integrating sexual pleasure as a focal point in STI prevention education and interventions rest on the understanding that pleasure is a motivator of behavior (Philpott et al., 2006). TGD people are concerned about their sexual pleasure and need HCPs who are knowledgeable about the diversity of sexual practices and anatomical functioning particular to TGD health care.

Statement 17.3

We recommend health care professionals who provide care to transgender and gender diverse people offer the possibility of including the partner(s) in sexuality-related care, if appropriate.

When appropriate and relevant to clinical concerns, inclusion of a sexual and/or romantic partner(s) in sexual health care decision-making can increase TGD patients' sexual well-being and satisfaction outcomes (Kleinplatz, 2012). TGD people may choose a range of transition-related medical interventions, and these interventions may have mixed results in shifting experiences of anatomical dysphoria (Bauer & Hammond, 2015). When discussing the impact of medical interventions on sexual functioning, pleasure, and satisfaction, inclusion of partner(s) can increase knowledge of potential changes and encourage communication between partners (Dierckx et al., 2019). Because the process of transitioning is often not a completely solitary endeavor, the inclusion of sexual and/or romantic partners in transition-related health care can facilitate the process of "co-transitioning" (Lindley et al., 2020;

Siboni et al., 2022; Theron & Collier, 2013) and can also support sexual growth and adjustment both in the individual as well as in the relationship. Social and psychological barriers to sexual functioning and pleasure, including experiences of gender dysphoria, stigmatization, lack of sexual and relationship role models, and limited skills, can have negative impacts on overall sexual health (Kerckhof et al., 2019). Supportive, gender-affirming sexual communication between partners improves sexual satisfaction outcomes for TGD people (Stephenson et al., 2017; Wierckx, Elaut et al., 2011).

Inclusion of sexual and/or romantic partners offers an additional opportunity to set realistic expectations, disseminate helpful and accurate information, and facilitate gender-affirming positive communication related to sexual health. Ultimately, however, it is important to recognize individual choices related to gender health and transition are the patients to make, not a partner's decision. It is important the inclusion of partners in sexual health-related care occur only when appropriate and as desired by patients. Contraindications might include interpersonal dynamics that are abusive or violent, in which case patient safety overrides partner involvement. Finally, it is critical HCPs treat all people in an affirming and inclusive manner, including sexual and romantic partners. This means, for example, monitoring and addressing assumptions and potential biases about the gender or sexual orientation of a patient's partner(s) or a patient's relationship structure.

Statement 17.4

We recommend health care professionals counsel transgender and gender diverse people about the potential impact of stigma and trauma on sexual risk behavior, sexual avoidance, and sexual functioning.

The TGD community is disproportionately impacted by stigma, discrimination, and violence (de Vries et al., 2020; European Union Agency for Fundamental Rights, 2020; McLachlan, 2019). These experiences are often traumatic in nature (Burnes et al., 2016; Mizock & Lewis, 2008) and can create barriers to sexual health, functioning, and pleasure (Bauer & Hammond, 2015). For example, stigmatizing narratives about transgender sexualities can increase dysphoria and sexual shame, increasing potential avoidance of the sexual communication needed for safety and optimizing pleasure (Stephenson et al., 2017). Research demonstrates stigma, a history of sexual violence, and body image concerns can negatively impact sexual self-esteem and agency, for example the ability to assert what is pleasurable or to negotiate condom use (Clements-Nolle et al., 2008; Dharma et al., 2019). Additionally, gender dysphoria can be exacerbated by past trauma experiences and ongoing trauma-related symptoms (Giovanardi et al., 2018). It may be difficult for some TGD individuals to engage sexually using the genitals with which they were born, and they may choose to avoid such stimulation altogether, disrupting arousal and/or orgasmic processes (Anzani et al., 2021; Bauer & Hammond, 2015; Iantaffi & Bockting, 2011) or result in complex feelings about orgasm (Chadwick et al., 2019). HCPs providing gender-affirming counseling and interventions must be knowledgeable about the spectrum of sexual orientations and identities (including asexual identities and practices) to avoid assumptions based in heteronormative, cisnormative, allonormative modes of behavior or satisfaction while also affirming the potential impacts of stigma and trauma on sexual health and pleasure (Nieder, Güldenring et al., 2020). Some level of disconnect or dissociation may at times be present, particularly in the case of acute trauma symptoms (Colizzi et al., 2015). It is important HCPs be aware of these potential impacts on sexual health, functioning, pleasure, and satisfaction, so they may refer patients as needed to trauma-informed sexual counselors, mental health providers, or both, who may be of further assistance and may also normalize and validate TGD patients exploring multiple diverse pathways of healing and accessing sexual pleasure.

Statement 17.5

We recommend any health care professional who offers care that may impact sexual health provide information, ask about the expectation of the transgender and gender diverse individual, and assess their level of understanding of possible changes.

Transition-related care can affect sexual function, pleasure, and satisfaction, both in positive and negative ways (Holmberg et al., 2018; Kerckhof et al., 2019; Thurston & Allan, 2018; Tirapegui et al., 2020). On the positive side, gender-affirming care can help TGD people improve their sexual functioning and increase their sexual pleasure and satisfaction (Kloer et al., 2021; Özer et al., 2022; T'Sjoen et al., 2020). On the negative side, however, data indicate problematic sexual health outcomes due to hormonal and surgical treatments (Holmberg et al., 2018; Kerckhof et al., 2019, Stephenson et al., 2017; Weyers et al., 2009). Transition-related hormones may affect mood, sexual desire, the ability to have an erection and ejaculation, and genital tissue health, which in turn can impact sexual function, pleasure and sexual self-expression (Defreyne, Elaut et al., 2020; Garcia & Zaliznyak, 2020; Kerckhof et al., 2019; Klein & Gorzalka, 2009; Wierckx, Elaut et al., 2014). TGD people who wish to use their original genital anatomy for penetrative sex may benefit from medications that address sexual health side effects of hormone therapy, such as erectile dysfunction, medications for TGD persons taking estrogen or antiandrogens, and topical estrogen and/or moisturizers for TGD persons experiencing vaginal atrophy or dryness due to testosterone therapy.

Sexual desire, arousal, and function may also be affected by the use of psychotropic drugs (Montejo et al., 2015). As some TGD people are prescribed medication to treat depression (Heylens, Elaut et al., 2014), anxiety (Millet et al., 2017) or other mental health concerns (Dhejne et al., 2016), their potential side effects on sexual health should be considered.

Many gender-affirming surgeries can have significant effects on erogenous sensation, sexual desire and arousal as well as sexual function and pleasure. The impact of these changes for patients may be mixed (Holmberg et al., 2018). Chest surgeries (breast reduction, mastectomy, and breast augmentation) and body contouring surgeries, for example, may offer desired changes in form and appearance thereby reducing psychological distress that can disrupt sexual functioning but may adversely affect erogenous sensation (Bekeny et al., 2020; Claes et al., 2018; Rochlin et al., 2020). Genital surgeries in particular can potentially affect sexual function and pleasure in adverse ways, although they are likely to be experienced positively as the patient's body becomes more aligned with their gender, potentially opening new avenues for sexual pleasure and satisfaction (Hess et al., 2018; Holmberg et al., 2018; Kerckhof et al., 2019).

There are numerous examples of this in the extant literature:

- Surgery may result in a decrease, a total loss, or a possible increase in erogenous stimulation and/or experienced sensation compared with the patient's presurgery anatomy (Garcia, 2018; Sigurjónsson et al., 2017).
- A particular surgical option may be associated with specific limitations to sexual function that may manifest immediately, in the future, or at both timepoints, and which patients should consider before finalizing their choice when considering different surgical options (Frey et al., 2016; Garcia, 2018; Isaacson et al., 2017).
- Postsurgical complications can adversely affect sexual function by either decreasing the quality of sexual function (e.g., discomfort or pain with sexual activity) or by precluding satisfactory intercourse (Kerckhof et al., 2019; Schardein et al., 2019).

In general, satisfaction with any medical treatment is heavily influenced by the patient's expectations (Padilla et al., 2019). Furthermore, when patients have unrealistic expectations before treatment, they are much more likely to be dissatisfied with the outcome, their care, and with their HCP (Padilla et al., 2019). Therefore, it is important to both provide patients with adequate information about their treatment options and to understand and consider what is important to the patient with regard to outcomes (Garcia, 2021). Finally, it is important the HCP ensure patients understand the potential adverse effects of a treatment on their sexual function and pleasure so that a well-informed decision can be made. This is relevant for both meeting the standard of informed consent (i.e.,

discussion and understanding) and for providing an opportunity to offer further clarification to patients and, if desired, to their partners (Glaser et al., 2020).

Statement 17.6

We recommend health care professionals who provide care to transgender and gender diverse people counsel adolescents and adults regarding prevention of sexually transmitted infections.

The WHO (2015) recommends HCPs implement brief sexuality-related communication in primary care for all adolescents and adults. Therefore, TGD persons who are sexually active or considering sexual activity may benefit from sexuality-related communication or counseling for the purpose of HIV/STI prevention. These conversations are particularly important as TGD persons are disproportionately impacted by human immunodeficiency virus (HIV) and other sexually transmitted infections (STIs) relative to cisgender persons (Baral et al., 2013; Becasen et al., 2018; Poteat et al., 2016). However, few data are available for non-HIV STIs, such as chlamydia, gonorrhea, syphilis, viral hepatitis, and herpes simplex virus (Tomson et al., 2021). The United Nations Joint Programme on HIV/AIDS estimates transgender women are 12 times more likely than other adults to be living with HIV (UNAIDS, 2019). A meta-analysis estimated a pooled global HIV prevalence of 19% among transgender women who have sex with men (Baral et al., 2013). HIV/STI risk is concentrated among TGD subgroups at the confluence of multiple biological, psychological, interpersonal, and structural vulnerabilities. In particular, transfeminine persons who have sex with cisgender men, belong to minoritized racial/ethnic groups, live in poverty, and engage in survival sex work are at elevated HIV/STI risk (Becasen et al., 2018; Poteat et al., 2015; Poteat et al., 2016). Less is known about HIV/STI risk among transgender men or gender diverse persons AFAB. Small studies in high-income countries indicate a laboratory-confirmed HIV prevalence of 0-4% among transmasculine people (Becasen et al., 2018; Reisner & Murchison, 2016). Almost no research has been conducted with transmasculine people who have sex with cisgender men in high-HIV-prevalence countries. Despite limited epidemiologic data, transmasculine persons who have sex with cisgender men frequently report HIV/STI risk related to receptive vaginal and/or anal sex (Golub et al., 2019; Reisner et al., 2019; Scheim et al., 2017) and may be more susceptible to HIV acquisition from vaginal intercourse than (pre-menopausal) cisgender women due to hormone-related vaginal atrophy.

HCPs will need to supplement general guidelines by developing the knowledge and skills needed for discussing sexual health issues with TGD people, such as the use of gender-affirming language (see Statement 17.1 in this chapter). It is critical HCPs avoid assumptions about HIV/STI risk based solely on a patient's gender identity or anatomy. For example, many transgender people are not sexually active, and TGD persons may use prosthetics or toys for sex. To provide appropriate prevention counseling, HCPs should inquire about the specific sexual activities TGD people engage in, and the body parts (or prosthetics) involved in those activities (ACON, 2022). Well-prepared HCPs (including, but not limited to mental health providers) may also engage in in-depth counseling with their patients to address the underlying drivers of HIV/STI risk (see Statement 17.3 in this chapter).

In all cases, HCPs should be sensitive to the collective and individual histories of TGD people (e.g., stereotypes and stigma about trans sexualities and gender dysphoria) and should explain to patients the reasons for sexuality-related inquiries and the voluntary nature of such inquiries. In discussing HIV/STI prevention, HCPs should refer to the full range of prevention options including barrier methods, post-exposure prophylaxis, pre-exposure prophylaxis, and HIV treatment to prevent onwards transmission (WHO, 2021). Trans-specific considerations for pre-exposure prophylaxis are addressed in Statement 17.8.

Statement 17.7

We recommend health care professionals who provide care to transgender and gender diverse people follow local and World Health Organization guidelines for human immunodeficiency virus/sexual transmitted infections (HIV/STIs) screening, prevention, and treatment.

Like cisgender patients, TGD adolescents and adults should be offered screening for HIV/STIs in accordance with existing guidelines and based on their individual risk of HIV/STI acquisition, considering anatomy and behavior rather than gender identity alone. Where local or national guidelines are unavailable, WHO (2019a) offers global recommendations; more frequent screening is recommended for transgender people who have sex with cisgender men as a key population affected by HIV.

Gender-affirming genital surgeries and surgical techniques have implications for STI risks and screening needs, as outlined in recent guidelines from the US Centers for Disease Control (Workowski et al., 2021). For instance, transfeminine persons who have had penile inversion vaginoplasty using only penile and scrotal skin to line the vaginal canal are likely at lower risk of urogenital Chlamydia trachomatis *(C. trachomatis)* and Neisseria gonorrhoeae *(N. gonorrhoeae)*, but newer surgical techniques that employ buccal or urethral mucosa or peritoneum flaps could in theory increase susceptibility to bacterial STIs relative to the use of penile/scrotal skin alone (Van Gerwen et al., 2021). Routine STI screening of the neovagina (if exposed) is recommended for all transfeminine persons who have had vaginoplasty (Workowski et al., 2021). For transmasculine persons who have had metoidioplasty with urethral lengthening, but not vaginectomy, testing for bacterial urogenital STIs should include a cervical swab because infections may not be detected in urine (Workowski et al., 2021).

Further, it is important for HCPs to offer testing at multiple anatomical sites as STIs in transgender patients are often extragenital (Hiransuthikul et al., 2019; Pitasi et al., 2019). Consistent with WHO (2020) recommendations, self-collection of samples for STI testing should be offered as an option, particularly if patients are uncomfortable or unwilling to undergo provider-collected sampling due to gender dysphoria, trauma histories, or both. Where relevant, integration of HIV/STI testing with regular serology used to monitor hormone therapy may better facilitate access to care (Reisner, Radix et al., 2016; Scheim & Travers, 2017).

Statement 17.8

We recommend health care professionals who provide care to transgender and gender diverse people address concerns about potential interactions between antiretroviral medications and hormones.

For TGD adolescents and adults at substantial risk of HIV infection (generally defined as an ongoing serodiscordant relationship or condomless sex outside of a mutually monogamous relationship with a known HIV-negative partner; WHO, 2017), pre-exposure prophylaxis (PrEP) is an important HIV prevention option (Golub et al., 2019; Sevelius et al., 2016; WHO, 2021). To encourage uptake of PrEP, in 2021 the US Centers for Disease Control recommended all sexually active adolescents and adults be informed about PrEP and offered it if requested (CDC, 2021). For treatment among people living with HIV, transgender-specific guidelines are available in some settings (e.g., Panel on Antiretroviral Guidelines for Adults and Adolescents, 2019).

For both HIV prevention and treatment, there are antiretroviral dosing and administration considerations specific to TGD persons. For oral PrEP, only daily dosing is currently recommended for TGD persons as studies demonstrating the effectiveness of event-driven PrEP with emtricitabine/tenofovir disoproxil fumarate (TDF) have been limited to cisgender men (WHO, 2019c). In addition, while emtricitabine/tenofovir alafenamide (TAF) is a new oral PrEP option, as of early 2022 it is not recommended for people at risk of HIV acquisition through receptive vaginal sex due to a lack of evidence (CDC, 2021). Finally, long-acting injectable formulations of both PrEP and HIV treatment are increasingly available (e.g., cabotegravir for PrEP), and while they are recommended for all patients who might benefit from injectable options, indicated injection sites (i.e., the gluteal muscle) may be unsuitable for individuals who have used soft tissue fillers (Rael et al., 2020).

There is little evidence supporting the occurrence of drug-drug interactions between gender-affirming hormones and PrEP medications. A few small studies, primarily relying on self-reported PrEP use, have shown reduced PrEP drug concentrations in transgender women undergoing hormone therapy, although

concentrations remained in the protective range (Yager & Anderson, 2020). A subsequent drug-drug interaction study using directly observed PrEP therapy failed to detect an impact of hormone therapy on PrEP drug concentrations in transgender women and found transgender women and men taking hormone therapy achieved high levels of protection against HIV infection (Grant et al., 2020). Most importantly, for many TGD people, no impact of PrEP on hormone concentrations has been detected. With regard to HIV treatment, specific antiretroviral medications may impact hormone concentrations; however, these can be managed by selecting alternative agents, monitoring and adjusting hormone dosing, or both (Cirrincione et al., 2020) as detailed in guidelines from the US Department of Health and Human Services (Panel on Antiretroviral Guidelines for Adults and Adolescents, 2019). Nevertheless, concerns about drug-drug interactions, particularly interactions that may limit hormone concentrations, represent a barrier to the implementation and adherence to antiretroviral therapy for HIV prevention or treatment (Radix et al., 2020; Sevelius et al., 2016). Therefore, it is advisable for HCPs to proactively address such concerns with those who are candidates for PrEP or HIV treatment. Integration of PrEP or HIV treatment with hormone therapy may further reduce barriers to implementation and adherence (Reisner, Radix et al., 2016). Integration may be achieved through colocation or through coordination with an HIV specialist if the primary care provider does not have the necessary expertise. Some TGD persons may benefit from standalone PrEP or sexual health services that provide greater privacy and flexibility, and thus differentiated service delivery models are needed (Wilson et al., 2021).

CHAPTER 18 Mental Health

This chapter is intended to provide guidance to health care professionals (HCPs) and mental health professionals (MHPs) who offer mental health care to transgender and gender diverse (TGD) adults. It is not meant to be a substitute for chapters on the assessment or evaluation of people for hormonal or surgical interventions. Many TGD people will not require therapy or other forms of mental health care as part of their transition, while others may benefit from the support of mental health providers and systems (Dhejne et al., 2016).

Some studies have shown a higher prevalence of depression (Witcomb et al., 2018), anxiety (Bouman et al., 2017), and suicidality (Arcelus et al., 2016; Bränström & Pachankis, 2022; Davey et al., 2016; Dhejne, 2011; Herman et al., 2019) among TGD people (Jones et al., 2019; Thorne, Witcomb et al., 2019) than in the general population, particularly in those requiring medically necessary gender-affirming medical treatment (see medically necessary statement in Chapter 2—Global Applicability, Statement 2.1). However, transgender identity is not a mental illness, and these elevated rates have been linked to complex trauma, societal stigma, violence, and discrimination (Nuttbrock et al., 2014; Peterson et al., 2021). In addition, psychiatric symptoms lessen with appropriate gender-affirming medical and surgical care (Aldridge et al., 2020; Almazan and Keuroghlian; 2021; Bauer et al., 2015; Grannis et al., 2021) and with interventions that lessen discrimination and minority stress (Bauer et al., 2015; Heylens, Verroken et al., 2014; McDowell et al., 2020).

Mental health treatment needs to be provided by staff and implemented through the use of systems that respect patient autonomy and recognize gender diversity. MHPs working with transgender people should use active listening as a method to encourage exploration in individuals who are uncertain about their gender identity. Rather than impose their own narratives or preconceptions, MHPs should assist their clients in determining their own paths. While many transgender people require medical or surgical interventions or seek mental health care, others do not (Margulies et al., 2021). Therefore, findings from research involving clinical populations should not be extrapolated to the entire transgender population.

Addressing mental illness and substance use disorders is important but should not be a barrier to transition-related care. Rather, these interventions to address mental health and substance use disorders can facilitate successful outcomes from

Statements of Recommendations

18.1- We recommend mental health professionals address mental health symptoms that interfere with a person's capacity to consent to gender-affirming treatment before gender-affirming treatment is initiated.
18.2- We recommend mental health professionals offer care and support to transgender and gender diverse people to address mental health symptoms that interfere with a person's capacity to participate in essential perioperative care before gender-affirmation surgery.
18.3- We recommend when significant mental health symptoms or substance abuse exists, mental health professionals assess the potential negative impact that mental health symptoms may have on outcomes based on the nature of the specific gender-affirming surgical procedure.
18.4- We recommend health care professionals assess the need for psychosocial and practical support of transgender and gender diverse people in the perioperative period surrounding gender- affirmation surgery.
18.5- We recommend health care professionals counsel and assist transgender and gender diverse people in becoming abstinent from tobacco/nicotine prior to gender-affirmation surgery.
18.6- We recommend health care professionals maintain existing hormone treatment if a transgender and gender diverse individual requires admission to a psychiatric or medical inpatient unit, unless contraindicated.
18.7- We recommend health care professionals ensure if transgender and gender diverse people need in-patient or residential mental health, substance abuse or medical care, all staff use the correct name and pronouns (as provided by the patient), as well as provide access to bathroom and sleeping arrangements that are aligned with the person's gender identity.
18.8- We recommend mental health professionals encourage, support, and empower transgender and gender diverse people to develop and maintain social support systems, including peers, friends, and families.
18.9- We recommend health care professionals should not make it mandatory for transgender and gender diverse people to undergo psychotherapy prior to the initiation of gender-affirming treatment, while acknowledging psychotherapy may be helpful for some transgender and gender diverse people.
18.10- We recommend "reparative" and "conversion" therapy aimed at trying to change a person's gender identity and lived gender expression to become more congruent with the sex assigned at birth should not be offered.

transition-related care, which can improve quality of life (Nobili et al., 2018).

All the statements in this chapter have been recommended based on a thorough review of evidence, an assessment of the benefits and harms, values and preferences of providers and patients, and resource use and feasibility. In some cases, we recognize evidence is limited and/or services may not be accessible or desirable.

Statement 18.1

We recommend mental health professionals address mental health symptoms that interfere with a person's capacity to consent to gender-affirming treatment before gender-affirming treatment is initiated.

Because patients generally are assumed to be capable of providing consent for care, whether the presence of cognitive impairment, psychosis, or other mental illness impairs the ability to give informed consent is subject to individual examination (Applebaum, 2007). Informed consent is central to the provision of health care. The health care provider must educate the patient about the risks, benefits, and alternatives to any care that is offered so the patient can make an informed, voluntary choice (Berg et al., 2001). Both the primary care provider or endocrinologist prescribing hormones and the surgeon performing surgery must obtain informed consent. Similarly, MHPs obtain informed consent for mental health treatment and may consult on a patient's capacity to give informed consent when this is in question. Psychiatric illness and substance use disorders, in particular cognitive impairment and psychosis, may impair an individual's ability to understand the risks and benefits of the treatment (Hostiuc et al., 2018). Conversely, a patient may also have significant mental illness, yet still be able to understand the risks and benefits of a particular treatment (Carpenter et al., 2000). Multidisciplinary communication is important in challenging cases, and expert consultation should be utilized as needed (Karasic & Fraser, 2018). For many patients, difficulty understanding the risks and benefits of a particular treatment can be overcome with time and careful explanation. For some patients, treatment of the underlying condition that is interfering with the capacity to give informed consent—for example treating an underlying psychosis—will allow the patient to gain the capacity to consent to the required treatment. However, mental health symptoms such as anxiety or depressive symptoms that do not affect the capacity to give consent should not be a barrier for gender-affirming medical treatment, particularly as this treatment has been found to reduce mental health symptomatology (Aldridge et al., 2020).

Statement 18.2

We recommend mental health professionals offer care and support to transgender and gender diverse people to address mental health symptoms that interfere with a person's capacity to participate in essential perioperative care before gender-affirmation surgery.

The inability to adequately participate in perioperative care due to mental illness or substance use should not be viewed as an obstacle to needed transition care, but should be seen as an indication mental health care and social support be provided (Karasic, 2020). Mental illness and substance use disorders may impair the ability of the patient to participate in perioperative care (Barnhill, 2014). Visits to health care providers, wound care, and other aftercare procedures (e.g., dilation after vaginoplasty) may be necessary for a good outcome. A patient with a substance use disorder might have difficulty keeping necessary appointments to the primary care provider and the surgeon. A patient with psychosis or severe depression might neglect their wound or not be attentive to infection or signs of dehiscence (Lee, Marsh et al., 2016). Active mental illness is associated with a greater need for further acute medical and surgical care after the initial surgery (Wimalawansa et al., 2014).

In these cases, treatment of the mental illness or substance use disorder may assist in achieving successful outcomes. Arranging more support for the patient from family and friends or a home health care worker may help the patient participate sufficiently in perioperative care for surgery to proceed. The benefits of mental health treatments that may delay surgery should be weighed against the risks of delaying surgery and should

include an assessment of the impact on the patients' mental health delays may cause in addressing gender dysphoria (Byne et al., 2018).

Statement 18.3

We recommend when significant mental health symptoms or substance abuse exists, mental health professionals assess the potential negative impact mental health symptoms may have on outcomes based on the nature of the specific gender-affirming surgical procedure.

Gender-affirming surgical procedures vary in terms of their impact on the patient. Some procedures require a greater ability to follow preoperative planning as well as engage in peri- and postoperative care to achieve the best outcomes (Tollinche et al., 2018). Mental health symptoms can influence a patient's ability to participate in the planning and perioperative care necessary for any surgical procedure (Paredes et al., 2020). The mental health assessment can provide an opportunity to develop strategies to address the potential negative impact mental health symptoms may have on outcomes and to plan support for the patient's ability to participate in the planning and care. Gender-affirming surgical procedures have been shown to relieve symptoms of gender dysphoria and improve mental health (Owen-Smith et al., 2018; van de Grift, Elaut et al., 2017). These benefits are weighed against the risks of each procedure when the patient and provider are deciding whether to proceed with the treatment. HCPs can assist TGD people in reviewing preplanning and perioperative care instructions for each surgical procedure (Karasic, 2020). Provider and patient can collaboratively determine the necessary support or resources needed to assist with keeping appointments for perioperative care, obtaining necessary supplies, addressing financial issues, and handling other preoperative coordination and planning. In addition, issues surrounding appearance-related and functional expectations, including the impact of these various factors on gender dysphoria, can be explored.

Statement 18.4

We recommend health care professionals assess the need for psychosocial and practical support of transgender and gender diverse people in the perioperative period surrounding gender-affirmation surgery.

Regardless of specialty, all HCPs have a responsibility to support patients in accessing medically necessary care. When HCPs are working with TGD people as they prepare for gender-affirming surgical procedures, they should assess the levels of psychosocial and practical support required (Deutsch, 2016b). Assessment is the first step in recognizing where additional support may be needed and enhancing the ability to work collaboratively with the individual to successfully navigate the pre-, peri-, and postsurgical periods (Tollinche et al., 2018). In the perioperative period, it is important to help patients optimize functioning, secure stable housing, when possible, build social and family supports by assessing their unique situation, plan ways of responding to medical complications, navigate the potential impact on work/income, and overcome additional hurdles some patients may encounter, such as coping with electrolysis and tobacco cessation (Berli et al., 2017). In a complex medical system, not all patients will be able to independently navigate the procedures required to obtain care, and HCPs and peer navigators can support patients through this process (Deutsch, 2016a).

Statement 18.5

We recommend health care professionals counsel and assist transgender and gender diverse people in becoming abstinent from tobacco/nicotine prior to gender-affirmation surgery.

Transgender populations have higher rates of tobacco and nicotine use (Kidd et al., 2018). However, many are unaware of the well-documented smoking-associated health risks (Bryant et al., 2014). Tobacco consumption increases the risk of developing health problems (e.g., thrombosis) in individuals receiving gender-affirming hormone treatment, particularly estrogens (Chipkin & Kim, 2017).

Tobacco use has been associated with worse outcomes in plastic surgery, including overall complications, tissue necrosis, and the need for surgical revision (Coon et al., 2013). Smoking also increases the risk for postoperative infection (Kaoutzanis et al., 2019). Tobacco use has been shown to affect

the healing process following any surgery, including gender-related surgeries (e.g., chest reconstructive surgery, genital surgery) (Pluvy, Garrido et al., 2015). Tobacco users have a higher risk of cutaneous necrosis, delayed wound healing, and scarring disorders due to hypoxia and tissue ischemia (Pluvy, Panouilleres et al., 2015). In view of this, surgeons recommend stopping the use of tobacco/nicotine prior to gender-affirmation surgery and abstaining from smoking up to several weeks postoperatively until the wound has completely healed (Matei & Danino, 2015). Despite the risks, cessation may be difficult. Tobacco smoking and nicotine use is addictive and is also used as a coping mechanism (Matei et al., 2015). HCPs who see patients longitudinally before surgery, including mental health and primary care providers, should address the use of tobacco/nicotine with individuals in their care, and either assist TGD people in accessing smoking cessation programs or provide treatment directly (e.g., varenicline or bupropion).

Statement 18.6

We recommend health care professionals maintain existing hormone treatment if a transgender and gender diverse individual requires admission to a psychiatric or medical inpatient unit, unless contraindicated.

TGD people entering inpatient psychiatric, substance use treatment, or medical units should be maintained on their current hormone regimens. There is an absence of evidence supporting routine cessation of hormones prior to medical or psychiatric admissions. Rarely, a newly admitted patient may be diagnosed with a medical complication necessitating suspension of hormone treatment, for example an acute venous thromboembolism (Deutsch, 2016a). There is no strong evidence for routinely stopping hormone treatment prior to surgery, and the risks and benefits for each individual patient should be assessed before doing so (Boskey et al., 2018).

Hormone treatment has been shown to improve quality of life and to decrease depression and anxiety (Aldridge et al., 2020; Nguyen et al., 2018; Nobili et al., 2018; Owen-Smith et al., 2018, Rowniak et al., 2019). Access to gender-affirming medical treatment is associated with a substantial reduction in the risk of suicide attempt (Bauer et al., 2015). Halting a patient's regularly prescribed hormones denies the patient of these salutary effects, and therefore may be counter to the goals of hospitalization.

Some providers may be unaware of the low risk of harm and the high potential benefit of continuing transition-related treatment in the inpatient setting. A study of US and Canadian medical schools revealed that students received an average of 5 hours of LGBT-related course content over their entire four years of education (Obedin-Maliver et al., 2011). According to a survey of Emergency Medicine physicians, who are often responsible for making quick decisions about medications as patients are being admitted, while 88% reported caring for transgender patients, only 17.5% had received any formal training about this population (Chisolm-Straker et al., 2018). As education about transgender topics increases, more providers will become aware of the importance of maintaining transgender patients on their hormone regimens during hospitalization.

Statement 18.7

We recommend health care professionals ensure if transgender and gender diverse people need inpatient or residential mental health, substance abuse, or medical care, all staff use the correct name and pronouns (as provided by the patient), as well as provide access to bathroom and sleeping arrangements that are aligned with the person's gender identity.

Many TGD patients encounter discrimination in a wide range of health settings, including hospitals, mental health treatment settings, and drug treatment programs (Grant et al., 2011). When health systems fail to accommodate TGD individuals, they reinforce the longstanding societal exclusion many have experienced (Karasic, 2016). Experiences of discrimination in health settings lead to avoidance of needed health care due to anticipated discrimination (Kcomt et al., 2020).

The experience of discrimination experienced by TGD individuals is predictive of suicidal ideation (Rood et al., 2015; Williams et al., 2021). Gender minority stress associated with rejection and nonaffirmation has also been associated with suicidality (Testa et al., 2017). Denial of access to gender appropriate bathrooms has been

associated with increased suicidality (Seelman, 2016). However, the use of chosen names for TGD people has been associated with lower depression and suicidality (Russell et al., 2018). Structural as well as internalized transphobia must be addressed to reduce the incidence of suicide attempts in TGD people (Brumer et al., 2015). To successfully provide care, health settings must minimize the harm done to patients because of transphobia by respecting and accommodating TGD identities.

Statement 18.8

We recommend mental health professionals encourage, support, and empower transgender and gender diverse people to develop and maintain social support systems, including peers, friends, and families.

While minority stress and the direct effects of discriminatory societal discrimination can be harmful to the mental health of TGD people, strong social support can help lessen this harm (Trujillo et al., 2017). TGD children often internalize rejection from family and peers as well as the transphobia that surrounds them (Amodeo et al., 2015). Furthermore, exposure to transphobic abuse may be impactful across a person's lifespan and may be particularly acute during the adolescent years (Nuttbrock et al., 2010).

The development of affirming social support is protective of mental health. Social support can act as a buffer against the adverse mental health consequences of violence, stigma, and discrimination (Bockting et al., 2013), can assist in navigating health systems (Jackson Levin et al., 2020), and can contribute to psychological resilience in TGD people (Bariola et al., 2015; Başar and Öz, 2016). Diverse sources of social support, especially LGBTQ + peers and family, have been found to be associated with better mental health outcomes, well-being, and quality of life (Bariola et al., 2015; Başar et al., 2016; Kuper, Adams et al., 2018; Puckett et al., 2019). Social support has been proposed to facilitate the development of coping mechanisms and lead to positive emotional experiences throughout the transition process (Budge et al., 2013).

HCPs can support patients in developing social support systems that allow them to be recognized and accepted as their authentic identity and help them cope with symptoms of gender dysphoria. Interpersonal problems and lack of social support have been associated with a greater incidence of mental health difficulties in TGD people (Bouman, Davey et al., 2016; Davey et al., 2015) and have been shown to be an outcome predictor of gender-affirming medical treatment (Aldridge et al., 2020). Therefore, HCPs should encourage, support, and empower TGD people to develop and maintain social support systems. These experiences can foster the development of interpersonal skills and help with coping with societal discrimination, potentially reducing suicidality and improving mental health (Pflum et al., 2015).

Statement 18.9

We recommend health care professionals should not make it mandatory for transgender and gender diverse people to undergo psychotherapy prior to the initiation of gender-affirming treatment, while acknowledging psychotherapy may be helpful for some transgender and gender diverse people.

Psychotherapy has a long history of being used in clinical work with TGD people (Fraser, 2009b). The aims, requirements, methods and principles of psychotherapy have been an evolving component of the Standards of Care from the initial versions (Fraser, 2009a). At present, psychotherapeutic assistance and counseling with adult TGD people may be sought to address common psychological concerns related to coping with gender dysphoria and may also help some individuals with the coming-out process (Hunt, 2014). Psychological interventions, including psychotherapy, offer effective tools and provide context for the individual, such as exploring gender identity and its expression, enhancing self-acceptance and hope, and improving resilience in hostile and disabling environments (Matsuno and Israel, 2018). Psychotherapy is an established alternative therapeutic approach for addressing mental health symptoms that may be revealed during the initial assessment or later during the follow-up for gender-affirming medical interventions. Recent research shows, although mental health symptoms are reduced following gender-affirming medical treatment, levels of anxiety remain high (Aldridge et al., 2020) suggesting psychological therapy can play a role in helping

individuals suffering from anxiety symptoms following gender-affirming treatment.

In recent years, the uses and potential benefits of specific psychotherapeutic modalities have been reported (Austin et al., 2017; Budge, 2013; Budge et al., 2021; Embaye, 2006; Fraser, 2009b; Heck et al., 2015). Specific models of psychotherapy have been proposed for adult transgender and nonbinary individuals (Matsuno & Israel, 2018). However, more empiric data is needed on the comparative benefits of different psychotherapeutic models (Catelan et al., 2017). Psychotherapy can be experienced by transgender persons as a fearful as well as a beneficial experience (Applegarth & Nuttall, 2016) and presents challenges to the therapist and to alliance formation when it is associated with gatekeeping for medical interventions (Budge, 2015).

Experience suggests many transgender and nonbinary individuals decide to undergo gender-affirming medical treatment with little or no use of psychotherapy (Spanos et al., 2021). Although various modalities of psychotherapy may be beneficial for different reasons before, during, and after gender-affirming medical treatments and varying rates of desire for psychotherapy have been reported during different stages of transition (Mayer et al., 2019), a requirement for psychotherapy for initiating gender-affirming medical procedures has not been shown to be beneficial and may be a harmful barrier to care for those who do not need this type of treatment or who lack access to it.

Statement 18.10

We recommend "reparative" and "conversion" therapy aimed at trying to change a person's gender identity and lived gender expression to become more congruent with the sex assigned at birth should not be offered.

The use of "reparative" or "conversion" therapy or gender identity "change" efforts is opposed by many major medical and mental health organizations across the world, including the World Psychiatric Association, Pan American Health Organization, American Psychiatric and American Psychological Associations, Royal College of Psychiatrists, and British Psychological Society. Many states in the US have instituted bans on practicing conversion therapy with minors. Gender identity change efforts refers to interventions by MHPs or others that attempt to change gender identity or expression to be more in line with those typically associated with the person's sex assigned at birth (American Psychological Association, 2021).

Advocates of "conversion therapy" have suggested it could potentially allow a person to fit better into their social world. They also point out some clients specifically ask for help changing their gender identities or expressions and therapists should be allowed to help clients achieve their goals. However, "conversion therapy" has not been shown to be effective (APA, 2009; Przeworski et al., 2020). In addition, there are numerous potential harms. In retrospective studies, a history of having undergone conversion therapy is linked to increased levels of depression, substance abuse, suicidal thoughts, and suicide attempts, as well as lower educational attainment and less weekly income (Ryan et al., 2020; Salway et al., 2020; Turban, Beckwith et al., 2020). In 2021, the American Psychological Association resolutions states that "scientific evidence and clinical experience indicate that GICEs [gender identity change efforts] put individuals at significant risk of harm" (APA, 2021).

While there are barriers to ending gender identity "change" efforts, education about the lack of benefit and the potential harm of these practices may lead to fewer providers offering "conversion therapy" and fewer individuals and families choosing this option.

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Conflict of Interest

Conflict of interests were reviewed as part of the selection process for committee members and at the end of the process before publication. No conflicts of interest were deemed significant or consequential.

Ethical Approval

This manuscript does not contain any studies with human participants performed by any of the authors.

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Appendix A METHODOLOGY

1. Introduction

This version of the Standards of Care (SOC-8) is based upon a more rigorous and methodological evidence-based approach than previous versions. This evidence is not only based on the published literature (direct as well as background evidence) but also on consensus-based expert opinion. Evidence-based guidelines include recommendations intended to optimize patient care and are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Evidence-based research provides the basis for sound clinical practice guidelines and recommendations but must be balanced by the realities and feasibility of providing care in diverse settings. The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process. (Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice, 2011; World Health Organization, 2019a).

The SOC-8 revision committee was multidisciplinary and consisted of subject matter experts, health care professionals, researchers and stakeholders with diverse perspectives and geographic representation. All committee members completed conflict of interest declarations.*

A guideline methodologist assisted with the planning and development of questions, and an independent team undertook systematic reviews that were used to inform some of the statements for recommendations. Additional input to the guidelines was provided by an international advisory committee, legal experts, and feedback received during a public comment period. Recommendations in the SOC-8 are based on available evidence supporting interventions, a discussion of risks and harms, as well as feasibility and acceptability within different contexts and country settings. Consensus of the final recommendations was attained using a Delphi process that included all members of the Standards of Care Revision committee and required that recommendation statements were approved by 75% of members. Supportive and explanatory text of the evidence for the statements were written by chapter members. Drafts of the chapters were reviewed by the Chair and the Co-Chairs of the SOC Revision Committee to ensure the format was consistent, evidence was properly provided, and recommendations were consistent across chapters. An independent team checked the references used in the SOC-8 before the guidelines were fully edited by a single professional. A detailed overview of the SOC-8 Methodology is described below.

2. Difference between the methodology of the SOC-8 and previous editions

The main differences in the methodology of the SOC-8 when compared with other versions of the SOC are:

- The involvement of a larger group of professionals from around the globe;
- A transparent selection process to develop the guidelines steering committee as well as to select chapter leads and members;
- The inclusion of diverse stakeholders in the development of the SOC-8
- Management of conflicts of interest
- The use of a Delphi process to reach agreement on the recommendations among SOC-8 committee members
- The involvement of an independent body from a reputable university to help develop the methodology and undertake independent systematic literature reviews where possible
- Recommendations were graded as either "recommend" or "suggest" based upon the strength of the recommendations.
- The involvement of an independent group of clinical academics to review citations.
- The involvement of international organizations working with the transgender and gender diverse (TGD) community, members of WPATH and other professional organizations as well as the general public who provided feedback through a public comment period regarding the whole SOC-8.

3. Overview of SOC-8 development Process

The steps for updating the Standards of Care are summarized below:

1. Establishing Guideline Steering Committee including Chair, and Co-Chairs (July 19, 2017)
2. Determining chapters (scope of guidelines)
3. Selecting Chapter Members based upon expertise (March 2018)
4. Selecting the Evidence Review Team: John Hopkins University (May 2018)
5. Refining topics included in the SOC-8 and review questions for systematic reviews
6. Conducting systematic reviews (March 2019)
7. Drafting the recommendation statements
8. Voting on the recommendation statements using a Delphi process (September 2019–February 2022)
9. Grading of the recommendations statements
10. Writing the text supporting the statements
11. Independently validating the references used in the supportive text
12. Finalizing a draft SOC-8 (December 1, 2021)
13. Feedback on the statements by International Advisory Committee
14. Feedback on the entire draft of the SOC-8 during a public comment period (November 2021–January 2022)
15. Revision of Final Draft based on comments (January 2022- May 2022)
16. Approval of final Draft by Chair and Co-Chairs (June 10, 2022)
17. Approval by the WPATH Board of Directors
18. Publication of the SOC-8
19. Dissemination and translation of the SOC-8

3.1. Establishment of Guideline Steering Committee

The WPATH Guideline Steering Committee oversaw the guideline development process for all chapters of the Standards of Care. Except for the Chair (Eli Coleman) who was appointed by the WPATH board to maintain a continuity from previous SOC editions, members of the Guideline Steering Committee were selected by the WPATH Board from WPATH members applying for these positions. Job descriptions were developed for the positions of Co-Chairs, Chapter Leads, Chapter Members and Stakeholder. WPATH members were eligible to apply by completing an application form and submitting their CV. The Board of WPATH voted for the position of co-chair (one member of the board did not participate in view of conflict of interest). The chairs and co-chairs selected the chapter leads and members (as well as stakeholders) based on the application form and CVs.

The Guideline Steering Committee for Standards of Care 8th Version are:

- Eli Coleman, PhD (Chair) Professor, Director and Academic Chair, Institute for Sexual and Gender Health, Department of Family Medicine and Community Health, University of Minnesota Medical School (USA)
- Asa Radix, MD, PhD, MPH (Co-chair) Senior Director, Research and Education Callen-Lorde Community Health Center Clinical Associate Professor of Medicine New York University, USA
- Jon Arcelus, MD, PhD (Co-chair) Professor of Mental Health and Well-being Honorary Consultant in Transgender Health University of Nottingham, UK
- Karen A. Robinson, PhD (Lead, Evidence Review Team) Professor of Medicine, Epidemiology and Health Policy & Management Johns Hopkins University, USA

3.2. Determination of topics for chapters

The Guideline Steering Committee determined the chapters for inclusion in the Standards of Care by reviewing the literature and by reviewing the previous edition of the SOC. The chapters in the Standards of Care 8th Version:

1. Terminology
2. Global Applicability
3. Population estimates
4. Education*
5. Assessment of Adults
6. Adolescent
7. Children
8. Nonbinary
9. Eunuch
10. Intersex
11. Institutional environments
12. Hormone Therapy
13. Surgery and Postoperative Care
14. Voice and communication
15. Primary care
16. Reproductive Health
17. Sexual Health
18. Mental Health

* The Education Chapter was originally intended to cover both education and ethics. A decision was made to create a separate committee to write a chapter on ethics. In the course of writing the chapter, it was later determined topic of ethics was best placed external to the SOC8 and required further in-depth examination of ethical considerations relevant to transgender health.

3.3. Selection of chapter members

A call for applications to be part of the SOC-8 review committee (chapter lead or member) was sent to the WPATH membership. The Chairs of the Guideline Steering Committee appointed the members for each chapter, ensuring representation from a variety of disciplines and perspectives.

Chapter Leads and Members were required to be WPATH Full Members in good standing and content experts in transgender health, including in at least one chapter topic. Chapter Leads reported to the Guideline Steering Committee and were responsible for coordinating the participation of Chapter Members. Chapter members reported directly to the Chapter Lead.

Each chapter also included stakeholders as members who bring perspectives of transgender health advocacy or work in the community, or as a member of a family that included a transgender child, sibling, partner, parent, etc. Stakeholders were not required to be full members of WPATH.

The Chapter Members were expected to:

- Participate in the development refinement of review questions
- Read and provide comments on all materials from the Evidence Review Team
- Critically review draft documents, including the draft evidence report
- Review and assess evidence and draft recommendations
- Participate in the Delphi consensus process
- Develop the text to back up the recommendation statements
- Grade each statement to describe the strength of the recommendation
- Review and address the comments from the Chairs during the whole process
- Develop the content of the chapters
- Review comments from public comments and assist in the development of a revision of guidelines
- Provide input and participate in the dissemination of guidelines

Training and orientation for Chapter Leads and Members was provided, as needed. Training content included formulation and refinement of questions (i.e., use of PICO), reviewing the evidence, developing recommendation state-

ments, grading the evidence and the recommendations, and information about the guideline development program and process.

A total of 26 chapter-leads were appointed (some chapters required co-leads), 77 chapter members and 16 stakeholders. A total of 127 were selected. During the SOC process, 8 people left, due to personal or work-related issues. Therefore, there were 119 final authors of the SOC-8.

3.4. Selection of the evidence review team

The WPATH Board issued a request for applications to become the Evidence Review Team. For Standards of Care 8th Version the WPATH Board engaged the Evidence Review Team at Johns Hopkins University under the leadership of Karen Robinson.

- Karen A. Robinson, PhD (Lead, Evidence Review Team) Professor of Medicine, Epidemiology and Health Policy & Management Johns Hopkins University, USA

Dr Robinson also guided the steering committee in the development of the SOC-8 by providing advice and training in the development of PICO questions, statements, and the Delphi process as well as undertaking a very rigorous systematic literature review where direct evidence was available.

Conflict of interest

Members of the Guideline Steering Committee, Chapter Leads and Members, and members of the Evidence Review Team were asked to disclose any conflicts of interest. Also reported, in addition to potential financial and competing interests or conflicts, are personal or direct reporting relationships with a chair, co-chair or a WPATH Board Member or the holding of a position on the WPATH Board of Directors.

3.5. Refinement of topics and review of questions

The Evidence Review Team abstracted the recommendation statements from the prior version of the Standards of Care. With input from the Evidence Review Team, the Guideline Steering Committee and Chapter Leads determined:

- Recommendation statements that needed to be updated
- New areas requiring recommendation statements

3.6. Conduct the systematic reviews

Chapter Members developed questions to help develop recommendation statements. For the questions eligible for systematic review, the Evidence Review Team drafted review questions, specifying the Population, Interventions, Comparisons, and Outcomes (PICO elements). The Evidence Review Team undertook the systematic reviews. The Evidence Review Team presented evidence tables and other results of the systematic reviews to the members of the relevant chapter for feedback.

Protocol

A separate detailed systematic review protocol was developed for each review question or topic, as appropriate. Each protocol was registered on PROSPERO.

Literature search

The Evidence Review Team developed a search strategy appropriate for each research question including MEDLINE®, Embase™, and the Cochrane Central Register of Controlled Trials (CENTRAL). The Evidence Review Team searched additional databases as deemed appropriate for the research question. The search strategy included MeSH and text terms and was not limited by language of publication or date.

The Evidence Review Team hand searched the reference lists of all included articles and recent, relevant systematic reviews. The Evidence Review Team searched ClinicalTrials.gov for any additional relevant studies.

Searches were updated during the peer review process.

The literature included in the systematic review was mostly based on quantitative studies conducted in Europe, the US or Australia. We acknowledge a bias towards perspectives from the global north that does not pay sufficient attention to the diversity of lived experiences and perspectives within transgender and gender diverse (TGD) communities across the world. This imbalance of visibility in the literature points to a research and practice gap that needs to be addressed by researchers and practitioners in the future in order to do justice to the support needs of all TGD people independent of gender identification.

Study selection

The Evidence Review Team, with input from the Chapter Workgroup Leads, defined the eligibility criteria for each research question *a priori*.

Two reviewers from the Evidence Review Team independently screened titles and abstracts and full-text articles for eligibility. To be excluded, both reviewers needed to agree that the study met at least one exclusion criteria. Reviewers resolved differences regarding eligibility through discussion.

Data extraction

The Evidence Review Team used standardized forms to abstract data on general study characteristics, participant characteristics, interventions, and outcome measures. One reviewer abstracted the data, and a second reviewer confirmed the abstracted data.

Assessment of risk of bias

Two reviewers from the Evidence Review Team independently assessed the risk of bias for each included study. For

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randomized controlled trials, the Cochrane Risk of Bias Tool was used. For observational studies, the Risk of Bias in Non-Randomized Studies—of Interventions (ROBINS-I) tool was used. Where deemed appropriate, existing recent systematic reviews were considered and evaluated using ROBIS.

Data synthesis and analysis

The Evidence Review Team created evidence tables detailing the data abstracted from the included studies. The members of the Chapter Workgroups reviewed and provided comments on the evidence tables.

Grading of the evidence

The Evidence Review Team assigned evidence grades using the GRADE methodology. The strength of the evidence was obtained using predefined critical outcomes for each question and by assessing the limitations to individual study quality/risk of bias, consistency, directness, precision, and reporting bias.

3.7. Drafting of the Recommendation Statements

Chapter Leads and Members drafted recommendation statements. The statements were crafted to be feasible, actionable, and measurable.

Evidence-based recommendation statements were based on the results of the systematic, and background literature reviews plus consensus-based expert opinions.

The Chair and Co-Chairs and Chapter Leads reviewed and approved all recommendation statements for clarity and consistency in wording. During this review and throughout the process any overlap between chapters was also addressed.

Many chapters had to work closely together to ensure consistency of their recommendations. For example, as there are now separate chapters for childhood and adolescence, to ensure consistency between both chapters, some authors were part of both chapters. For a similar reason, when applicable, a workgroup collaborated with other Chapter Workgroups on topics shared between the chapters (i.e., Assessment of Children, Assessment of Adults, Hormone Therapy, Surgery and Postoperative Care and Reproductive Health).

3.8. Approval of the recommendations using the Delphi process

Formal consensus for all statements was obtained using the Delphi process (a structured solicitation of expert judgements in three rounds). For a recommendation to be approved, a minimum of 75% of the voters had to approve the statement. A minimum of 65% of the SOC-8 members had to take part in the Delphi process for each statement. People who did not approve the statement had to provide information as to the reasons for their disapproval, so the statement could be modified (or removed) according to this feedback. Once modified, the statement was put through the Delphi process again. If after 3 rounds the statement was not approved, the statement was removed from the SOC. Every member of the SOC voted for each statement. There was a response rate between (74.79% and 94.96%) for the statements.

3.9. Grading criteria for statements

Once the statements passed the Delphi process, chapter members graded each statement using a process adapted from the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) framework. This a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations (Guyatt et al., 2011). The statements were graded based on factors such as:

- The balance of potential benefits and harms
- Confidence in that balance or quality of evidence
- Values and preferences of providers and patients
- Resource use and feasibility

The statements were classified as:

- Strong recommendations ("we recommend") are for those interventions/therapy/strategies where:
  - the evidence is of high quality
  - estimates of the effect of an intervention/therapy/strategy (i.e., there is a high degree of certainty effects will be achieved in practice)
  - there are few downsides of therapy/intervention/strategy
  - there is a high degree of acceptance among providers and patients or those for whom the recommendation applies.
- Weak recommendations ("we suggest") are for those interventions/therapy/strategies where:
  - there are weaknesses in the evidence base
  - there is a degree of doubt about the size of the effect that can be expected in practice
  - there is a need to balance the potential upsides and downsides of interventions/therapy/strategies
  - there are likely to be varying degrees of acceptance among providers and patients or those for whom the recommendation applies.

3.10. Writing of the text supporting the statements

Following the grading of the statements, the Chapter Workgroups wrote the text providing the rationale or reasoning for the recommendation. This included providing the available evidence, providing details about potential benefits and harms, describing uncertainties, and information about implementation of the recommendation, including expected barriers or challenges among others. References use APA-7 style, to support the information in the text. Links to resources are also provided, as appropriate. The text, including whether a recommendation has been described as strong or weak, was reviewed and approved by the Chair and Co-Chairs.

3.11. External validation of references used to support the statements

A group of independent clinical academics working in the field of transgender health reviewed the references used in every chapter in order to validate that the references were appropriately used to support the text. Any queries regarding the references were sent back to the chapters for review.

3.12. Finalizing a draft SOC-8

A final SOC-8 draft was made available for comments.

3.13. Distribute Standards of Care for review by international advisors

The statements of the recommendations of Standards of Care 8th were circulated among the broader Standards of Care Revision Committee and the WPATH International Advisory Group, which included the Asia Pacific Transgender Network (APTN), the Global Action for Transgender Equality (GATE), the International Lesbian, Gay, Bisexual, Transgender, Intersex Association (ILGA), and Transgender Europe (TGEU).

3.14. Public comment period

The revised draft version of the Standards of Care document was posted online for comment from the public, including WPATH members, on the WPATH website. A 6-week period was allocated for comments. A total of 1,279 people made comments on the draft with a total of 2,688 comments.

3.15. Revision of final draft based on comments

The Chapter Leads and Guideline Steering Committee considered the feedback and made any necessary revisions. All public comments were read and, where appropriate, integrated into the background text.

As part of this process, 3 new Delphi statements were developed and 2 were modified enough to require a new vote by the SOC-8 committee. This meant a new Delphi process was initiated in January 2022. The results of this Delphi process were accepted by the chapters, and the new statements were added or modified accordingly. The new supportive text was added.

All the new versions of the chapters were reviewed again by the Chair and Co-Chairs and changes or modifications were suggested. Finally, once the Chairs and the Chapter Members were satisfied with the draft, the chapter was finalized.

All new references were double checked by an independent member.

3.16. Approval of final draft by Chair and Co-Chairs

Modifications were reviewed by the Chairs and were accepted by them.

3.17. Approval by the WPATH Board of Directors

The final document was presented to the WPATH Board of Directors for approval and it was approved on the 20th of June 2022.

3.18. Publication of the SOC-8 and dissemination of the Standards of Care

The Standards of Care was disseminated in a number of venues and in a number of formats including publication in the International Journal of Transgender Health (the official scientific journal of WPATH).

4. Plan to Update

A new edition of the SOC (SOC-9) will be developed in the future, when new evidence and/or significant changes in the field necessitating a new edition is substantial.

*The development of SOC-8 was a complex process at a time of COVID-19 and political uncertainties in many parts of the world. Members of the SOC-8 worked on the SOC-8 on top of their day-to-day job, and most of the meetings took place out of their working time and during their weekends via Zoom. There were very few face-to-face meetings, most of them linked to WPATH, USPATH or EPATH conferences. Committee members of the SOC-8 were not paid as part of this process.

Appendix B GLOSSARY

CISGENDER refers to people whose current gender identity corresponds to the sex they were assigned at birth.
DETRANSITION is a term sometimes used to describe an individual's retransition to the gender stereotypically associated with their sex assigned at birth.
EUNUCH refers to an individual assigned male at birth whose testicles have been surgically removed or rendered non-functional and who identifies as a eunuch. This differs from the standard medical definition by excluding those who do not identify as eunuch.
EUNUCH-IDENTIFIED: An individual who feels their true self is best expressed by the term eunuch. Eunuch-identified individuals generally desire to have their reproductive organs surgically removed or rendered non-functional.
GENDER: Depending on the context, gender may reference gender identity, gender expression, and/or social gender role, including understandings and expectations culturally tied to people who were assigned male or female at birth. Gender identities other than those of men and women (who can be either cisgender or transgender) include transgender, nonbinary, genderqueer, gender neutral, agender, gender fluid, and "third" gender, among others; many other genders are recognized around the world.
GENDER-AFFIRMATION refers to being recognized or affirmed in a person's gender identity. It is usually conceptualized as having social, psychological, medical, and legal dimensions. Gender affirmation is used as a term in lieu of transition (as in medical gender-affirmation) or can be used as an adjective (as in gender-affirming care).
GENDER-AFFIRMATION SURGERY (GAS) is used to describe surgery to change primary and/or secondary sex characteristics to affirm a person's gender identity.
GENDER BINARY refers to the idea there are two and only two genders, men and women; the expectation that everyone must be one or the other; and that all men are males, and all women are females.
GENDER DIVERSE is a term used to describe people with gender identities and/or expressions that are different from social and cultural expectations attributed to their sex assigned at birth. This may include, among many other culturally diverse identities, people who identify as nonbinary, gender expansive, gender nonconforming, and others who do not identify as cisgender.
GENDER DYSPHORIA describes a state of distress or discomfort that may be experienced because a person's gender identity differs from that which is physically and/or socially attributed to their sex assigned at birth. Gender Dysphoria is also a diagnostic term in the DSM-5 denoting an incongruence between the sex assigned at birth and experienced gender accompanied by distress. Not all transgender and gender diverse people experience gender dysphoria.
GENDER EXPANSIVE is an adjective often used to describe people who identify or express themselves in ways that broaden the socially and culturally defined behaviors or beliefs associated with a particular sex. Gender creative is also sometimes used. The term gender variant was used in the past and is disappearing from professional usage because of negative connotations now associated with it.
GENDER EXPRESSION refers to how a person enacts or expresses their gender in everyday life and within the context of their culture and society. Expression of gender through physical appearance may include dress, hairstyle, accessories, cosmetics, hormonal and surgical interventions as well as mannerisms, speech, behavioral patterns, and names. A person's gender expression may or may not conform to a person's gender identity.
GENDER IDENTITY refers to a person's deeply felt, internal, intrinsic sense of their own gender.
GENDER INCONGRUENCE is a diagnostic term used in the ICD-11 that describes a person's marked and persistent experience of an incompatibility between that person's gender identity and the gender expected of them based on their birth-assigned sex.
INTERSEX refers to people born with sex or reproductive characteristics that do not fit binary definitions of female or male.
MISGENDER/MISGENDERING refers to when language is used that does not correctly reflect the gender with which a person identifies. This may be a pronoun (he/him/his, she/her/hers, they/them/theirs) or a form of address (sir, Mr.).
NONBINARY refers to those with gender identities outside the gender binary. People with nonbinary gender identities may identify as partially a man and partially a woman or identify as sometimes a man and sometimes a woman, or identify as a gender other than a man or a woman, or as not having a gender at all. Nonbinary people may use the pronouns they/them/theirs instead of he/him/his or she/her/hers. Some nonbinary people consider themselves to be transgender or trans; some do not because they consider transgender to be part of the gender binary. The shorthand NB or "enby" is sometimes used as a descriptor for nonbinary. Examples of nonbinary gender identities are genderqueer, gender diverse, genderfluid, demigender, bigender, and agender.
RETRANSITION refers to second or subsequent gender transition whether by social, medical, or legal means. A retransition may be from one binary or nonbinary gender to another binary or nonbinary gender. People may retransition more than once. Retransition may occur for many reasons, including evolving gender identities, health concerns, family/societal concerns, and financial issues.
SEX ASSIGNED AT BIRTH refers to a person's status as male, female, or intersex based on physical characteristics. Sex is usually assigned at birth based on appearance of the external genitalia. AFAB is an abbreviation for "assigned female at birth." AMAB is an abbreviation for "assigned male at birth."
SEXUAL ORIENTATION refers to a person's sexual identity, attractions, and behaviors in relation to people on the basis of their gender(s) and or sex characteristics and those of their partners. Sexual orientation and gender identity are distinct terms.
TRANSGENDER or trans are umbrella terms used to describe people whose gender identities and/or gender expressions are not what is typically expected for the sex to which they were assigned at birth. These words should always be used as adjectives (as in "trans people") and never as nouns (as in "transgenders") and never as verbs (as in "transgendered").

TRANSGENDER MEN or **TRANS MEN** or **MEN OF TRANS EXPERIENCE** are people who have gender identities as men and who were assigned female at birth. They may or may not have undergone any transition. FTM or Female-to-Male are older terms that are falling out of use.
TRANSGENDER WOMEN or **TRANS WOMEN** or **WOMEN OF TRANS EXPERIENCE** are people who have gender identities as women and who were assigned male at birth. They may or may not have undergone any transition. MTF or Male-to-Female are older terms that are falling out of use.
TRANSITION refers to the process whereby people usually change from the gender expression associated with their assigned sex at birth to another gender expression that better matches their gender identity. People may transition socially by using methods such as changing their name, pronoun, clothing, hair styles, and/or the ways that they move and speak. Transitioning may or may not involve hormones and/or surgeries to alter the physical body. Transition can be used to describe the process of changing one's gender expression from any gender to a different gender. People may transition more than once in their lifetimes.
TRANSPHOBIA refers to negative attitudes, beliefs, and actions concerning transgender and gender diverse people as a group. Transphobia may be enacted in discriminatory policies and practices on a structural level or in very specific and personal ways. Transphobia can also be internalized, when transgender and gender diverse people accept and reflect such prejudice about themselves or other transgender and gender diverse people. While transphobia sometimes may be a result of unintentional ignorance rather than direct hostility, its effects are never benign. Some people use the term anti-transgender bias in place of transphobia.

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Appendix C GENDER-AFFIRMING HORMONAL TREATMENTS

Table 1. Expected time course of physical changes in response to gender-affirming hormone therapy

Testosterone Based Regimen		
Effect	**Onset**	**Maximum**
Skin Oiliness/acne	1–6 months	1–2 years
Facial/body hair growth	6–12 months	>5 years
Scalp hair loss	6–12 months	>5 years
Increased muscle mass/ strength	6–12 months	2–5 years
Fat redistribution	1–6 months	2–5 years
Cessation of menses	1–6 months	1–2 years
Clitoral enlargement	1–6 months	1–2 years
Vaginal atrophy	1–6 months	1–2 years
Deepening of voice	1–6 months	1–2 years
Estrogen and testosterone-lowering based regimens		
Effect	**Onset**	**Maximum**
Redistribution of body fat	3–6 months	2–5 years
Decrease in muscle mass and strength	3–6 months	1–2 years
Softening of skin/ decreased oiliness	3–6 months	Unknown
Decreased sexual desire	1–3 months	Unknown
Decreased spontaneous erections	1–3 months	3–6 months
Decreased sperm production	Unknown	2 years
Breast growth	3–6 months	2–5 years
Decreased testicular volume	3–6 months	Variable
Decreased terminal hair growth	6–12 months	> 3 years
Increased scalp hair	Variable	Variable
Voice changes	None	

Adapted from Hembree et al., 2017.

Table 2. Risks associated with gender affirming hormone therapy (bolded items are clinically significant) (Updated from SOC-7)

RISK LEVEL	Estrogen-based regimens	Testosterone-based regimens
Likely increased risk	**Venous Thromboembolism** **Infertility** Hyperkalemia[S] Hypertrigyceridemia Weight Gain	**Polycythemia** **Infertility** Acne Androgenic Alopecia Hypertension Sleep Apnea Weight Gain Decreased HDL Cholesterol and increased LDL Cholesterol
Likely increased risk with presence of additional risk factors	Cardiovascular Disease Cerebrovascular Disease Meningioma[C] Polyuria/Dehydration[S] Cholelithiasis	Cardiovascular Disease Hypertriglyceridemia
Possible increased risk	Hypertension Erectile Dysfunction	
Possible increased risk with presence of additional risk factors	Type 2 Diabetes Low Bone Mass/ Osteoporosis Hyperprolactinemia	Type 2 Diabetes Cardiovascular Disease
No increased risk or inconclusive	Breast and Prostate Cancer	Low Bone Mass/ Osteoporosis Breast, Cervical, Ovarian, Uterine Cancer

[C]cyproterone-based regimen
[S]spironolactone-based regimen

Table 3. Gender-Affirming Hormone Regimens In Transgender And Gender Diverse Youth (Adapted from the Endocrine Society Guidelines; Hembree et al., 2017)

Induction of female puberty (estrogen-based regimen) with oral 17ß-estradiol

Initiate at 5µg/kg/d and increase every 6 months by 5 µg/kg/d up to 20 µg/kg/d according to estradiol levels

Adult dose = 2-6 mg/day

In postpubertal TGD adolescents, the dose of 17ß-estradiol can be increased more rapidly:

1 mg/d for 6 months followed by 2 mg/d and up according to estradiol levels

Induction of female puberty (estrogen-based regimen) with transdermal 17ß-estradiol

Initial dose 6.25-12.5 µg/24 h (cutting 24 g patch to ¼ then ½)

Titrate up by every 6 months by 12.5 µg/24 h according to estradiol levels

Adult dose = 50-200 µg/24 hours

For alternatives once at adult dose (Table 4)

Induction of male puberty (testosterone-based regimen) with testosterone esters

25 mg/m^2/2 weeks (or alternatively half this dose weekly)

Increase by 25 mg/m^2/2 weeks every 6 months until adult dose and target testosterone levels are achieved. See alternatives for testosterones (Table 4)

Table 4. Hormone regimens in transgender and gender diverse adults*

Estrogen-based regimen (Transfeminine)	
Estrogen	
Oral or sublingual	
Estradiol	2.0-6.0 mg/day
Transdermal	
Estradiol transdermal patch	0.025-0.2 mg/day
Estradiol gel various	‡ daily to skin
Parenteral	
Estradiol valerate or cypionate	5-30 mg IM every 2 weeks 2-10 IM every week
Anti-Androgens	
Spironolactone	100–300 mg/day
Cyproterone acetate	10 mg/day**
GnRH agonist	3.75–7.50 mg SQ/IM monthly
GnRH agonist depot formulation	11.25/22.5 mg SQ/IM 3/6 monthly
‡ Amount applied varies to formulation and strength	
Testosterone-Based Regimen (Transmasculine)	
Transgender males	
Testosterone	
Parenteral	
Testosterone enanthate/ cypionate	50–100 IM/SQ weekly or 100–200 IM every 2 weeks
Testosterone undecanoate	1000 mg IM every 12 weeks or 750 mg IM every 10 weeks
Transdermal testosterone	
Testosterone gel	50-100 mg/day
Testosterone transdermal patch	2.5–7.5 mg/day

Doses are titrated up or down until sex steroid hormone levels are in the therapeutic range. Hormone regimens do not reflect all formulations that are available in all pharmacies throughout the world. Hormone regimens may have to be adapted to what is available in local pharmacies.

**Kuijpers et al (2021).

Table 5. Hormone monitoring of transgender and gender diverse people receiving gender-affirming hormone therapy (Adapted from the Endocrine Society Guidelines)

Transgender male or trans masculine (including gender diverse/nonbinary) individuals

1. Evaluate patient approximately every 3 months (with dose changes) in the first year and 1 to 2 times per year thereafter to monitor for appropriate physical changes in response to testosterone.
2. Measure serum total testosterone every 3 months (with dose changes) until levels are at goal
   a. For parenteral testosterone, the serum total testosterone should be measured midway between injections. The target level is 400-700 ng/dL. Alternatively, measure peak and trough peaks to ensure levels remain in the range of reference men.
   b. For parenteral testosterone undecanoate, testosterone should be measured just before injection. If the level is < 400 ng/dL, adjust the dosing interval.
   c. For transdermal testosterone, the testosterone level can be measured no sooner than after 1 week of daily application (at least 2 hours after application of product).
3. Measure hematocrit or hemoglobin concentrations at baseline and approximately 3 months (with dose changes) for the first year and then one to two times a year.

Transgender Female or trans feminine (including gender diverse/nonbinary) individuals

1. Evaluate patient approximately every 3 months (with dose changes) in the first year and one to two times per year thereafter to monitor for appropriate physical changes in response to estrogen.
   a. Serum testosterone levels should be less than 50 ng/dL.
   b. Serum estradiol should be in the range of 100-200 pg/mL.
2. For individuals receiving spironolactone, serum electrolytes, in particular potassium, and kidney function, in particular creatinine, should be monitored.
3. Follow primary care screening per primary care chapter recommendations

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Appendix D SUMMARY CRITERIA FOR HORMONAL AND SURGICAL TREATMENTS FOR ADULTS AND ADOLESCENTS

The SOC-8 guidelines are intended to be flexible in order to meet the diverse health care needs of TGD people globally. While adaptable, they offer consensus-based standards derived from the best available scientific evidence for promoting optimal health care and guiding the treatment of people experiencing gender incongruence. As in all previous versions of the SOC, the criteria put forth in this document for gender affirming interventions are clinical guidelines; individual health care professionals and programs, in consultation with the TGD person, may modify them. Clinical departures from the SOC may occur due to a TGD person's unique anatomic, social, or psychological situation; an experienced health care professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies. These departures should be recognized as such, discussed with the TGD person, and documented. This documentation is also valuable for the accumulation of new data, which can be retrospectively examined to allow for health care—and the SOC—to evolve. This summary criteria needs to be read in conjunction with the relevant chapters (see Adult Assessment and Adolescent chapters).

SUMMARY CRITERIA FOR ADULTS

Related to the assessment process

- Health care professionals assessing transgender and gender diverse adults seeking gender-affirming treatment should liaise with professionals from different disciplines within the field of trans health for consultation and referral, if required*
- If written documentation or a letter is required to recommend gender affirming medical and surgical treatment (GAMST), only one letter of assessment from a health care professional who has competencies in the assessment of transgender and gender diverse people is needed.

Criteria for hormones

a. Gender incongruence is marked and sustained;
b. Meets diagnostic criteria for gender incongruence prior to gender-affirming hormone treatment in regions where a diagnosis is necessary to access health care;
c. Demonstrates capacity to consent for the specific gender-affirming hormone treatment;
d. Other possible causes of apparent gender incongruence have been identified and excluded;
e. Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
f. Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options.

Criteria for surgery

a. Gender incongruence is marked and sustained;
b. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;
c. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;
d. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options;
e. Other possible causes of apparent gender incongruence have been identified and excluded;
f. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;
g. Stable on their gender affirming hormonal treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated).*

*These were graded as suggested criteria

SUMMARY CRITERIA FOR ADOLESCENTS

Related to the assessment process

- A comprehensive biopsychosocial assessment including relevant mental health and medical professionals;
- Involvement of parent(s)/guardian(s) in the assessment process, unless their involvement is determined to be harmful to the adolescent or not feasible;
- If written documentation or a letter is required to recommend gender-affirming medical and surgical treatment (GAMST), only one letter of assessment from a member of the multidisciplinary team is needed. This letter needs to reflect the assessment and opinion from the team that involves both medical and mental health professionals (MHPs).

Puberty blocking agents

a. Gender diversity/incongruence is marked and sustained over time;
b. Meets the diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care;
c. Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment;
d. Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally.
e. Informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility;
f. Reached Tanner stage 2.

AR-001842

Hormonal treatments

a. Gender diversity/incongruence is marked and sustained over time;
b. Meets the diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care;
c. Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment;
d. Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally.
e. Informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility;
f. Reached Tanner stage 2.

Surgery

a. Gender diversity/incongruence is marked and sustained over time;
b. Meets the diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care;
c. Demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment;
d. Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally.
e. Informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility;
f. At least 12 months of gender-affirming hormone therapy or longer, if required, to achieve the desired surgical result for gender-affirming procedures, including breast augmentation, orchiectomy, vaginoplasty, hysterectomy, phalloplasty, metoidioplasty, and facial surgery as part of gender-affirming treatment unless hormone therapy is either not desired or is medically contraindicated.

Appendix E GENDER-AFFIRMING SURGICAL PROCEDURES

As the field's understanding of the many facets of gender incongruence expands, and as technology develops which allows for additional treatments, it is imperative to understand this list is not intended to be exhaustive. This is particularly important given the often lengthy time periods between updates to the SOC, during which evolutions in understanding and treatment modalities may occur.

FACIAL SURGERY	
Brow	• Brow reduction • Brow augmentation • Brow lift
Hair line advancement and/or hair transplant	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	
Facelift/mid-face lift (following alteration of the underlying skeletal structures)	• Platysmaplasty
Blepharoplasty	• Lipofilling
Rhinoplasty (+/- fillers)	
Cheek	• Implant • Lipofilling
Lip	• Upper lip shortening • Lip augmentation (includes autologous and non-autologous)
Lower jaw	• Reduction of mandibular angle • Augmentation
Chin reshaping	• Osteoplastic • Alloplastic (implant-based)
Chondrolaryngoplasty	• Vocal cord surgery (see voice chapter)
BREAST/CHEST SURGERY	
Mastectomy	• Mastectomy with nipple-areola preservation/reconstruction as determined medically necessary for the specific patient • Mastectomy without nipple-areola preservation/reconstruction as determined medically necessary for the specific patient
Liposuction	
Breast reconstruction (augmentation)	• Implant and/or tissue expander • Autologous (includes flap-based and lipofilling)
GENITAL SURGERY	
Phalloplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Metoidioplasty (with/without scrotoplasty)	• With/without urethral lengthening • With/without prosthesis (penile and/or testicular) • With/without colpectomy/colpocleisis
Vaginoplasty (inversion, peritoneal, intestinal)	• May include retention of penis and/or testicle
Vulvoplasty	• May include procedures described as "flat front"
GONADECTOMY	
Orchiectomy	
Hysterectomy and/or salpingo-oophorectomy	
BODY CONTOURING	
Liposuction	
Lipofilling	
Implants	• Pectoral, hip, gluteal, calf
Monsplasty/mons reduction	
ADDITIONAL PROCEDURES	
Hair removal: Hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process. (see Statement 15.14 regarding hair removal)	• Electrolysis • Laser epilation
Tattoo (i.e., nipple-areola)	
Uterine transplantation	
Penile transplantation	

AR-001844

U.S. Department of Justice

Federal Bureau of Prisons

Washington, D.C. 20534
November 26, 2014

MEMORANDUM FOR:

DONNA ZICKEFOOSE, WARDEN FCC ALLENWOOD,
JODY R. UPTON, WARDEN FMC CARSWELL,
N. C. ENGLISH, WARDEN FCI MARIANNA,
D. R. STEPHENS, WARDEN FCI MEMPHIS,
R. C. CHEATHAM, WARDEN FCI MIAMI,
MONICA RECKTENWALD, WARDEN FCI OTISVILLE,
ERIC D. WILSON, WARDEN FCC PETERSBURG,
LINDA SANDERS, WARDEN USMCFP SPRINGFIELD,

FROM: RADM Newton E. Kendig, Assistant Director
Health Services Division

SUBJECT: Transgender Clinical Care Consultant Team

The Health Services multi-divisional Mental Health Clinical Care Committee (MHCC) has established the Transgender Clinical Care Consultant Team. This team will provide consultation to Bureau clinical staff treating inmates with transgender concerns. Each of these professionals has participated in training on transgender issues and has shown an interest in developing and providing expertise in this area. I ask for your support in allowing your staff to participate on this team (for which they have volunteered). Participation on the team will likely involve an occasional in-person or continuing education session; but the bulk of the work will be done virtually on an as-needed basis.

Transgender Clinical Care Consultant Team:
The following individuals have been nominated to participate on the team:

- Dr. Elizabeth Santos, Clinical Director, FCI Allenwood - **Chair**
- Dr. Vu Huy Le, Psychiatrist, USMCFP Springfield
- Dr. Todd Cornett, Chief Psychiatrist, FCI Miami

- CDR Amanda Irving, Board Certified Psychiatric Pharmacist (BCPP), FCI Petersburg
- LCDR William Lehault, BCPP, Chief Pharmacist, FCI Otisville
- Zachary McDonough - Social Worker, FMC Carswell
- Audra McConnell - Social Worker, USMCFP Springfield
- Dr. Kevin Pistro, SOMP Coordinator, FCI Marianna
- Dr. Keidy Ding, Staff Psychologist, FCI Memphis
- Dr. Jim Pelton, Regional Medical Director, WXR

Please respond via e-mail to BOP-HSD/Assistant Director, with a copy to LaShonda Taylor-Weaver, Administrative Officer at lxtaylor@bop.gov to indicate your decision about your staff's involvement. Once we have heard from you, we will send an e-mail to the Committee (through you) to notify your staff member of his/her selection.

If you have questions regarding this initiative, please feel free to contact Dr. Deborah Schult, SDAD at dschult@bop.gov or (202)307-3055.

Attachment

cc: Linda McGrew, AD, RSD
Ken Hyle, SDAD, OGC
Deborah Schult, SDAD, HSD
Patti Butterfield, Administrator, PSB
Chris Bina, Chief Pharmacist, HSD
Don Lewis, Chief Psychiatrist, HSD
Jay Seligman, Chief Social Worker, HSD



FEDERAL BUREAU OF PRISONS

TRANSGENDER

RESOURCE GUIDE

November 2014

Introduction

This document serves as a resource guide for Bureau of Prisons (BOP) staff working with inmates diagnosed with Gender Dysphoria (GD), by compiling information from various sources, such as BOP policies, the Diagnostic and Statistical Manual of Mental Disorders – Fifth Edition (DSM-5), World Professional Association for Transgender Health (WPATH) standards, and regulations promulgated under the Prison Rape Elimination Act (PREA).

Please note that this resource guide is meant to assist staff in working with inmates with GD by providing general information. [1] The Master Agreement, regulations, and policy, should be followed at all times. Clinicians should also use the most up to date DSM and medical criteria. Further, specific practices will need to be determined by institution staff, based on an inmate's individual treatment needs.

Definitions

GD is defined by DSM-5 as, "A strong and persistent cross-gender identification. It is manifested by a stated desire to be the opposite sex and persistent discomfort with his or her biologically assigned sex."

Other terms which may useful include:

- **Gender** – a psychosocial construct used to classify a person as man, woman, both or neither. Gender encompasses all relational aspects of social identity, psychological identity, and human behavior.
- **Gender identity** – a person's sense of their own gender, which is communicated to others by their gender expression.
- **Gender expression** – includes mannerisms, clothing, hair style and choice of activities
- **Transgender** – can often be used instead of GD. It is the state of one's gender not matching one's assigned sex. It does not imply any form of sexual orientation
- **Sexual orientation** – the direction of one's sexual interest towards members of the same, opposite or both genders
- **Heterosexual** – a person attracted to the opposite sex
- **Homosexual** – a person attracted to the same sex
- **Lesbian** – a female homosexual
- **Gay** – a person of homosexual orientation, mostly reserved for male homosexuals
- **Bisexual** – a person attracted to both sexes
- **Asexual** – a person not attracted to either sex
- **Intersex** - a person whose sexual or reproductive anatomy or chromosomal pattern does not seem to fit typical biological definitions of male or female.

[1] In May, 2013, the DSM updated its terminology, changing "Gender Identity Disorder" or "GID" to "Gender Dysphoria" or "GD" Although GID is used in references from before the change in the DSM, this document uses GD for consistency purposes.

Standards for Assessment of GD

Identification of GD involves two important components: 1) the diagnosis of GD; and 2) a comprehensive assessment of affective, cognitive, and psychosocial factors that determine the optimal approach to clinical care.

The DSM-5 criteria for a diagnosis of GD are:

A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

The comprehensive assessment includes a large number of factors for consideration in determining the optimal clinical care for each GD inmate. It is necessary for the clinician to explore the complex interplay between diagnostic and psychosocial factors present in the inmate's current social environment. The presence of co-morbid mental disorders further complicates the diagnostic picture. To conduct a comprehensive assessment, the following sources of data should be considered:

- Psychosocial evaluation, including a review of the inmate's developmental history (especially with reference to gender identity), history of sexual behavior, mental health history, and anticipated family and social support upon release.

- Review of institution adjustment, including review of sexual behavior in prison; current relations with inmate peers; level of identification with subpopulations in the correctional environment; current or anticipated safety concerns in the institution; and history of sexual victimization in prison.

- Mental status examination: 1) as part of an assessment to determine an appropriate diagnosis, and 2) as a review of such mental status factors such as level of insight, judgment, etc.

- Psychometric testing may be considered as part of an assessment to determine an appropriate diagnosis.

- Medical history and physical assessment.

Examples of factors to consider in determining optimal clinical care:

- Antisocial personality disorder may have a bearing on the inmate's motivation for seeking treatment;

- Borderline personality disorder may reflect longstanding issues of personal identity, problems with judgment or impulsivity, affective instability, etc.

- A pattern of lifestyle instability may also reflect a pattern of inconsistency in following through on stated plans or intentions;

- The presence of a paraphilia or sexual deviancy may suggest a need for treatment of a psychosexual disorder; and

- Peer associations and institution conduct may have a bearing on the inmate's motivation for seeking treatment (desire for approval from inmate peers; desire to allay concerns for personal safety; etc.).

These factors will need to be considered when determining the optimal approach to inmate care. Treatment options include:

- Supportive psychotherapy to validate the inmate's gender identity concerns, fostering self-acceptance and appropriate adjustment in the correctional setting.

- Psychotherapy to address co-morbid conditions such as borderline personality disorder (e.g., focusing on management of risk of self-harm).

- Psycho-educational interventions to review the full range of treatment options and their short-term and long-term implications; and/or

- Release counseling to assist the inmate in preparing for his/her return to the community and reintegration into his/her family.

General Treatment Methods for GD

The WPATH standards are an information resource which may provide guidance on medical and mental health treatment, which may include education, counseling, medical evaluations, hormone treatments, "real-life" experience, and, in some but not all cases, sexual reassignment surgery.

The WPATH standards define three stages of treatment for GD:

Stage 1: This is the evaluation stage where patients with possible GD are identified. A diagnosis can be made at this stage and individual or group therapy can begin if indicated. Education about GD is an important part of this stage as well.

Stage 2: If applicable, a referral to a health care provider for hormone therapy is made at this stage. This stage is also used for confirmation of the diagnosis of GD. There is continuing individual or group therapy if indicated as well.

Stage 3: At this stage, health care providers monitor gender role transition, and serve as an authoritative intermediary in matters pertaining to work and family. If applicable, providers make referral for gender reassignment surgery after an appropriate time in the preferred gender role. Post-operative follow-up is scheduled as necessary.

Medical Treatment in BOP Facilities

Program Statement 6031, Patient Care, section 30, states[2]:

"Inmates with a possible diagnosis of GD, including inmates who assert they have GD, will receive thorough medical and mental health evaluations from medical professionals with basic competence in the assessment of the DSM-5/ICD-10 sexual disorders and who have participated in BOP's GD training, including the review of all available community health records. The evaluation will include an assessment of the inmate's treatment and life experiences prior to incarceration as well as experiences during incarceration (including hormone therapy, completed or in-process surgical interventions, real life experience consistent with the inmate's gender identity, private expressions that conform to the preferred gender and counseling). If a diagnosis of GD is reached, a proposed treatment plan will be developed which promotes the physical and mental stability of the patient.

"The development of the treatment plan is not solely dependent on services provided or the inmate's life experiences prior to incarceration. The treatment plan may include elements or services that were, or were not, provided prior to incarnation, including, but not limited to: those elements of the real life experience consistent with the prison environment, hormone therapy and counseling. Treatment plans will be reviewed regularly and updated as necessary.

"Current, accepted standards of care will be used as a reference for developing the treatment plan. All appropriate treatment options prescribed for inmates with GD in currently accepted standards of care will be taken into consideration during evaluation by the appropriate medical and mental health care staff. Each treatment plan or denial of treatment must be reviewed by the Medical Director or BOP Chief Psychiatrist. Hormone therapy must be requested through the non-formulary review process, and approved by the Medical Director and /or Chief Psychiatrist. Consultation with the Chief of Psychology prior to such approval may be appropriate in some cases.

"In summary, inmates in the custody of the Bureau with a possible diagnosis of GD will receive a current individualized assessment and evaluation. Treatment options will not be precluded solely due to level of services received, or lack of services, prior to incarceration."

Specifically, treatment should involve the following:

- Inmates with GD will receive thorough medical and mental health evaluations, including the review of all available community records. The evaluation will include an assessment of the inmate's treatment prior to incarceration (including hormone therapy, completed or in-process surgical interventions, and on-going counseling).

- A proposed treatment plan will be developed which promotes the physical and mental stability of the patient. Current, published standards of care may be used as a reference when developing the treatment plan. If a plan includes advancing the treatment for a patient with GD, i.e. hormones, the Chief of Psychiatry for the BOP will be notified.

[2] Please insure most current version of policy is applied in individual cases.

- An endocrinology consult should be obtained in the case of many inmates with GD, especially those who have not been on hormones before and wish to start treatment.

- The Chief of Psychiatry will review the case and outside records, and will consult with the Medical Director and Chief of Psychology to determine the best course of action for this inmate, which may include hormone therapy.

- Should a GD diagnosis be made, continued psychological counseling will be offered if warranted.

- The Chief of Psychiatry will consult with the Medical Director and Chief of Psychology to determine if advancement of therapy, such as the beginning of a hormone regimen, is medically indicated. Each inmate will be individually evaluated on a case-by-case basis. Medication administration will be documented through the non-formulary review process. The approval of the Chief of Psychiatry is required.

- Findings and course of treatment should be documented fully in PDS/BEMR

Hormone Therapy

As noted above, providing an inmate hormone therapy may be an appropriate measure to address GD. However, hormone therapy may have potential side effects that need to be considered by the clinician, and by the inmate requesting the treatment.

Estrogen use may increase the risks of cardiovascular disease including hypertension, myocardial infarction, stroke, pulmonary emboli, and deep vein thrombosis. Estrogen users may notice a decrease or an increase in libido. Males taking estrogens may experience erectile dysfunction, impotence, and decrease in the size of the testicles.

Other side effects include breast enlargement, dark brown patches on the skin, headache, depression, migraines, elevated cholesterol levels, pancreatitis, and gallbladder disease.

Long term use of estrogens is linked to the development of endometrial cancer in women and breast cancer in both males and females. Estrogen use in males may contribute to the development of prostate cancer.

Contraindications for estrogen use are a strong family history of breast cancer or a lactotroph adenoma. Contraindications for androgen use are lipid disorders with cardiovascular complications. Contraindications for the use of either androgen or estrogen include: Cardiovascular disease, cerebrovascular disease, thromboembolic disease, marked obesity, poorly controlled diabetes, and active liver disease.

Side effects of testosterone may include gynecomastia, extensive urination, hirsuitism, acne, retention of electrolytes, nausea, jaundice, suppression of clotting factors, headache, anxiety and depression.

Contraindications for testosterone use are a known hypersensitivity to the drug, males with carcinoma of the breast, males with known or suspected carcinoma of the prostate gland, woman who are or may become pregnant, or inmates with serious cardiac, hepatic or renal disease.

Psychology Services

Bureau psychologists are available to provide assessment and treatment services for inmates with GD, using the DSM-5 to diagnose GD, if appropriate. If a diagnosis of GD is rendered, the psychologist will provide the inmate with information regarding the range of treatment options available in the Bureau and their implications. In addition, based upon the psychologist's preliminary assessment and the inmate's expressed interest, a referral to the Medical Director and/or Chief of Psychiatry may be generated.

In addition to a referral to medical services, inmates with GD may also be offered individual psychotherapy. Individual psychotherapy goals for inmates with GD might include: (1) helping the inmate live more comfortably within a gender identity and to deal effectively with non-gender issues; (2) emphasizing the need to set realistic life goals related to daily living, work, and relationships, including family of origin; (3) seeking to define and address issues which may have undermined a stable lifestyle, such as substance abuse and/or criminality; and (4) addressing any co-occurring mental health issues. Mood disorders, anxiety disorders, substance use disorders, and personality disorders, etc., may co-occur with GD and any effective treatment plan will fully address these symptoms, if present.

If an institution has multiple inmates with GD, group psychotherapy facilitated by a psychologist may also be a component of the treatment plan. Common concerns of inmates with GD, which may be addressed effectively in a group setting, include self-esteem issues and relationship issues.

Psychologists who provide mental health treatment for GD should maintain their professional set concerning suicide/crisis intervention skills and the ability to identify differential mental health diagnoses, and should further develop if necessary a capacity to promote awareness of GD needs and issues; and an overall understanding of basic gender and sexual identify concerns.

Psychologists working with inmates with GD are encouraged to consult the Psychology Services Branch and Health Services Division in Central Office for additional resources.

Initial Designation

The PREA regulations, incorporated into BOP Program Statement 5324.11, Sexually Abusive Behavior Prevention and Intervention Program, states, "In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates . . . the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems." See 28 C.F.R. § 115.42 (c).

As with all inmates, designation will be determined at the BOP's Designation and Sentence Computation Center (DSCC). Such decisions are made by weighing several factors, to include the inmate's security level, custody level, and anticipated level of required health care and programmatic requirements.

Intake Screening

The PREA regulations, incorporated into BOP Program Statement 5324.11, Sexually Abusive Behavior Prevention and Intervention Program, states, "The intake screening shall consider, at a minimum, the following criteria to assess inmates for risk of sexual victimization . . . Whether the inmate is or is perceived to be gay, lesbian, bisexual, transgender, intersex, or gender nonconforming . . ." See 28 C.F.R. § 115.41 (d).

Inmates may not be disciplined for refusing to answer, or for not disclosing complete information in response to, questions about being gay, lesbian, bisexual, transgender, intersex, or gender nonconforming. See 28 C.F.R. § 115.41 (h).

Staff shall not search or physically examine a transgender or intersex inmate for the sole purpose of determining the inmate's genital status. If the inmate's genital status is unknown, it may be determined during conversations with the inmate, by reviewing medical records, or, if necessary, learning that information as part of a broader medical examination conducted in private by a medical practitioner. See 28 C.F.R. § 115.15(e). This provision does not limit searches of inmates to ensure the safe and orderly running of the institution.

Housing and Programming Assignments

The PREA regulations, incorporated into BOP Program Statement 5324.11, Sexually Abusive Behavior Prevention and Intervention Program, states, " . . . in making . . . housing and programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems." See 28 C.F.R. § 115.42 (c).

Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experienced by the inmate. See 28 C.F.R. § 115.42 (d).

In making housing or programming assignments, a transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration. See 28 C.F.R. § 115.42 (e).

Transgender and intersex inmates shall be given the opportunity to shower separately from other inmates. See 28 C.F.R. § 115.42 (f).

The agency shall train security staff in how to conduct cross-gender pat-down searches, and searches of transgender and intersex inmates, in a professional and respectful manner, and in the least intrusive manner possible, consistent with security needs. See 28 C.F.R. §

115.15 (f). The Correctional Services Branch updates and maintains training materials on conducting pat-down searches of transgender and intersex inmates. Currently, that training instructs that transgender or intersex inmates will present different physical characteristics, which may change over the course of incarceration. Staff members should be mindful of these physical characteristics when conducting pat searches, and adjust procedures accordingly. For example, if a transgendered inmate has or develops breasts, staff should use the back of the hand to conduct a search of this area, as is appropriate for female inmates. (Note: The PREA prohibitions regarding male staff performing pat searches on female inmates does not take effect until August 2015).

Inmates should not be placed in a Special Housing Units (SHU) based solely on the inmate's GD status. In addition, if there has been an identified risk of sexual victimization, an inmate cannot be placed in involuntary segregated housing unless an assessment of all available alternatives has been made, and a determination has been made that there is no available alternative means of separation from likely abusers. See 28 C.F.R. § 115.43.

Further, an agency shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates. See 28 C.F.R. § 115.42 (g)

Staff Interactions

It is difficult for many staff members to understand that GD inmates genuinely see themselves as the opposite gender, and that being referred to as their biological gender can be irritating and demoralizing for the inmate. Ideally, staff would refer to the inmate as the identified gender once a diagnosis of GD has been given to the inmate by mental health staff. This practice is more likely to facilitate a cooperative relationship between the inmate and staff members, and to reduce the stress of gender transformation in a correctional environment. Please note this is distinct from a legal name change while in BOP custody, which must be done consistent with Program Statement 5800.15, or the most current version of policy.

Clothing and Commissary Items

Typically, GD inmates will want to wear clothing that reflects their identified gender. To the extent possible consistent with security and safety concerns, these inmates should be allowed to dress as the identified gender even if they are not housed with inmates of the identified gender. This practice allows for increased gender comfort, which is an important part of gender transformation. The idea is not to go beyond what the agency allows for the identified gender, but rather to allow items that are typically allowed for the identified gender which may not be readily available at a facility that houses inmates of the biological gender. In other words, items typically allowed to female inmates may not be readily available at a male prison, but should be made available to GD inmates because of their dysphoria. It should not be necessary to go beyond what is typically given to female inmates, however, to facilitate gender comfort.

Multi-Disciplinary Approach

The needs of an inmate with GD may impact several departments at an institution, to include Health Services, Psychology Services, Correctional Services, Legal, Unit Team, etc. It is therefore recommended that the necessary Department Heads consult as needed for treatment issues, and accommodations that may be needed to assist with an inmate's adjustment.

Similarly, if there are specific issues concerning GD treatment of an individual inmate, a Warden or the Chief, DSCC can make a request for further guidance to the Medical Director. The Medical Director will then have the matter reviewed by Health Services, Psychology Services, Correctional Services, the Office of General Counsel, and other appropriate office.

Summary

The most important thing to remember is to treat every inmate with GD as an individual. This Resource Guide can be used as a tool in the multi-disciplinary treatment approach to inmates with GD, but is not the only way to treat the inmate. Please contact local Psychology or Psychiatry Services for further questions.

MEDICAL MANAGEMENT OF TRANSGENDER INMATES

Federal Bureau of Prisons

Clinical Guidance

DECEMBER 2016

Federal Bureau of Prisons (BOP) Clinical Guidance is made available to the public for informational purposes only. The BOP does not warrant this guidance for any other purpose, and assumes no responsibility for any injury or damage resulting from the reliance thereof. Proper medical practice necessitates that all cases are evaluated on an individual basis and that treatment decisions are individual-specific. Referenced Program Statement versions within this guideline are for informational purposes only. Please refer to the most current versions of any referenced Program Statement(s). Consult the BOP Health Management Resources Web page to determine the date of the most recent update to this document: http://www.bop.gov/resources/health_care_mngmt.jsp

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1. PURPOSE

The Federal Bureau of Prisons (BOP) Clinical Guidance for *Medical Management of Transgender Inmates* provides recommendations for the medical management and treatment of transgender federal inmates, referred to in these guidelines as *individual(s) or person(s)*.

2. INTRODUCTION

NATURAL HISTORY

TRANSGENDER (**TG**) individuals are those whose gender identity is different from their biological sex. **GENDER DYSPHORIA** (**GD**), previously known as **GENDER IDENTITY DISORDER** (**GID**), is the *discomfort or distress* caused by a discrepancy between a person's **GENDER IDENTITY** and that person's **GENDER** assigned at birth. Not all **TG** will be diagnosed with **GD**, and a diagnosis of **GD** is not required for access to services. Data indicate significantly higher rates of mental health morbidity among **TG** individuals, compared with the general population—particularly anxiety, depression, and suicidality. Present-day treatment approaches involve supporting individuals in modifying their lifestyle—and if indicated, physically modifying their body—to better match the gender with which they psychologically identify.

DEFINITIONS

ASEXUAL: Refers to a person not attracted to either sex.

BISEXUAL: Refers to a person attracted to both sexes.

BOP TRANSGENDER CLINICAL CARE TEAM (TCCT): A multidisciplinary group of BOP personnel with **TG** subject matter expertise. The team provides assistance to institution staff and develops clinical treatment recommendations for the BOP **TG** population.

BOP TRANSGENDER EXECUTIVE COUNCIL (TEC): A group of BOP management personnel who mitigate executive level non-clinical issues. This group provides oversight to the **BOP TCCT**.

FEMALE-TO-MALE (FTM): Refers to a biological female who identifies as, or desires to be, a member of the male gender. The term *transgender male*, or *trans male* for short, is used to refer to the **GENDER IDENTITY** of a person who is **FTM**. (See the definition of **TRANSGENDER** below.)

GAY: Refers to a person who is romantically or sexually attracted to persons of the same gender. The term is mostly used to describe males. (See the definition of **LESBIAN** below.)

GENDER: A biopsychosocial construct used to classify a person as male, female, both, or neither. **GENDER** encompasses all relational aspects of social identity, psychological identity, and human behavior.

GENDER-AFFIRMING HORMONES: Hormonal therapy utilized to facilitate biological change(s) during **TRANSITION.** The term **CROSS-SEX HORMONES** is often utilized in the medical literature.

GENDER CONFORMITY: Behavior and appearance that adheres to the social expectations of a particular **GENDER**. (See the definition of **GENDER NONCONFORMITY** below.)

GENDER DYSPHORIA (GD): The condition of feeling that one's emotional and psychological identity as male or female is different from one's biological sex. By definition, **GD** implies that there is a state of distress or anxiety directly related to this conflict. In the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)*, released in May 2013, people whose assigned sex at birth is contrary to the one they identify with *and* who are experiencing a state of distress should be diagnosed with **GD**. This diagnosis is a revision of the criteria in the *DSM-IV* for **GENDER IDENTITY DISORDER**, and is intended to better characterize the experiences of affected individuals.

➔ *Individuals identifying as TG do not necessarily have GD.*

GENDER EXPRESSION: Includes mannerisms, clothing, hair style, and choice of activities that individuals use to express their **GENDER IDENTITY**.

GENDER IDENTITY: Individuals' own sense of their **GENDER**, which they may choose to communicate to others by means of **GENDER EXPRESSION**.

GENDER IDENTITY DISORDER (GID): Strong, persistent feelings of identification with the opposite gender and discomfort with one's own assigned sex.

➔ *The DSM-5 no longer uses this term. See the definition of* **GENDER DYSPHORIA** *above.*

GENDER NONCONFORMITY: Behavior or appearance that does not match the societal roles or expectations for one's assigned **GENDER**.

HETEROSEXUAL: Refers to a person attracted to the opposite gender.

HOMOSEXUAL: Refers to a person attracted to the same gender.

INTERSEX: Refers to a person whose sexual/reproductive anatomy or chromosomal pattern does not seem to fit the typical biological definition of male or female.

LESBIAN: Refers to a female who is attracted to other females.

MALE-TO-FEMALE (MTF): Refers to a biological male who identifies as, or desires to be, a member of the female gender. The term *transgender female*, or *trans female* for short, is used to refer to the **GENDER IDENTITY** of a person who is **MTF**. (See the definition of **TRANSGENDER** below.)

REAL-LIFE EXPERIENCE (RLE): When individuals live as the **GENDER** with which they identify.

SEX: A biological classification based on chromosomal composition, reproductive anatomy (primary sex characteristics), and phenotypic characteristics (secondary sex characteristics) that develop during pubertal maturation.

SEX REASSIGNMENT SURGERY: The surgical component of an individual's **TRANSITION**; also referred to as **GENDER-AFFIRMING SURGERY**.

SEXUAL ORIENTATION: The direction of one's sexual interest toward members of the same sex, the opposite sex, both, or neither.

TRANSGENDER (TG): A general term used for individuals whose **GENDER IDENTITY** does not conform to the typical expectations associated with the gender they were assigned at birth.

- While the term is often used synonymously with the term **GD**, being **TG** does not necessarily imply anxiety or distress about one's gender not matching one's assigned sex.
- The term **TRANSGENDER** also does *not* imply a particular **SEXUAL ORIENTATION.**
- A **MALE-TO-FEMALE (MTF) TRANSGENDER** person refers to a biological male who identifies as, or desires to be, a member of the female gender; a **FEMALE-TO-MALE (FTM) TRANSGENDER** person refers to a biological female who identifies as, or desires to be, a member of the male gender.

TRANSITION: The period during which **TG** individuals change their physical, social, and legal characteristics to the gender with which they identify. **TRANSITION** may also be regarded as an ongoing process of physical change and psychological adaptation.

SPECIAL CONSIDERATIONS

STIGMA

Stigma and prior negative experiences in institutions can impede transition services, and/or diagnosis and treatment of **GD**.

SUICIDALITY

Transgender adults with **GD** are at an increased risk of suicidal ideation and suicide prior to initiation of their gender transition, regardless of the clinical endpoint of their **TRANSITION—** whether that endpoint is living as the psychologically identified gender, hormone therapy, cosmetic treatments, breast augmentation/removal, and/or sex reassignment surgery. For many individuals, the risk of suicide may decrease after receiving the appropriate, individual treatment.

COMORBID CONDITIONS

- The most common comorbid conditions seen in **TG** adults with **GD** are anxiety and depression.
- Epidemiologic studies indicate a higher prevalence of HIV in the **TG** populations, specifically among **MtF** persons.

➔ *See CDC, HIV Among Transgender People, #13 in the References section.*

GENERAL INTERACTIONS WITH TRANSGENDER INDIVIDUALS

Respect and trust are essential to a clinician-client (physician-patient) relationship. Respectful language and terms should always be used when discussing or referring to all individuals regardless of gender. Once an individual has identified as **TG**, use of pronouns or salutations preferred by the **TG** individual is appropriate, especially for those inmates with a Case Management Activity (CMA) Sentry assignment of **TRANSGENDER** (either TRN M2F or TRN F2M). This practice is more likely to facilitate a cooperative relationship between the **TG** individual and others, and generally reduces the stress of gender transition.

➔ *Please note that this informal approach is distinct from a legal name change while in BOP custody; a legal name change must conform to the policy requirements in the Correctional Systems manual, currently Program Statement 5800.15 (or the most recent version).*

MULTIDISCIPLINARY TREATMENT APPROACH

A multidisciplinary approach is recommended for managing issues associated with the incarceration of **TG** individuals, including the provision of medical treatment when indicated. Institutional staff training programs should consider incorporating Continuing Medical Education on the clinical care of **TG** individuals.

The BOP offers **TRAUMA-INFORMED CORRECTIONAL CARE (TICC),** which incorporates an understanding that inmate attitudes, behaviors, and concerns are likely to be affected by prior traumatic experiences. **TICC** includes both training and treatment programs, emphasizes the recognition of trauma in all forms, and incorporates the principle that all staff may have a role in reducing its impact. Subject matter experts within the BOP are available to assist providers and other staff working with **TG** inmates.

HOUSING ASSIGNMENTS, PROGRAM ASSIGNMENTS, AND PAT SEARCHES

- *Refer to the current version of BOP Program Statement 5324.11, Sexually Abusive Behavior Prevention and Intervention Program.*
- *Refer also to the Transgender Offender Manual Program Statement.*

3. INTAKE SCREENING REGULATIONS

Prison Rape Elimination Act (PREA) regulations, incorporated into *BOP Program Statement 5324.11, Sexually Abusive Behavior Prevention and Intervention Program*, state that the intake screening shall consider, at a minimum, the following criteria to assess individuals for risk of sexual victimization—whether the individual is known or perceived to be gay, lesbian, bisexual, **TG**, intersex, or gender nonconforming.

- ***See 28 C.F.R. § 115.41 (d).***

Individuals may not be disciplined for refusing to answer, or for not disclosing complete information in response to, questions about being gay, lesbian, bisexual, **TG**, intersex, or gender nonconforming.

- ***See 28 C.F.R. § 115.41 (h).***

Staff shall not search or physically examine any inmate, to include a **TG** or intersex individual, for the sole purpose of determining the individual's genital status. If the individual's genital status is unknown, and as appropriate, it may be determined during conversations with the individual, by reviewing medical records, or, if necessary, learning that information as part of a broader medical examination conducted in private by a medical provider.

- ***See 28 C.F.R. § 115.15 (e).*** *This provision does not limit searches of individuals to ensure the safe and orderly running of the institution.*

4. TRANSGENDER-IDENTIFYING CHARACTERISTICS

Transgender status is based on an individual's self-report of identifying characteristics. When an individual self-identifies as **TG**—or requests referral or evaluation for treatment—a medical and/or mental health evaluation is conducted according to policy, and as clinically appropriate to fully evaluate the individual's treatment needs.

The following criteria may be useful in identifying a person's status as **TG**:

A persistent and marked difference between a person's preferred gender and their biologic or natal sex, which may be experienced as or accompanied by:

- ***Strong feelings about primary or secondary sex characteristics;***
- ***Strong feelings about being treated as or becoming another gender; or***
- ***Belief that one's actions, feelings, or mannerisms are more characteristic of another gender.***

ELECTRONIC MEDICAL RECORD (EMR) CODES

For purposes of providing appropriate medical treatment and management, all individuals who identify as **TG**—whether or not they are receiving hormone treatment—need to have the appropriate code for transgender individuals entered into the EMR health problem list, as listed below in *Table 1.*

TABLE 1. EMR CODES FOR TRANSGENDER INDIVIDUALS

BOP Transgender Determination	EMR Codes[1,2]	Corresponding Sentry CMA Codes
Transgender, male to female	F64.0f	TRN M2F
Transgender, female to male	F64.0m	TRN F2M

[1] *EMR Transgender codes are solely for the use of clinical providers during the course of medical intervention and treatment. The respective codes are to be applied to inmates whose transgender identity has been confirmed and for whom medical treatment is appropriate, as described in the Transgender Offender Manual Program Statement and in this BOP Clinical Guidance.*

[2] *If an individual has undergone sex reassignment surgery, use code Z87.890 (Personal History of Sex Reassignment) along with the appropriate F64 code above.*

IMPORTANCE OF CODING TG INDIVIDUALS: Coding of the **TG** determination status is imperative for accurate individual records to ensure all individuals are receiving appropriate care and management. All BOP individuals who self-identify as **TG**, or are identified by history or current presentation as **TG**, need to be assessed by the appropriate psychology and/or health service staff in a timely fashion. Treatment and management of the **TG** individual are individualized and proceed from a thoughtful assessment, consideration of the individual's presentation and preferences, and attention to safety and security needs of the individual. This is all performed within the context of ensuring the safe and orderly operation of the institution.

5. ASSESSMENT AND MANAGEMENT OF THE TG INDIVIDUAL – A MULTIDISCIPLINARY APPROACH

Healthcare for **TG** individuals requires a multidisciplinary approach. The following process is recommended for transgender individuals (especially those newly identifying as **TG**) seeking medical intervention to assist with gender transition needs:

- **FIRST STEP – MENTAL HEALTH ASSESSMENT:** The first step in the process is for the individual to be seen by psychology staff for a comprehensive mental health assessment. Psychology staff will be able to confirm an individual's **TG** identity, diagnose mental health conditions based on DSM criteria, address the inmate's mental health concerns, and provide individualized counseling support and other interventions as appropriate.

  ➔ *See Section 6, Mental Health Assessment.*

- **SECOND STEP – MEDICAL ASSESSMENT:** The second step is for psychology staff to refer the individual for an evaluation by a medical provider if the patient desires medical intervention. If appropriate, the medical provider can initiate hormone therapy after the risks and benefits have been discussed with the individual, and the **BOP TCCT** has been consulted. Pharmacists may also play a role in treatment by counseling individuals on medications and recommending appropriate medication selection and/or lab monitoring to the medical provider. Psychiatrists may be consulted in cases of significant mental health challenges requiring medical intervention.

  ➔ *See Section 7, Medical Assessment.*

- **THIRD STEP – INDIVIDUALIZED TREATMENT:** In many cases, treatment is designed to reduce characteristics of the natal sex and induce those of the identified gender, allowing individuals to project their **GENDER IDENTITY**. The treatment and management of the **TG** individual requires individualized care guided by treatment goals to allow for successful **TRANSITION** through education, counseling, real-life experience, medical evaluation, hormone treatment, and in some cases, sex reassignment surgery.

  ➔ *See Section 8, Stepwise Approach to Medical and Mental Health Treatment of TG Individuals.*

GENDER DYSPHORIA (GD) CRITERIA

Individuals identifying as transgender do not necessarily have GD. Although data are insufficient to know the prevalence rates of **GD** in the transgender population, anecdotally many clinicians report that most transgender individuals experience some degree of dysphoria in the absence of treatment. Because untreated or under-treated **GD** is associated with increased morbidity and mortality, screening for **GD** in **TG** individuals is essential. Without treatment, this population may experience higher rates of depression, anxiety, and suicidality. Treatment modalities may include psychotherapy, supportive changes in gender expression and role, hormone therapy, and surgical therapy. Where indicated, hormonal interventions may improve **GD**, mental health comorbidities, and overall quality of life.

The DSM-5 criteria may be used to make the diagnosis of GD, and include two major categories: (1) Gender incongruence, i.e. a significant difference between a person's experienced or expressed gender and their assigned gender, and **(2)** significant distress or dysfunction that results from the gender incongruence. Readers are referred to the DSM-5 or to the DSM website (subscription required for access to copyrighted material) for the specific DSM-5 criteria.

➔ *See DSM-5, #1 in the References section.*

A diagnosis of **GD** will be recorded in the EMR health problem list under the appropriate DSM code (F64.1). Referral to a mental health professional for co-management of **GD** is recommended.

6. MENTAL HEALTH ASSESSMENT

Transgender status is based on an individual's self-report. Therefore, the history or subjective component of the evaluation serves as the primary source for identifying a person as TG. When transgender individuals request mental health services or are referred to Psychology Services, or when medical intervention for **TG** transition is being considered, it is appropriate to conduct a mental health evaluation.

The mental health assessment typically includes: (1) Obtaining a history of gender identity and screening for **GD**; **(2)** screening for other mental health disorders related to autism, eating, mood, personality, psychosis, and substance use; **(3)** identifying a history of abuse or neglect and any current or past self-harm ideations or attempts; **(4)** performing an assessment of affective, cognitive, and psychosocial functioning, if indicated; **(5)** psychosocial treatment recommendations; and/or **(6)** medical referral, if indicated.

➔ *Please also refer to APA, Guidelines for psychological practice with transgender and gender nonconforming people, #12 in the References section.*

DIAGNOSTIC ASSESSMENT

Diagnostic assessments are completed in PDS-BEMR under the title Diagnostic and Care Level Formulation and include the following:

- **PRESENTING PROBLEMS/SYMPTOMS:** Outline the individual's concerns, including who made the referral and when.
- **RELEVANT HISTORICAL INFORMATION:** This psychosocial history may include a review of the individual's developmental history (including gender identity), sexual history (including sexual predation or victimization), trauma, mental health history, suicide attempts or self-harm, criminal history, educational experience and progress, family dynamics, peer relations, and social support expected upon release.
- **DIAGNOSTIC FORMULATION:** If applicable, list diagnostic impressions.
- **CARE LEVEL FORMULATION:** Provide a discussion of the individual's ongoing need for mental health services and assign a care level consistent with the individual's needs.

MENTAL HEALTH TREATMENT CONSIDERATIONS

The mental health team plays an important role in diagnosing individuals, as well as providing psychotherapy and counseling:

- **INDIVIDUAL'S UNDERSTANDING/EXPECTATIONS OF TREATMENT OPTIONS:** Prior to engaging in treatment, conversations regarding the individual's expectations of outcome are required in order to identify realistic goals.
  - ➔ *A collaborative education session for the inmate, with both psychology and medical services staff, is highly recommended.*
- **PSYCHOTHERAPY:** This is a general term for treating mental health problems by the individual discussing them with a mental health provider. Psychotherapy can be used to learn about and treat an individual's moods, thoughts, and behaviors. It can also be supportive to individuals experiencing distressing thoughts and/or feelings.
- **PSYCHIATRY SERVICES:** Individuals can also be referred to psychiatry services for mental health concerns or medication management of other mental illness in conjunction with **GD**.
  - ➔ *A psychiatry consult is not needed for a diagnosis of GD. The diagnosis may be made by another mental health provider, based on DSM-5 criteria.*

7. MEDICAL ASSESSMENT

Once Psychology Services has completed the mental health assessment and ascertained the individual's **TG** goals—or otherwise determined that the individual is in need of a medical evaluation—the psychologist will refer the individual to the appropriate Health Services staff for specific medical interventions. A medical assessment should include:

- **REVIEW OF THE MENTAL HEALTH ASSESSMENT**
- **ASSESSMENT OF OVERALL HEALTH**
- **ASSESSMENT OF PREVIOUS TREATMENT** (hormonal therapy, surgery, etc.).
- **CO-OCCURRING MEDICAL DISORDERS:** Given the increased risk for individuals with thrombotic, hepatic, and oncological conditions who undergo hormonal therapy, it is crucial that comorbid conditions be managed appropriately and carefully.
  - ➔ *Please note that comorbidities are not necessarily a contraindication to therapy and must be assessed for each individual. See more about drug risks in Table 3 (**MTF**) and Table 4 (**FTM**).*
- **INFORMED CONSENT:** Individuals must be counseled on the risks and long-term effects of hormonal therapy. Use of gender-affirming hormones in the management of **TG** individuals is considered an off-label use and does not currently have FDA approval. Due to the irreversibility of some of the treatment options and the side effects, the individual's informed consent is required before initiating treatment and must be documented within the medical record.
  - ➔ *See Section 12, Patient Education & Informed Consent.*

- **CONTRAINDICATIONS:**
  - ➔ *See the Treatment Summary Charts in Appendix 1a (**MTF**) and Appendix 1b (**FTM**) for medication-specific contraindications.*

  MTF

  - **ABSOLUTE:** History of estrogen-sensitive cancer (e.g., breast cancer); history of thromboembolic disease (unless provided with concurrent anti-coagulation therapy); history of macroprolactinoma.
  - **RELATIVE:** Liver, kidney, or heart disease/stroke (or risk factors for heart disease such as high cholesterol, diabetes, obesity, smoking); strong family history of breast cancer or thromboembolic disease; gallbladder disease.

  FTM

  - **ABSOLUTE:** Pregnancy; breast feeding; history of breast cancer (testosterone may have anti-proliferative effects on most, but not all, breast cancers).
  - **RELATIVE:** Androgen-sensitive epilepsy; migraines; sleep apnea; polycythemia (elevated red blood cell count); cardiac failure; renal failure or severe hypertension susceptible to salt retention and fluid overload; significant liver disease; coronary artery disease (CAD) or risk factors for CAD; history of uterine cancer; bleeding disorders (for injected testosterone); significant history of violent behavior.

8. STEPWISE APPROACH TO MEDICAL AND MENTAL HEALTH MANAGEMENT OF TG INDIVIDUALS

Table 2 summarizes the step-by-step approaches to medical and mental health management of **TG** individuals in the BOP. It should be noted that ongoing release preparation and BOP Social Worker referral may facilitate a successful return to the community.

➔ *See Section 9, Hormone Treatment, Section 10, Medications for MtF Individuals, and Section 11, Medications for FtM Individuals for more detailed information on medical treatment.*

TABLE 2. STEPWISE APPROACH TO MTF AND FTM MEDICAL AND MENTAL HEALTH MANAGEMENT

1	Individual identifies as **TG** and seeks medical intervention to assist with transition; mental health assessment provided (see *Section 6*); continuation of counseling by psychology services if indicated; and implementation/initiation of **REAL-LIFE EXPERIENCE (RLE)**.	
2	Referral to medical provider for medical evaluation; laboratory workup; discussion of realistic expectations of hormonal therapy; and informed consent for hormone treatment. See Section 7.	
3	Discussion with **BOP TCCT** and psychiatric clinical pharmacist consultant, followed by a non-formulary request submission.	
4	***MtF***	***FtM***
	Once non-formulary request has been approved, begin hormonal therapy with anti-androgen (spironolactone first, unless contraindicated) and estrogen (see *Appendix 1a* for choosing a preparation). Start low and titrate to appropriate level while using lowest effective dose. ➔ *See Hormone Therapy for MtF in Section 9.*	Once non-formulary request has been approved, begin hormonal therapy with testosterone (see *Appendix 1b* for choosing a preparation). Start low and titrate to appropriate level while using lowest effective dose. ➔ *See Hormone Therapy for FtM in Section 9.*
5	***MtF***	***FtM***
	If treatment has reached maximum estrogen dose without seeing desired effects, consider adding another anti-androgen such as finasteride, gonadotropin-releasing hormone (GnRH) agonist, or medroxyprogesterone. Consult **BOP TCCT**.	If still experiencing uterine bleeding after first few months of high-dose testosterone therapy, consider adding medroxyprogesterone or a GnRH agonist to suppress menstruation. Consult **BOP TCCT**.
6	Evaluation of individual by **BOP TCCT** for potential appropriateness of surgical intervention upon institution referral. ➔ *See Section 12 for general criteria for consideration of surgery.*	
7	Surgical intervention.*****	

***** For further considerations, please refer to the most recent guidelines from the World Professional Association on Transgender Health (WPATH), the Endocrine Society, and the American Association of Obstetricians and Gynecologists (Committee Opinion), available at: *http://www.wpath.org/site_page.cfm?pk_association_webpage_menu=1351*.

Cases will be reviewed on a case by case basis by BOP Central Office through a referral from the **BOP TCCT**.

9. HORMONE TREATMENT: ELIGIBILITY, GOALS, OVERVIEW

Hormone supplementation is an important part of transitional treatment for many transgender individuals. Studies demonstrate improvement (in the range of 70–80%) in gender dysphoria, mental health, quality of life, and sexual function, for transgender treatment that included hormone therapy. The goals of hormone treatment are **(1)** to suppress endogenous hormones and physical characteristics of the natal sex and **(2)** to supplement hormones and enhance characteristics of the preferred gender, utilizing the principles of hormone replacement therapy for hypogonadal individuals of the **TG** individual's identified gender.

➔ *The information in this section is in part adapted from VA Pharmacy Benefits Management Services, Transgender Cross-Sex Hormone Therapy Use, (#2 in the References section) and Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline (#3 in the References section).*

ELIGIBILITY AND READINESS FOR GENDER-AFFIRMING HORMONE THERAPY

WPATH CRITERIA: Current WPATH guidelines identify four eligibility criteria for hormone therapy, but also emphasize the need for individualized treatment plans that may include hormone therapy in selected cases that do not meet all four criteria. The WPATH criteria are as follows:

(1) Gender dysphoria that is persistent and documented.

(2) Medical and/or mental health conditions, if present, are reasonably well-controlled.

(3) Legal age of majority (currently 18 years in all states except Alabama and Nebraska, which use 19 years).

(4) Informed consent.

ENDOCRINE SOCIETY CRITERIA: As part of their eligibility criteria, the Endocrine Society also includes ICD-10 criteria for transsexualism as an alternate criterion for gender dysphoria, and requires three months of documented real life experience or psychotherapy. The Endocrine Society further describes readiness criteria to include further consolidation of the preferred gender identity and progress in the gender transition, as well as willingness and ability to take hormones as prescribed.

HORMONE THERAPY FOR MALE-TO-FEMALE (MTF)

Feminizing treatment is generally the more complex of the two gender-affirming regimens and consists of either one medication alone or a combination of an anti-androgen and an estrogen, with a potential progestin adjunct. Most clinical studies and guidelines recommend therapy with an anti-androgen and an estrogen, although androgen suppression may be used alone in individuals desiring a more androgynous appearance.

- **Individuals should have realistic expectations of the treatment results, as well as the timeline of when to expect them.** Medical staff should provide enough information on an ongoing basis to help individuals set these realistic expectations. Every case is different, and slow change can lead to frustration. It is important to discuss realistic expectations with the

individual in order to avoid any attempts to self-increase the dosage in hopes of speeding up results.

- Within the first six months of treatment, changes may be seen in body fat redistribution, loss of muscle mass, breast growth, testicular atrophy, decreased erections, decreased sperm production, and a slowing of body/facial hair growth.
- The maximum effect of treatment may not be seen for more than two years.
- Treatment does not provide voice alteration, and training to feminize the voice with a speech pathologist may be indicated, based on consultation with the **BOP TCCT**.

- Most treatment results are reversible upon cessation of treatment, but breast growth is permanent and infertility may be irreversible.
- Goal levels of treatment are serum estradiol <200 pg/ml (premenopausal level) and testosterone <55 ng/dl. Serum estradiol levels should not exceed those of a premenopausal female, but doses used to achieve an adequate level may be significantly higher than those used in hormone replacement therapy in menopausal women.
  - It is important to note that there are individuals who do not require estradiol as part of their hormonal therapy regimen and do well on an anti-androgen therapy alone. There are others who require very little estrogen to obtain desired body characteristics and adequately treat any presenting dysphoria.
  - Individuals should uniformly be treated with the lowest effective hormone doses. As previously stated, estradiol levels should not routinely exceed a premenopausal level of 200 pg/ml, but the average individual does not usually require levels near that threshold. The same holds true for testosterone levels. While the goal is <55 ng/dl, there is a subset of individuals who do poorly with levels below 35 ng/dl. The ideal levels for these individuals would be between 35–55 ng/dl.
  - ➔ *Dose adjustments, based on the individual's response, are made once hormone levels are in the target range.*

HORMONE THERAPY FOR FEMALE-TO-MALE (FTM)

Masculinizing treatment is the less complex of the two gender-affirming regimens and consists mainly of testosterone supplementation.

- **The individual's realistic expectations about treatment results and the associated timeline are essential prior to beginning treatment.**
- Within the first six months of treatment, body fat redistribution, an increase in libido, an increase in acne, clitoral enlargement, vaginal atrophy, cessation of menses, and infertility may be evident. Alterations in hair growth, voice depth, and muscle mass may take longer—reaching full effects of treatment in two to five years.
- Uterine bleeding should cease within a few months of high-dose testosterone therapy, but treatments such as gonadotropin-releasing hormone (GnRH) agonists, medroxyprogesterone, and endometrial ablation may be used to stop menses prior to starting testosterone therapy or to decrease estrogen levels.

- Most effects are reversible upon cessation of treatment, but changes in hair, voice depth, and fertility may be irreversible.
- Goal treatment levels are serum estradiol <50 pg/ml and serum total 350–700 ng/dl (male physiologic range; some sources quote a normal reference range of 400-800 ng/dl). If a peak testosterone level is drawn for injectable testosterone, the level should not exceed 1,000 ng/ml. Prior to the ninth month of treatment, total testosterone levels may read high, while free testosterone levels are within the normal range. This may be due to the possibility of high levels of sex hormone binding to globulin in some women.
  - ➔ *Dose adjustments, based on the individual's response, are made once hormone levels are in the target range.*

HORMONE THERAPY DURING PREGNANCY

Gender-affirming hormone therapy is contraindicated during pregnancy. While therapy may lead to potentially irreversible infertility, it does not function as contraception, and pregnancy is still possible during treatment.

➔ *Precautions should be taken to avoid pregnancy during treatment.*

10. MEDICATIONS FOR MTF INDIVIDUALS

MTF MEDICATIONS: DRUG CLASSES

➔ *See the **MTF Treatment Summary Chart** in Appendix 1a for summarized information on each of the medication groups below—including dosing, adverse effects, contraindications, interactions, and monitoring.*

ANTI-ANDROGENS

Anti-androgens reduce testosterone levels, allowing estrogen therapy to be used in lower doses while still reaching a maximum effect. Medications with anti-androgen effects include spironolactone, finasteride, GnRH agonists, and progestins.

- **SPIRONOLACTONE** is a potassium-sparing diuretic that directly inhibits testosterone secretion and androgen binding to the androgen receptor. Spironolactone can suppress facial and body hair growth, male pattern baldness, libido, and sexually stimulated erections. It decreases symptoms of benign prostate hypertrophy (BPH) and can lead to modest breast growth.
  - ➔ *The use of spironolactone is contraindicated in renal insufficiency and with a potassium value greater than 5.5 mEq/L. Spironolactone can cause hyperkalemia and hypotension. It is important to monitor potassium levels and blood pressure of individuals taking spironolactone, as stated in Appendix 1a.*
- **FINASTERIDE** inhibits the enzyme responsible for converting testosterone to its potent form. It can be used alone at high doses (5–10 mg/day) in individuals intolerant to spironolactone, or as an adjunct to spironolactone. Effects are similar to those of spironolactone treatment, but spironolactone treatment is considered first line due to observed responses. Finasteride can be used in low doses (1 mg/day) to treat male pattern baldness. Finasteride can reduce BPH symptoms by reducing the size of the prostate.
  - ➔ *Finasteride should not be used when prostate cancer is suspected, due to its ability to lower prostate-specific antigen levels.*

- **GnRH Agonists** include goserelin, nafarelin, and leuprolide. These medications suppress pituitary gonadotropin levels and gonadal steroids. They are most often used in adolescents for suppression of puberty, but can be used to decrease testosterone levels and the amount of estrogen needed for **MtF TG** individuals. One advantage of using GnRH agonists in adolescents is that their effects are generally fully reversible. GnRH agonists do not carry the risk of thromboembolic disease.

- **Progestins** are a group of hormones that include medroxyprogesterone. Use of medroxyprogesterone is controversial and not routinely recommended, but it can be used alone in individuals intolerant to other agents, or as an adjunct for individuals receiving maximum estrogen doses without desired effects. Medroxyprogesterone has anti-androgen effects at high doses, but is not more effective than spironolactone. It is purported to aid in breast development at a cellular level, but its effect is mainly on the uterus, and evidence as an effective agent in gender-affirming hormone therapy is lacking.
  - ➔ *Medroxyprogesterone treatment comes with risk of developing mood disorders (depression/irritability), lipid abnormalities, weight gain, and edema. There is also a concern of increased cardiovascular risk.*

- **Other anti-androgenic agents** include flutamide and cyproterone acetate, but are not commonly used in the U.S. Cyproterone acetate is widely used in Europe, but is not available in the United States. Flutamide blocks androgen binding, but comes with a risk of hepatotoxicity and has little to no efficacy in reducing testosterone levels.

Estrogens

Estrogens are used to provide feminization in the form of physical appearance and sexual characteristics. Effects include development of breasts, redistribution of body fat, softening of the skin, shrinkage of the testes, and testicular atrophy. Many formulations of estrogen are available, including parenteral, transdermal, and oral. Estrogen may have positive health effects more generally, including increased high-density lipoprotein, decreased low-density lipoprotein, and preservation of bone mineral density.

➔ *A list of adverse events and necessary lab monitoring can be found in Appendix 1a.*

- All estrogens come with a risk of thromboembolism, but lower doses and transdermal formulations are considered safer and should be used in populations at higher risk of thromboembolism (>35 years old, smoker, obese). Synthetic estrogens, especially ethinyl estradiol, have been shown to have a higher risk of thromboembolism.
- Intramuscular (IM) injections can cause greater peaks and troughs in estrogen levels, causing more mood issues than oral and transdermal preparations, making oral and transdermal preparations preferable.
- Use of estrogen should be individualized and adjusted regularly, based on serum estradiol levels and individual-specific concerns. Estrogen should be started at low doses and titrated up as needed, based on hormone levels and individual tolerance. If discontinuation is necessary, consider tapering therapy to alleviate mood disturbances.
  - ➔ *Conjugated and synthetic estrogen formulations cannot be measured through serum estradiol concentrations and are no longer recommended for gender-affirming hormone therapy.*

MTF MEDICATIONS: DRUG EFFECTS TIMELINE

➔ *Refer to the Endocrine Society guideline, Table 14, page 3145 (reference 3 in the References section of this guidance) for specific expectations of feminizing effects of medication therapy.*

In general, a person may expect decreased libido and spontaneous erections to occur within one to three months of starting therapy, with a maximum effect in three to six months. Effects that usually develop in the first three to six months of treatment include redistribution of body fat, decrease in muscle mass and strength, softening and decreased oiliness of skin, breast growth, and decreased testicular volume with a maximum effect in one to three years. A decrease in terminal hair growth usually does not occur until six to 12 months into treatment, with a maximum effect not occurring for at least three years or more. The timelines for male sexual dysfunction and decreased sperm production are either variable or unknown. Voice changes do not occur with hormone treatments.

MTF MEDICATIONS: DRUG RISKS

Table 3 lists conditions that can be exacerbated by gender-affirming estrogen therapy. See *Appendix 1a* for more information on the adverse effects of estrogen therapy and androgen suppression.

TABLE 3. MEDICAL CONDITIONS EXACERBATED BY GENDER-AFFIRMING ESTROGEN THERAPY (MTF)

Very high risk of serious adverse outcomes:	
• Thromboembolic disease	
Moderate to high risk of adverse outcomes:	
• Macroprolactinoma • Breast cancer • Severe liver dysfunction *(transaminases >3x upper limit of normal)*	• Coronary artery disease • Cerebrovascular disease • Severe migraine headaches

MTF MEDICATIONS: MONITORING

Gender-affirming hormone therapy has the same risks associated with hormone replacement therapy in biological males and females. Appropriate monitoring is crucial. Weight, blood pressure, physical exams, risk factors, medications, complete blood counts, renal and liver function, and lipid and glucose metabolism should be monitored for all **TG** individuals receiving gender-affirming hormone therapy.

- Clinical and laboratory monitoring is appropriate every three months during the first year, and then once or twice yearly thereafter, except as noted.
  - ➔ *Monitor for development of feminine characteristics, for target blood levels, and for adverse effects of medication and other treatment.*

- Cardiovascular risk assessment is recommended periodically for all patients treated with hormones in accordance with established guidelines and BOP guidance when available.
  - ➔ *Specific parameters that need to be monitored include weight and body mass index, blood pressure, lipids, and blood sugar/glycohemoglobin levels, in accordance with established guidelines.*

- Serum testosterone and estradiol levels are obtained before starting those respective medications, and then every three months while on treatment.
  - ➔ *Target levels are < 55 ng/dl for testosterone and < 200 pg/ml for estradiol. Higher levels of testosterone indicate inadequate suppression; higher levels of estradiol are associated with increased risks for thromboembolic disease, liver dysfunction, and development of hypertension.*
- Serum electrolytes, most importantly potassium, and renal function are obtained prior to starting spironolactone, every three months during the first year of treatment, periodically thereafter, or more frequently with increases in dosage or as clinically indicated.
  - ➔ *Dose adjustment or discontinuation of spironolactone is recommended for elevated potassium levels or serum creatinine > 4 mg/dL.*
- Screening for colon, and prostate cancer is recommended in accordance with established guidelines and BOP guidance when available.
- Breast cancer screening guidelines for women are followed for **MTF TG** individuals treated with hormone therapy.
- Screening for osteoporosis with a DEXA scan may be appropriate in some cases.
  - ➔ *In the absence of sufficient data to formulate evidence-based guidelines, it is considered appropriate to screen those who are at least five years post-gonadectomy, those who are 50 to 65 years old and have risk factors for osteoporosis, and all those who are 65 years or older.*
  - ➔ *Bone density measurements for transgender women (**MTF**) are compared with standards for biological females.*
- Baseline and periodic monitoring of liver enzymes and prolactin levels may be appropriate in those treated with estradiol but there is insufficient data available to make a specific recommendation.

11. MEDICATIONS FOR FTM INDIVIDUALS

DRUG CLASSES AND MEDICATION INFORMATION

➔ *See the **FTMTreatment Summary Chart** in Appendix 1b for a full list of the different formulations of testosterone—including summarized information on dosing, adverse effects, contraindications, interactions, and monitoring.*

TESTOSTERONE

Androgen supplementation is used to induce male sex characteristics, including cessation of menses, voice changes, increased facial/body hair growth, increased muscle mass, and clitoral enlargement. Other effects include increased libido and energy.

- Several formulations are available, ranging from IM injections to transdermal patches and gels. The IM injections release slowly from the muscle, but may induce cyclical side effects that coincide with varying plasma concentrations. To avoid these effects, transdermal preparations can be used; alternatively, for testosterone cypionate and enanthate, a lower dose of IM testosterone can be given once-weekly (instead of every two or more weeks).
- Transdermal patches may take longer than IM doses to reach adequate levels. As a result, testosterone levels should be checked after completing at least one week of therapy with a patch. Precautions should be taken to avoid unintentional exposure.

- While oral formulations are available, they are not used, due to extensive liver metabolism and the associated potential for hepatic complications.
- Androgen use should be individualized and adjusted based on serum testosterone levels, tolerance, and efficacy. As with estrogen, dosing should start low and be titrated up to an appropriate level while keeping the dose as low as possible to minimize side effects.
- Ovulation may still be possible even when undergoing long-term testosterone therapy.
  - ➔ *Measures should be taken to avoid pregnancy in those undergoing hormonal therapy.*

Due to the classification of all testosterone preparations as DEA-controlled substances and their associated risk of potential abuse and/or diversion, transdermal patches or gels should be avoided in the correctional environment, if possible.
➔ ***INJECTABLE TESTOSTERONE is the preferred formulation in the correctional environment.***

PROGESTINS AND GNRH AGONISTS

Medroxyprogesterone and GnRH agonists are not typically used, but may be beneficial in individuals wishing to cease menstruation and decrease estrogen levels prior to testosterone treatment. These medications may also have a use in individuals receiving high-dose testosterone therapy who still experience uterine bleeding after the first few months of treatment.

➔ *See Appendix 1a and Appendix 1b for information on Medroxyprogesterone and GnRH agonists.*

DRUG EFFECT TIMELINE FOR FTM MEDICATIONS

➔ *Refer to the Endocrine Society guideline, Table 13, page 3145 (reference 3 in the References section of this guidance) for specific expectations of masculinizing effects of medication therapy.*

In general, a person may expect the following to occur:

- Effects that develop within the first six months of treatment include increased skin oiliness and acne, fat redistribution, cessation of menses, clitoral enlargement, and vaginal atrophy, with onset within the first three months. Maximum effect usually occurs in one to two years, but may take up to five years in some cases.
- Effects that develop in the six-to-12 month time frame include increased facial and body hair, scalp hair loss, increased muscle mass and strength, and deepening of the voice, with maximum effect often occurring in one to two years.

FTM MEDICATIONS: DRUG RISKS

Table 4 lists conditions that can be exacerbated by gender-affirming testosterone therapy. See Appendix 1b for more information on the adverse effects of testosterone therapy.

TABLE 4. MEDICAL CONDITIONS EXACERBATED BY GENDER-AFFIRMING TESTOSTERONE THERAPY (FTM)

Very High Risk of Serious Adverse Outcomes	Moderate-to-High Risk of Adverse Outcomes
• Breast or uterine cancer • Erythrocytosis (hematocrit >50%)	• Severe liver dysfunction (transaminases >3x upper limit of normal)

FTM MEDICATIONS: MONITORING

Gender-affirming hormone therapy has the same risks associated with hormone replacement therapy in biological males and females. Some of the adverse effects experienced with chronic testosterone therapy are erythrocytosis, liver dysfunction, hypertension, excessive weight gain, salt retention, lipid changes, excessive or cystic acne, and adverse psychological changes. Appropriate monitoring is crucial. Weight, blood pressure, physical exams, risk factors, medications, complete blood counts, renal and liver function, and lipid and glucose metabolism should be monitored for all **TG** individuals receiving gender-affirming hormone therapy.

- Clinical and laboratory monitoring is appropriate prior to starting treatment, every three months during the first year, and then once or twice yearly thereafter, except as noted.
  - ➔ *Monitor for development of masculine characteristics, for target blood levels, and for adverse of effects of medication and other treatments.*
- Cardiovascular risk assessment is recommended periodically for all patients treated with hormones, in accordance with established guidelines and BOP guidance when available.
  - ➔ *Specific parameters that need to be monitored include weight and body mass index, blood pressure, lipids, and blood sugar/glycohemoglobin levels.*
- A pregnancy test is obtained prior to starting treatment for all biological females with child bearing potential.
- Serum testosterone levels are obtained before starting treatment with testosterone, and then every three months while on treatment.
  - ➔ *Target testosterone levels are 350–700 ng/d. Higher levels may be associated with increased risk of side effects and complications.*
  - ➔ *Timing of the testosterone level is determined by the route of administration. Trough testosterone levels are obtained prior to the next dose of **injectable** testosterone. Testosterone levels are recommended three to five hours after an **oral** dose, and any time after one week of therapy on **topical** testosterone.*
- Serum estradiol levels are obtained before starting hormone therapy, and then every three months while on treatment until estradiol levels are < 50 pg/ml and cessation of menses has been six months.
- A complete blood count (CBC) and liver panel are obtained prior to starting hormone therapy, every three months during the first year of treatment, once or twice yearly thereafter, or more frequently as clinically indicated.
  - ➔ *Dose adjustment or discontinuation of testosterone is indicated if the hematocrit is > 54%.*
- Screening for colon cancer is recommended in accordance with established guidelines and BOP guidance when available.
- Breast cancer screening guidelines for women are followed for **FTM TG** individuals treated with hormone therapy and who have not had mastectomies.
- Cervical cancer screening is performed annually in those who are treated with hormone therapy and have cervical tissue (i.e., no hysterectomy).

(List continues on next page.)

- Screening for osteoporosis with a DEXA scan may be appropriate in some cases.
  - *In the absence of sufficient data to formulate evidence-based guidelines, it is considered appropriate to assess bone mineral density prior to starting treatment in those with risk factors for osteoporosis, those who are at least five years status post-gonadectomy, and all those who are 60 to 65 years or older.*
  - *Bone density measurements for transgender men are compared with standards for biological males.*

12. GENDER-AFFIRMING (A.K.A. SEX REASSIGNMENT) SURGERY

Although individuals may live successfully as transgender persons without surgery, gender-affirming surgery may be appropriate for some and is considered on a case-by-case basis.

CRITERIA: In addition to the eligibility and readiness criteria for hormone therapy, general criteria for consideration of surgery include at least 12 months of successful use of hormone therapy, participation in psychotherapy as clinically indicated, full-time real life experience in their preferred gender, and consolidation of gender identity. The inmate must request consideration for and demonstrate via informed consent a practical understanding of gender-affirming surgery including, but not limited to, permanence, potential complications, and short- and long-term treatment plans.

Requests for surgery are submitted to the **BOP TCCT** for initial review and recommendation to the Medical Director, who is the approving authority. Each referral should include comprehensive medical and mental health summaries, a comprehensive psychosocial assessment (preferably by a licensed clinical social worker), and a criminal history and institutional adjustment report.

13. PATIENT EDUCATION & INFORMED CONSENT

Patient education and informed consent are crucial to the treatment process. Sample consent and counseling documents can be found in *Appendix 2* and *Appendix 3*. Psychology and medical staff should allow individuals to read the appropriate consent forms, as well as discuss the forms with the individuals to ensure that they understand them thoroughly. Informed consent must be documented within the electronic medical record.

See Section 7, Medical Assessment and *Section 8, Stepwise Approach to Medical and Mental Health Management of TG Individuals for more information*.

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APPENDIX 1A. TREATMENT SUMMARY CHART FOR MTF THERAPY

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL <200 PG/ML AND SERUM TESTOSTERONE <55 NG/DL ★						
Anti-Androgen Drugs	**Dose**	**Mode of Action**	**Adverse Effects**	**Contraindications**	**Interactions**	**Notes/Monitoring**
SPIRONOLACTONE	**Starting:** 25–50 mg BID **Typical:** 50 mg BID **Max:** 200 mg BID	Potassium-sparing antihypertensive that directly inhibits testosterone secretion and androgen binding to the androgen receptor	• Mild diuretic • Hyperkalemia • Excretion of sodium, calcium, and chloride • Decreased libido	• Renal insufficiency • Potassium >5.5 mmol/L • Avoid after orchiectomy	• Digoxin • ACE inhibitors • ARBs • Potassium-sparing diuretics	• **Baseline labs:** BMP • **Follow-up labs:** Serum potassium and renal function in 1 week, monthly for three months, and every three months during first year. • **When stable:** BMP every 6 to 12 months
FINASTERIDE	**Low:** 1 mg daily **High:** 5–10 mg daily	5α reductase inhibitor, which blocks the conversion of testosterone to the more active 5α dihydrotestosterone	Sexual dysfunction	None pertinent	Antiretrovirals and diltiazem may increase finasteride levels.	• **High dose:** Unable to take spironolactone • **Low dose:** Treatment of male pattern baldness • Use in combo with spironolactone for rare individuals not achieving desired effects • May be used after orchiectomy if hirsutism or male pattern baldness are present
APPENDIX 1A, PAGE 1 OF 3 *(See APPENDIX 1C for sources and abbreviations.)*						

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL <200 PG/ML AND SERUM TESTOSTERONE <55 NG/DL ★						
Anti-Androgen Drugs	**Dose**	**Mode of Action**	**Adverse Effects**	**Contraindications**	**Interactions**	**Notes/Monitoring**
GNRH AGONISTS: **GOSERELIN** **NAFARELIN** **LEUPROLIDE**	**Goserelin:** 3.6 mg SQ monthly **Nafarelin:** 600 µg intranasal daily **Leuprolide:** 3.75–7.5 mg IM monthly	Neurohormones that block the GnRH receptor, thus blocking release of FSH & LH, leading to highly effective gonadal blockade	• Loss of BMD • Hot flashes • Sexual dysfunction • Diarrhea	None pertinent	None noted	• MTF: Use anti-androgen to decrease estrogen use • Fully reversible when used in adolescents to delay puberty
PROGESTERONE, MEDROXYPROGESTERONE	**Starting:** 2.5 mg daily **Typical:** 5–10 mg daily **Max:** 20 mg daily	• Anti-androgen effect at high doses • May help breast development at cellular level	• Increased CV risk • Weight gain • Edema • Mood disorder • Increased facial and body hair	See below; same contraindications as estrogen.	Antiretrovirals	• Not as effective as spironolactone • Adjunct for individuals on maximum estrogen doses with unsatisfactory effects • **Monitoring:** Same as estrogen; see below
APPENDIX 1A, PAGE 2 OF 3 *(See APPENDIX 1C for sources and abbreviations.)*						

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL <200 PG/ML AND SERUM TESTOSTERONE <55 NG/DL ★					
Estrogen	**Dose**	**Adverse Effects**	**Contraindications**	**Notes**	**Monitoring**
ESTRADIOL	**Starting:** 2–3 mg daily **Typical:** 4 mg daily **Max:** 8 mg daily	**Common:** • Increase in weight, VTE, dyslipidemia, insulin resistance, prolactin levels, edema, N/V, migraine • Decrease in erections • Melasma and skin irritation from estradiol patches **Less Common:** • LFT abnormalities • Increase in CV events especially in those older than 50 taking progesterone with estrogens • Increased triglycerides in those taking oral estrogens • Increased risk of pancreatitis, cholelithiasis, diabetes mellitus, hypertension, and hyperkalemia (in spironolactone users) **Rare or plausible but have not been observed:** • Liver damage • Prolactinoma • Breast cancer (compared with men never exposed to estrogen)	**Absolute:** • Estrogen-dependent cancer **Precautions:** • History of VTE • Coronary artery disease • Hyperlipidemia • Diabetes mellitus • Cigarette smoking • Highly sedentary lifestyle • Migraine • Seizure disorder • Retinopathy • Heart failure • Valvular heart disease • Family history of estrogen-dependent tumor	• **Interactions:** CYP 3A4, 1A2 inhibitors/inducers • Transdermal formulations better for older individuals or those with risk factors for VTE • Stop estrogens two weeks prior to surgery or immobilizing event. Restart after mobilization or one week after surgery • Consider adding aspirin therapy to those at high risk for VTE • Individuals who enter the BOP on conjugated estrogen should be switched to a different form of estrogen due to inability to monitor estrogen levels with this preparation • IM injections cause greater peaks and troughs in estrogen levels making oral and transdermal preparations preferable	• **Baseline:** fasting glucose, lipids, LFTs, prolactin, BMP, BMD if at risk for fracture • **Follow-up:** glucose and lipids every 2–3 months after starting or dose increase and 1 year after starting • Check serum testosterone and estradiol every 3 months in first year then 1–2 times per year after for feminization and adverse events • Optional: LFTs and prolactin after 1 year • Routine prostate and breast cancer screening
ESTRADIOL SUBLINGUAL (ESTRADIOL MICRONIZED, ESTRACE)	**Starting:** 0.5–1 mg **Typical:** 2 mg daily **Max:** 4 mg daily				
ESTRADIOL VALERATE (DELESTROGEN)	**Starting:** 20–40 mg IM q2wk **Average:** 40 mg IM q2wk **Max:** 40–80 mg IM q2wk **Endocrine guidelines:** 2–10 mg IM q1wk				
ESTRADIOL CYPIONATE (DEPO-ESTRADIOL)	**Starting:** 20–40 mg IM q2wk **Average:** 40 mg IM q2wk **Max:** 40–80 mg IM q2wk **Endocrine guide:** 2–10 mg IM q1wk				
ESTRADIOL PATCH (CLIMARA, ESTRADERM, ALORA, VIVELLE-DOT)	**Starting:** 0.1 mg/24hr **Average:** 0.2 mg/24hr **Max:** 0.4 mg/24hr **Endocrine guide:** 0.1–0.4 mg twice weekly				
ESTRADIOL GEL (DIVIGEL, ELESTRIN, ESTRASORB, ESTROGEL)	Roughly equivalent to patch dosing				
CONJUGATED EQUINE ESTROGENS (PREMARIN)	**Starting:** 1.25–2.5 mg daily **Typical:** 5 mg daily **Max:** 10 mg daily				
APPENDIX 1A, PAGE 3 OF 3 *(See APPENDIX 1C for sources and abbreviations.)*					

APPENDIX 1B. TREATMENT SUMMARY CHART FOR FTM THERAPY

★ **GOAL LEVELS FOR FTM: SERUM ESTRADIOL <50 PG/ML AND SERUM TESTOSTERONE 320–1000 NG/DL** ★

Drug	Dose	Adverse Effects	Contraindications	Notes	Monitoring
TESTOSTERONE CYPIONATE (in cottonseed oil) **TESTOSTERONE ENANTHATE (in sesame oil)**	**Starting:** 50–100 mg q2wk or 25–50 mg/wk **Typical:** 200 mg q2wk or 100 mg/wk **Max:** 400 mg q2wk or 200 mg/wk	**Common:** • Increase in weight, oily skin, acne, and male pattern baldness • Vaginal atrophy • Infertility (possibly irreversible) • Dyslipidemia • Mood changes • Skin irritation with patch • Risk of exposing partners or children to testosterone with topicals **Less Common:** • Increase in edema, blood pressure, and aggressiveness • Erythrocytosis • Abnormal LFTs • Sleep apnea **Rare or plausible but not observed:** • Increased risk of CV disease, breast/ ovarian cancer, and endometrial hyperplasia	**Absolute:** • Pregnancy • Breast cancer (testosterone may have anti-proliferative effects on most, but not all, breast cancers) • Breastfeeding **Precautions:** • Erythrocytosis • Cardiac, hepatic, renal, or vascular disease with edema or risk of edema • Sleep apnea or high risk of sleep apnea due to obesity or chronic lung disease • Dyslipidemia	• **Interactions:** Warfarin Cyclosporine Insulin • Causes drop in blood glucose in DM individuals • May notice cyclic variation in mood with IM dosing Q 2–4 weeks. Use a lower, more frequent dose, or transdermal • Transdermal reaches same levels as IM, but in longer timeframe • Menses typically stop in early months of treatment, but may persist when using transdermals **Use in Corrections: Injectable testosterone is the preferred formulation in the correctional environment due to potential risk of abuse and/or diversion. Testosterone is a DEA Controlled Substance**	• **Baseline:** CBC, lipids, urine hCG, glucose, & LFTs (if PCOS suspected) • **Follow-up:** 2–3 months after starting or changing dose CBC, lipids • **1 year after start or change:** CBC, lipids, LFTs (optional) • Serum testosterone: every 2–3 months in first year then 1–2 times/year for virilization/AEs • Serum estradiol: q 2–3 months in first 6 months or until no uterine bleeding for 6 months • **When to check specific formulations:** **IM:** Testosterone levels just prior to next dose. Adjust to mid-normal range of 350–700 ng/dl **Patch:** Testosterone levels after week 1 • Continue screenings for cervical and breast cancer if tissue still present
TESTOSTERONE PATCH **Available strengths: 2 mg, 2.5 mg, 4 mg, 5 mg**	**Starting:** 2–2.5 mg/day **Typical:** 5 mg/day **Max:** 7.5 mg/day				
TESTOSTERONE GEL (TESTIM 1%, ANDROGEL 1%)	**Starting:** 2.5 mg every morning **Typical:** 5 mg every morning **Max:** 10 mg every morning				
TESTOSTERONE GEL (ANDROGEL 1.62%)	No published or anecdotal experience with these preparations				
TESTOSTERONE SOLUTION (AXIRON axillary solution)					
MEDROXYPROGESTERONE AND GNRH AGONISTS	See *page 2* of APPENDIX 1A for dosing and other information.			Used to suppress menstruation if persists after early months of testosterone treatment	

(See APPENDIX 1C for sources and abbreviations.)

APPENDIX 1C. TREATMENT SUMMARY CHARTS: SOURCES AND ABBREVIATIONS

SOURCES FOR TREATMENT SUMMARY CHARTS: *See References 2, 3, 4, 5, 8, 9, and 10.*

ABBREVIATIONS:

AEs	Adverse events
ARB	Angiotensin II receptor blocker
BMD	Bone mineral density
BMP	Basic metabolic panel, including glucose, calcium, sodium, potassium, CO_2, chloride, blood urea nitrogen, and serum creatinine
CBC	Complete blood count
CV	Cardiovascular
DM	Diabetes mellitus
FSH	Follicle-stimulating hormone
FtM	Female-to-male
GnRH	Gonadotropin-releasing hormone
hCG	Human chorionic gonadotropin
IM	Intramuscular
LFT	Liver function test
LH	Luteinizing hormone
MtF	Male-to-female
N/V	Nausea and vomiting
PCOS	Polycystic ovarian syndrome
q	"Every" (*Example:* q2wk = every 2 weeks)
SQ	Subcutaneous
VTE	Venous thromboembolism

APPENDIX 2. FEMINIZING GENDER-AFFIRMING HORMONE TREATMENT FOR TG PATIENTS – CONSENT AND COUNSELING FORM

A sample ***Consent and Counseling Form*** for feminizing gender-affirming hormone treatment for **TG** patients appears on the next five pages.

FEMINIZING GENDER-AFFIRMING HORMONE TREATMENT FOR TRANSGENDER PATIENTS

CONSENT AND COUNSELING FORM

INSTITUTION NAME: _____

PATIENT NAME: _____ **ID #:** _____

You want to take estrogen and other medications to feminize your body. Once you start these medications, some of them will need to be taken for the rest of your life in order to maintain their effects. Before using these medications, you need to know more about how they might affect you, including possible benefits, side effects, risks, and warning signs. We have listed them here for you. It's important that you understand all of this information before you start. We are happy to answer *any* questions you might have, so please ask!

WHAT ARE THE DIFFERENT MEDICATIONS THAT CAN HELP TO FEMINIZE YOU?

Estrogen is the female gender-affirming hormone and there are different types of estrogen that can help you appear more like a woman. There are also medications—called androgen antagonists or anti-androgens or androgen blockers—that can help you appear less like a man. Androgen is the male gender-affirming hormone.

WARNING — WHO SHOULD NOT TAKE ESTROGEN?

It should NOT be used by anyone who has a history of:

- An estrogen-dependent cancer
- Blood clots that could or did travel to the lungs

It should be used WITH CAUTION, and only after a full discussion of risks, by anyone who:

- Has a strong family history of breast cancer or other cancers that grow faster when estrogens are present
- Has diabetes
- Has eye problems such as retinopathy
- Has heart disease, heart valve problems, or a tendency to have easily clotted blood
- Has hepatitis
- Has high cholesterol
- Has kidney or liver disease
- Has migraines or seizures
- Is obese
- Smokes cigarettes

Please review and initial each statement to show you understand the benefits, risks, and changes that may occur from taking these medications. At the end of the document, indicate your preference regarding hormone therapy, then sign and date it.

FEMINIZING EFFECTS:

_____ I know that estrogen or anti-androgens—or both—may be prescribed to help me appear less like a man and more like a woman.

_____ I know that it can take several months or longer for the effects to become noticeable. I know that no one can predict how fast—or how much—change will happen.

_____ I know that if I am taking estrogen, I will probably develop breasts.

- I know it can take several years for breasts to get to their full size.
- I know the breasts will remain, even if I stop taking estrogen.
- I know I should examine my breasts for irregularities as soon as they start growing. I should also have a clinician examine them every year.
- I know I might have a milky discharge from my nipples (galactorrhea). If I do, I know I should have it evaluated by my clinician because it could be caused by the estrogen or by something else.
- I know that no one knows if taking estrogen increases the risk of breast cancer.

_____ I know that the following changes are usually not permanent—they are likely to go away if I stop taking the medicines:

- I know my body hair will become less noticeable and will grow more slowly, but it won't stop completely, even if I take the medicines for years.
- I know I will probably have less fat on my abdomen and more on my buttocks, hips, and thighs. It will be redistributed to a more female shape, changing from an "apple" shape to more of a "pear" shape.
- I know that if I already have male pattern baldness, it may slow down, but will probably not stop completely. It is also unlikely that hair that has been lost will grow back.
- I know I may lose muscle and strength in my upper body.
- I know my skin may become softer.

_____ I know that my body will make less testosterone. Upon release, this may affect my sex life in different ways and my future ability to cause a pregnancy:

- I know my sperm may no longer reach maturity. This could make me less able to cause a pregnancy. I also know I might never produce mature sperm again, but I know that it's also possible that my sperm could still mature. So, I know that I might get someone pregnant if we have vaginal intercourse, and we don't use birth control. The options for sperm banking have been explained to me.
- I know my testicles may shrink down to half their size. Even so, I know that I will need regular checkups for them.
- I know it is likely that my penis won't be hard in the morning as often as it has been before. it is also likely that I will have fewer spontaneous erections.
- I know I may lose the ability to obtain an erection for intercourse.
- I know I may have less sex drive.
- I know this treatment may (but is not assured to) make me permanently unable to make a woman pregnant.

_____ I know that some parts of my body will not change much by using these medicines.

- I know the hair of my beard and moustache may grow more slowly than before. It may become less noticeable, but it will not go away.
- I know the pitch of my voice will not rise, and my speech patterns will not become more like a woman's.
- I know my Adam's apple will not shrink.
- Although these medicines can't make these changes happen, there are other treatments that may be helpful.

RISKS OF TAKING FEMINIZING MEDICATIONS:

_____ I know that the side effects and safety of these medicines are not completely known. There may be long-term risks that are not yet known.

_____ I know that I should not to take more medicine than I am prescribed. I know it increases health risks. I know that taking more than I am prescribed won't make changes happen more quickly or more significantly. I know my body can convert extra estrogen into testosterone, and that can slow down or stop my appearing more womanly.

_____ I know these medicines may damage the liver and may lead to liver disease. I know I should be checked for possible liver damage as long as I take them.

_____ I know these medicines cause changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones. I know I can reach out to psychology services to help me find support resources. I also know that the BOP does not tolerate harassment, discrimination, and violence in any circumstances. If I feel I am the recipient of any of these actions, I will notify a BOP staff member.

RISKS OF TAKING ESTROGEN:

_____ I know that taking estrogen increases the risk of blood clots that can result in:

- Chronic problems with veins in the legs
- Heart attack
- Pulmonary embolism (blood clot to the lungs), which may cause permanent lung damage or death
- Stroke, which may cause permanent brain damage or death

_____ I know that the risk of blood clots is much worse if I smoke cigarettes, especially if I am over 40. I know the danger is so high that I should stop smoking completely if I start taking estrogen and that I should not start to smoke again when I am released from a BOP institution.

_____ I know that taking estrogen can increase the deposits of fat around my internal organs. This can increase my risk for diabetes and heart disease.

_____ I know that taking estrogen can raise my blood pressure. I know that if my blood pressure goes up, my clinician can work with me to try to control it with diet, lifestyle changes, and/or medication.

_____ I know that taking estrogen increases my risk of getting gallstones. I know that I should talk with my clinician if I get severe or long-lasting pain in my abdomen.

_____ I know that estrogen can cause nausea and vomiting. I know that I should talk with my clinician if I have long-lasting nausea or vomiting.

_____ I know that estrogen can cause headaches or migraines. I know I should talk with my clinician if I have headaches or migraines often, or if the pain is unusually severe.

_____ I know that it is not yet known if taking estrogen increases the risk of prolactinomas. These are non-cancerous tumors of the pituitary gland. I know they are not usually life-threatening, but they can damage vision and cause headaches. I know this possibility needs to be checked periodically by a clinician for at least three years after I start taking estrogen.

_____ I know that I am more likely to have dangerous side effects if:

- I smoke.
- I am overweight.
- I am over 40 years old.
- I have a history of blood clots.
- I have a history of high blood pressure.
- My family has a history of breast cancer.

RISKS OF TAKING ANDROGEN ANTAGONISTS:

_____ I know that spironolactone affects the balance of water and salts in the kidneys, which may:

- Increase the amount of urine I produce, making it necessary to urinate more frequently.
- Increase thirst.
- Reduce blood pressure.
- Cause (although rarely) high levels of potassium in the blood, possibly leading to changes in heart rhythms that may be life-threatening.

_____ I know that some androgen antagonists make it more difficult to evaluate test results for cancer of the prostate. I know that if I am over 50, I should have my prostate evaluated every year with a prostate-specific antigen test, as applicable.

PREVENTION OF MEDICAL COMPLICATIONS:

_____ I agree to take feminizing medications as prescribed, and I agree to tell my clinician if I have any problems or if I am unhappy with the treatment.

_____ I know that the dose and type of medication that is prescribed for me may not be the same as for someone else.

_____ I know that I need periodic physical exams and blood tests to check for any side effects.

_____ I know that feminization medications can interact with other drugs and medicines—including alcohol, diet supplements, herbs, other hormones, and street drugs—causing complications. I know that I need to prevent complications because they can be life-threatening. That's why I need to be honest with my clinician about whatever else I take or use. I also know that this will not interfere with my getting medical care; I will continue to get medical care here no matter what information I share about what I take.

_____ I know that it can be risky for anyone with certain conditions to take feminizing medicines. I agree to be evaluated if my clinician thinks I may have such a condition. Then, we will decide if it's a good idea for me to start or continue using these medications.

_____ I know that I should stop taking estrogen two weeks before any surgery or when I may be immobile for a long time. This will lower the risk of getting blood clots. I know that I can start taking estrogen again a week after I'm back to normal or when my clinician says it's okay.

_____ I know that using these medicines to appear more womanly is an "off-label" use. I know that this means that using these medicines for this purpose is not approved by the Food and Drug Administration (FDA). I know that the medicine and dose that is recommended for me is based on the judgment and experience of the clinician.

_____ I know that I can choose to stop taking these medicines at any time. I know that if I decide to do that, I should do it with the help of my clinician. This will help me make sure there are no negative reactions. I also know that my clinician may suggest that I cut the dose or stop taking it altogether if certain conditions develop. This may happen if the side effects are severe or if there are health risks that cannot be controlled.

MY SIGNATURE BELOW CONFIRMS THAT:

- My clinician has talked with me about:
  - The benefits and risks of taking feminizing medication.
  - The possible or likely consequences of hormone therapy.
  - Potential alternative treatments.
- I understand the risks that may be involved.
- I know that the information in this form includes the known effects and risks. I also know that there may be unknown long-term effects or risks.
- I have had enough opportunity to discuss treatment options with my clinician.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to take, refuse, or postpone therapy with feminizing medications.
- I am 18 years old or older.

BASED ON ALL THIS INFORMATION:

_____ I want to begin taking estrogen.

_____ I want to begin taking androgen antagonists (e.g., spironolactone).

_____ I do not wish to begin taking feminizing medication at this time.

_____ _____
Patient's Signature *Date*

_____ _____
Prescribing Physician's Signature *Date*

Your health is important to us. If you have any questions or concerns, please come to sick call and an appointment with your PA/Physician will be made.

APPENDIX 3. MASCULINIZING GENDER-AFFIRMING HORMONE TREATMENT FOR TG PATIENTS – CONSENT AND COUNSELING FORM

A sample ***Consent and Counseling Form*** for masculinizing gender-affirming hormone treatment for **TG** patients appears on the next four pages.

MASCULINIZING GENDER-AFFIRMING HORMONE TREATMENT FOR TRANSGENDER PATIENTS
CONSENT AND COUNSELING FORM

INSTITUTION NAME: _____

PATIENT NAME: _____ **ID #:** _____

You have expressed a desire to take testosterone to masculinize your body. Before beginning treatment, there are several details about treatment that you need to be familiar with, including the possible advantages, disadvantages, risks, warnings, and alternatives. These topics are covered below. It is important that you understand all of this information before initiating treatment. We are happy to answer *any* questions you might have, so please ask!

WHAT IS TESTOSTERONE?

Testosterone is the hormone responsible for male features. It builds muscle, causes the development of facial hair, and is responsible for the deepening of a person's voice during puberty. Testosterone also may increase sex-drive.

HOW IS TESTOSTERONE TAKEN?

Testosterone is usually injected every one to four weeks. It is not used as a pill because the body may not absorb it properly, and it can cause liver problems. Some people use skin creams and patches, but these are not used in the correctional environment.

The doses used for injections differ from product to product, and from patient to patient. Doses may range from 100 mg to 400 mg. The injections are administered into a large muscle to slow the release of the hormone. There can be unwanted swings in hormone levels. This can be controlled by changing how often the dose is given, how much of a dose is given, or by changing formulations.

WARNING — WHO SHOULD NOT TAKE TESTOSTERONE?

Testosterone should ***not*** be used by anyone who is pregnant or has uncontrolled coronary artery disease.

It should be used ***with caution and only after a full discussion of risks*** by anyone who has: acne, family history of heart disease or breast cancer, blood clot history, high levels of cholesterol, liver disease, or high red-blood-cell count. Caution should also be used in obese patients and persons who smoke.

MONITORING:

Periodic blood tests to check on the effects of the hormone will be required for treatment. Routine breast exams and pelvic exams with pap tests should be continued, when applicable.

BENEFITS AND RISKS OF TESTOSTERONE TREATMENT:

Benefits	Risks

• Appearing more like a man:
  • Larger clitoris*****
  • Coarser skin
  • Deeper voice*****
  • Increased body hair*****
  • Increased facial hair*****
  • Increased muscle mass
  • Increased strength
  • Elimination of menstrual periods
• Increased physical energy
• Protection against bone thinning (osteoporosis)
 	
*****_These are permanent changes._
	• Acne (may permanently scar)
	• Blood clots (thrombophlebitis)
	• Emotional changes
	• Headache
	• High blood pressure (hypertension)
	• Increased red-blood-cell count
	• Infertility
	• Inflamed liver
	• Interaction with drugs for diabetes and blood thinning — e.g., Coumadin and Warfarin
	• Male pattern baldness
	• Increased abdominal fat
	• Increased risk of heart disease
	• Swelling of hands, feet, and legs
	• Weight gain

Please review and initial each statement to show that you understand the benefits, risks, and changes that may occur from taking these medications. At the end of the document, indicate your preference regarding hormone therapy, then sign and date it.

MASCULINIZING EFFECTS OF TESTOSTERONE:

_____ I know that testosterone may be prescribed to make me appear less like a woman and more like a man.

_____ I know that it can take several months or longer for the effects to become noticeable.

_____ I know that no one can predict how fast or how much change will take place.

_____ ***I know that the changes may not be complete for two to five years after starting testosterone.***

_____ ***I know the following changes are likely to be permanent, even if I stop taking testosterone:***

- Bigger clitoris — typically about half an inch to a little more than an inch
- Deeper voice
- Growth of facial hair (moustache and beard)
- Hair loss at the temples and crown of the head and the possibility of becoming completely bald
- More, thicker, and coarser hairs on abdomen, arms, back, chest, and legs

_____ I know that the following changes are usually ***not permanent*** and will likely go away if I stop taking testosterone:

- Acne (however, acne scars will be permanent)
- Elimination of menstrual periods (typically stop one to six months after starting testosterone)
- Increased abdominal fat (redistribution of fat to a more masculine shape)
- Decreased fat on buttocks, hips, and thighs
- More muscle mass and strength
- Vaginal dryness

_____ I know that the effects of testosterone on fertility are unknown. I have been told that I may or may not be able to get pregnant even if I stop taking testosterone. I know I might still get pregnant even after testosterone stops my menstrual periods. I know my birth control options upon release (if applicable). I know I cannot take testosterone if I am pregnant.

_____ I know that some aspects of my body will not be changed:

- Losing some fat may make my breasts appear slightly smaller, but they will not shrink very much.
- Although my voice may deepen, other aspects of the way I speak will not change.

_____ I know that there are other treatments that may be helpful to make my breasts smaller or my speech manlier. If I have concerns, I can discuss treatment options with my clinician.

RISKS OF TESTOSTERONE:

_____ I know that the medical effects and safety of testosterone are not completely known. There may be long-term risks that are not yet known.

_____ I know not to take more testosterone than prescribed. I know this would be a risk to my health. I know that taking more testosterone than I am prescribed will not make changes happen more quickly or more significantly. I know that my body can convert extra testosterone into estrogen, which can slow down or reverse the progress of my transition.

_____ I know that testosterone can cause changes that increase my risk of heart disease. I know these changes include:

- Less good cholesterol (HDL), which is needed to protect against heart disease, and more bad cholesterol (LDL), which may increase the risk of heart disease
- Higher blood pressure
- Increased deposits of fat around my internal organs

_____ I know that my risk of heart disease is higher if people in my family have had heart disease, if I am overweight, or if I smoke.

_____ I know that I should have periodic heart-health checkups for as long as I take testosterone. I know I must watch my weight and cholesterol levels and have them checked by my clinician.

_____ I know that testosterone can damage the liver and possibly lead to liver disease. I know I should be checked periodically for possible liver damage for as long as I take testosterone.

_____ I know that testosterone can increase my red blood cell count and hemoglobin. I know the increase is usually only to the level that is normal for a man. I know normal levels would have no health risks; however, higher increases can cause problems that can be life-threatening. These problems include stroke and heart attack. As such, I know I need to have periodic blood checks for as long as I take testosterone.

_____ I know that taking testosterone can increase my risk for diabetes. It may decrease my body's response to insulin, cause weight gain, and increase deposits of fat around my internal organs. I know I should have periodic checks of my blood glucose for as long as I take testosterone.

_____ I know that my body can turn testosterone into estrogen. I know that no one knows if this could increase the risk of cancers of the breast, ovaries, or uterus.

_____ I know that taking testosterone can thin the tissue of my cervix and the walls of my vagina. This can lead to tears or abrasions during vaginal intercourse. I know it does not matter if my partner is a woman or a man. This raises my risk of getting a sexually transmitted infection, including HIV. I know I should speak frankly with my provider regarding the best ways to prevent and check for infections. I am aware that sex between inmates, or between inmates and staff, is not permitted within the BOP.

_____ I know that testosterone can give me headaches or migraines. I know it is best to talk with my clinician if I get them frequently or if the pain is unusually severe.

_____ I know that testosterone can cause emotional changes. For example, I could become more irritable, frustrated, or angry. I know my provider can help me find resources to explore and cope with these changes.

_____ I know that testosterone causes changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones. I know I can reach out to psychology services to help me find support resources. I also know that in the BOP, harassment, discrimination, and violence are not tolerated under any circumstances. If I feel I am the recipient of any of these actions, I will notify a BOP staff member.

PREVENTION OF MEDICAL COMPLICATIONS:

_____ I agree to take testosterone as prescribed, and I agree to tell my clinician if I have any problems or am unhappy with the treatment.

_____ I know that the dose and type of medication prescribed for me may not be the same as it is for someone else.

_____ I know that I need periodic physical exams and blood tests to check for any side effects.

_____ I know that testosterone can interact with other drugs and medicines, including alcohol, diet supplements, herbs, other hormones, and street drugs. This kind of interaction can cause complications. I know that I need to prevent complications because they can be life-threatening. I need to be honest with my clinician about other items I am taking. I also know that this will not interfere with my getting medical care; I will continue to get medical care here no matter what information I share about what I take.

_____ I know that it can be risky for anyone with certain conditions to take testosterone. I agree to be evaluated if my clinician thinks I may have one of these conditions. Then, we will decide if it is a good idea to start or continue using testosterone.

_____ I know that using testosterone to appear more masculine is an "off-label" use. I know this means it is not approved by the Food and Drug Administration (FDA) for this purpose. I know the medicine and dose recommended for me is based on the judgment and experience of the clinician.

_____ I know that I can choose to stop taking testosterone at any time. I know if I decide to stop, I should discontinue with the help of my clinician to ensure there are no negative reactions. I know my clinician may suggest I cut the dose or stop taking it altogether if certain medical conditions develop. This may happen if the side effects are severe or if there are health risks that cannot be controlled.

MY SIGNATURE BELOW CONFIRMS THAT:

- My clinician has talked with me about:
  - The benefits and risks of taking testosterone.
  - The possible or likely consequences of hormone therapy.
  - Potential alternative treatments.
- I understand the risks that may be involved.
- I know that the information in this form includes the known effects and risks. I also know that there may be unknown long-term effects or risks.
- I have had enough opportunity to discuss treatment options with my clinician.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to take, refuse, or postpone testosterone therapy.
- I am 18 years old or older.

BASED ON ALL THIS INFORMATION:

_____ I want to begin taking testosterone.

_____ I do not wish to begin taking testosterone at this time.

_____ _____

Patient's Signature *Date*

_____ _____

Prescribing Physician's Signature *Date*

Your health is important to us. If you have any questions or concerns, please come to sick call and an appointment with your PA/Physician will be made.

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Suicidal ideation and suicide attempts in persons with gender dysphoria

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Abstract

Background: The little research there is about suicidal behaviour in those with gender dysphoria indicates that they are at a much higher risk of death by suicide and suicidal behaviour than the general population. The objective of this research is to analyse the prevalence of suicidal ideation and suicide attempts reported by people who attended consultations at the Gender Identity Treatment Unit between 2007 and 2017 presenting complaints related to gender dysphoria. **Method:** An ex-post facto study with a sample of 151 people who were clients at the unit, 97 in the male to female trans group, 54 female to male. Clinical evaluations were carried out assessing variables of suicidal ideation and attempts, along with a possible psychiatric diagnosis. **Results:** Almost half (48.3%) reported suicidal ideation, 23.8% had attempted suicide. **Conclusions:** There are higher levels of suicidal ideation and suicide attempts in people with gender dysphoria than in the general population. No differences were seen between groups in terms of gender/sex. Psychiatric morbidity was not an influential variable for suicidal behaviour. This suggests that suicidal ideation is one of the best indicators of the risk of suicidal behaviours.

Keywords: Gender dysphoria, suicidal ideation, suicide attempts.

Resumen

Ideación e intención suicida en personas con disforia de género. **Antecedentes:** las escasas investigaciones sobre la conducta suicida de personas con disforia de género han señalado que estas tienen un riesgo de mortalidad y comportamiento suicida muy superior a la población general. El objetivo de la presente investigación es analizar la prevalencia de la ideación suicida y de los intentos de suicidio autoinformado de las personas que han realizado consulta entre 2007-2017, en una Unidad de Tratamiento de Identidad de Género por presentar quejas relacionadas con disforia de género. **Método:** estudio ex post facto con una muestra de 151 personas que realizaron demanda en esta unidad, 97 del grupo de hombre a mujer (64,2%) y 54 de mujer a hombre (35,8%). Se les realizó una evaluación clínica contemplando variables sobre ideación e intentos de suicidio, así como un posible diagnóstico psiquiátrico. **Resultados:** el porcentaje de estas personas con ideación autolítica asciende al 48,3% y un 23,8% ha intentado suicidarse. **Conclusiones:** hay más tasas de ideación y tentativa de suicidio en las personas con disforia de género que en población general. No se observan diferencias significativas en razón de la variable sexo/género. La morbilidad psiquiátrica no resultó ser una variable influyente en la conducta suicida.

Palabras clave: disforia de género, ideación suicida, intentos de suicidio.

Suicide is currently a serious public health problem, with more than 800,000 deaths annually worldwide (Word Health Organization - WHO, 2014). In 2014 in Spain, according to data from the Statistical National Institute (2016), suicide remained the leading external cause of death, with 3,910 fatalities, almost 10 suicides per day. Despite this, the number of suicides is often underestimated, the associated stigma, social and political factors, and insurance policy rules also influence this underestimation (WHO, 2014).

In terms of suicide attempts, epidemiological results are even more problematic, this is because only a small percentage of those who attempt suicide need, or seek, medical attention so the majority of suicide attempts are unreported and unrecorded (WHO, 2014). Nonetheless, the WHO estimates the frequency or attempts as 10 or 20 times greater than that of suicides.

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Given the amount and complexity of behaviours related to suicide, in this study we focus on suicide attempts and suicidal ideation following the definitions put forward by O'Carrol, et al. (1996). They define a *suicide attempt* as: a potentially self-injurious behaviour with a nonfatal outcome, for which there is evidence (either explicit or implicit) that the person intended at some level to kill themselves. A suicide attempt may or may not result in injuries. On the other hand, *suicidal ideation* would be whenever the subject has thoughts of carrying out suicide-related behaviours.

Within gender dysphoria (GD), transsexual people have the conviction that they are of the opposite sex to that which they were born into, with a continued sense of dissatisfaction and rejection of their own primary and secondary sexual characteristics, and with a profound feeling of rejection and a desire for medical and surgical changes to modify their body and make it conform with the gender they feel to be. From infancy their mental identity is different to their genital phenotype: they are women who feel "trapped" in a man's body (Female transsexual FT), and men who feel "trapped" in a woman's body (Male transsexual MT). They do not have any serious psychiatric disorders that would distort their perception of reality and only need to be accepted by society and

legally as their chosen gender (Fernández Rodríguez, & García-Vega, 2012; Gómez Gil, Esteva, & Bergero, 2006).

There is little information available about suicidal behaviours in people with GD, (Jiménez Zarazúa, Rodríguez Salinas, Motilla, & Mascareñas, 2015; Mathy, 2002) but various studies have found that they have a higher risk of death by suicide and suicidal behaviour than the general population, although the data are quite variable (Asscheman et al., 2011; Dhejne et al., 2011; Sánchez, Casquero, Chávez, & Liendo, 2014).

With respect to suicidal ideation, the research suggest between 37% and 74% of those with GD reported suicidal ideation (see table 1), very different to the results from Miret et al (2014) reporting 3,67% of the general population.

Miret et al. (2014) carried out research in which they used an adapted version of the Composite International Diagnostic Interview (CIDI), an interview which allows the diagnosis of the principal mental disorders. In that research they found that, of the 4,583 people interviewed, 3.67% had had suicidal thoughts, and 1.46% had attempted suicide at some point.

In non-random interviews with transsexuals it was found that up to a third of those interviewed had attempted suicide one or more times in their lives (Dixen, Maddever, Maasdam, & Edwards ,1984). A more recent study by Haas, Rodgers, & Herman (2014), showed that rates of suicide attempts in transsexual people reached 44%, an extremely high percentage compared to the 1.6% rate found in the general population (see table 2)

Finally, the relationship between psychiatric disorders and suicide has been the focus of much research, and has provoked significant debate, leading them to be generally established as significant risk factors in suicidal behavior (Gómez-Duran et al., 2006). We assume the non-pathologization of gender dysphoria (Mas-Grau, 2017), and consider that it is possible that suicide attempts may be more related to a psychiatric disorder than to gender dysphoria.

Based on this, the aim of this research is to analyse the prevalence of suicidal ideation and suicide attempts in a sample of 151 users of the Gender Identity Treatment Unit (UTIGPA), and to examine whether there are significantly significant differences in terms of sex/gender or psychiatric morbidity . The following hypotheses are proposed: 1) People with GD will exhibit rates of suicidal ideation and suicide attempts that are in line with similar research, and higher than those of the general population; 2) No significant differences are expected in suicidal ideation and suicide attempts in terms of sex/gender; and 3) Psychiatric morbidity will be an influential variable both in suicidal ideation and suicide attempts.

Table 1
Studies that refer to the percentage of people with GD who have attempted suicide

Authors (year)	FT (%)	MT (%)	Total (%)
Mathy, (2002)	–	–	23.3
Bockting et al,. (2005)	–	–	47
Kenagy, (2005)	–	–	30.1
Xavier et al., (2005)	–	–	16
Clements-Nolle, Marx & Katz, (2006)	32	32	32
Grossman & D'Augelli, (2007)	–	–	26
Scanlon et al., (2010)	–	–	43
Grant et al., (2011)	–	–	41
Spack et al., (2012)	–	–	9.3
Haas, Rodgers & Herman, (2014)	42	46	44
Holt, Skagerberg & Dunsford, (2014)	12.3	13.9	13.3
Guzmán-Parra, et al., (2016)	21.8	24	22.8

Table 2
Studies that refer to the percentage of people with GD who have had suicidal ideation

Authors (year)	FT %	MT %	Total %
Mathy, (2002)	–	–	37
Xavier et al., (2005)	52	33	42.5
Hoshiai et al.,(2010)	76.1	71.9	74
Holt, Skagerberg & Dunsford, (2014)	38.3	32.8	35.5
Guzmán-Parra et al., (2016)	46.5	58.3	52.4

Method

Participants

The sample was made up of *N*=151 people with a mean age of 35.3 years old (*SD*=12.27) who had had consultations with the UTIGPA in the time since it opened ten years ago (2007-2017).

The UTIGPA clients were in varying stages of their transsexual processes. Some had not yet started feminising or masculinising hormone treatments, whereas others were on courses of hormone treatment, or had already had some facial or other surgery, and a small number were on the waiting list for genitoplasty.

Out of the 151 people making up the sample, 97 were FT and 54 MT. The gender ratio is 1.8:1 in favour of FT.

The age of the person in the sample when they first attended the UTIGPA ranged between 12 and 79 years old (*M*= 30.32; *SD*= 11.49) (see table 3).

Instruments

Each person completed a semistructured interview, carried out in the aforementioned unit in accordance with the criteria in the

Table 3
Sociodemographic data

	FT n (%)	MT n (%)	Total N (%)	
Age consultation UTIGPA	**M= 36,4 DT= 12,67**	**M= 33,41 DT=11,39**	**M= 35,3 DT= 12,76**	**$F_{(143)}$ =0,109**
Origin				
Spain	73 (75,3)	46 (85,2)	119 (78,81)	$\chi^2_{(1)}$ =10,29*
Latin america	19 (19,6)	4 (7,4)	23 (15,23)	
Europe	2 (5,1)	4 (7,4)	6 (6,2)	
Level of education				
Primary	61 (63,2)	27 (50,0)	87 (57,6)	$\chi^2_{(1)}$ = 2,004
Secondary	30 (31,6)	15 (28,6)	45 (30,3)	
University	5 (5,1)	11 (21,4)	18 (12,1)	
Psychiatric morbidity				
No history	42 (43,3)	23 (42,6)	65 (43)	
Depression	18 (18,6)	11 (20,4)	29 (19,2)	$\chi^2_{(1)}$ =0,374
Anxiety	5 (5,2)	3 (5,6)	8 (5,3)	
Substance use disorders	10 (10,3)	5 (9,3)	15 (9,9)	
Other pathologies	9 (9,3)	6 (11,1)	15 (9,9)	
Depression and anxiety	13 (13,4)	6 (11,1)	19 (12,6)	

* p<,05

DSM 5 (American Psychiatric Association, 2013) (and initially DSM IV) and ICD-10 (World Health Organization, 1992), in which sociodemographic, clinical, and psychiatric information is gathered. The following variables were extracted from these evaluation protocols: age, sex/gender, country of origin, level of educational attainment, and psychiatric morbidity. The latter was categorized as: depressive disorders, anxiety disorders, anxiety and depressive disorders, and substance abuse. A further category of "other pathology" was added, in which the varied diagnoses in the subjects' histories were included, such as: personality disorders, eating disorders, bipolar disorder, unspecified mood disorders, post-traumatic stress disorders, compulsive gambling, hyperactivity, agoraphobia, impulse control disorders, adaptive disorders, and dyslexia, among others.

Suicidal ideation: There are no specific instruments for this population, the scale from Okasha, Lotaif, & Sadek (1981) was used. This scale is self-administered, and made up of four questions, the first three explore suicidal ideation and the fourth looks at suicide attempts. It has high validity α=.82, and the advantage of evaluating suicide risk without needing to perform a psychiatric diagnosis. The sample in this study registered an α=.96.

As a dependent variable, ideation was scored dichotomously, where (1) was equivalent to answering "yes" to all the questions and (2) was equivalent to answering "no" to at least one question; (0) would be the absence of ideation. The question of whether ideation continued every day for at least two weeks was also examined.

Suicidal ideation was evaluated through three questions, which were those used to define the three categories for this variable:

- I have never thought about suicide- absence of suicidal ideation
- *Ideation 1 (Q1):* Have you ever thought that life was not worth living and thought a lot about death?
- *Ideation 2 (Q2):* Have you ever wished you were dead, have you ever felt that you wanted to die?
- *Ideation 3 (Q3):* Have you ever thought about ending your life, have you ever considered suicide?

If the subject responded yes to one of these questions it would satisfy the criteria of suicidal ideation. The ideation would be considered severe if the answer to two or three questions were yes, and mild if only one question received an affirmative response.

If the subject responded yes to one or more of the three questions, the scale included a fourth question about attempted suicide.

Suicide attempts. Have you ever attempted suicide? If the subject responded yes to this question, it would satisfy the criteria of suicidal intent.

In addition to the questions in the scale, the study also considered:

- *Age*, age at the time of suicidal ideation, and age at the time of any suicide attempts.
- *Number of suicide attempts*. The subject is asked how many suicide attempts they have made.
- *Methods used in suicide attempts*. The subject is asked about the method (plan) used when they attempted suicide. This variable was operationalised using the coding method in the ICD-10 related to suicide and intentional self-harm (codes X60-X84).
- *Psychiatric comorbility*: Diagnostic assessment was made after several sessions with both mental health professionals (psychiatrist and psychologist).

Procedure

Once the plan of work was produced and accepted by the Health Area III Research Committee, subject selection was carried out by consecutive sampling of people who had attended the UTIGPA. These people had presented complaints related to gender dysphoria, and on evaluation had been diagnosed with gender dysphoria according to the current criteria of the DSM-5 (initially the DSM-IV) and ICD-10, and in met the criteria in the care standards from the World Professional Association for Transgender Health (WPATH). Those with other gender identity disorders were not considered for this study. Data collection was carried out during consultations which had been previously planned as diagnostic evaluations. The instruments were applied individually.

Data analysis

The SPSS statistics package was used for data analysis. Descriptive analysis was performed in order to obtain means and percentage scores of the variables. The non-parametric the chi-squared test were used to test whether there were statistically significant differences in suicidal ideation or suicide attempts in terms of gender/sex or other sociodemographic variables. With the aim of selecting the subset of predictor variables for suicidal ideation and suicide attempts, a regression analysis was performed with suicidal ideation and suicide attempts as dependent variables, and psychiatric diagnosis as related variables. The significance level in this study is $p<.05$.

Results

Suicidal ideation: From the total sample, 73 people answered "yes" to one or more of the three questions in the suicidal ideation questionnaire from Okasha et al (1981). This represents 48.34%, of whom 47 were FT and 26 MT. Following the statistical analysis of this variable we can conclude that there is no statistically significant difference between the two groups ($\chi^2(1, N=73) =0.001$, p=.971).

In terms of age, the mean age at which subjects first thought about suicide is 19.55 years old (SD = 9.77) , and ranges from 8 to 40 for MT (M=14.9, SD=0.48), and 12 to 52 for FT (M=23.35, SD=11.00). No significant differences were found between the two groups (χ^2 (24, N=73) = 19.163, p=.743).

Forty six people responded "yes" to all three questions, 27 FT and 19 MT, which indicates severe ideation. Mild ideation, answering "yes" to just one of the three questions was indicated by 17 FT and 13 MT. No significant differences were found between the FT and MT groups (χ^2 (2, N=73) =1.753, p=.416)

In terms of suicide attempts, 36 people answered "yes" to the question of whether they had ever attempted suicide, 22 FT and 14 MT. Following analysis of this variable we can conclude that there are no statistically significant differences between the two groups χ^2 (1, N=36)=121, p=.728. Sixteen of the subjects had attempted

suicide on one occasion, 20 on two or more occasions, and one person had tried to end their life seven times. The mean number of attempts was 2.1 (*SD*=2.89).

If we examine the subjects' ages at their first attempt at suicide, 16 were under 18 years old, 12 were between the ages of 18 and 29, and 4 were between 30 and 46. The mean age was 19.97 (*SD*=8.85).

With respect to the methods used, and following the coding schema from ICD-10 related to suicide and self-inflicted harm (codes X60-X84), the results are detailed in Table 4.

In terms of psychiatric background, from the overall sample, 29 people had been diagnosed with depression (19.2%), of whom 32.65% had attempted suicide on one or more occasions. Eight UTIGPA clients (5.3%) had been diagnosed with anxiety, 26.9% of whom had attempted suicide on one or more occasions. If we look at intoxicating substances, 15 people from the sample (9.9%) had problems associated with consumption of this kind of substance, of whom 36.36% had attempted suicide at least once. A regression analysis was carried out looking at ideation and suicide attempts as dependent variables and the psychiatric diagnosis as predictor variables: depression, anxiety, medication overdose, anxiety and stress, and other pathologies. The only statistically significant relationship found was between suicidal ideation and other pathologies, and between suicide attempts and other pathologies, although in both cases the variation explained is very small. $F_{(5)}$ =2.150, p<.05, R^2 = .037 y $F_{(5)}$=3.175, p<.05, R^2 = .068. The best predictor variable for suicide attempts is suicidal ideation. $F_{(7)}$ = 14.787, p<.01, R^2 = .392.

Discussion

The persistent sense of discrepancy that people with GD feel about their assigned gender and their felt gender posts them in a vulnerable situation, due to a continuing dissatisfaction with and a rejection of their own primary and secondary sexual characteristics. This may represent a risk factor for suicidal behaviours, as various studies have found that GD is associated with an increased number of suicides compared to the general population (Bodlund & Kullgren, 1996; Clements-Nolle et al., 2006; Hepp, Kraemer, Schnyder, Miller & Delsignore, 2005; Jiménez Zarazúa et al., 2015).

Table 4
Methods used by UTIGPA clients in suicide attempts, in terms of sex/gender, according to the ICD-10 criteria for suicide and intentional self-harm

Method used (ICD-10 code)	FT *n* (%)	MT *n* (%)
Intentional medication overdose (X60 – X64)	9 (9.28)	5 (9.26)
Intentional overdose by other and unspecified chemicals and noxious substances (X69)	2 (2.06)	0
Suicide and intentional self-harm by hanging, strangulation and suffocation (X70)	0	3 (5.56)
Suicide and intentional self-harm by sharp object (X78)	4 (4.12)	4 (7.41)
Suicide and intentional self-harm by jumping from a high place (X80)	3 (3.09)	1 (1.85)
Suicide and intentional self-harm by crashing of motor vehicle (X82)	2 (2,06)	0
No information about the method used	2 (2,06)	1 (1,85)

Because the types of pills used in suicide attempts are unknown, the various codes for different substances, X60, X61, X62, X63, and X64 have been grouped together under X60-X64

The UTIGPA has recorded a total of 151 clients since it opened in 2007. This represents a prevalence of 1.5 per 10,000 inhabitants, which is higher than in other Spanish studies, for example in Catalonia the prevalence was estimated to be 1/34,000, and in Andalucía 1/12,500 (Hurtado Murillo, 2015). The gender ratio of clients in the unit is 1.8:1 FT/MT, which is similar to Andalucía (1.6:1) but lower than in Catalonia (2.1:1) (Gómez-Gil et al., 2011).

Analysis of the suicidal ideation variable shows us that almost half of UTIGPA clients (48.34%) have had thoughts of this nature at some point in their lives, result is similar to that found in other studies. This is an extremely high proportion, and is much greater than the percentage found in the general population (3.67% according to research by Miret et al., 2014). If we consider sex/gender, the percentage of FT who have had suicidal ideation is almost identical to that of MT. These results are in line with other research into suicidal thoughts in people with GD (see table 2), but are very different to data from the general population. In most countries where suicide has been studied, women exhibit higher levels of suicidal ideation and suicide attempts than men, but there are a higher number of deaths by suicide in men (Hawton, 2000).

Analysis of the suicide attempts variable shows that almost a quarter of UTIGPA clients had tried to end their lives on at least one occasion. This is almost three times the rate found in the general population (8.42% according to data collected by Statistics National Institute in Spain in 2014). The percentages are similar for both gender/sex groups: 22.68% of FT have attempted suicide at some point, compared to 25.96% of MT. These results are consistent with previous research, in which those with GD have been seen to have higher risks of suicidal behaviour and death by suicide than the general population (Asscheman et al., 2011; Dhejne et al., 2011; Sánchez et al., 2014). Although the mean age at first suicide attempt was 19.97 (*SD*=8.85), the majority (*n*=16) were under 18 years old. The most commonly used method was medication overdose.

It is well known that people with psychiatric diagnoses present a greater risk of suicide than the general population, and according to most research, depression is the main cause of both attempted suicide, and death by suicide (Hawton, Casañas, Comabella, Haw, & Saunders, 2013). This is a reasonable conclusion for patients whose principal diagnosis is depression and for those who present co-morbid depressive symptomatology, or associated with substance use. However, we did not see significant differences in our sample related to psychiatric diagnosis, either in ideation or in suicide attempts. There was a close relationship between suicidal ideation and suicide attempts. Therefore, one might suppose that in this population, suicidal ideation may be associated with an emotional process which might limit the perception of available solutions and drive a person towards a state of hopelessness, thus increasing the probability of suicide. More specifically, one of the hypotheses about which there is most consensus when it comes to explaining suicidal ideation and actual suicidal behaviour suggests the need for some stressful event which provokes certain emotions (especially frustration or rejection), the desire to escape from a situation or to communicate their problems to others,

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together with the evaluation that such options are not possible, and a lack of resources to alleviate the crisis (e.g. social support). This sequence of ideas, together with the availability of methods or models of such behaviour lead to feelings of helplessness which encourage suicidal behaviours (O'Connor, & Nock, 2014; Palmer, 2007). As such, with persistent ideation being a risk factor which encourages people to engage in self-injurious, and in some cases fatal behaviour, it is essential to establish action plans to reduce ideation (Hirsch, Cohn, Rowe, & Rimmer, 2017; Irwin, Coleman, Fisher, & Marasco, 2014)

There were some general issues limiting this study. Primarily, in the absence of a non-transsexual population control group, it is impossible to draw conclusions as to whether there were differences in psychopathology and psychosocial adjustment compared to the transsexual population On the other hand, the sample was not representative of the entire transsexual population as not all members of this population sought treatment at the Unit. Finally, it is important to note that we analysed attempted suicides, but it was not possible to evaluate whether they were suicide attempts without the apparent intention to die, or were frustrated suicides.

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UCLA School of Law Williams Institute

SUICIDE RISK AND PREVENTION FOR TRANSGENDER PEOPLE

Summary of Research Findings

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FACT SHEET / SEPTEMBER 2021

Transgender people have the same suicide risk factors as cisgender people, plus additional risk factors associated with minority stress and lack of access to gender-affirming medical care. These additional risk factors contribute to a higher prevalence of suicide thoughts and attempts among transgender people as compared to cisgender people. Studies have found that around 40% of transgender adults have attempted suicide in their lifetimes and that 30% of transgender youth have attempted suicide in the past year.[1] Yet, studies have found that certain experiences, like family and social support, are associated with reduced prevalence of suicide thoughts and attempts. Below is a summary of select research findings on this important topic. Notably, this research summary is limited to suicide thoughts and attempts because we currently lack mortality data about suicide deaths among transgender people across the United States.

Like the general U.S. population, transgender people have elevated prevalence of suicide thoughts and attempts among those with lower socioeconomic status (i.e., less education, unemployed, lower household income, experiencing homelessness), those experiencing serious psychological distress, reporting heavy alcohol or illicit drug use, or in poor general health.[2] Many of these characteristics are associated with, or are downstream effects of, exposure to stigma, discrimination, and violence.[3]

Minority stressors, such as discrimination experiences, family rejection, and stigma, are commonly reported by transgender people and are associated with higher risk of suicide thoughts and attempts.[4] These include experiences of discrimination, mistreatment, or violence in education, employment, housing, health care, in places of public accommodations, from law enforcement, and in other areas of life.[5]

- Respondents to the 2015 U.S. Transgender Survey (2015 USTS), a national survey of transgender adults, who reported that they had been denied equal treatment in services or public places in the past year due to anti-transgender bias had more than double the prevalence of past year suicide attempts than those who had not experienced such treatment (13.4% compared to 6.3%).
- Over 30% of USTS respondents who were physically attacked in a place of public accommodation reported attempting suicide in the past year, which is over four times the prevalence (7%) among respondents who were not similarly attacked.
- Those rejected by their spouses or children, families of origin, or religious communities had a higher prevalence of past-year suicide thoughts and attempts; 13.1% of those who had experienced religious rejection in the past year had attempted suicide in the past year compared to 6.3% of respondents who were accepted in their religious communities.

Transgender people who need access to gender-affirming care, such as hormone therapy or surgical care, may experience barriers to receiving that care, including costs, lack of providers, and state laws. Over 45,000 transgender youth live in states where laws have passed or been proposed to prohibit youth from accessing gender-affirming care.[6] Yet, gender-affirming care is associated with reduced prevalence of suicide thoughts and attempts for those who receive the care they need.[7]

- A recent study found that transgender adults who received pubertal suppression hormone therapy as adolescents were less likely to experience suicide ideation in their lifetime.[8]
- Respondents to the 2015 USTS who have had the gender affirming hormone therapy or surgical care they need had lower prevalence of past-year suicide attempts compared to those who had not received the care they needed (5.1% vs. 8.5%); this difference persists even after controlling for race, age, sex assigned at birth, binary/nonbinary gender identity, and education.[9]

Several factors have been found to reduce suicide thoughts and attempts. These include, but are not limited to, access to gender-affirming care, family support and acceptance, acceptance in religious communities, and social support.[10]

- 2015 USTS respondents who reported their families were supportive had lower prevalence of past-year suicide attempts compared to those with unsupportive families (5.8% vs. 13.1%).[11]
- Transgender youth with families that used their chosen name reported less suicide ideation compared to those whose families would not use their chosen name at home.[12]
- Transgender adults with supportive classmates or co-workers reported a lower prevalence of past-year suicide thoughts or attempts than those with unsupportive classmates or co-workers.[13]

These factors that reduce suicide thoughts and attempts suggest that implementing laws, policies, and programs that aim to reduce discrimination against transgender people, increase family and social support, and improve access to gender-affirming care can improve people's lives and reduce suicide thoughts and attempts. However, more research is needed to create and implement effective suicide intervention and prevention strategies for transgender people. Filling gaps in official data collection systems, like the National Violent Death Reporting System, is one action that would help inform prevention planning.

ENDNOTES

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Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria

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Abstract

Individuals who experience a gender identity that is discordant with biological sex are increasingly presenting to physicians for assistance in alleviating associated psychological distress. In contrast to prior efforts to identify and primarily address underlying psychiatric contributors to gender dysphoria, interventions that include uncritical social affirmation, use of gonadotropin-releasing hormone agonists to suppress normally timed puberty, and administration of cross-sex steroid hormones to induce desired secondary sex characteristics are now advocated by an emerging cohort of transgender medicine specialists. For patients with persistent gender dysphoria, surgery is offered to alter the appearance of breasts and genital organs. Efforts to address ethical concerns regarding this contentious treatment paradigm are dependent upon reliable evidence on immediate and long-term risks and benefits. Although strong recommendations have been made for invasive and potentially irreversible interventions, high-quality scientific data on the effects of this approach are generally lacking. Limitations of the existing transgender literature include general lack of randomized prospective trial design, small sample size, recruitment bias, short study duration, high subject dropout rates, and reliance on "expert" opinion. Existing data reveal significant intervention-associated morbidity and raise serious concern that the primary goal of suicide prevention is not achieved. In addition to substantial moral questions, adherence to established principles of evidence-based medicine necessitates a high degree of caution in accepting gender-affirming medical interventions as a preferred treatment approach. Continued consideration and rigorous investigation of alternate approaches to alleviating suffering in people with gender dysphoria are warranted.

Summary: This paper provides an overview of what is currently known about people who experience a gender identity that differs from their biological sex and the associated desire to engage the medical profession in alleviating associated discomfort and distress. The scientific evidence used to support current recommendations for affirming one's preferred gender, halting normally timed puberty, administering cross-sex hormones, and surgically altering primary and secondary sexual traits are summarized and critically evaluated. Serious deficits in understanding the cause of this condition, the reasons for the marked increase in people presenting for medical care, together with immediate and long-term risks relative to benefit of medical intervention are exposed.

Keywords

Cross-sex hormones, Evidence-based medicine, Gender dysphoria, Gender identity, Medical research, Puberty blockade, Risk–benefit analysis, Sexuality, Suicide, Transgender operations

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Patients who experience a gender identity that is discordant with biological sex have an alarmingly high incidence of serious psychosocial morbidity including depression, anxiety, eating disorders, substance abuse, HIV infection, and homelessness (Connolly et al. 2016). Most concerning, nearly half of all affected individuals will contemplate suicide and a third will attempt suicide (Adams, Hitomi, and Moody 2017). While a need for effective treatment modalities is clear, there are significant deficiencies in understanding the etiology of this condition, the risks and benefits of proposed medical interventions, and the long-term success of various approaches in achieving the primary desired goal of preventing suicide (Institute of Medicine 2011; Olson-Kennedy et al. 2016). With a desire to provide real and sustained assistance to patients who experience gender dysphoria within established ethical boundaries, it is essential to understand the scientific evidence used to support proposed medical interventions and acknowledge the limits of these data.

To adequately address the role of healthcare providers in treating patients with gender dysphoria, it is necessary to define this clinical condition in a way consistent with established scientific understanding of sex as a biological trait intrinsically ordered to the purpose of procreation. Despite ideologically influenced efforts to portray sex along a continuum, reproductive biology is inherently binary. Specifically, there are only two gonads (testes and ovaries) that contribute to the conception of new human life. The existence of individuals with disorders of sexual development (DSDs) does not alter this basic biological reality (Eid and Biason-Lauber 2016). In many individuals with DSDs, fertility is absent or severely impaired (Lee et al. 2006, 2016). When genital ambiguity is present, there are established clinical pathways involving hormonal, genetic, and imaging studies to assist clinicians in determining the sex of the affected child (Lee et al. 2016). In these rare cases, which affect <0.02 percent of all infants, the physician must make a tentative sex assignment at the time of birth. For the remaining 99.9% of infants, sex is not "assigned" at birth but rather is correctly recognized by the observation of the appearance of the external genitalia. Nearly all patients who present to medical establishments for the treatment of gender dysphoria have normally formed and functioning sexual anatomy and function prior to hormonal or surgical intervention.

Although the ability to obtain accurate information on the number of people who experience a gender identity that is discordant with biological sex has remained challenging, several sources have reported a marked increase in the number of patients presenting to specialized clinics that offer gender affirmation services. In the Fifth Edition of the *Diagnostic and Statistical Manual* (DSM-5) used to classify psychiatric disease, the reported prevalence of "gender dysphoria" was 0.005 percent to 0.014 percent for adult males and 0.002 percent to 0.003 percent for adult females (American Psychiatric Association [APA] 2013). Epidemiologic data from Sweden have demonstrated rising prevalence of individuals claiming a transgendered identity who sought treatment over the past fifty years, with most of the increase since 2000 (Dhejne et al. 2014). Some more recent estimates have suggested a prevalence as high as .4 percent of the US population (Meerwijk and Sevelius 2017).

Assessing the accuracy of these estimates requires consideration of the methodologies used. Higher estimates rely upon patient responses to questionnaires in which answers appear to be influenced by the wording of the questions asked. There is evidence that male to female ratio of individuals with sex–gender identity discordance has reversed, with more recent estimates showing that much of the observed increase is due to biological females who identify as male (Zucker 2017). It is frequently claimed, without documented scientific evidence, that this increase is driven by an increase in existing patients coming forward for treatment rather than a change in overall incidence or change in rates of persistence among affected youth. The degree to which social affirmation of transgendered identity has affected these epidemiologic trends is unknown. Recently, the phenomenon of adolescent girls with no prior expression of gender dysphoria presenting as having a transgendered identity in social networks has been reported (aka rapid onset gender dysphoria; Littman 2018). This study is limited by relatively small sample size and a significant risk of ascertainment bias. Further research is required to establish the validity and extent of this phenomenon.

Understanding of the cause of any medical condition greatly assists efforts to develop effective treatment strategies. To date, the cause of discordance between sex and gender identity remains unknown. There is no available blood test or imaging procedure that can be used to determine a person's self-perceived gender identity. Evaluation relies exclusively in the domain of patient report of internally held feelings and beliefs. There are, however, published data that provide potential clues to influencing factors (Saleem and Rizvi 2017). This includes several reports of structural and functional differences between brains of individuals with sex-

discordant gender identity compared to brains from people with gender identity that matches sex (Burke et al. 2014; Luders et al. 2009; Kruijver et al. 2000). Among the limitations of these data are significant overlap between male and female brain structures and heterogeneity between individuals. This precludes the ability to determine sex by examining structure alone. Furthermore, the existing data on brain structure and function do not account for the known phenomenon of neuronal plasticity (i.e., environmental stimuli can alter brain structure; Ismail, Fatemi, and Johnston 2017). Thus, it is not clear whether changes in brain structure are the cause or effect of transgendered identity and behavior.

It is known that prenatal and perinatal hormone exposure can alter sexual phenotype (i.e., the physical appearance of the body; Jost et al. 1973). The degree to which these hormones influence gender identity remains an area of active investigation (Berenbaum and Beltz 2016). Although insight has been gained by study of DSDs, there is conflicting evidence on the nature and magnitude of this effect and the dependence upon the etiology of the developmental defect. For example, female infants born with congenital adrenal hyperplasia (CAH), a condition that exposes the developing baby to high levels of male hormones (androgens), often exhibit typical male preferences and behaviors. Several potential explanations for this phenomenon that are independent of prenatal male hormone exposure have been proposed (Jordan-Young 2012). Importantly, the vast majority of affected children with CAH historically did not experience self-perceived transgender identity or gender dysphoria (Zucker et al. 1996).

Limited data also suggest a role of genetics in gender identity. This includes investigation of identical twins (Heylens et al. 2012). Because identical twins have exactly the same genes, if gender identity is exclusively determined by genetics, one would predict that there would be 100 percent concordance in identical twin pairs (i.e., if one twin experienced transgender identity, the other twin would also share this experience). However, the observed concordance is closer to 40 percent of affected twins. There are ongoing efforts to sequence the genomes of individuals with sex-discordant gender identity to find a specific gene (or genes) that contribute(s) to this experience (Yang et al. 2017). The data published to date addressing this question provide potential clues, but similar to the limitations of with brain structures, there is considerable overlap between affected and nonaffected individuals (Foreman et al. 2019). Thus, it is likely that influences, whether primary or secondary, are polygenetic (i.e., the genetic differences are many, with each contributing only a small fraction of the observed phenotype).

The presence of genetic differences does not mean that the genetic variation is the cause of an individual's identity. There are numerous alternate hypotheses that can be proposed (e.g., a genetic difference in resiliency). Several reports have found high co-occurrence of autism in children with gender dysphoria (Glidden et al. 2016). Thus, in light of existing data, it can be reasonably concluded that the cause of gender dysphoria is multifactorial with both genetic and environmental contributions. Further research is needed to establish the number of contributing factors and to determine relative influences for individual patients. Heterogeneity among patient populations is likely to complicate efforts to make generalizable outcome predictions in clinical studies, particularly with small randomized trial designs.

In children who express gender discordance, the majority will experience reintegration of gender identity with biological sex by the time of puberty in the absence of directed medical or societal intervention. This is supported by nearly a dozen published studies over the past forty years. Many of the earlier studies included a small number of subjects and used definitions of gender discordance (e.g., gender identity disorder) that differ from current criteria for gender dysphoria as listed in the *DSM-V* (APA 2013). In some studies, loss of patients to follow-up hinders determination of desistance (Wallien and Cohen-Kettenis 2008). The most recent studies report desistance rates near 85 percent (Steensma et al. 2011; Drummond et al. 2008).

There is some evidence that the degree of distress experienced by a gender dysphoric child correlates with the likelihood of spontaneous resolution (Steensma et al. 2013). Whether and to what extent changes in social and medical approaches to dealing with individuals with transgender identity alters the rate of desistance is unclear, but there is indirect evidence that such effects may occur (de Vries et al. 2011). For patients who experience sex-discordant gender identity beyond puberty, there are relatively few published reports of desistance. Most of these data are found among case reports and personal testimony outside of peer-reviewed journals (Heyer 2018; Meijer et al. 2017). There are several hypotheses that can be put forth to account for this observation including differences between children and adults with respect to underlying etiology and the effects of extended social reinforcement. As in affected children, there are few data on the influence of gender-affirming medical procedures on altering desistance rates.

Before addressing specific aspects of medical interventions intended to alleviate gender dysphoria, several general observations can be made regarding the published literature in this field. Despite the endorsement of gender affirmation approaches by several medical organizations including the Endocrine Society (Hembree et al. 2017) and the World Professional Alliance for Transgender Health (WPATH; Coleman et al. 2012), it is important to recognize the low quality of scientific evidence used in generating these treatment recommendations. With the publication of both the initial treatment guidelines by the Endocrine Society guidelines in 2009 and revised guidelines in 2017, the Grading of Recommendations, Assessment, Development and Evaluations system was used to assess data quality (Guyatt et al. 2008). This system ranks evidence into four categories (strong, moderate, low, and very low). Nearly all of the recommendations made were based upon "low" or "very low" quality evidence. By definition, these designations mean that there is a high likelihood that the attainment of new data will necessitate changes to the guidelines provided. The only data that reached the level of "moderate" quality were related to adverse medical outcomes. The limitations of the published studies in the growing field of transgender medicine are many. They include a general lack of randomized controlled trial design, small sample sizes, high potential for recruitment bias, questions regarding the precision of measured parameters, nongeneralizable population groups, relatively short follow-up, high numbers of patients lost to follow-up, and frequent reliance upon "expert opinion" alone. While such deficiencies are not unique to this field of investigation, the strength of the recommendations made on the basis of this type of evidence is, in many respects, disproportionate. In other areas of medicine, much greater caution is generally applied to advancing a single treatment approach over other potential interventions.

The care of patients who experience gender dysphoria has included efforts to understand and address underlying psychosocial morbidity (Brown and Jones 2016; de Graaf et al. 2018; Kaltiala-Heino et al. 2015). Underlying factors that have been investigated include unresolved developmental challenges, underlying depression and anxiety disorders, strained family relationships, sexual abuse, autism, and peer conflicts (Saleem and Rizvi 2017). The pioneering work of Zucker established that many but not all patients who received psychological counseling and support were able to manage and resolve conflicts arising from discordant gender identity, particularly in affected children (Zucker et al. 2012).

Among contemporary approaches to alleviate gender dysphoria are efforts to support and encourage affected patients to adopt a social role in accord with gender identity irrespective of biological sex. Social transition includes the use of preferred name and pronouns, cross-dressing, and access to sex-segregated facilities corresponding to perceived gender identity. Since the widespread adoption of interventional strategies directed toward affirming transgender identity, efforts to identify psychological approaches to mitigate dysphoria, with or without desistance as a desired goal, have largely been abandoned. The WPATH has rejected psychological counseling as a viable means to address sex–gender discordance with the claim that this approach has been proven to be unsuccessful and is harmful (Coleman et al. 2012). Yet the evidence cited to support this assertion, mostly from case reports published over forty years ago, includes data showing patients who benefited from this approach (Cohen-Kettenis and Kuiper 1984). Although largely unstudied, cognitive behavioral therapy in particular may have significant benefit to this patient population by reducing social anxiety (Busa, Janssen, and Lakshman 2018). To date, there have been no randomized controlled trials investigating the risks and benefits of social transition.

There have been studies that report positive effects of nonmedical interventions: cross-sectional data on preferred name use have reported significant short-term improvement in self-reported sense of well-being (Russell et al. 2018). Furthermore, children who have undergone social transition with parental support have reported reduced levels of dysphoria (Durwood, McLaughlin, and Olson 2017; Olson et al. 2016). Limitations of these data include small sample size, restriction of study subjects to those with mild dysfunction, reliance on parental report, and lack of long-term follow-up.

A variety of medical interventions have been introduced to support physical changes in the appearance and function of primary and secondary sexual organs to align with an individual's desired gender role when this is discordant with biological sex. This includes hormonal blockade of normal pubertal development in adolescent children, administration of cross-sex hormones (i.e., testosterone to females desiring to appear male and estrogen to males desiring to appear female), and surgery to alter the appearance of primary and secondary sexual features. While surgical procedures have been available to affected adults for decades, the use of such

interventions in children has only recently been advocated (de Vries and Cohen-Kettenis 2012).

Long-acting gonadotropin-releasing hormone (GnRH) agonists (aka "puberty blockers") have been recommended to halt pubertal progression when this process occurs prematurely in children (Carel et al. 2009). Purported justification of this intervention for children with persisting dysphoria includes overall safety of these medications, allowance of more time for a child to explore their gender identity, reversibility upon treatment cessation for desisting individuals, and prevention of irreversible changes in secondary sexual characteristics for patients with persistent gender discordance. Yet the use of this intervention remains controversial (Vrouenraets et al. 2015; Giovanardi 2017). There are a few relatively small studies that have demonstrated improved sense of well-being and reduced dysphoria in adolescent transgendered youth who receive puberty-blocking drugs (de Vries et al. 2011, 2014), but there are also significant concerns related to associated risks (Hruz, Mayer, and McHugh 2017). First, there are limited data specifically assessing the long-term safety of delaying normally timed puberty (Schagen et al. 2016). This class of medication has not been approved by the US Food and Drug Administration for use in halting normally timed puberty for gender-dysphoric youth (AbbVie 2018). Risks include osteopenia (low bone density), altered adult height, and impaired special memory (de Vries et al. 2011; Hough et al. 2017). Rather than merely providing more time for the exploration of gender identity, there is a concern that most if not all children exposed to this intervention will proceed to cross-sex hormone therapy (de Vries et al. 2011). While cessation of GnRH agonist administration will allow resumption of the signals that direct gonadal maturation, the interruption of a normal developmental process, which is time-dependent, cannot be "reversed."

In the peer-reviewed literature on individuals who have undergone gender-affirming medical procedures to change bodily appearance, relatively low rates of regret and desire to "de-transition" to a gender role corresponding to biological sex have been observed (Wiepjes et al. 2018). Due to limitations in available data, questions remain regarding long-term satisfaction, particularly when initiated in adolescent children (Mahfouda et al. 2019). Most reports are from retrospective chart review or longitudinal study design.

None of the available studies include matched randomized prospective control groups. There is a deficiency of scientific study systematically assessing this patient population to understand factors that are correlated with and may contribute to failure to achieve lasting relief of dysphoria following the affirmation of discordant gender identity. Affected individuals who desire to transition back to a gender role concordant with biological sex have reported negative social stigma similar to or in some cases exceeding that encountered prior to their initial medical intervention to support transgendered identity (Heyer 2018).

The available data on the long-term effects of gender affirmation in this patient population indicate that the most serious concern, suicide, remains significantly elevated above the background population after medical intervention to alter sexual appearance. Specifically, a thirty-year follow-up study in Sweden on patients who had undergone medical transition showed a rate of completed suicide that was nineteenfold above the backgrounds population (Dhejne et al. 2011). Because this was not a controlled study, it is not possible to assess the impact of the medical treatments themselves on outcomes. However, these data clearly show that this approach did not resolve the problem of depression and suicide.

Further indicating a lack of efficacy of this approach is a recent meta-analysis in North American patients, where suicidal ideation was assessed over the course of an individual's lifetime and within the past year (Adams, Hitomi, and Moody 2017). In this report, suicide rates were similar in both groups. The few studies that examined suicidal ideation before and after gender transition found suicidal ideation to be increased.

In addition to remaining questions regarding the efficacy of hormonal and surgical efforts to align the body of an individual with gender dysphoria to his or her desired sex, the safety of these interventions is only partially understood, particularly when administered to children. A known consequence of cross-sex hormone administration is the disruption of gonadal function and the signals that regulate human reproduction. The infertility that results can be irreversible, particularly where this intervention is undertaken prior to full gonadal maturation (Hembree et al. 2017). Androgen levels achieved in female patients given testosterone exceed those observed in women with polycystic ovarian syndrome and frequently reach levels seen in androgen-secreting tumors with associated cardiovascular risk (Macut, Antić, and Bjekić-Macut 2015). Males receiving estrogen have a fivefold increase in the incidence of thromboembolic stroke (Getahun et al. 2018). Adverse metabolic effects that increase the risk of cardiovascular disease have also been reported (Irwig 2018; Maraka et al. 2017). The

influence of cross-sex hormones on cancer risk remains unclear. Potential risks for cancer development include exposure to cross-sex hormones, effects of sexually transmitted diseases (i.e., some sexually transmitted diseases increase risk of some cancers), and failure to obtain recommended screening in patients presenting to medical facilities with a gender that does not match biological sex. Further research is needed to adequately address this serious concern (Braun et al. 2017).

In summary, the information presented in this report highlights many of the deficiencies in the existing knowledge base regarding the etiology and prevalence of gender dysphoria and current treatment approaches. Although far from exhaustive, these data provide a rationale for exercising caution in accepting the currently proposed gender affirmation treatment paradigms that have been advocated by the WPATH (Coleman et al. 2012) and other professional organizations (Hembree et al. 2017). With heightened awareness of the suffering experienced by individuals who experience a gender identity that is discordant with biological sex, there remains a strong moral imperative to engage this vulnerable patient population. As increasing numbers of affected people, both children and adults, are presenting to medical centers for help, there is a need to better understand this condition and provide means to address all associated medical needs. This includes efforts to welcome and support individuals claiming a transgendered identity with the provision of routine medical care and treatment (Rahman, Li, and Moskowitz 2019). As in all other areas of medicine, efforts to provide safe and effective clinical care of patients with gender dysphoria should be grounded on sound scientific evidence. Where this evidence is lacking, academic healthcare institutions have an opportunity to contribute to rigorous clinical investigation of novel treatment approaches. This can include efforts to better understand psychological influences on gender identity and the design of properly controlled clinical trials using modern psychiatric approaches such as cognitive behavioral therapy (Butler et al. 2006). Administrators who are charged with developing institutional policy and educating staff on the complexity of this unique condition and diverse patient population can benefit from recognizing the ambiguities present. Physicians who deliver this care can also remain mindful of the long history of the harms that have been done to patients from the use of unproven medical interventions (Johnson 2014). Ongoing critical appraisal of emerging scientific evidence and continued open dialogue regarding potential alternate approaches to the care of individuals with sex–gender discordance provides hope for lasting benefit, both to affected patients and to society as a whole.

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Suicide-Related Outcomes Following Gender-Affirming Treatment: A Review

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Abstract

Gender-affirming treatment remains a topic of controversy; of particular concern is whether gender-affirming treatment reduces suicidality. A narrative review was undertaken evaluating suicide-related outcomes following gender-affirming surgery, hormones, and/or puberty blockers. Of the 23 studies that met the inclusion criteria, the majority indicated a reduction in suicidality following gender-affirming treatment; however, the literature to date suffers from a lack of methodological rigor that increases the risk of type I error. There is a need for continued research in suicidality outcomes following gender-affirming treatment that adequately controls for the presence of psychiatric comorbidity and treatment, substance use, and other suicide risk-enhancing and reducing factors. There is also a need for future systematic reviews given the inherent limitations of a narrative review. There may be implications on the informed consent process of gender-affirming treatment given the current lack of methodological robustness of the literature reviewed.

Categories: Psychiatry, Psychology, Epidemiology/Public Health
Keywords: suicide, transgender, suicide prevention, transgender youth, transgender health, transgender and gender-diverse, suicide risk

Introduction And Background

Gender-affirming treatment remains a topic of controversy, with many calling for greater access to gender-affirming treatments to foster psychological well-being for transgender, nonbinary, and intersex individuals [1-6]. There is accumulating literature that suggests transgender individuals suffer worse mental health outcomes than their cisgender peers; of particular concern is increased suicidality [4,7-13].

The literature to date reveals concerning trends regarding suicidality in transgender individuals. A high prevalence of suicide attempts and thoughts of suicide occur in transgender youth compared to their cisgender peers [11,12,14]. Transgender US military veterans have more than 20 times higher rates of suicide-related events than cisgender veterans [7]. The prevalence of suicidal ideation and attempts varies by sample [8], with the prevalence of suicidal ideation sometimes as high as 50-75% [4,10,15]. Rates of attempted suicide can reach peaks of 30% and above [4,14,15]. One longitudinal study of over 6,000 transgender individuals in the US indicates that the highest risk of suicide is among those under 18 years of age [9].

Transgender individuals are also at increased susceptibility for various suicide risk-enhancing factors, as a growing body of literature suggests that transgender individuals face a high burden of chronic health conditions [16,17], psychiatric illnesses and their comorbidities [18-20], substance use [21], trauma and victimization [20,22-24], and housing and employment discrimination [25].

In light of this high prevalence of suicidality and the proliferation of gender-affirming treatments, a common argument by advocates of gender-affirming treatments is that such treatments are needed to reduce suicidality [26-29]. This review is the first of its kind to evaluate mental health outcomes from gender-affirming treatments solely from the standpoint of suicidality, with the recognition that this evaluation of suicide-related outcomes pertains to transgender individuals as a single group; however, transgender and gender-diverse individuals comprise a heterogeneous population that may experience varying degrees of health outcomes and biopsychosocial stressors [20].

Review

Methods

On October 21, 2022, the following search strategy was used in PubMed: ("Suicide"[Mesh] OR suicid*[tiab]) AND ("Sex Reassignment Procedures"[Mesh] OR "sex change*"[tiab] OR "gender change"[tiab] OR "sex reassignment*"[tiab] OR gender reassignment*[tiab] OR "sex confirmation*"[tiab] OR "gender confirmation*"[tiab] OR "gender affirm*"[tiab] OR transitional surgery[tiab] OR "Gonadal Steroid Hormones"[Mesh] OR"Gonadotropin-Releasing Hormone"[Mesh] OR Hormon*[tiab]) AND ("Transgender Persons"[Majr] OR "Gender Dysphoria"[Majr] OR "Gender Identity"[Majr] OR transgender[tiab] OR "gender dysphoria"[tiab]

OR "gender identity"[tiab]) AND (following[tiab] OR after[tiab] OR outcome[tiab]).

The search terms resulted in 49 articles, of which the title and abstract were screened for inclusion. Included studies were required to be quantitative, peer-reviewed, published in English, and had an outcome measure of suicidal ideation and/or attempt after gender-affirming surgical procedures (hysterectomy, oophorectomy, mastectomy, phalloplasty, scrotoplasty, and breast, penile, or scrotal prosthesis), hormone treatment (including puberty-blocking treatment), and any combination thereof.

Out of screening the titles and abstracts of these 49 results for relevance, 19 were evaluated via full-text review for inclusion, of which 15 met the inclusion criteria. Based on references contained in the papers initially reviewed, the full text of an additional 11 papers was screened, with eight meeting the inclusion criteria (Figure *1*). The papers that met the inclusion criteria are grouped according to the type of gender-affirming treatment. Most studies that include surgery had patients on cross-sex hormones, but they used surgery as the designation of categorizing outcomes before and after an intervention (Table *1*).

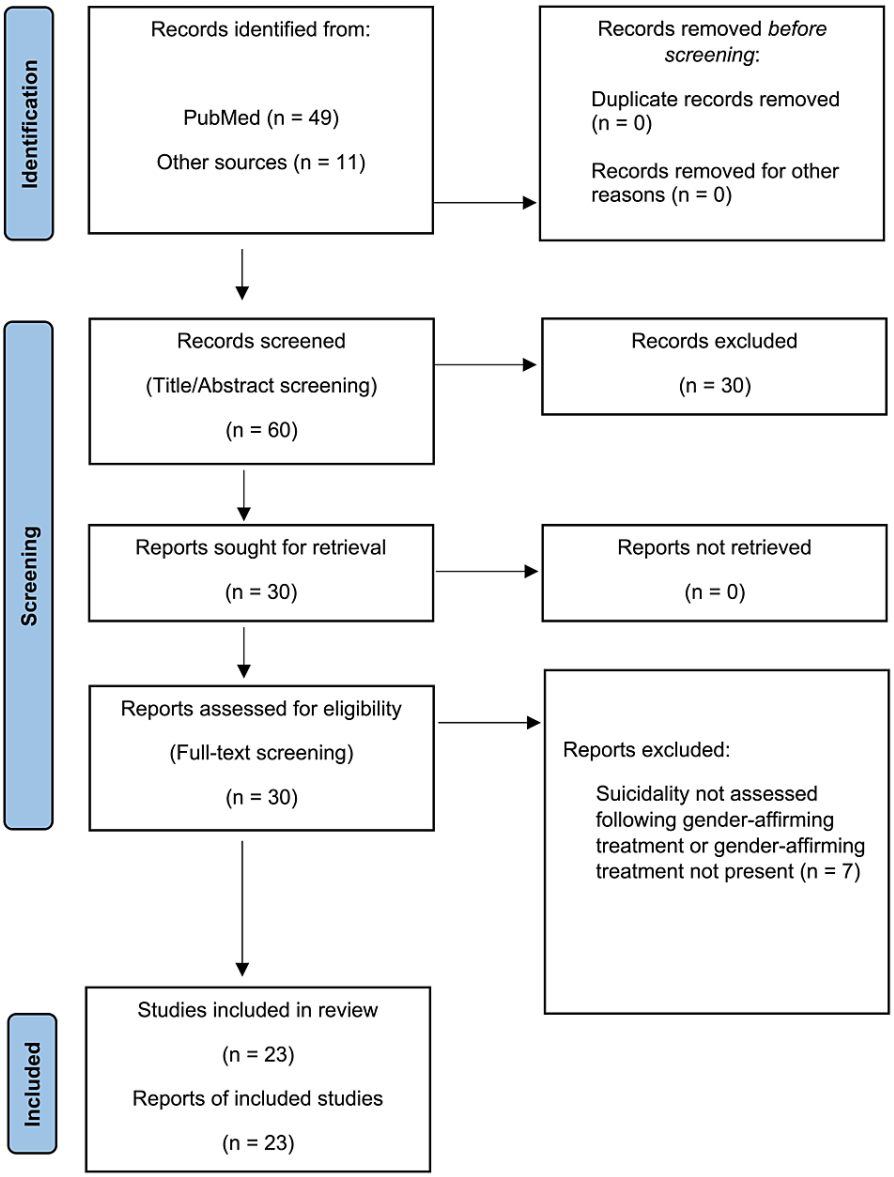

FIGURE 1: PRISMA flow diagram

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

From: Page MJ, McKenzie JE, Bossuyt PM, et al.: The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ. 2021, 372:n71. doi: 10.1136/bmj.n71 [30].

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	Study type	Treatment type	Gender	Control for time elapsed since treatment	Before and after comparison	Within-groups or between-groups	Measure of statistical significance	Measure of effect size	Correction for multiple testing	Control for psychiatric diagnoses (axis I and II) or the presence of mood disturbance	Control for psychiatric treatment before or after gender-affirming treatment	Control for substance use or abuse	Control for other suicide risk-enhancing or risk-reducing factors	Accounts for death by suicide
Almazan and Keuroghlian (2021) [31]	Cross-sectional survey	Surgery	MtF, FtM, and nonbinary	No	No	Between-groups	Yes	Yes	Yes	Yes	No	No	Age, sex, gender identity, race/ethnicity, employment status, education, sexual orientation, family rejection, income, and health insurance status	No
Bränström and Pachankis (2020) [32]	Total population prospective	Combination or not specified	MtF and FtM	Yes	No	Within-groups	Yes	Yes	No	No	No	No	Legal gender, age, country of birth, education, urbanicity, and household income	No
Chaovanalikit et al. (2022) [33]	Prospective cohort	Surgery	MtF	Yes	Yes	Within-groups	Yes	No	No	No	No	No	No	No
De Cuypere et al. (2006) [34]	Retrospective cohort	Surgery	MtF and FtM	No	Yes	Within-groups	Yes	No	No	No	No	No	No	No
Dhejne et al. (2011) [35]	Population-based matched cohort	Surgery	MtF and FtM	No	No	Between-groups	Yes	Yes	No	No	Yes	Yes	Sex, age, immigration status, and inpatient psychiatric treatment	Yes
Glynn et al. (2016) [36]	Cross-sectional survey	Combination or not specified	MtF	No	No	Both	Yes	Yes	No	No	No	No	Age, ethnicity, and HIV status	No
Heylens et al. (2014) [37]	Prospective cohort	Combination or not specified	MtF and FtM	Yes	Yes	Within-groups	Yes	No	No	No	No	No	No	Yes
Hisle-Gorman et al. (2021) [38]	Retrospective cohort	Hormones (including puberty blockers)	Transgender and gender-diverse	Yes	Yes	Both	Yes	Yes	No	No	Total healthcare contacts per year	No	Sex, total healthcare contacts per year, age at gender-affirming treatment initiation, use of puberty blockers vs. gender-affirming hormones, and parental rank	No
Hughto et al. (2020) [39]	Cross-sectional survey	Combination or not specified	MtF and FtM	No	Yes	Within-groups	Yes	Yes	No	No	No	No	Age, education, and gender-related	No

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													discrimination	
Hunt and Hampson (1980) [40]	Cross-sectional survey	Surgery	MtF	No	No	Within-groups	No	No	No	No	No	No	No	No
McNichols et al. (2020) [41]	Cross-sectional survey	Surgery	FtM	No	Yes	Within-groups	Yes	No	No	No	No	No	No	No
Park et al. (2022) [42]	Cross-sectional survey	Surgery	MtF and FtM	No	Yes	Within-groups	No	No	No	No	No	No	No	No
Rehman et al. (1999) [43]	Cross-sectional survey	Surgery	MtF	No	Yes	Within-groups	No	No	No	No	No	No	No	No
Rood et al. (2015) [44]	Cross-sectional survey	Combination or not specified	MtF and FtM	No	No	Between-groups	Yes	Yes	No	No	No	No	Age, race, ethnicity, education, and gender identity	No
Simonsen, Giraldi, et al. (2016) [45]	Retrospective cohort	Surgery	MtF and FtM	No	Yes	Both	Yes	Yes	No	No	No	No	No	Yes
Simonsen, Hald, et al. (2016) [46]	Retrospective cohort	Surgery	MtF and FtM	No	Yes	Both	Yes	Yes	No	No	No	No	No	Yes
Tordoff et al. (2022) [5]	Prospective cohort	Hormones (including puberty blockers)	MtF, FtM, and nonbinary	Yes	No	Between-groups	Yes	Yes	No	Yes	Yes	Yes	Self-reported gender, race, and ethnicity, self-report of conflict with parents due to gender identity or expression, and resilience	No
Tucker et al. (2018) [47]	Cross-sectional survey	Combination or not specified	MtF and FtM	No	No	Between-groups	Yes	Yes	No	Yes	No	No	Age, gender, race, and income	No
Turban et al. (2020) [48]	Cross-sectional survey	Hormones (including puberty blockers)	MtF and FtM	No	No	Between-groups	Yes	Yes	No	No	No	No	Age, gender identity, relationship status, family support, income, sexual orientation, education, and employment	No
Turban et al. (2022) [49]	Cross-sectional survey	Hormones (including puberty blockers)	MtF and FtM	No	Yes	Between-groups	Yes	Yes	Yes	No	No	No	Age, gender, sex, level of family support, sexual orientation, race/ethnicity, income, relationship status, education, employment, and harassment	
van der Miesen et al.	Cross-sectional	Hormones (including	MtF and FtM	No	No	Between-	Yes	Yes	Yes	No	No	No	Age, ethnicity, education, and	No

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(2020) [50]	survey	puberty blockers)				groups						parent's marital status		
Wilson et al. (2015) [51]	Cross-sectional survey	Combination or not specified	MtF	No	No	Between-groups	Yes	Yes	No	No	No	No	Age and race/ethnicity	No
Zaliznyak et al. (2021) [6]	Cross-sectional survey	Hormones (including puberty blockers)	MtF and FtM	No	Yes	Within-groups	No	No	No	No	No	No	No	Yes

TABLE 1: Results

MtF: male-to-female; FtM: female-to-male.

Results

Combination or Not Specified

Hughto et al. (2020) utilized a cross-sectional, online survey of 288 US-based transgender adults via the Transgender Stress and Health Study. Bivariate and multivariable mixed-effect logistic regression analyses were used.

Participants were asked if they ever had a history of suicide attempt(s) or thoughts of suicide as a dichotomous variable before gender-affirming treatment. Prior to initiating unspecified gender-affirming treatment(s), 73.3% of the sample reported a history of suicidal ideation; this percentage dropped to 43.4% following the initiation of gender-affirming treatment. Prior to treatment initiation, 35.8% of the sample reported a history of suicide attempt(s), and 9.4% reported a history of suicide attempt(s) after initiation of gender-affirming treatment [39].

Adjusted multivariate analyses revealed greater odds of suicidal ideation (adjusted odds ratio (aOR), 3.86; 95% CI, 2.67-5.57; $p < 0.001$) and suicide attempt(s) (aOR, 5.52; 95% CI, 3.45-8.84; $p < 0.001$) before gender-affirming treatment compared to after [39]. Odds were adjusted for age, education, and gender-related discrimination. Potential interactions of psychiatric diagnostic history, psychiatric treatment after gender-affirming treatment, substance use, or time elapsed since gender-affirming treatment initiation were not evaluated.

Bränström and Pachankis (2020) conducted a total population study using the Swedish Total Population Register to evaluate the likelihood of mental health treatment following the initiation of hormone treatment or since the last surgical treatment. Hospitalization after a suicide attempt was the measure of suicidality implemented via the International Classification of Diseases, Tenth Revision (ICD-10) codes for intentional self-harm as a primary or secondary diagnosis. The population data from 2015 were utilized to avoid confounding by societal trends over time. As the primary outcome was the likelihood of mental health treatment as a function of time since the initiation of hormone treatment or since the last surgical treatment, the likelihood of mental health treatment that compared before and after gender-affirming treatment was not assessed.

Compared to the general population, transgender individuals had an increased odds of being hospitalized after a suicide attempt (aOR, 6.79; 95% CI, 4.45-10.35); however, a statistically significant relationship was not found for the odds of hospitalization after a suicide attempt after adjusting for the amount of time following the initiation of hormone treatment (aOR, 1.12; 95% CI, 0.97-1.30) or since the last surgical treatment (aOR, 0.87; 95% CI, 0.61-1.24) [32]. The odds ratios were adjusted for legal gender, age, country of birth, education, urbanicity, and household income. The odds ratios were not adjusted for any potential confounding by psychiatric diagnosis, psychiatric treatment besides inpatient hospitalization for a suicide attempt, or substance abuse.

In a subsequently published erratum, the authors noted no statistically significant difference in odds of hospitalization following a suicide attempt between transgender individuals matched by age, legal gender, education, and country of birth who had and who had not received any gender-affirming hormone or surgical treatment. The authors also reported that there was an absence of information that could be gathered on transgender individuals who died by suicide before 2015 [52].

Heylens et al. (2014) compared data from 57 Belgian transgender individuals before and after gender-affirming hormone treatment and surgery. Follow-up data were collected three to six months following the initiation of gender-affirming hormones and one to 12 months following gender-affirming surgery. Data on

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the history of suicide attempt(s) and thoughts of suicide via a biographic questionnaire were collected for 54 patients before treatment and 42 patients provided data after treatment. The presence of a history of suicide attempt(s) did not reach statistical significance between data collection periods (p-values not provided). One patient died by suicide [37]. There was no accounting for any potential effect of psychiatric diagnostic differences, concurrent psychiatric treatment, substance use, or other suicide risk-reducing or enhancing factors.

Glynn et al. (2016) conducted a secondary analysis of data gathered from a sample of transgender women who engaged in sex work in California. A structured questionnaire was completed by 573 transgender women. Suicidality was measured by "a single dichotomous (yes/no) item ('Have you ever thought about committing suicide?')." Over half of the participants (56%) reported a history of ever experiencing suicidal ideation. Bivariate analyses revealed "no significant group differences among… surgery status or hormone use regarding endorsing suicidal ideation or not" [36].

A history of ever experiencing suicidal ideation was associated with "significantly lower levels of psychological and familial social affirmation than those who did not report lifetime suicidal ideation" via independent sample t-tests. Despite the statistically significant results, no correction for multiple testing was done for suicide-related outcomes following gender-affirming treatment (Tukey's tests were done for pairwise comparisons between racial groups), and effect sizes were not provided; however, they are likely small: receiving "psychological affirmation gender comfort" was associated with 0.5% fewer respondents experiencing suicidal ideation. Receiving "familial social affirmation satisfaction with family support" was associated with 0.11% fewer respondents experiencing suicidal ideation. Of the respondents, 2.89% were more likely to have a history of ever having suicidal ideation if they were of older age. Chi-square analysis demonstrated that white transgender women were more likely to have ever experienced suicidal ideation than other racial/ethnic groups.

Multivariate analyses demonstrated no statistically significant relationship between gender-affirmation treatments and a lifetime history of ever having suicidal ideation. Adjusted odds ratios showed a weak effect size with older age increasing the odds of ever having suicidal ideation. Adjusted odds ratios showed lower odds of ever having suicidal ideation among Latinas and Asian/Pacific Islanders, with Asian/Pacific Islanders having a larger effect size. There was no accounting of any potential confounding relationship of the results with psychiatric diagnostic history, concurrent treatment, substance use, or other suicide risk-reducing or enhancing factors besides age, ethnicity, or HIV status. The reporting of ever experiencing suicidal ideation as a dichotomous variable precluded any analysis of any relationship between the number of suicide attempts or frequency of suicidal ideation before and after any gender-affirming treatment.

Rood et al. (2015) utilized questionnaires from 350 transgender individuals in Virginia to evaluate the potential relationships between discrimination and transition status on suicide risk. Transition status according to the type and extent of treatment was not specified. Suicidality was measured by the question, ''Have you ever thought about killing yourself?'' as a dichotomous item. Regression analyses were adjusted for demographic variables; psychiatric diagnostic history was not ascertained by the questionnaire and thus was not controlled for [44].

Out of 350 individuals, 64.9% reported a history of ever experiencing suicidal ideation. Adjusted odds ratios revealed higher odds of a history of ever experiencing suicidal ideation in those who planned to pursue transition compared to those with no plan to receive treatment for transitioning (aOR, 2.85; $p < 0.01$). Those who lived full-time in their gender/had a full social transition had greater odds of ever experiencing thoughts of suicide compared to those with no plan to receive treatment for transitioning (aOR, 2.68; $p < 0.01$). Individuals who identified as female-to-male (FTM) had greater odds of ever experiencing thoughts of suicide compared to those who identified as male-to-female (MTF) (aOR, 2.48; $p < 0.01$). Compared to those who never experienced gender-related discrimination and had no plan to receive treatment for transitioning, those who experienced gender-related discrimination and either planned to receive gender-affirming treatment or were already living full-time as their identified gender had an increased odds of ever experiencing thoughts of suicide (aOR, 1.17; $p < 0.05$).

The authors interpreted these results by heavily relying on Meyer's minority stress model [53]. When discussing the limitations of the study, there was no mention of a lack of controlling for potential confounding variables of psychiatric diagnostic history, concurrent psychiatric treatment, substance use, or time elapsed since gender-affirming treatment. Furthermore, there was no discussion of the potential limitations on the validity and generalizability of the findings based on the statistical considerations: the adjusted odds ratio for the interaction of discrimination on suicide is of low magnitude (1.17) and vulnerable to the risk of type I error given the lack of controlling for confounding variables. Likewise, the adjusted odds ratios of increased risk of thoughts of suicide for those who lived full-time in their gender (2.68) and those who planned to pursue gender-affirming treatment (2.85) compared to those with no plan to pursue gender-affirming treatment, while of a moderate magnitude, are vulnerable to either type I error or a decreased magnitude given the lack of adequate controlling for confounding variables.

Wilson et al. (2015) conducted a secondary analysis on 314 surveyed transwomen in San Francisco to

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compare the odds of various health outcomes according to the type of gender-affirming treatment. All but 22 of these individuals had gender-affirming treatment consisting of hormones, genital surgery, breast augmentation, or any combination thereof. Suicidality was measured as a dichotomous variable by asking the respondents if they had ever experienced thoughts of suicide [51].

Compared to those in the sample with no history of gender-affirming treatment, receiving treatment with hormones (OR = 0.2, 95% CI (0.1, 0.5)) or breast augmentation surgery (OR = 0.3, 95% CI (0.1, 0.6)) were associated with lower odds of ever having thoughts of suicide or attempting suicide. Individuals who received genital surgery did not have a statistically significant difference from those who did not receive gender-affirming treatment. The results were adjusted for age and race/ethnicity. There was no correction for any potential relationship with psychiatric diagnostic history, psychiatric treatment, substance use, or time elapsed since gender-affirming treatment, increasing the likelihood that the statistically significant results were vulnerable to a high risk of type I error.

Tucker et al. (2018) conducted a cross-sectional survey of 206 transgender veterans to compare outcomes among those who received a combination of gender-affirming hormones and surgery on both chest and genitals, hormone treatment only, hormone treatment and surgery on either chest or genitals but not both, and those with a history of no gender-affirming treatment. Participants were asked to rate the frequency of suicidal ideation from one (never) to five (very often or five or more times) within the past year. Respondents were also given question nine of the Patient Health Questionnaire-9 (PHQ-9) to assess suicidal thoughts over the previous two weeks at the time of the survey [47].

Mean scores were adjusted for age, gender, race, ethnicity, and annual household income. Analysis of covariance revealed statistically significant results with large effect sizes in lower past-year suicidal ideation for those receiving both genital and chest surgeries vs. those either receiving one surgery type only or gender-affirming hormones only ($\eta 2 = 0.051$). This pattern of results continued when analyzing suicidal ideation within the past two weeks, with the addition of there being lower scores of suicidal ideation that were statistically significant and with large effect size ($\eta 2 = 0.052$) for those with both genital and chest surgeries vs. no history of gender-affirming treatment.

An indirect-effects analysis was done to determine if the percentage of variance in suicidal ideation over the past two weeks between groups was due to the amount of depression over the past two weeks while controlling for covariates. An indirect effect was found for those receiving both chest and genitalia gender-affirming surgery vs. those who received no gender-affirming treatment; depression scores predicted 52.3% of the variance in suicidal ideation over the past two weeks. Similar indirect effects were found when comparing receiving surgery in one area alone or receiving gender-affirming hormones alone vs. receiving both chest and genitalia gender-affirming surgery. Psychiatric treatment, substance use, or other risk-reducing or enhancing factors for suicide besides age, gender, race, and income were not considered potential confounders.

Surgery

Chaovanalikit et al. (2022) conducted a prospective cohort study in which 37 transgender women in Thailand were assessed for quality of life and mental health outcomes before and after gender-affirming surgery. Suicidality was measured utilizing the Hamilton Depression Rating Scale (HAM-D). There were statistically significant improvements in quality of life, depression, and self-esteem. There was no correction for multiple testing, measures of effect size, or control for potential confounders such as psychiatric diagnosis, history of psychiatric treatment, substance use, or demographic variables. None of these patients reported suicidal ideation or attempts after treatment [33].

McNichols et al. (2020) conducted a survey of 246 transgender men who underwent any form of masculinizing/gender-affirming surgery at Johns Hopkins. Suicidality was assessed in the survey via the questions, “Do you have a history of any of the following? (check all that apply)” and “If you had any of the following prior to surgery, which of these have improved? (check all that apply)” with “Suicide Attempt” as an answer choice. A history of suicide attempt(s) was reported by 27% of respondents, and 14% of respondents reported an improvement, with $p < 0.003$. While the survey questions explicitly refer to “Suicide Attempt” as an indication of suicidality, the authors refer to improvements in “suicidal ideation” in the results section [41]. There was no indication of any measurement of the number of suicide attempts before and after masculinization procedures that were more specific than whether they “improved.” There was no accounting for diagnostic history that was clinically determined and verified beyond self-report, current or past psychiatric treatment, substance use, or any interaction of time elapsed since the masculinization procedure as potential confounders. There were no measures of effect size or correction of p-values for multiple testing.

Dhejne et al. (2011) conducted a population-based matched cohort study of 324 Swedish transgender individuals who underwent gender-affirming surgery with controls matched for age, biological sex, and who were residing in Sweden during the time the case person underwent treatment. Immigrant status and history of inpatient psychiatric treatment were more common among transgender individuals than controls, so

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these were covariates in the calculation of hazard ratios. The two-sided significance value was set at 0.05, with no correction for multiple testing. The adjusted hazard ratio (aHR) of history of suicide attempt(s) among transgender individuals who underwent gender-affirming surgery was 4.9 (95% CI, 2.9-8.5) compared to matched controls across the entire time frame of the cohort (1973-2003). The odds of death by suicide were higher among transgender individuals who underwent gender-affirming surgery (aHR, 19.1; 95% CI, 5.8-62.9). The aHR was 7.9 (95% CI, 4.1-15.3) for the date range of 1973-1988. The aHR did not reach statistical significance for the period of 1989-2003 (aHR, 2.0; 95% CI, 0.7-5.3) [35].

Transgender women were more at risk of suicide attempt(s) than controls of either sex (aHR, 9.3; 95% CI, 4.4-19.9 for female and aHR, 10.4; 95% CI, 4.9-22.1 for male controls). Transgender men were more at risk for suicide attempt(s) compared to male controls (aHR, 6.8; 95% CI, 2.121.6), but the comparison to female controls did not reach statistical significance. The authors state, “[t]his suggests that male-to-females are at higher risk for suicide attempts after sex reassignment, whereas female-to-males maintain a female pattern of suicide attempts after sex reassignment.”

The authors did not correct for multiple testing. While psychiatric morbidity (including substance use) was controlled for in the form of a history of inpatient treatment, different psychiatric diagnostic categories were not taken into account as potential confounders. There was no consideration of any possible interaction of time elapsed since gender-affirming surgery. Most crucially, these findings refer to transgender individuals who received surgery compared to matched controls, not to these transgender individuals before their surgeries or to transgender individuals who have not undergone gender-affirming surgery.

Almazan and Keuroghlian (2021) conducted a secondary analysis of the 2015 US Transgender Survey (USTS). They evaluated 3,559 transgender individuals who underwent gender-affirming surgery of any kind, at least two years prior to responding to the survey. Suicidality was measured as dichotomous variables to whether a participant had thoughts of suicide or had a suicide attempt within the past year. Post-hoc analyses also evaluated the lifetime presence of suicidal ideation and suicide attempt(s). Undergoing gender-affirming surgery was associated with lower odds of suicidal ideation (aOR, 0.56; 95% CI, 0.50-0.64; $p < 0.001$) and lower odds of suicide attempt(s) (aOR, 0.65; 95% CI, 0.47-0.90; $p = 0.009$) within the past year compared to those who desired gender-affirming surgery but had not yet received it. The adjusted odds ratio for suicide attempt(s) did not reach statistical significance following the Bonferroni correction, which required a $p < 0.002$ [31].

Post-hoc analyses revealed that exposure to gender-affirming surgeries and lifetime measures of suicidal ideation or suicide attempt(s) did not reach statistical significance. Patients who received some of their desired gender-affirming surgeries had lower odds of suicidal ideation (aOR, 0.72; 95% CI, 0.63-0.81; $p < 0.001$) and suicide attempt(s) (aOR, 0.70; 95% CI, 0.53-0.93; $p = 0.01$) over the past year compared to those who desired gender-affirming surgery but had not received any, with past-year suicide attempts not reaching statistical significant following Bonferroni correction. Patients who received all of their desired surgeries had lower odds of suicidal ideation (aOR, 0.44; 95% CI, 0.38-0.51; $p < 0.001$) and suicide attempt(s) (aOR, 0.44; 95% CI, 0.28-0.70; $p < 0.001$) compared to those who desired gender-affirming surgery but had not received any. No interactions of history of mental health treatment besides gender-affirming counseling, substance use history, or time elapsed from surgery were utilized as potential confounders for initial and post-hoc analyses.

Park et al. (2022) conducted a postoperative survey of 15 patients who underwent gender-affirming surgeries from 1975 to 1989 at the University of Virginia. The postoperative data were compared to the preoperative data of 97 patients. Preoperative data revealed that 23.7% of the original sample had a history of suicidal ideation or suicide attempt(s). Of the 15 patients who responded to the postoperative survey, two reported a preoperative history of suicidal attempt(s); of those two, one reported a history of suicidal attempt(s) in the postoperative period. Eight of the 15 respondents reported a preoperative history of suicidal ideation; of these eight, one reported a history of suicidal ideation in the postoperative period [42].

There was no accounting for any possible interaction of psychiatric diagnostic history, psychiatric treatment, substance use, or other suicide risk-reducing or enhancing variables with suicidality. There was no significance testing or measure of effect size. A strength of the study was the gathering of long-term outcome data; however, contacting patients via phone to conduct the survey did not allow the authors to ascertain if any of the clinic’s patients died by suicide following the initial preoperative data collection.

De Cuypere et al. (2006) conducted a long-term follow-up study on 62 Belgians who had received gender-affirming surgery at the Gender Identity Clinic in Gent since 1986. A minimum of one year following surgery was an inclusion criterion for participation in the study. A semi-structured interview assessed suicidality via the rate of suicide attempts. Though not explicitly defined, the rate of suicide attempts was understood for the purposes of this review as the percentage of patients who had ever attempted suicide rather than the frequency of suicide attempts per person. The Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) axis I and II diagnoses were derived from the initial evaluation before surgery; it was unspecified if diagnostic revisions were made at long-term follow-up [34].

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The suicide-attempt rate before gender-affirming surgery was 29.3%; following gender-affirming surgery, the suicide-attempt rate decreased to 5.1% (p = 0.004). The authors concluded that MTF patients attempted suicide as a means to cope with stress more frequently than FTM patients based on semi-structured interviews: “The postoperative male-to-females gave the following reasons for their suicide attempts: the end of a relationship (which they perceived as a challenge to their new gender), postoperative complications or an unease with their looks. They are more fragile when they are less credible in their new gender and when they have more pre-morbid psychiatric problems, especially personality disorders.”

Despite the claims made regarding the differences in the contributing factors for suicide attempts between MTF and FTM patients, there were no quantitative data used to support these findings. Despite the extensive gathering of various demographic and clinical data, even including data on social satisfaction before and after surgery and perceived credibility in one’s new gender, these data were not used to evaluate potential effects on differences in suicide outcomes. There was no controlling for any relationship between psychiatric diagnostic history, or the presence of psychiatric treatment on the rate of suicide before and after gender-affirming surgery was undertaken. There was no correction for multiple testing. A potential relationship of the amount of time elapsed since gender-affirming surgery on the rate of suicide was not assessed, though at least a minimum of one year had passed from surgery to the time of the survey.

Simonsen, Giraldi, et al. (2016) and Simonsen, Hald, et al. (2016) analyzed morbidity and mortality of Danish patients before and after gender-affirming surgery from 1978 to 2010. Both studies identified 104 individuals who had undergone gender-affirming surgery according to the Danish National Health Register. According to the Danish Register of Causes of Death, 10 of these 104 individuals had died following gender-affirming surgery from 1978 to 2014. Out of these 10 individuals, two had died by suicide at 19 and 26 years, respectively, following gender-affirming surgery. The studies discussed limitations from a small sample size, including insufficient statistical power [45,46]. Data concerning death by suicide or any other measure of suicidality before gender-affirming surgery were not compiled, preventing any before-and-after treatment comparison.

Rehman et al. (1999) conducted a follow-up study of 28 MTF individuals who had received gender-affirming surgery in New York from 1980 to 1997. Respondents had a minimum of three years post-surgery at the time of data collection. Suicidality was measured via a questionnaire by the item, “Did you have any suicidal thoughts or gestures before or after the surgery?” Two patients reported thoughts of suicide “shortly after surgery.” The authors noted a “marked decrease of suicide attempts” following surgery; however, their questionnaire did not ask about suicide attempts. It may have been that additional interviews were given [43]. Nonetheless, there was no indication that the data were collected through this method, and exact figures were not provided. One patient died by suicide in jail. A comparison via quantitative analysis of suicidality before and after gender-affirming surgery was not provided.

Hunt and Hampson (1980) conducted a follow-up study on 17 MTF individuals who underwent gender-affirming surgery. Two patients attempted suicide following surgery, within a year and six years after treatment, respectively. Both suicide attempts were in “response to the break-up of a relationship” [40]. No comparison of suicidality before and after surgery was undertaken, and the study would likely have been too underpowered to control for possible confounders of suicide risk-enhancing factors.

Hormones

Hisle-Gorman et al. (2021) conducted a retrospective cohort study of 3,754 transgender and gender-diverse (TGD) youth aged eight to 21 years of age in the US military healthcare system. Mental healthcare utilization of TGD individuals was compared before and after the initiation of gender-affirming hormones or puberty blockers. Mental healthcare utilization of TGD individuals was also compared to their cisgender siblings. Suicidality was measured by the presence of a diagnosis of suicidal ideation or self-harm (non-suicidal self-injury or self-harm with suicidal intent not specified). Odds ratios and incidence rate ratios were adjusted for sex, total healthcare contacts per year, age at gender-affirming treatment initiation, use of puberty blockers vs. gender-affirming hormones, and parental rank.

TGD youth had greater odds of receiving a diagnosis for suicidal ideation or self-harm than their siblings (aOR, 7.45; 95% CI, 6.11-9.08). About a quarter of the TGD cohort were on either puberty blockers or gender-affirming hormones. Data were analyzed to compare their mental healthcare utilization from roughly seven years prior to gender-affirming treatment with one-and-a-half years following treatment initiation. The adjusted incidence rate ratio of mental healthcare visits for suicidality was higher following the initiation of gender-affirming care (adjusted incidence rate ratio, 1.74; 95% CI, 1.18-2.56) [38].

The authors noted an increased use of neuroleptics by the transgender cohort, citing concern that the result meant that lack of gender-affirming care may lead to major depressive disorder with psychotic features. The question of whether off-label use of antipsychotics for what was actually comorbid personality pathology, particularly borderline personality disorder, was never addressed, despite that TGD youth had greater odds of a personality disorder diagnosis than their cisgender siblings (aOR, 2.54; 95% CI, 1.71-3.78) and the increasing recognition of personality disorders occurring in adolescence [54,55]. Had the presence of

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personality disorders been controlled for, it is possible that the higher incidence rate ratio of mental healthcare visits for suicidality following initiation of gender-affirming treatment would not have reached statistical significance.

Tordoff et al. (2022) conducted a prospective, observational cohort study of 104 transgender and nonbinary persons aged 13-20 years at a Seattle gender clinic. Thoughts of self-harm or suicide were assessed via the PHQ-9 question nine; at baseline, 43.3% of patients reported thoughts of self-harm or suicide in the prior two weeks. Potential confounders included as covariates were temporal trends, self-reported gender, race, and ethnicity, ongoing psychiatric treatment, self-report of conflict with parents due to gender identity or expression, any substance use within the past year, and resilience.

Bivariate and multivariate analyses compared mental health outcomes from the 33.7% of participants who did not receive gender-affirming hormone treatment or puberty blockers and the 66.3% of participants who had by the end of 12-month follow-up. Bivariate analyses revealed an association of substance use with increased odds of thoughts of self-harm and suicide (aOR, 2.06; 95% CI, 1.08-3.93). The receipt of puberty blockers or gender-affirming hormones was associated with decreased odds of thoughts of suicide or self-harm (aOR, 0.47; 95% CI, 0.26-0.86). Temporal trends, self-reported gender, race, and ethnicity, ongoing psychiatric treatment, self-report of conflict with parents due to gender identity or expression, and resilience did not reach statistical significance.

Multivariate analysis demonstrated further reduced odds of thoughts of self-harm and suicide associated with the receipt of puberty blockers or gender-affirming hormones (aOR, 0.27; 95% CI, 0.11-0.65). There was an increased likelihood of thoughts of suicide or self-harm for those who did not receive puberty blockers or gender-affirming hormones at six months (aOR, 2.76; 95% CI, 1.22-6.26) but not at the other measured points in time.

This study provides fairly rigorous methods to control for confounding; in addition to the covariates accounted for in multivariate analyses, the authors employed E-value calculations to control for unmeasured confounding. In their supplementary attachment, they state that “the observed OR of 0.27 could be explained away by an unmeasured confounder that was associated with both the PB/GAH and the moderate to severe depression by a risk ratio of 3.25-fold each, above and beyond the measured confounders, but weaker confounding could not do so” [5]. The large effect size observed in this study warrants further investigation, particularly to determine how robust the effect would be after controlling for axis II diagnoses.

Zaliznyak et al. (2021) reviewed the age of first experiencing persistent gender dysphoria, age of social transition, and age of receiving gender-affirming hormone treatment in a sample of 155 transgender women and 55 transgender men in a Los Angeles clinic. All of these patients had socially transitioned and had received gender-affirming hormone treatment for at least a year. Their mental health histories were also taken. Out of the 55 transgender men, 21% had a history of at least one suicide attempt. The authors reported that out of those patients with a history of suicide attempt(s), 10% reported suicidal ideation after receiving gender-affirming hormone treatment or socially transitioning.

The authors appear to designate "Reported Current Feelings of Suicide Ideation" as whether suicidal ideation occurred after initiating gender-affirming hormone treatment or socially transitioning, thereby conflating the current reporting of suicidal ideation in a snapshot of time as the history of any suicidal ideation occurring after gender-affirming hormone treatment or socially transitioning. No patients reported suicide attempt(s) following gender-affirming hormone treatment or socially transitioning. There were no results given on the average amount of time following transitioning and suicide measures, nor were there tests of statistical significance.

The results for transgender women were reported similarly. Of 155 transgender women, 30% reported a history of suicide attempt(s); 27% of those who had a history of suicide attempt(s) reported current suicidal ideation (though later described as occurring after initiating gender-affirming hormone treatment or socially transitioning). No patients reported suicide attempt(s) following transitioning. There were no results given on the average amount of time following transitioning and suicide measures, nor were there tests of statistical significance.

The authors did not indicate whether they reviewed clinic records for any patients who died by suicide following gender-affirming hormone treatment or socially transitioning. There was no consideration of the effect of confounding diagnoses on the suicidality measures. Nevertheless, the authors conclude: “Given the high prevalence of suicidality, depression, and anxiety among transgender communities, it follows that proper measures should be taken to address the underlying condition – untreated GD [gender dysphoria]” [6].

Turban et al. (2022) examined data from over 21,000 transgender adults from the 2015 USTS. Suicidality was ascertained by inquiring whether there was any suicidal ideation with or without a plan, suicide attempt(s), or suicide attempt(s) requiring hospitalization over the year prior to the survey being taken. Individuals were

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asked about various demographic and other confounding variables, but any current or prior mental health treatments besides hospitalization secondary to suicide attempt(s) were not gathered and controlled for.

Those who received gender-affirming treatment during adolescence and adulthood were compared to those who desired access to these treatments but never received them. Access to these treatments in early adolescence was associated with lower odds of suicidal ideation over the past year (aOR, 0.4; 95% CI, 0.2-0.6; $p < 0.001$) compared to those who desired but did not attain these treatments. For late adolescence (aOR, 0.5; 95% CI, 0.4-0.7; $p < 0.0001$) and for adulthood (aOR, 0.8; 95% CI, 0.7-0.8; $p < 0.0001$), there were also lower odds of suicidality over the year preceding the survey for those who had access to gender-affirming hormones during those periods of life [49].

Post-hoc analyses revealed that access to gender-affirming hormones during adolescence rather than adulthood was associated with lower odds of suicidality (aOR, 0.7; 95% CI; 0.6-0.9; $p = 0.0007$); there was no difference when comparing early vs. late adolescence. As mentioned, any current or prior mental health treatments besides hospitalization secondary to suicide attempt(s) were not gathered and controlled for. The authors tried to assess a potential confounding of mental-health differences within the sample by examining those who had a lifetime history of suicidal ideation but none over the past year. There were greater odds of a lifetime history of suicidal ideation (aOR, 1.4; 95% CI, 1.3-1.5; $p < 0.0001$) but none in the past year for those who accessed gender-affirming hormones in adulthood. Such a comparison in adolescence did not reach statistical significance.

The authors stated that a post-hoc analysis was done by examining those who had a lifetime history of suicidal attempt(s) but none over the past year; however, the results of such an analysis were not described. It is possible that assessing the confounding of mental-health differences by comparing suicidality over the past year to a lifetime history is insufficient. There will be a higher likelihood of the presence of lifetime suicidal ideation but none for the past year not just due to mental health differences but as a function of increased age, i.e., there is a possibility that those who received gender-affirming hormones 30 years ago have a higher chance of a lifetime history of suicidality compared to those who received such treatments five years ago. Additionally, older individuals may have the benefit of potentially having a longer period of time receiving mental health treatment, which may account for no suicidality over the past year. There was no information from those who died by suicide. Finally, there was no accounting for effects due to psychiatric diagnostic history.

Puberty Blockers

Turban et al. (2020) analyzed data from the 2015 USTS to include “3,494 individuals between the ages of 18 and 36 who ever wanted pubertal suppression as part of their gender-affirming medical care” as an adolescent. The results indicated that 89 (2.5%) of this sample received puberty blockers. Univariate analyses indicated lower odds of lifetime suicidal ideation as well as suicidal ideation within the past year for those who received puberty blockers. Multivariate analyses revealed that the receipt of puberty blockers “was associated with decreased odds of lifetime suicidal ideation” (aOR, 0.3; 95% CI, 0.2-0.6). Suicidal ideation within the past year did not reach statistical significance. Lifetime suicide attempts did not reach statistical significance depending on receipt of blockers in univariate analyses and thus were not assessed with multivariate analysis [48]. The presence of mental health treatment, substance use, or psychiatric diagnostic history was neither mentioned nor controlled for.

Van der Miesen et al. (2020) compared outcomes at a gender clinic in the Netherlands between a sample from the general population: 272 transgender adolescents at referral who had not begun puberty blockers, and 178 adolescents who were currently on puberty blockers. Suicidality was measured by items asking, “I deliberately try to hurt or kill myself” and “I think about killing myself” [50].

The control group and those who were currently on puberty blockers did not have any statistically significant difference in suicidality, whereas those who were referred to the clinic but had not begun puberty blockers scored higher in suicidality than the other groups, but Cohen’s *d* revealed small effect sizes. There was neither mention nor control for psychiatric diagnostic history, substance use, or current psychiatric treatment.

Discussion

The majority of the 23 studies reviewed claimed that various forms of gender-affirming treatment were associated with reductions in suicidality; however, the validity and robustness of their results suffered from either a lack of measures of statistical significance and effect size, correction for multiple testing, controlling for psychiatric diagnostic makeup or psychiatric treatment history, substance use, the interaction of time since receiving gender-affirming treatment, or any combination of these. The two studies that showed an increase in suicidality for those who received gender-affirming treatment suffered from many of the same problems in validity and robustness. Additionally, one of these studies did not compare suicidality outcomes before and after treatment but rather to the general population [35], and the other [38] yielded a small effect size that would likely constitute little clinical relevance; moreover, its results may not have

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reached statistical significance if there was adequate controlling for confounders.

Controlling for a potential effect of psychiatric diagnoses or degree of mood disturbance was undertaken by three of the studies reviewed [5,31,47]. The need to control for comorbid psychiatric diagnoses or degree of mood disturbance is highlighted by the findings of Tucker et al. (2018). Through indirect analysis, they found that depression scores predicted over half of the variance in suicidality over the past two weeks before their sample responded to the survey. The lack of accounting for psychiatric comorbidity and other dynamic suicide risk-enhancing factors may be the greatest limitation in the body of literature to date regarding suicidality outcomes following gender-affirming treatment.

The presence, type, and timing of psychiatric treatment history represent a potential confounder that was not considered by the majority of studies. Three of the reviewed studies accounted for some form of psychiatric treatment [5,35,38]. Hisle-Gorman et al. (2021) controlled for the total healthcare contacts per year (inpatient and outpatient), Dhejne et al. (2011) controlled for inpatient psychiatric treatment, and Tordoff et al. (2022) controlled for "ongoing mental health therapy." There is accumulating evidence of the efficacy of psychiatric treatments that may lower the risk of suicide [56-58]. It would be beneficial for future studies to collect data for psychiatric treatment both before and after gender-affirming treatments.

Comorbid substance use has been well-documented as a concern for TGD individuals [19-21,59-61]. In addition to substance use being a dynamic risk factor for suicide [62,63], this relationship is borne out for TGD individuals as well [24]. Only two of the studies reviewed accounted for substance use [5,35], revealing a glaring risk of type I error in the literature, as access to gender-affirming treatment may or may not also serve as a proxy to access to other medical treatments, such as treatment for substance use.

Given that the 23 studies spanned a wide range of locations and dates conducted, it is not surprising that a uniform measure of suicidality was not employed across studies. An evaluation of the number of suicide attempts before and after gender-affirming treatment will likely be the most robust measure for suicidality rather than the presence and frequency of thoughts of suicide, particularly measures of suicidal ideation significantly limited in the expanse of time, such as the PHQ-9 question nine employed in Tordoff et al. (2022) and Tucker et al. (2018). A suicide attempt represents a more circumscribed occurrence, thus more easily and reliably quantifiable than thoughts of suicide; however, given that suicide attempts are a rarer phenomenon, the use of this outcome variable alone would yield less power and increase the risk of type II error. Nonetheless, the presence of thoughts of suicide at distinct points in time may be confounded by a diverse experience of such thoughts by individuals. For instance, individuals may be aware of a nearly ever-present sense of suicidal ideation, particularly in the presence of axis II pathology rather than a significant stressor or exacerbation of axis I pathology [64].

The potential confounding nature of utilizing the presence of suicidal ideation as the sole measure of suicidality may be reflected in the literature reviewed. For example, Almazan and Keuroghlian (2021) reported a lack of a statistically significant relationship between gender-affirming surgery and suicide attempts within the past year or the lifetime number of suicidal ideation. However, while there was not a statistically significant relationship with lifetime suicidal ideation, there was a statistically significant relationship with suicidal ideation within the past year. To have three measures of suicidality not reach statistical significance but suicidal ideation within the past year to reach statistical significance may represent multiple possibilities: suicidal ideation may be a more sensitive measure of suicidality as it is more prevalent and thus has more statistical power. Conversely, the presence of a high risk of type I error associated with recall bias and the potential inherent unreliability of suicidal ideation as a measurable construct may be detractors of its use. Finally, differing results according to suicidal ideation vs. attempts of suicide may represent the underpowered nature of the reporting of suicide attempts, which may represent the presence of a high risk of type II error.

The need for clear, objective reporting of suicide risk in transgender persons, including any change attributed to gender-affirming treatment, is highlighted further by the immense difficulty psychiatry as a field has in accurately predicting suicide risk. Even for at-risk populations, suicide attempts and parasuicidal behaviors are statistically rare enough to make it "impossible to predict on the basis of risk factors either alone or in combination" one's risk of suicide [65].

A dearth of high-quality studies that evaluate outcomes in suicide following gender-affirming treatment poses severe limitations on the extent of claims made during the informed consent process for gender-affirming treatment. An abundance of claims that are not backed by evidence does not represent quality empirical evidence but rather guidelines endorsed by various medical organizations. Just as in practice guidelines for the assessment and treatment of patients at risk for suicide, "practice guidelines do not represent the standard of care, much less for a fact-specific case in litigation" [66].

Clinical judgment, rather than an indiscriminatory tabulation of risk-enhancing factors for suicide, will ultimately be needed, as "no study has identified one specific risk factor or set of risk factors as specifically predictive of suicide or other suicidal behavior" [65]. Risk-enhancing factors for suicide may act in a synergistic manner, with mood disorders, substance use, physical and sexual abuse, minority sexual

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orientation, disturbed family relationships, parental psychopathology, and various precipitating stress events [67] leading to near-infinite permutations of suicide risk that is ultimately expressed and unique on an individual level. This is especially the case for TGD individuals, for they constitute “heterogeneous groups of individuals with multiple intersecting identities” [20,59] that may contribute to different levels of risk for suicide.

Such permutations of suicide risk reinforce the need to control for various confounders, which is pervasively lacking in the literature to date. Most studies have ignored complex relationships among various risk factors for suicide, despite literature that suggests a nuanced intersection of these factors with suicide, such as victimization and substance use [24]. Given the heterogeneity of risk factors for this population [20,59], adequate control for confounding variables is needed to represent as accurately as possible the variance that can be attributed to gender-affirming treatment on suicide-related outcomes for transgender individuals as a whole and according to other defining characteristics.

In addition to trauma and abuse, other psychosocial stressors, “such as sudden unemployment, interpersonal loss, social isolation, and dysfunctional relationships, can increase the likelihood of suicide attempts as well as increase the risk of suicide” (“Practice Guideline for the Assessment and Treatment of Patients With Suicidal Behaviors,” 2006). It is notable that Tordoff et al. (2022) reported that conflict with caregivers over gender identity did not have a statistically significant relationship with thoughts of suicide, whereas Glynn et al. (2016) reported a statistically significant increase in suicidal ideation for those with less affirmation by one’s family. Additionally, Almazan and Keuroghlian (2021) reported lifetime suicide attempts and thoughts of suicide were not statistically significant with familial rejection as a covariate, potentially meaning that familial rejection accounted for some of the variances in suicide risk. The variety of findings regarding any potential effect of familial conflict on suicide may represent type I error, the unreliability of thoughts of suicide as a measure compared to suicide attempts, and/or the heterogeneous nature of the TGD population.

The collection of data that includes long-term follow-up is ideally suited to take into account the effects of a transgender individual’s time course, which may include a “honeymoon period” after receiving gender-affirming treatment [34]. Equally important is the controlling of time elapsed before and after gender-affirming treatment with regards to suicidality; otherwise, the number of suicide attempts or frequency of thoughts of suicide may be falsely lowered if the relative time after gender-affirming treatment is less than the pre-treatment period. However, the majority of studies did not control for the amount of time elapsed.

Limitations

The limitations inherent in a narrative review format are noted, particularly the absence of a second, independent reviewer for the inclusion and exclusion of studies as well as the lack of a systematized evaluation of publication bias and methodological rigor. Moreover, a single database was utilized, albeit with fairly extensive search criteria. Future systematic and/or scoping reviews are needed. Finally, this review may have limited generalizability. The studies included in this review span multiple countries, cultures, and decades; furthermore, TGD individuals comprise a heterogeneous group.

Conclusions

There is a need for continued research on suicidality outcomes following gender-affirming treatment. Future research that incorporates multiple measures of suicidality and adequately controls for the presence of psychiatric comorbidity, substance use, and other suicide risk-enhancing factors is needed to strengthen the validity and increase the robustness of the results. There may be implications for the informed consent process of gender-affirming treatment given the current lack of methodological robustness of the literature reviewed.

Additional Information

Disclosures

Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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Researchers slam HHS report on gender-affirming care for youth

Critics say the report, which declines to disclose its authors, contradicts decades of scientific research

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A report published this week is the latest in a series of actions—some of which have sparked protest—from President Donald Trump's administration targeting gender-affirming care for trans individuals. STEPHANIE KEITH/BLOOMBERG VIA GETTY IMAGES

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In response to a directive from President Donald Trump, the Department of Health and Human Services (HHS) yesterday released an expansive review of the scientific literature surrounding treatments for gender dysphoria—the sense of distress many transgender people experience when their gender identity doesn't align with the sex they were assigned at birth.

The 400-page document, whose authors are not named, asserts that the evidence does not support providing gender-affirming medical interventions for children and adolescents. It adds that such treatments—including puberty-blocking medications and hormones—are associated with significant risks. That claim challenges the guidance of multiple major medical associations, including the American Academy of Pediatrics (AAP), which was quick to issue a response reaffirming its stance. "This report misrepresents the current medical consensus and fails to reflect the realities of pediatric care," an AAP statement read.

Advocates for trans youth also expressed outrage at the report. The HHS report "is a rejection of decades of science, evidence, and direct experiences by young people, their doctors, and their families," says Casey Pick, who serves as the director of law and policy at the Trevor Project—a nonprofit organization focused on suicide prevention efforts for LGBTQ young people.

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"The finger was already on the scale when this report was commissioned," says Kellan Baker, a health services researcher who serves as executive director of the Whitman-Walker Institute for Health Research and Policy. In recent years, more than half of all states, including Florida and Tennessee, have implemented policies restricting or banning gender-affirming care for minors. Soon after taking office in January, Trump gave HHS a 90-day deadline to publish the review in an executive order titled "Protecting Children from Chemical and Surgical Mutilation," which claimed without evidence that medical professionals in the United States "are maiming and sterilizing a growing number of impressionable children" and threatened to revoke federal funding from hospital clinics that provide gender-affirming care to minors.

A mere 90 days is not enough time to conduct a thorough review, Baker argues. By contrast, the most recent standards for the treatment of gender dysphoria in youth issued by the World Professional Association for Transgender Health (WPATH)—an organization that determines the clinical protocols used by the majority of professionals who work with trans people—took more than a decade to compile with numerous systematic reviews, and "reflect the consensus of hundreds of experts in transgender health from around the world," Baker says. (In its report, HHS dismisses WPATH as an ideologically motivated organization.)

Baker and others say the report misrepresents existing scientific evidence and promotes misinformation. In several places, for example, it references "social contagion" and "rapid-onset gender dysphoria" as reasons why more youth are identifying as transgender—a theory popularized by a 2018 study that has been criticized as having methodological flaws and dismissed by major medical associations. It also suggests autism is a cause of gender dysphoria, an implication that the Autistic Self Advocacy Network, a nonprofit organization run by and for autistic people, condemned in a statement.

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Sean Cahill, who serves as director of health policy research at the Fenway Institute, also disputes the report's claim that treatments such as puberty blockers and hormones have shown no evidence of benefits. It either downplays or dismisses studies that have found that access to these treatments leads to improved mental health, Cahill says. The report also claims these treatments are associated with significant harms even though it found "sparse" to no evidence of such harm.

The report raises a familiar concern about gender-affirming care: that youth who receive it will stop identifying as trans as adults and come to regret the medical interventions they received. But critics note that studies have found gender-affirming care is associated with high levels of satisfaction and very low rates of detransition or regret.

The report promotes psychotherapy as the only safe approach for treating gender dysphoria in children and adolescents, Cahill notes, even though there is no evidence to suggest therapy can change a person's gender identity. "Ex-trans therapy doesn't work," he says, "and it causes harm."

Cahill argues that the HHS report's focus on "exploratory psychotherapy" is a subtle endorsement of conversion therapy—the attempt to change sexual orientation or gender identity through therapy, a practice that has been linked to high rates of depression and suicide among LGBTQ youth. Although the report itself denies promoting conversion therapy, the approach it encourages "is basically conversion therapy by another name," Cahill says.

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reason why I can tell you this is an ideological, political document and not a scientific one," Pick says. "Scientists stand by their work. There is nobody standing by this thing."

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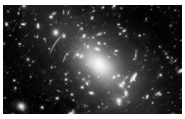

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BMC Psychiatry

RESEARCH Open Access

Discontinuing hormonal gender reassignment: a nationwide register study

Riittakerttu Kaltiala[1*], Mika Helminen[2], Timo Holttinen[3] and Katinka Tuisku[4]

Abstract

Background With increasing numbers of people seeking medical gender reassignment, the scientific community has become increasingly aware of the issue of detransitioning from social, hormonal or even surgical gender reassignment (GR). This study aimed to assess the proportion of patients who discontinued their established hormonal gender transition and the risk factors for discontinuation.

Methods A nationwide register-based follow-up was conducted. Data were analysed via cross-tabulations with chi-square statistics and t tests/ANOVAs. Multivariate analyses were performed via Cox regression, which accounts for differences in follow-up times.

Results Of the 1,359 subjects who had undergone hormonal GR in Finland from 1996 to 2019, 7.9% discontinued their established hormonal treatment during an average follow-up of 8.5 years. The risk for discontinuing hormonal GR was greater among later cohorts. The hazard ratio was 2.7 (95% confidence interval 1.1–6.1) among those who had accessed gender identity services from 2013 to 2019 compared with those who had come to contact from 1996 to 2005. Discontinuing also appeared to be emerging earlier among those who had entered the process in later years.

Conclusions The risk of discontinuing established medical GR has increased alongside the increase in the number of patients seeking and proceeding to medical GR. The threshold to initiate medical GR may have lowered, resulting in a greater risk of unbalanced treatment decisions.

Trial registration number (TRN) Not applicable (the paper does not present a clinical trial).

Keywords Gender dysphoria, Gender reassignment, Masculinizing hormones, Feminizing hormones, Detransition, Register study, Time trend

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Background

In gender medicine, transition refers to people with sex-discordant gender identities making changes in their lives to live in their experienced gender, socially (appearance, name, personal pronouns), juridically (identity documents) or medically (hormonal and surgical medical interventions that modify secondary sex characteristics*)*. Detransition refers to people aborting their initiated transition and reversing it, totally or partially, to live in a sex-accordant role by reversing the abovementioned steps of transition.

Recent decades have witnessed an exponential increase in those seeking medical interventions to support their transition (medical gender reassignment, GR), with an increasing share of younger individuals of the female sex [1, 2]. Psychiatric morbidity among people who contact specialized gender identity services (GISs) has increased simultaneously [2, 3] and is particularly pronounced among the youngest age groups [4].

It has long been assumed that very few patients embarking on medical GR regret their choice and seek to reverse it. From the 1970s to the 2010s, estimates of those regretting their initiated GR were only in the region of 2% [5, 6]. However, more recent research suggests that alongside the increase in the number of people accessing medical gender reassignment, reversing the initiated transition seems to be increasing [7]. In recent samples, 20–30% of those who initiated hormonal GR discontinued hormonal treatment in four to five years [8, 9]. It is possible that some patients discontinue hormonal treatment because they have reached their transition goals. Some changes, such as lowering of the voice, can be reached with relatively short hormonal treatments and are permanent, while maintaining some other changes require permanent treatment.

People abandoning their gender transition have reported various reasons for doing so, such as coming to terms with their natal sex, concerns about medical complications, attributing gender dysphoria to reasons other than gender identity, such as trauma or mental disorders, finding that the transition did not alleviate distress, struggles with sexual orientation and discrimination [10, 11]. More importantly, those who have detransitioned have repeatedly reported that before their embarking on medical GR, insufficient attention was given to their mental health and psychosocial problems, which, in retrospect, they believed played a major role in their desire to transition. They have expressed concerns that assessments for medical gender reassignment were too superficial, with no search for explanations for their distress beyond an assumed stable sex-discordant identity requiring transition. [10, 11]. This contradicts calls to lower the threshold for medical gender reassignment [12, 13]. Several recent national guidelines and recommendations [4, 14, 15], however, emphasize the appropriate treatment of psychiatric comorbidities and associated difficulties as well as a psychosocial intervention facilitating identity exploration as first-line interventions for gender dysphoria before considering medical interventions, particularly for young people.

In Finland, gender identity assessments potentially leading to medical GR interventions are conducted at two of the country's five university hospitals. Services for legal adults (>18 years) have been available since the early 1990s [16] and became available to minors in 2011 [17]. The national guidelines require minors presenting with feelings of gender dysphoria to first undergo psychosocial intervention to support identity exploration and to receive appropriate treatment for any severe mental disorders [14], after which they can proceed to the centralized GIS, where diagnostic assessments are carried out by specialized mental health teams. Both GISs have separate diagnostic teams for minors and for adults. Hormonal GR interventions are initiated at the same hospitals in gynecological outpatient clinics, and after stabilization, hormonal treatment is transferred to services in the patients' places of residence. Genital surgeries with gender identity indication are nationally centralized to one university hospital and require recommendations from both nationally centralized diagnostic GIS units. Psychiatric treatment for any concomitant mental health condition is provided at the specialized secondary care or primary health care facility in the patient's place of residence. Until 2022, diagnostic assessments at the nationally centralized GIS were also a prerequisite for registered sex change, but since 3 April 2023, legal adults have been granted legal GR on the basis solely of their own request. Medical GR remains nationally centralized and is available case-by-case after a comprehensive diagnostic assessment by a multidisciplinary mental health team, as outlined in the national guidelines [14, 18, 19].

An important ethical principle in all medicine is to not harm. A more severe or life-threatening condition may justify greater risks in its treatment. In medical gender reassignment, hormonal and surgical interventions are performed on physically healthy bodies. If the patient subsequently regrets the changes brought by the treatments, not to mention undesired side effects, this can be considered harmful. As in other Western countries, alongside the vastly increasing number of referrals to the GIS, increasing numbers of younger people with increasingly common psychiatric needs have initiated medical GR in Finland [2]. This may be followed by increasing numbers of people who later feel otherwise about their medical GR. On the other hand, the purpose of the nationally centralized and comprehensive assessment before medical GR is to ensure reasoned treatment decisions and satisfactory patient outcomes, avoiding

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possible regrets. This may counteract the risks related to the more complex presentations among those seeking medical GR. Those abandoning their gender transitions have repeatedly claimed that the distress accompanying their situation is not appropriately addressed [20]. It is crucial to take seriously the desire to reverse medical GR and to ascertain its likelihood and predictors to target medical GR safely and provide appropriate services for those opting out of treatment that has resulted in irreversible changes in a healthy pretreatment body. In the present study, we referred to national registry data to determine which patients are likely to discontinue hormonal GR. More specifically, we asked:

1. How commonly did people who proceeded to hormonal GR after assessment in the nationally centralized GIS from 1996 to 2019 discontinue their established hormonal GR?
2. What are the predictors of discontinuation in terms of age, age at admission to the GIS, direction of transition, surgical treatment, psychiatric treatment needs and cohort effects?
3. Has the risk of discontinuing hormonal GR changed over time?

Methods

Design and setting

A register-based follow-up study was conducted using information held in health care registers in Finland. These comprehensive and reliable national registers can be used to study large patient groups and collate information from different registers (on an individual level) via the unique personal identity code assigned to each permanent resident of Finland. Register data can be applied for research purposes from the Finnish Social and Health Data Permit Authority Findata and Statistics Finland. Data extraction, linkages and pseudonymization are carried out by these authorities, and researchers are allotted a special secure connection for pseudonymized data only. Analyses producing unduly precise information potentially enabling a person to be identified must be amended to ensure the anonymity of the persons included. The present study obtained ethical approval from the ethics committee of Tampere University Hospital (R20040R) and relevant permissions from Findata (THL/5188/14.02.00/2020) and Statistics Finland (TK/1016/07.03.00/2020). In accordance with Articles 6e and 9i and j of Regulation (EU) 2016/679 of the European Parliament and of the Council [21], no individual informed consent was needed.

A personal identity code is assigned at birth (or upon obtaining Finnish citizenship). This indicates sex (male or female). Legal sex change entails a new identity code. People are listed in the national registers according to their currently valid personal identity code. This code serves to retrieve data from various registers (including earlier data under the original identity code). Researchers cannot obtain information about identity code changes (changes in juridical sex). Researchers using the data never see the actual identity codes.

Data extraction

Subjects referred to either of the two nationally centralized GISs were identified from the hospital databases of Tampere and Helsinki University Hospitals. The first contact with a diagnostic team in either of the two GISs was recorded as the index date. The Finnish Social and Health Data Permit Authority Findata combined the lists from the two hospitals. A total of 3,665 individuals were identified as having contacted the nationally centralized gender identity units between 1996 and 2019. Of these, 1,359 had initialized and embarked on feminizing or masculinizing hormonal treatment (see below, next paragraph) and formed the subjects of the present study.

The register of the Social Insurance Institution of Finland (KELA), with information on prescription medications purchased and information on reimbursement, was used to obtain information on hormonal GR in the clinical GD group. Persons diagnosed with F64.0 (since 2020, also F64.8) in the nationally centralized gender identity units are entitled to special reimbursement (code 121) for their hormonal treatment, as are patients suffering from specified endocrine disorders. In the treatment of gender dysphoria, special reimbursement is available when hormonal treatment has continued for more than a year. The data on prescription medications were collected up to the end of 2021.

The Care Register for Health Care [22] was used for information on all treatment contacts to specialist-level psychiatric services from 1994 to 2022. The register, which has been in operation since 1994, includes all outpatient and inpatient contacts with specialist-level health services in Finland. For all contacts, admission and discharge dates were extracted. The Care Register for Health Care was further used to provide information on gender reassignment surgeries.

The Population Register provided information on those deceased and their dates of death.

Measures.

Discontinuing hormonal GR

Subjects entitled to special reimbursement for hormonal treatments were considered to have discontinued their hormonal GR if they had purchased no hormones for more than 12 months before the end of the data collection or, if deceased, for 12 months or more before their death, or if they had been purchasing specially

reimbursed feminizing hormones but had later switched to masculinizing hormones, or vice versa. To obtain reimbursements for prescription medications from the Social Insurance Institution of Finland (KELA), these medications can be purchased for only three months at a time. Thus, not purchasing them for over a year means that they are most likely not being taken. The last date of purchase of the originally prescribed hormonal GR medication was recorded. Patients who discontinue hormonal GR may require birth-sex accordant hormonal replacement to detransition after gonad removal or if their natural hormone production does not resume. For subjects whose specially reimbursed hormone treatment had changed from masculinizing to feminizing or vice versa, the last date of purchase of the originally initiated type of hormonal GR was recorded.

Types and durations of hormonal GR

In the analyses, hormonal GR was divided into feminizing and masculinizing. The duration of hormonal GR with special reimbursement was calculated in months from the dates of first and last/latest purchase of the originally initiated masculinizing/feminizing hormones.

Time variables

The subject's year of birth was used in the analyses as a continuous variable. The year of initial contact with the GIS (index year) was categorized into intake cohorts with the first contact with the GIS in 1996–2005 vs. 2006–2012 vs. 2013–2019. As the inclusion period did not fall into three even periods, the first period, with a clearly lower case load, was extended.

Age

Age at first contact with the GIS (index date) was calculated from the dates of index contact and birth. Age in years was used in bivariate analyses as a continuous variable. In multivariable analyses, age was divided into adolescent (up to 22 years old) and adult (23+) at index contact.

Gender reassignment surgeries

The gender reassignment surgeries recorded were genital surgery (vaginoplasty, phalloplasty/metoidioplasty) and chest masculinization.

Specialist-level psychiatric treatment contact

Specialist-level psychiatric treatment contacts other than those related to gender identity assessment were recorded. Having received specialist-level psychiatric treatment was used in the analyses as a comprehensive dichotomous variable (yes/no). Furthermore, having specialist-level psychiatric treatment contact before entering the GIS (yes/no) was used, as was having specialist-level psychiatric treatment two or more years after entering the GIS (yes/no).

Statistical analyses.

Bivariate associations between discontinuing hormonal GR and the explanatory variables were studied via cross-tabulations with chi-square statistics (Fisher's exact test where appropriate) and the Mantel–Haenszel test for categorical variables and t tests and ANOVA for continuous variables. Multivariate associations were studied via Cox regression, accounting for differences in follow-up times. Discontinuing hormonal GR was entered as the dependent variable. The independent variables entered were (1) direction of hormonal treatment (masculinizing/feminizing), year of birth and index year cohort; (2) GR surgeries; (3) age at first entering the GIS (adolescent vs. adult); and (4) and, finally, having received specialist-level psychiatric treatment (yes/no). Hazard ratios (HRs) with 95% confidence intervals are given. The cut-off for statistical significance was considered $p<0.05$.

Results

The sample

There were 1,359 people who, after having been assessed in the nationally centralized GIS, had purchased masculinizing or feminizing hormones with a special reimbursement code. The mean (sd) age of the participants on admission to the GIS was 25.6 (9.3) years, and 49.1% of them were under 23 years of age. In total, 467 (34.4%) had received feminizing treatment, and 892 (65.6%) had received masculinizing treatment. At index contact with the GIS, those who subsequently initiated feminizing GR were older than those who proceeded to masculinizing GR (29.7 (11.1) vs. 23.4 (7.3) years, $p<0.001$). The mean (sd) duration of hormonal GR was 62.0 (57.0) months, with a median of 44.5 months, with no difference between masculinizing and feminizing treatments. Genital surgeries were more commonly performed on those who had proceeded to feminizing treatment (46.7% vs. 14.9%, $p<0.001$). Among those on masculinizing treatment, 41.5% had undergone chest masculinization. Among all patients proceeding to hormonal GR, 57.4% had ever had treatment contact with specialist-level psychiatric care.

Discontinuing hormonal GR

A total of 107 subjects (7.9% of those who had started hormonal GR and obtained special reimbursement for it) had not been purchasing GR hormones for at least a year before the end of data collection (or before the subject died) or had changed from feminizing GR to masculinizing treatment, or vice versa. These were considered to have discontinued hormonal GR. Among those who had obtained feminizing GR, 10.5% had discontinued hormonal treatment, and among those who had obtained

masculinizing GR, 6.5% ($p=0.004$). Those who discontinued hormonal GR were slightly older at the index contact and at their latest purchase of specially reimbursed hormones than those who continued hormonal GR. The two groups had used hormonal GR for comparable periods. Those who discontinued and those who stayed on hormonal GR had comparable specialist-level psychiatric treatment contacts. (Table 1)

Those who discontinued and those who continued hormonal GR had equally common specialist-level psychiatric treatment contact before contacting the GIS (15.3% vs. 17.8%, $p=0.5$) as well as two or more years after entering the GIS (59.9% vs. 57.0%, $p=0.2$).

Changes across intake cohorts

The basic characteristics of the subjects changed across intake cohorts. The mean (sd) age among those who had contacted the GIS from 1996 to 2005 and subsequently proceeded to hormonal GR was 31.1 (7.9); from 2006 to 2012, it was 25.7 (9.3); from 2013 to 2019, it was 24.8 (9.2) years ($p<0.001$); and the proportion of adolescents (<23-year-olds) was 13.7% vs. 48.9% vs. 53.6% ($p<0.001$). The proportion of those seeking change towards masculinity increased, and the same change was observed among those discontinuing hormonal GR. The proportion of those with specialist-level psychiatric treatment contacts fluctuated between cohorts among those continuing hormonal GR but remained unchanged among those who discontinued it (Table 1).

Multivariable analyses

The hazard ratio (HR) for discontinuing hormonal GR was greater among those in the latest intake cohort (2013–2019) as compared to those in the earliest cohort (1996–2005) when the type of hormonal GR (masculinizing vs. feminizing) and year of birth were accounted for (Table 2 Model 1) and when surgical GR (Table 2 Model 2), age at index admission (adolescent vs. adult) (Table 2 Model 3) and, finally, specialist-level psychiatric treatment contact (Table 2 Model 4) were added. Genital

Table 1 Follow up times, type (feminizing/ masculinizing) of prescribed and continued/ discontinued hormonal gender reassignment, timing and duration of contacting gender identity services and using hormonal GR, and specialist level psychiatric treatment contact among subjects who continued/ discontinued their established hormonal gender reassignment. Distributions (%, n/N) of the categorical variables and mean(sd) of the continuous variables, and their comparison between the intake cohorts

	All, index date 1996–2019	Index date 1996–2005	Index date 2006–2012	Index date 2013–2019	p (between cohorts)
Follow-up-time from index contact to 31.12.21, mean(sd) in years	8.5 (4.3)	20.3 (4.0)	11.7 (1.6)	6.0 (1.6)	
Specially reimbursed hormonal GR (n)	1359	102	438	819	
Specially reimbursed hormonal GR was (% (n/N)					0.002*
towards female	34.4% (467/1359)	41.2% (42/102)	39.0% (171/438)	31.0% (254/819)	
towards male	65.6% (892 /1359)	58.8% (60/102)	61.0% (267/438)	69.0% (565/819)	
Had discontinued using in 31.12.21 (n)	107	24	45	38	
Discontinued hormonal GR (% (n/N)) was					0.003*
towards female	45.8% (49/107)	70.8% (17/24)	44.4% (20/45)	31.6% (12/38)	
towards male	54.2% (58/107)	29.2% (7/24)	55.6% (25/45)	68.4% (26/38)	
Age at index contact, years (mean(sd))					
continued hormonal GR	25.3 (9.0)	30.2 (7.8)	25.6 (9.1)	24.6 (9.0)	<0.001
discontinued hormonal GR	29.4 (10.7)	34.0 (7.9)	27.2 (10.2)	29.0 (11.9)	0.04
p	p<0.001	p=0.04	p=0.3	p=0.03	
Age at latest purchase of hormones, years (mean(sd)					
continued hormonal GR	34.3 (10.5)	50.7 (8.6)	37.7 (9.6)	30.9 (9.0)	<0.001
discontinued hormonal GR	37.7 (11.6)	47.9 (7.5)	35.7 (10.4)	33.7 (11.5)	<0.001
p	p=0.001	p=0.2	p=0.2	p=0.07	
Months on hormonal GR (mean(sd); median)					
continued hormonal GR	61.6 (57.0); 44	209.7 (59.3); 207	94.8 (35.2); 95	30.1 (22.1); 27	<0.001
discontinued hormonal GR	66.6 (58.0); 48	120.6 (58.6); 128	65.9 (41.8); 57	33.3 (43.6); 16	<0.001
p	p=1.0	*p<0.001*	*p<0.001*	*p=0.6*	
Specialist level psychiatric treatment contact					
continued hormonal GR	56.5% (708/1252)	57.7% (45/78)	63.4% (249/393)	53.0% (414/781)	0.003
discontinued hormonal GR	67.3% (72/107)	66.7% (16/22)	66.7% (30/45)	68.4% (26/38)	1
p	p=0.03	p=0.5	p=0.7	p=0.07	

*Mantel-Henzel test for linear association

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Table 2 Predictors of desisting from hormonal gender reassignment in multivariable models (Cox regression). Hazard ratios (HR) with 95% confidence intervals (CI) are reported

	Model 1: type of hormonal GR, birth year, index year		Model 2: add surgical GR		Model 3: add age group at entering gender identity assessment		Model 3: add psychiatric treatment	
Hormonal GR								
masculinizing	ref		ref		ref		ref	
feminizing	1.3 (0.9-2.0)	0.2	1.4 (0.9–2.1)	0.1	1.4 (0.9–2.2)	0.2	1.3 (0.9–2.4)	0.2
birth year	**0.98 (0.96-1.0)**	**0.04**	**0.98 (0.96-1.0)**	**0.03**	1.0 (1.0–1.0)	0.2	1.0 (1.0–1.0)	0.1
index year at								
1996–2005	ref		ref		ref		ref	
2006–2012	1.6 (0.8–3.1)	0.1	1.4 (0.7–2.7)	0.2	1.3 (0.7–2.7)	0.4	1.4 (0.7–2.7)	0.4
2013–2019	**3.1 (1.4–6.9)**	**0.007**	**2.5 (5.1–5.8)**	**0.03**	**2.5 (1.1–5.7)**	**0.03**	**2.7 (1.1–6.1)**	**0.02**
genital surgery	-	-	**0.4 (0.3–0.7)**	**< 0.001**	**0.4 (0.3–0.7)**	**< 0.001**	**0.5 (0.3–0.7)**	**0.01**
chest masculinization	-	-	0.8 (0.5–1.4)	0.4	0.8 (0.5–1.4)	0.4	0.8 (0.4–1.3)	0.3
age group at index	-	-	-	-	1.2 (0.7-2.0)	0.6		
adolescent (until 22 yrs)							ref	
adult (23 + yrs)							1.2 (0.7-2.0)	0.6
specialist level psychiatric treatment contact*	-	-	-	-	-	-	1.4 (0.9–2.2)	0.1

*Findings did not change when specialist level psychiatric treatment contact beyond 2 years after entering GIS was used instead of contact at any time

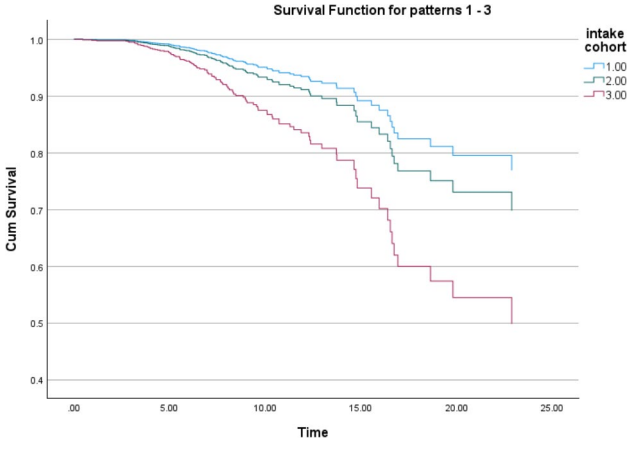

Fig. 1 Time (in years)* to discontinuing hormonal gender reassignment in the different intake cohorts (1 = 1996–2005, 2 = 2006–2012, 3 = 2013–2019). *modeled by Cox regression

surgeries were associated with a decreased HR for the discontinuation of hormonal GR. Earlier year of birth was very slightly but statistically significantly associated with increased HR for discontinuing hormonal GR in the first models but levelled out in subsequent models.

Confirmatory analyses

Because the oldest individuals in the sample may have discontinued hormonal GR due to reaching the age of natural decline in hormonal levels, the final model was repeated among individuals younger than 60 at the end of data collection, but this did not change the findings.

A further confirmatory analysis was carried out using data from those subjects whose index contact was before 2018 because of the rather short follow-up times among those who had started their gender identity assessments in 2018 or 2019. This caused no changes to the findings presented in Table 2.

Changes in the discontinuation of hormonal GR over time

Survival curves for the three index date cohorts suggested that the discontinuation of hormonal GR emerged in a shorter time from the earliest to the latest intake cohort (Fig. 1). To explore this further, discontinuation within two years of obtaining special reimbursement for hormonal GR was scrutinized among those with index dates before 2018. Among the two earlier intake cohorts (combined due to small cell frequencies in the original categories), 1.3% of those who had started hormonal GR discontinued it within two years; among the latest intake cohort, 2.9% ($p = 0.06$).

Discussion

In this nationally representative register study covering subjects proceeding to hormonal GR over three decades, 7.9% discontinued their established hormonal GR. The risk for discontinuing hormonal GR was greater in the latest intake cohort (2013–2019) than in the earliest cohort (1996–2005). Genital surgeries were associated with a decreased risk of discontinuing hormonal GR. Over the decades, the time to discontinuation grew shorter.

The proportion of those who discontinued treatment was smaller than that reported in the most comparable study [9] from the USA, where almost one-third of adolescents and young adults discontinued their hormonal GR within four years. The relatively low discontinuation rate in our study may be due to the comprehensive

assessment in the nationally centralized GIS before initiating hormonal treatments. When severe psychiatric comorbidities are present, great care is taken in considering physical interventions [2, 14, 17]. The proportion of those who discontinued their established hormonal GR was nevertheless manifold compared with earlier reports of proportions regretting medical transition among samples who had initiated their treatments between the 1960s and 2010s [5, 6]. However, both of those reports focused on actively expressed regrets, and in the latter study [6], the proportion lost to follow-up—with later development thus unknown—was high. The proportion discontinuing their established hormonal GR in the present study was comparable to the proportion defined as detransitioners (those who discontinued treatment and reverted to living in their original gender role) in a register-based study of 175 subjects initially assessed in 2017–18 in the UK [7]. However, in that UK study, a clearly greater additional share of the studied group also subsequently disengaged from the treatments or did not adhere to their treatment plan. In a study evaluating the situation of people diagnosed with GD in a specified GP practice population [8] and, as noted, in a register study in the USA [9], much greater shares discontinued their medical GR. Direct comparisons among these studies are not feasible because of their different focuses and methodologies. However, together with the most recent studies, our study suggests that discontinuing hormonal GR is a significant phenomenon in gender medicine, and studies reporting the experiences of detransitioners [10, 11] suggest that it is often related to profound psychological distress.

In multivariate models accounting for differences in follow-up times and for changes in patient characteristics across intake cohorts, the risk of discontinuing hormonal GR was almost threefold among those patients who had contacted the GIS from 2013 to 2019 compared with those who had contacted the GIS from 1996 to 2005. Our findings also suggest that the time to discontinuation of hormonal GR may have shortened among the later patients; however, in the latest intake cohort, more discontinuations may still emerge, and this will eventually affect the final conclusions about the average time to discontinuation. The proportion of subjects who discontinued after short use, a maximum of two years of specially reimbursed medication use, nevertheless appeared to have increased. (This will mean a maximum of three years of total use, given the rules on special reimbursement). Over the whole study period, the number of people seeking GR increased manifoldly [2], as did the number of subjects proceeding to hormonal GR. Alongside with this, the risk of discontinuing established medical GR has also increased. The populations seeking medical GR may have changed in a way that limits positive treatment outcomes. It is already known that subjects currently seeking medical GR are, unlike earlier, predominantly birth-registered females, who are younger than before and present with more psychiatric comorbidities than before [1–3, 20]. These observations may suggest that an increasing share of GD patients actually do not present with achieved, consolidated identity [20, 23]. In particular, medical transition early in terms of identity development may increase the risk of unbalanced treatment decisions, and this risk appears to have increased towards the present day, with detransitioning as the next step. Greater attention to gender identity issues and GR in the media and social media as well as assertive advocacy for medical GR may play a role in these developments [20, 24, 25].

Somewhat unexpectedly, the need for specialist-level psychiatric care did not differentiate those who continued and those who discontinued hormonal GR. Approximately one in six of the patients who had started hormonal GR, both those who later discontinued and those who continued the treatment, had needed specialist-level psychiatric treatment before embarking on gender identity assessments. This number was clearly less than that of all patients who were in contact with the GIS [2]. It is expected that the two groups would be comparable at the time of the decision to initiate medical GR and suffer fewer psychiatric comorbidities than those who could not start medical GR. However, psychiatric treatment needs increased vastly after the index contact with the GIS in both groups who proceeded to medical GR, those who subsequently discontinued it and those who continued on hormonal GR. A more detailed analysis of the nature of psychiatric needs and subsequent identity struggles is needed to better understand the discontinuation of medical GR in the future. According to the multivariable analyses, the risk for discontinuing hormonal GR did not differ between those who had initially contacted the GIS during adolescence (<23 years) and those who had contacted in adulthood. This may be due to assessments being particularly cautious with younger patients, whereas with middle-aged subjects, self-determination may be accorded greater significance.

Having undergone genital surgeries was predictive of a decreased risk of discontinuing hormonal treatments. This may be due to strict treatment protocols requiring psychological stability as part of eligibility for genital surgeries. A recommendation letter is required from both the nationally centralized GIS for gender surgeries to ensure both the patient's capacity to consent and that their psychological and psychosocial resources will suffice to recover from major surgery.

Methodological considerations.

A strength of the present study is the use of nationwide registry data over three decades. The registers are

comprehensive since treatment providers are required by law to report to them all the information on which this study relies. The subjects were identified in the databases of the hospitals where the nationally centralized GISs operate, thereby ensuring the reliability of sampling. The long inclusion period made it possible to analyse changes over time. A limitation is that only subjects who had obtained the special reimbursement code for their hormonal GR were included. There may be subjects who discontinued hormonal GR before their entitlement to special reimbursement (which can take place after a year), and their number is not known. Another limitation is that registers include no information on the reasons for discontinuing hormonal GR. Given the ample publicly funded health services and the special reimbursement for hormonal GR, financial problems are an unlikely reason. Further changes in identity, medical complications or concerns over them, not being helped by GR or social reasons, may contribute [10, 11, 20]. It is also possible that some achieved their goals and therefore discontinued, although this seems implausible in the case of discontinuation after many years. A more profound understanding of the reasons for discontinuing medical GR will require studies using information elicited directly from patients. A further limitation is that regarding the need for psychiatric treatment, this research focused on specialist-level service contacts reflecting severe psychiatric needs. Mild to moderate mental disorders are treated in primary health care. Thus, the need for psychiatric treatment was likely somewhat underestimated in the present study. A limitation is that the possible use of hormonal GR through unofficial routes was not addressed. Publicly funded medical GR interventions are possible only through nationally centralized gender identity services. Obtaining hormonal GR via unofficial routes would likely be related to medical GR not being considered timely in the official treatment route. This finding may suggest that the discontinuation of hormonal GR can be more common among those who obtain hormones unofficially. We combined minors (<18 at intake to the GIS) and late adolescents (18–22-year-olds at intake) because before 2011, minors entered the assessments only occasionally. Brain development, personality development and identity consolidation continue well beyond the age of reaching legal adulthood [23, 26–30]. Finally, discontinuing hormonal GR, desisting from identifying in a sex-discordant way, detransitioning and regretting medical GR are concepts referring partly to the same phenomenon but not totally overlapping [20]. A register-based study cannot reach these nuances.

Conclusion

Discontinuing established medical GR appears to be less common in Finland than reported elsewhere. This is likely due to careful, comprehensive assessment before initiating physical treatments. The risk of discontinuing established medical GR has nevertheless increased alongside increases in the number of patients seeking and proceeding to medical GR. In later intake cohorts, discontinuation also appears to emerge earlier. The threshold to initiate medical GR may have decreased, resulting in greater risks of suboptimal decisions. More research is needed on practically all aspects of detransitioning from medical GR.

Abbreviations

GD Gender dysphoria
GIS Gender identity service
HR Hazard ratio
CI Confidence interval

Author contributions

RK, MH, TH and KT all contributed substantially to the design of the work; TH and RK curated the data; RK performed the analyses; MH consulted in statistical analyses; RK, MH, TH and KT interpreted the results; RK had the main responsibility of drafting the manuscript; MH, TH and KT participated in drafting the manuscript and approved the version submitted. All the authors have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature. All the authors reviewed and approved the manuscript.

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Data availability

The authors are not allowed to give the data to any party. Information about how to apply Finnish register data for research purposes can be found in www.findata.fi.

Declarations

Ethics approval and consent to participate

The present study obtained ethical approval from the ethics committee of Tampere University Hospital (R20040R) and relevant permissions from Findata (THL/5188/14.02.00/2020) and Statistics Finland (TK/1016/07.03.00/2020). In accordance with Articles 6e and 9i and j of Regulation (EU) 2016/679 of the European Parliament and of the Council [21], individual informed consent of each registrar was not needed.

Consent for publication

The manuscript does not contain information that would require consent for publication from individual subjects.

Competing interests

The authors declare no competing interests.

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RESEARCH

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Prevalence of suicidal thoughts and attempts in the transgender population of the world: a systematic review and meta-analysis

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Abstract

Background The aim of this meta-analysis was to determine global pooled prevalence of suicide thoughts and attempts in transgender population.

Methods For doing comprehensive search strategy related to objectives in the presence meta-analysis, all international databases like PubMed (Medline), Scopus, Embase, Web of Sciences, PsycINFO, and the Cumulative Index to Nursing and Allied Health Literature (CINHAL) were searched from January 1990 to December 2022. The quality of the final selected studies was evaluated according to Newcastle–Ottawa Quality Assessment Scale for cross-sectional studies. The subgroup analysis was done based on type of transgender (female to male, male to female) and prevalence (point, period, and lifetime), country, and criteria of diagnosis. All analysis was done in STATA version 17.

Results From the total number of 65 selected studies, 71 prevalence of suicidal thoughts, including point, period, and lifetime prevalence were extracted and combined. After combining these values, the prevalence of suicidal thoughts in the transgender population in the world was 39% in the past month (pooled point prevalence: 39%; 95% CI 35–43%), 45% in the past year (pooled period prevalence: 45%; % 95 CI 35–54%) and 50% during lifetime (pooled lifetime prevalence: 50%; % 95 CI 42–57%). Also, the prevalence of suicide attempt in the transgender population of the world was 16% in the past month (pooled point prevalence: 16%; 95% CI 13–19%), 11% in the past year (pooled period prevalence: 11%; % 95 CI 5–19%) and 29% during lifetime (pooled lifetime prevalence: 29%; % 95 CI 25–34%).

Conclusion The present meta-analysis results showed the prevalence of suicidal thoughts and attempts in the transgender community was high, and more importantly, about 50% of transgenders who had suicidal thoughts, committed suicide.

Keywords Suicidal thoughts, Suicidal attempts, Transgender, Meta-analysis

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Background

Transgender is a comprehensive term which includes the definitions of transsexuals, trans people, travesties, another gender identity and people whose gender identity or gender expression is different from their gender at birth. There are two groups of transsexuals including trans-women groups (male to female/MTF) referring to people whose gender was male at the time of birth but they consider themselves as women and trans-men groups (female to male/FTM) referring to people who are women at the time of birth but they accept themselves as men and are gender-nonconforming individuals [1, 2]. Transgenders are a minority group of society but their population is under growing and needs focusing on their life problems and life-threatening factors [3, 4].

In groups excluded from society, including the Black population, refugees, immigrants, lesbians, homosexuals, bisexuals, transgenders, intersex people and indigenous people, a higher prevalence of negative mental health outcomes such as depression, anxiety, substance use disorders, suicide attempts and suicidal thoughts has been reported. Suicide is one of the major problems in the transgender community. According to statistics of the World Health Organization (WHO), the annual global prevalence of suicide has increased and become a public health problem while it is the leading cause of death in the United States (US) and the 10th leading cause of death among youth and adolescents [5]. Effective prevention measures include identifying people at risk, understanding the circumstances of suicide and evaluating the effectiveness of interventions [2]. It has been estimated that 5.6–14.4% of all people in society think about suicide at some point in their lives and 1.9–8.7% commit suicide. Furthermore, the prevalence of suicide attempts in trans people has been estimated to be 16–42% [6]. According to a longitudinal study in Sweden, the risk of death by suicide in trans people is 19 times higher than that of the control group [7]. According to a study in India, the prevalence of suicide in trans people is 32–50% [8]. Based on a study done in Argentina, the lifetime prevalence of suicide in trans-women and trans-men was reported to be 33% [1]. In a study in the US, 15% of transgender students reported committing suicide in the last 12 months and in another study in America, 41% of transgender students reported committing suicide during their lifetime [9]. One of the important factors exposing trans people to depression and suicide is prejudice towards them. In addition to the general stressful life factors, trans people are exposed to high levels of discrimination, violence and rejection due to their gender identity or its expression [2]. Among other factors related to suicide in trans people, the third one is drug use while age, mental health problems, education levels and income levels can be mentioned [1]. According to the data of the WHO, family support, friends and other important relationships, social participation, satisfactory social life and access to mental health care services are protective and preventive factors against suicide for trans people and the public [2].

In the study, we included (number of papers) and documented suicide thoughts and attempts among transgender people. The suicide was evaluated in two ways: (1) self-reporting of suicidal thoughts; (2) self-reporting of suicide attempts. The data indicated different suicide statistics in trans people and no fixed suicide statistics were available based on the regions. In this study, we calculated the suicide prevalence based on the regions and estimated the exact prevalence of suicide thoughts and attempts in trans people based on the regions.

Methods

The study protocol has been registered on the Prospero website with the code CRD42022376073. This study was a systematic review and meta-analysis conducted with the aim of estimating the global pooled prevalence (point, period, and lifetime) of suicidal thoughts and attempts in transgender people through the following steps and based on the structure of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (Additional file 1: PRISMA 2020 Checklist) [10].

Eligibility criteria

The study aimed to determine the global prevalence of suicidal thoughts and attempts in transgender people. All cross-sectional studies, both descriptive and analytical, were reviewed and other studies (case controls, cohorts, clinical trials, letters to the editor, case or case reports and review studies) were excluded from the study. Reporting suicidal thoughts or attempts as a frequency in cross-sectional studies and articles in English were other inclusion criteria. Also, the articles which reported the suicide (suicide thoughts or attempts) in the form of a mean score along with standard deviation and other indicators other than frequency were excluded from the study. In this way, only cross-sectional studies reporting percentage or frequency were included in the present meta-analysis. Finally, only articles conducted on the transgender population were included and ones performed on other gender minorities such as lesbians, bisexuals, gays, etc., were excluded from the study.

Information sources and search strategy

Articles published from January 1990 to December 2022 in the international databases including Scopus, PubMed (Medline), Web of Science, PsycoInfo, the Cumulative Index to Nursing and Allied Health Literature (CINHAL), and Embase were retrieved and screened. The

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main keywords in this study included "Suicide Attempt", "Suicide Ideation", and "Transgender" synonyms of the main keywords in the Mesh search engine. In addition, by examining other studies, other synonyms were also found and used in the search strategy. In order to carry out a comprehensive search strategy, the authors also searched the first ten pages of google scholar and selected related articles. In addition, manual search was also performed by checking the resources of related articles. After creating a library in Endnote software version 9 for each database, they were placed in a combined form and duplicate articles were removed based on the software default. Then, the remaining articles were evaluated based on their title, abstract and full text considering the inclusion criteria. Two of the authors (PK and MN) independently and separately screened the articles based on their title, abstract and full text and if there was a discrepancy, the results were reviewed by the supervisor.

Data extraction

After screening the articles to identify those that were relevant to the study's purpose, a checklist was created based on the opinions of experts. This checklist included several components, such as the authors' names, study type, publication year, total sample size, country, continent, population type, age, and frequency of suicidal thoughts or attempts. The purpose of using this checklist was to ensure that all relevant data were extracted from each selected studies in this meta-analysis and consistent manner. By using a standardized checklist, the researchers could reduce the risk of bias and increase the reliability of the data extracted from each study.

Risk of bias

NOS (Newcastle–Ottawa Quality Assessment Scale) checklist was used to evaluate the risk of bias [11]. This checklist has been designed to evaluate the quality of cross-sectional studies. Each of the items is given a score of 1 if observed in the studies. The maximum score for each study is 9. This step was independently performed by two authors (PK and MCH) and in case of disagreement, the cases were referred to the third researcher (YM).

Statistical analysis

To perform the analysis, the total sample size of the studies along with the number of transgender people with suicidal thoughts or attempts were extracted from all the selected studies for meta-analysis. According to the extracted information, the Metaprop command was used to calculate the pooled estimate and the results were analyzed. To check the heterogeneity and variance between the selected studies, Cochran's *Q* and *I*2 tests were used. Statistical analysis was performed using STATA 17 and P-value < 0.05 was considered. In addition, funnel plot and Egger's test were used to check publication bias. Meta-regression analysis was also applied to investigate the effect of age on the prevalence of suicidal thoughts and attempts. Finally, subgroup analyzes were performed and reported based on the type of gender such as FTM (female to male) or MTF (male to female), the continent and type of prevalence (point, period and lifetime) which point prevalence indicates the prevalence in the past month, period prevalence indicates the prevalence in the past year and life time prevalence indicates the prevalence during the lifetime.

Results

Qualitative results

In this meta-analysis, after completing the search in the desired databases, 2907 studies were retrieved. After removing duplicates (777 studies), 2130 were screened based on their titles and 1706 studies were excluded while 424 ones were entered into the screening stage based on the abstract. In the screening stage based on the abstract, 198 studies were excluded and 226 were included in the screening stage based on the full text. Finally, at this stage, 161 studies were excluded and 65 related studies were selected and entered into the meta-analysis (Fig. 1).

Data of the 65 selected studies are summarized in Table 1. The community investigated in these studies was different types of the transgender community such as FTM and MTF. All studies were descriptive or analytical cross-sectional, conducted in different countries and diverse societies. From the 65 selected studies, 21 received a scores of 6, 35 a scores of 7, and 9 a scores of 8 according to the quality assessment based on the NOS checklist (Table 1). Most of the selected studies reported the number of trans people with suicidal thoughts or attempts (Table 1).

Quantities results

Suicidal thoughts in the transgender

From the total number of 65 selected studies, 71 prevalence of suicidal thoughts, including point, period, and lifetime prevalence were extracted and combined. After combining these values, the meta-analysis results showed the pooled prevalence of suicidal thoughts in the transgender community of the whole world was equal to 48% (pooled prevalence: 48%; 95% CI 42–54%; I_{square}: 88.53%; $P_{\text{heterogeneity}} < 0.0001$). In the present meta-analysis, the overall prevalence was also calculated into three states of point, period, and lifetime prevalence and the results showed these values were equal to 39%, 45%, and 50%, respectively, in the transgender community of the world. In this way, the prevalence of suicidal thoughts

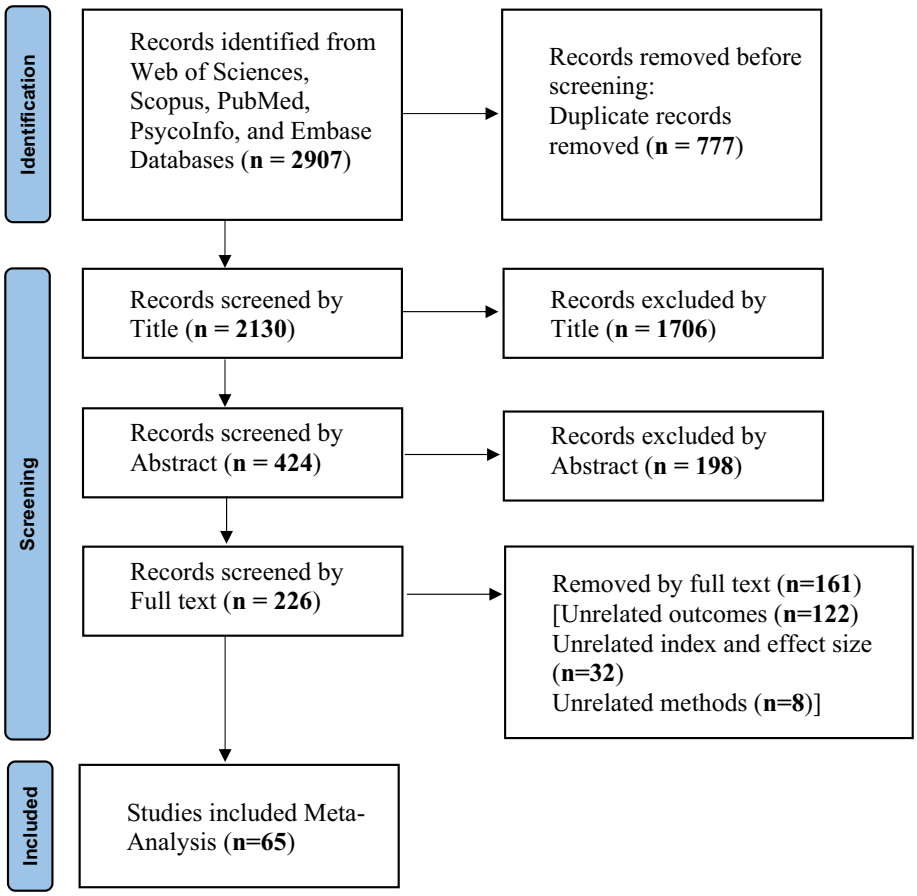

Fig. 1 A flow diagram demonstrating the study selection process

in the transgender community in the world was 39% in the past month (pooled point prevalence: 39%; 95% CI: 35–43%), 45% in the past year (pooled period prevalence: 45%; % 95 CI 35–54%) and 50% during lifetime (pooled lifetime prevalence: 50%; % 95 CI 42–57%) (Table 2).

Subgroup analysis

The results of subgroup analyze based on the gender change type were also examined. In total, 11 studies reported the prevalence of suicidal thoughts in the FTM trans community and 20 studies reported it in the MTF trans community. The rest of the selected studies did not report suicidal thoughts based on these two communities; in other words, they examined the transgender community in general to report the prevalence of suicidal thoughts (both). After combining these studies, the meta-analysis results showed the period prevalence of suicidal thoughts in the FTM community was equal to 40% (pooled period prevalence: 40%; 95% CI 35–45%) while the lifetime prevalence in this community was equal to 53% (pooled lifetime prevalence: 53%; 95% CI 44–62%). The overall prevalence of suicidal thoughts in this trans community was equal to 51% (pooled prevalence: 51%; 95% CI 43–59%) whereas in the MTF community, this prevalence was equal to 44% (pooled prevalence: 44%; 95% CI 35–53%). In the MTF community, the period prevalence and lifetime prevalence were equal to 47% (pooled period prevalence: 47%; 95% CI 33–61%) and 43% (pooled lifetime prevalence: 43%; 95 CI 33–53%), respectively (Table 2).

The prevalence of suicidal thoughts among transgender people in the world was different based on the different continents so that the present meta-analysis showed in America, the period prevalence of suicidal thoughts in the transgender community was equal to 50% (pooled period prevalence: 50%; 95% CI 37–63%) while this prevalence in European and Asian transgenders was 38% (pooled period prevalence: 38%; 95% CI 35–40%) and 23% (pooled period prevalence: 23%; 95% CI 33–15%), respectively. However, the lifetime prevalence in the transgender community living in the Asian continent was equal to 54% (pooled lifetime prevalence: 54%; 95% CI 48–61%) which was more than that of

Table 1 The characteristics of included studies

Author	Year	Country	Study design	Study population	Mean age	Sample size	Suicidal ideation	Suicide attempt	NOS score
Andreas K	2021	European countries	Cross-sectional	TS	30.7	5267	1827	1797	7
Yossi Levi-B	2022	Israel	Cross-sectional	TS	55	195	151	77	6
Shira M	2009	USA	Cross-sectional	FTM	47	153	NR	9	6
				MTF	47	153	NR	12	
Brandon D. L. M	2015	Argentina	Cross-sectional	FTM	30	482	NR	18	6
				MTF	30	482	NR	141	
Robin M. M	2002	USA	Cross-sectional	TS	36.88	73	27	17	7
Azar N	2021	Iran	Cross-sectional	MTF	27.6	127	91	64	7
Arianne R	2021	Brazil	Cross-sectional	MTF	30	763	191	238	7
Sari L. R	2014	USA	Cross-sectional	TS	37.3	31	18	9	7
Katharine A.R	2019	UK	Cross-sectional	FTM	19.7	210	108	46	7
				MTF	20.2	105	58	24	
Ankur S	2021	California	Cross-sectional	TS	NR	120	NR	17	6
				VTS	NR	120	NR	51	
Gareth J. T	2020	Australia	Cross-sectional	TS	26	392	157	66	6
				VTS	26	392	367	209	
Raymond P.T	2017	USA	Cross-sectional	TS	NR	170	62	NR	6
					NR	170	99	NR	
					41.14	36	14	NR	
					41.14	36	19	NR	
Jack L. T	2020	USA	Cross-sectional	TS	23.4	3494	3129	1775	8
Sahika Y	2015	Turkey	Cross-sectional	MTF	NR	42	23	13	7
				FTM	NR	99	55	29	
Galit Z	2018	Sweden	Cross-sectional	MTF	NR	149	60	54	8
				FTM	NR	187	75	79	
				TS	NR	796	283	251	
Sav Z	2021	Australia	Cross-sectional	TS	28	928	NR	394	8
Ashley A	2020	USA	Cross-sectional	TS	NR	372	320	208	7
Greta R. B	2015	Canada	Cross-sectional	TS	32.7	380	133	43	7
Runsen C	2019	China	Cross-sectional	MTF	23.3	687	413	141	7
				FTM	23.3	622	319	68	
Itala Raymundo C	2021	Brazil	Cross-sectional	TS	26.8	378	256	163	7
Ricardo de M. R. R	2021	Brazil	Cross-sectional	MTF	NR	345	163	64	6
Anthony F	2020	USA	Cross-sectional	TS	NR	572	85	184	6
				VTS	NR	572	40	184	
Peter G	2012	USA	Cross-sectional	TS	37.1	290	NR	83	6
Arnold H. G	2016	USA	Cross-sectional	TS	18	129	52	29	6
Shelley H	2021	USA	Cross-sectional	TS	22.5	3471	977	179	6
		Canada	Cross-sectional	TS	22.5	717	196	54	
Adam G. H	2020	USA	Cross-sectional	MTF	NR	33	10	8	7
				FTM	NR	98	45	30	
Sanna S	2021	Nepal	Cross-sectional	MTF	NR	139	58	26	7
Yiu T. S	2017	Hong Kong	Cross-sectional	TS	NR	106	71	22	6
Seishi T	2011	Japan	Cross-sectional	MTF	32.2	188	141	NR	6
				FTM	26.4	312	219	NR	
Brian C. T	2019	USA	Cross-sectional	TS	NR	1148	974	577	7

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Table 1 (continued)

Author	Year	Country	Study design	Study population	Mean age	Sample size	Suicidal ideation	Suicide attempt	NOS score
Galit Z	2018	Sweden	Cross-sectional	MTF	NR	149	60	54	7
				FTM	NR	187	75	79	
Sav Z	2021	Australia	Cross-sectional	TS	NR	928	NR	399	7
Rao A	2019	Pakistan	Cross-sectional	TS	39	156	67	NR	6
Itala R. C	2019	Brazil	Cross-sectional	TS	26.8	378	256	163	6
Collier M. C	1997	USA	Cross-sectional	MTF	32	318	38	NR	7
				FTM	30	117	25	NR	
Rachel L	2016	Lebanon	Cross-sectional	TS	27	54	NR	25	7
Aboussouan A	2019	USA	Cross-sectional	TS	49.01	154	NR	110	7
				TS	49.01	159	NR	56	
				TS	31.11	2841	NR	1540	
				TS	31.11	1131	NR	226	
				TS	49.01	154	98	21	
				TS	49.01	159	43	6	
				TS	31.11	2841	1936	392	
				TS	31.11	1131	432	40	
Yockey A	2020	USA	Cross-sectional	TS	NR	790	272	287	7
Azeem R	2019	Pakistan	Cross-sectional	TS	39.26	156	67	NR	6
Bauer G	2015	Canada	Cross-sectional	TS	32.7	380	NR	43	7
Boyer L	2021	USA	Cross-sectional	TS	NR	8112	NR	66	7
Chang R	2022	China	Cross-sectional	MTF	34	198	73	NR	7
Chen R	2019	China	Cross-sectional	MTF	22.89	687	413	141	7
				FTM	23.78	622	319	68	
				TS	23.31	1309	732	209	
Chen Y	2020	China	Cross-sectional	MTF	27.9	250	55	64	7
Chinazzo I	2021	Brazil	Cross-sectional	TS	NR	378	256	163	7
Clements-N. K	2006	USA	Cross-sectional	MTF	NR	392	NR	127	7
				FTM	NR	123	NR	39	
Drakeford L	2018	USA	Cross-sectional	TS	NR	6450	NR	3394	8
Duffy M	2018	USA	Cross-sectional	TS	NR	122	92	91	7
				TS	NR	436	102	33	
Green A	2021	USA	Cross-sectional	TS	19.95	1216	NR	173	7
				TS	16.91	4537	NR	956	
Grossman A	2007	USA	Cross-sectional	MTF	17.5	31	12	6	7
				FTM	19.5	24	13	8	
Jin H	2020	USA	Cross-sectional	MTF	23.2	297	56	NR	7
Kittiteerasack P	2020	Thailand	Cross-sectional	TS	NR	96	22	NR	8
				TS	NR	96	39	12	
Kota K	2020	USA	Cross-sectional	MTF	35	92	30	NR	7
Kuper L	2018	USA	Cross-sectional	TS	21.07	1896	1587	207	7
Lehavot K	2016	USA	Cross-sectional	TS	49.28	212	120	68	7
Maksut J	2020	USA	Cross-sectional	MTF	NR	381	226	50	8
Marshall B	2015	Argentina	Cross-sectional	TS	30	482	NR	159	7
Perez-Brumer A	2017	USA	Cross-sectional	TS	15.23	7653	2467	NR	7
Perez-Brumer A	2015	USA	Cross-sectional	TS	32.74	1229	NR	355	8
				TS	32.74	1229	NR	51	
Peterson C	2016	USA	Cross-sectional	TS	17.1	96	NR	27	6
Rabasco A	2020	USA	Cross-sectional	TS	26.44	133	NR	62	6

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Table 1 (continued)

Author	Year	Country	Study design	Study population	Mean age	Sample size	Suicidal ideation	Suicide attempt	NOS score
Rabasco A	2021	USA	Cross-sectional	TS	26.01	180	NR	75	6
Schweizer V	2020	USA	Cross-sectional	MTF	NR	229	131	NR	7
				FTM	NR	121	94	NR	
Seelman L	2016	USA	Cross-sectional	TS	31.02	2325	NR	1081	6
Mustanski B	2010	USA	Cross-sectional	TS	NR	20	2	2	6

MTF: male to female; FTM: female to male; TS: transgender; VTS: veteran transgender

transgenders living in other continents such as Europe and America (Table 2).

The prevalence of suicidal thoughts in the different continents based on FTM and MTF gender change was also investigated and compared, the results of which are shown in Table 2. The results of the meta-analysis showed the prevalence of suicidal thoughts in the MTF community of Europe was equal to 47% (pooled prevalence: 47%; 95% CI 38–55%), in America, it was equal to 35% (pooled prevalence: 35%; 95% CI 23—48%) and in Asia, it was equal to 52% (pooled prevalence: 52%; 95% CI 65–39%). While the prevalence of suicidal thoughts in the European FTM community was equal to 46% (pooled prevalence: 46%; 95% CI 39–54%), in America, it was equal to 50% (pooled prevalence: 50%; 95% CI 22–77%) and in Asia, it was equal to 58% (pooled prevalence: 58%; 95% CI 68–47%). In general, the meta-analysis results showed the prevalence of suicidal thoughts in the trans community living in Asia was equal to 53% (pooled prevalence: 53%; 95% CI 46–59%) which was more than those of Europe and America (Table 2).

Publication bias and meta-regression

The results of publication bias and meta-regression based on the transgender population's age are shown in Fig. 2. According to the results of this figure and Eggers' test (B: − 0.38; SE: 0.174; P: 0.0477), publication bias has occurred in these results. Trim and fill analysis was used to more closely examine the publication bias effect on the estimated pooled prevalence, the results of which also showed it did not significantly affect the overall result (Fig. 2). The meta-regression results showed with age, the prevalence of suicidal thoughts in the transgender community slightly increased but it was not statistically significant (B: 0.0001; SE: 0.0033; P: 0.969) (Fig. 2).

Suicidal attempts in the transgender

From the total number of 65 selected studies, 82 prevalence of suicidal attempts, including point, period, and lifetime prevalence were extracted and combined. The meta-analysis results showed the pooled prevalence of suicide attempts in the transgender community of the whole world was equal to 26% (pooled prevalence: 26%; 95% CI 22–31%; I_{square}: 95.51%; $P_{\text{heterogeneity}} < 0.0001$). The overall prevalence was also calculated into three states of point, period, and lifetime prevalence and the results showed these values for suicide attempts in the transgender community of the world were equal to 16%, 11% and 29%, respectively. In this way, the prevalence of suicide in the transgender community of the world was 16% in the past month (pooled point prevalence: 16%; 95% CI 13–19%), 11% in the past year (pooled period prevalence: 11%; % 95 CI 5–19%) and 29% during lifetime (pooled lifetime prevalence: 29%; % 95 CI 25–34%) (Table 3).

Subgroup analysis

The results of subgroup analyze based on the gender change type were also examined and in total 11 studies reported the prevalence of suicide attempts in the FTM trans community in the form of lifetime prevalence. After combining these results, the pooled prevalence of suicide attempts in the FTM community was equal to 22% (pooled lifetime prevalence: 22%; 95% CI 13–31%) (Table 3).

17 studies reported the prevalence of suicide attempts in the MTF trans community. After combining these studies, the meta-analysis results showed the pooled prevalence of suicide attempts in this community was equal to 25% (pooled prevalence: 25%; 95% CI 21–30%) while the period and lifetime prevalence was equal to 13% (pooled period prevalence: 13%; 95% CI 10–17%) and 26% (pooled lifetime prevalence: 26%; 95% CI 22–34%), respectively (Table 3).

The prevalence of suicide attempts among transgender people in the world was different based on the different continents so that the present meta-analysis showed in the European continent, it was equal to 33% (pooled lifetime prevalence: 33%; 95% CI was 29–36%) while this prevalence in American and Asian transgenders was 29% (pooled lifetime prevalence: 29%; 95% CI 24–35%) and 23% (pooled lifetime prevalence: 23%; 95% CI 18–28%), respectively (Table 3).

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Table 2 The pooled prevalence of suicide ideation in transgender population based on type of TS, and continents

Outcomes	Number of studies	Pooled prevalence %	95% CI		Heterogeneity assessment		
			Lower %	Upper %	*I* square %	Z	*P* value
Overall prevalence	71	48	42	54	88.53	26.62	< 0.0001
Type of prevalence							
Point prevalence	3	39	35	43	86.99	22.09	< 0.0001
Period prevalence	16	45	35	54	89.93	26.33	< 0.0001
Life time prevalence	52	50	42	57	88.43	26.41	< 0.0001
Type of TS							
Female to male							
Overall	11	51	43	59	93.40	12.28	< 0.0001
Period prevalence	2	40	35	45	93.71	12.22	< 0.0001
Life time prevalence	9	53	44	62	88.90	10.33	< 0.0001
Male to female							
Overall	20	44	35	53	97.56	19.21	< 0.0001
Period prevalence	3	47	33	61	80.09	16.00	< 0.0001
Life time prevalence	17	43	33	53	90.88	18.29	< 0.0001
Both							
Overall	40	49	41	58	89.60	17.05	< 0.0001
Period prevalence	11	45	33	57	89.68	11.45	< 0.0001
Point prevalence	3	39	35	43	98.88	30.36	< 0.0001
Life time prevalence	26	53	40	65	94.66	12.45	< 0.0001
Continents							
Europe							
Overall	10	43	39	48	86.44	27.69	< 0.0001
Period prevalence	5	38	35	40	0.00	47.97	0.500
Life time prevalence	5	50	38	62	93.52	11.94	< 0.0001
Asia							
Overall	17	53	46	59	95.75	23.67	< 0.0001
Period prevalence	1	23	15	33	-	8.87	< 0.0001
Life time prevalence	16	54	48	61	95.51	24.74	< 0.0001
America							
Overall	42	46	37	55	97.99	15.30	< 0.0001
Point prevalence	2	37	30	44	89.03	16.69	< 0.0001
Period prevalence	10	50	37	63	89.43	10.82	< 0.0001
Life time prevalence	30	45	33	58	88.99	11.13	< 0.0001
Australia							
Overall	2	71	68	74	88.90	54.59	< 0.0001
Continents							
Europe							
MTF	4	47	38	55	65.29	16.66	0.0380
FTM	4	46	39	54	73.46	18.85	0.0109
Both	2	35	34	37	88.00	96.18	< 0.0001
Asia							
MTF	7	52	39	65	97.26	11.68	< 0.0001
FTM	3	58	47	68	88.09	14.90	< 0.0001
Both	7	50	39	62	95.00	12.63	< 0.0001
America							
MTF	9	35	23	48	97.59	8.55	< 0.0001
FTM	4	50	22	77	96.45	4.94	< 0.0001
Both	29	49	38	60	99.68	13.06	< 0.0001
Australia							
Both	2	71	68	74	89.04	54.59	0.0089

MTF: male to female; FTM: female to male; TS: transgender; CI: confidence interval

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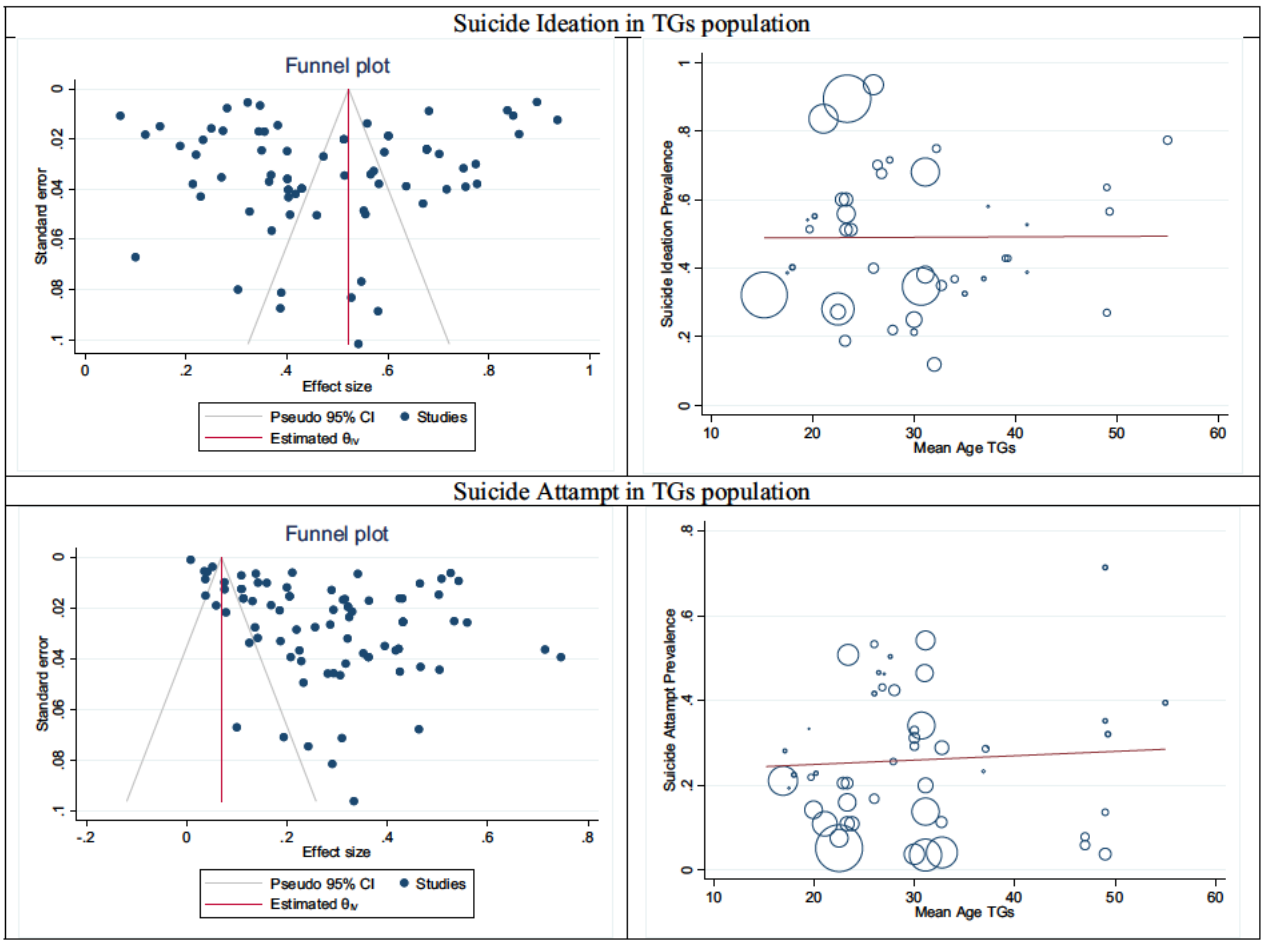

Fig. 2 The funnel and meta-regression plots related to pooled prevalence suicide in transgender

The prevalence of suicide attempts in the different continents based on FTM and MTF gender change was also investigated and compared, the results of which are shown in Table 3. The meta-analysis results showed the prevalence of suicide attempts in the European MTF community was equal to 32% (pooled prevalence: 32%; 95% CI 25–39%), in America, it was equal to 21% (pooled prevalence: 21%; 95% CI 15–29%) and in Asia, it was equal to 26% (pooled prevalence: 26%; 95% CI 19–34%). While the prevalence of suicide attempt in the European FTM community was equal to 34% (pooled prevalence: 34%; 95% CI 23–45%), in America, it was equal to 18% (pooled prevalence: 18%; 95% CI 6–35%) and in Asia, it was equal to 11% (pooled prevalence: 11%; 95% CI 9–13%). In general, the meta-analysis results showed the prevalence of suicide attempts in the trans people living in Australia and Oceania was equal to 38% (pooled prevalence: 38%; 95% CI 26–52%) and higher than those of Europe, America and Asia (Table 3).

Publication bias and meta-regression

The results of publication bias and meta-regression based on the transgender population's age are shown in Fig. 2. According to the results of this figure and Egger's test (B: 2.18; SE: 0.974; *P*: 0.0214), publication bias has occurred in these results. Trim and fill analysis was used to more closely examine the publication bias effect on the estimated pooled prevalence, the results of which also showed it did not significantly affect the overall result (Fig. 2). The meta-regression results showed with increasing age, the prevalence of suicide attempts in the transgender community slightly increased but it was not statistically significant (B: 0.010; SE: 0.002; *P*: 0.666) (Fig. 2).

Discussion

The transgender population in the world has been investigated by many different studies. Determining their exact number both in terms of prevalence and

Table 3 The pooled prevalence of suicide attempt in transgender population based on type of TS, and continents

Outcomes	Number of studies	Pooled prevalence %	95 CI		Heterogeneity assessment		
			Lower %	Upper %	*I* square %	Z	*P* value
Overall prevalence	82	26	22	31	95.51	18.01	< 0.0001
Type of prevalence							
Point prevalence	2	16	13	19	88.10	17.18	< 0.0001
Period prevalence	10	11	5	19	99.26	5.66	< 0.0001
Life time prevalence	70	29	25	34	99.11	22.54	< 0.0001
Type of TS							
Female to male							
Overall/life time prevalence	11	22	13	31	96.79	7.98	< 0.0001
Male to female							
Overall	17	25	21	30	91.14	18.83	< 0.0001
Period prevalence	1	13	10	17	–	13.54	< 0.0001
Life time prevalence	16	26	22	30	89.56	19.74	< 0.0001
Both							
Overall	54	28	22	34	98.67	14.53	< 0.0001
Period prevalence	9	11	5	20	89.31	5.29	< 0.0001
Point prevalence	2	16	13	19	88.88	17.18	< 0.0001
Life time prevalence	43	33	27	38	89.38	18.81	< 0.0001
Continents							
Europe							
Overall/life time prevalence	10	33	29	36	74.95	30.53	< 0.0001
Asia							
Overall/life time prevalence	12	23	18	28	94.51	14.17	< 0.0001
America							
Overall	56	25	19	32	99.64	13.24	< 0.0001
Point prevalence	1	14	8	22	87.33	7.56	< 0.0001
Period prevalence	10	11	5	19	89.26	5.66	< 0.0001
Life time prevalence	45	29	24	35	89.36	16.23	< 0.0001
Australia							
Overall	4	38	26	52	97.87	9.42	< 0.0001
Point prevalence	1	17	13	21	–	15.80	< 0.0001
Life time prevalence	3	46	40	52	88.79	24.57	< 0.0001
Continents							
Europe							
MTF	4	32	25	39	54.76	14.98	0.080
FTM	4	34	23	45	88.87	10.00	< 0.0001
Both	2	34	33	35	88.00	94.50	< 0.0001
Asia							
MTF	5	26	19	34	91.97	11.52	< 0.0001
FTM	2	11	9	13	88.79	22.44	< 0.0001
Both	5	26	15	38	94.41	6.94	< 0.0001
America							
MTF	8	21	15	29	93.46	10.44	< 0.0001
FTM	5	18	6	35	96.30	3.88	< 0.0001
Both	43	27	20	35	98.72	11.84	< 0.0001
Australia							
Both	4	38	26	52	97.87	9.42	< 0.0001

MTF: male to female; FTM: female to male; TS: transgender; CI: confidence interval

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occurrence depends on the basic definition but according to a systematic review published in 2016, approximately 9.2 out of every 100,000 people in the world were transgender [12]. These results show the study of these populations and factors affecting health outcomes such as their socioeconomic status is very important. This study was a systematic review and meta-analysis conducted with the aim of accurately determining the prevalence of suicidal thoughts and attempts among transgender people in the world, in which the lifetime prevalence of suicidal thoughts and attempts in transgender people was 50% and 29%, respectively. These results prove the fact that almost half of the transgenders who have suicidal thoughts commit suicide. These results are very important for health policy makers and health decision-makers in the world, especially in the developing countries, because it shows the lack of proper efficiency and effectiveness of health, educational and therapeutic interventions to prevent suicide attempts and successful suicide in the transgender community. Various factors, including economic, social, cultural, health and medical factors play a role in increasing the prevalence of suicidal thoughts and, of course, suicide attempts.

On the other hand, the results of past studies have shown transgender people are at a higher risk of experiencing suicidal thoughts during their lifetime compared to other gender minority populations such as bisexuals and MSM (50% vs. 23% and 34%, respectively). This indicates compared to other sexual minorities, there are other factors which put transgender people at greater risk of suicidal thoughts and actions [13, 14]. Among the important influencing factors, we can mention the costs related to hormone therapy and how to access it, taking into account the space and environment of providing hormones, as well as direct and indirect costs related to it. Transgenders, whether FTM or MTF, need to receive sex hormones, especially estrogen or testosterone, for a long time and before performing any related surgery in order to establish their desired gender identity in their society, family and peers. The results of past studies have shown hormone therapy among transgender people causes beneficial effects such as strengthening psychological function and reducing depression and anxiety but it should be kept in mind that various factors have an effect on it. Some transgender people may be deprived of this type of treatment and access to it due to lack of financial ability, social stigma and discrimination, fear of gender identity disclosure and sexual and work abuse. As a result of this problem, they suffer from complications such as depression and anxiety disorders and suicidal thoughts leading to commit suicide [15–19].

In order to supply the required hormones in this society, which is considered one of their most important needs in the process of gender change, economic obstacles and problems can be considered as the most important factor in access to hormones. To solve this challenge, basically, there are two ways ahead of transgender people. First, these people have the support of their family and friends; in this case, the main challenge is the existence of stigma and discrimination in centers providing care or treatment services, such as pharmacies, hospitals, or care centers. Second, they do not have the support of their family and friends, and in other words, they have been rejected by them. In this case, they face economic problems and the existence of stigma in order to provide the needed hormones in the service centers. In the first case, transgender people, due to lack of direct access to needed hormones or other essential services, are forced to spend exorbitant economic costs to indirectly access the drugs they need. In the second case, these people are forced to find a job and create a source of income in order to cover the costs required for the provision of medicines and services. In this case, the possibility of work and sexual abuse of these people is very high. In both cases, these people are exposed to diseases and mental disorders such as depression, anxiety, seclusion and loneliness [19–24], because receiving the required hormones and necessary treatments in gender minorities especially transgender is one of the important factors in suicide prevention [25–27]. The results of past studies have shown the presence of mental disorders such as anxiety and depression in gender minorities, especially transgenders, is the main cause of suicide. Also, the results of these studies have shown due to the existence of these mental disorders, the rate of suicide in homosexuals and heterosexual people who have homosexual behavior is higher than that of heterosexual ones [28–30].

Among other worrisome cases, we can mention the high prevalence of drug use among these people so that according to reports, lifetime use of drugs such as cocaine, heroin and methamphetamines in these people was 27.1%, 26.1%, 24.9%, respectively, which can cause an increase in suicide attempts by these people. One of the risk factors exposing these people to drug use is their victimization of violence, rejection from society, family and surrounding people, and lack of access to needed facilities due to stigma and discrimination [31, 32]. On the other hand, these people are forced to have sex at a young age in order to meet their living expenses and find trust and support from the people around them. According to the results of past studies, transgender students are more likely than cisgender ones to experience the first

sex before the age of 13 years and to have more than four sexual partners [31–34]. These early sexual experiences can expose these people to emotional damage caused by relationships, an increase in the risk of sexually transmitted infections and finally the occurrence of mental disorders and suicide.

Gender minorities, especially transgender people, face unique challenges and discrimination, such as high rates of institutionalized prejudice, bullying, violence, and physical attacks. Exclusion from the family, stigma and discrimination and other social factors expose transgender people to a phenomenon called internalized transphobia and a negative self-concept related to their gender identity. These feelings can include self-loathing or shame. Internalized transphobia increases the likelihood of suicide attempts in the transgender population [35–37].

Subgroup analyzes in the present meta-analysis showed the prevalence of suicidal thoughts in the trans community living in Asia was higher than that of other continents. This difference can be attributed to differences between various cultures and fixed traditions in families. In some Asian societies, such as Thailand, despite social supports, transgender people do not have a favorable acceptance in their families, which can be attributed to the existence and stability of traditional cultures in the family after several years [38]. However, the prevalence of suicide attempts in the trans community living in Australia and Oceania was higher than those of other continents. Based on the meta-analysis findings, the prevalence of suicidal thoughts in the FTM trans community in the Asian and American continents was higher than that of the MTF trans community. This may be due to the fact that in these communities, FTMs experience more victimization than MTFs and have more lifetime suicidal ideation [39]. Also, living more in stigmatizing communities can facilitate vulnerability to experiencing stigma-related stressors, which increases suicidal thoughts and attempts among FTM trans people [40]. In general, the prevalence of suicide attempts in the MTF trans community was higher than that of the MTF trans community. Previous studies have shown sexual abuse rates were higher among MTF individuals, which was significantly associated with suicide [41]. Among those known as transgender, men are consistently at higher risk of suicide than women [41]. Also, based on previous studies, trans-men report higher levels of gender discrimination compared to trans-women [42, 43].

In this study, the primary target group is transgender individuals, who are considered one of the key and high-risk populations in society. This group, along with other groups such as lesbian, gay, and bisexual, fall under the umbrella of the LGBT community (lesbian, gay, bisexual, transgender and queer people). These groups differ from each other in terms of high-risk behaviors, susceptibility to viral diseases and infections such as Hepatitis B (HBV) and C (HCV), or human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS). Of course, considering their different circumstances, they also differ in terms of susceptibility to physical and mental disorders. For example, in terms of the degree of social discrimination and intolerance, these individuals face varying degrees of it, which may have an impact on the development of mental disorders and ultimately suicide. All previous studies have two comprehensive limitations. First, they have not been conducted on a specific group of LGBT individuals. This means that they have considered all of these groups as a single entity and reported the prevalence and incidence outcomes in this group as a whole, without paying attention to the differences between these groups [44–47].

The second limitation is that the published studies have mainly focused on the risk or tendency towards suicide ideation or attempts in these communities, rather than the actual prevalence and incidence of suicide. For example, a study by Mattia Marchi and colleagues [47] has specifically examined the risk of suicide attempts in LGBT communities. However, determining the exact prevalence of suicide, especially among transgender individuals, is of utmost importance for allocating healthcare services and providing necessary care in this community.

In addition, suicide can be categorized into two forms; suicide ideation and suicide attempts, and both should be investigated. However, in previous published studies, this aspect has received less attention. In the current meta-analysis, this issue has been analyzed and reported.

Other strengths of the present meta-analysis are the large number of analyzed cross-sectional studies and the subgroup analyzes based on the important variables reported in the primary studies. This can be effective in applying the present meta-analysis results to compile and allocate health services and care programs for the transgender community in different countries. In addition, the present meta-analysis results can be considered as a warning to health policy makers and health decision-makers in different countries because these results show the prevalence of suicidal thoughts and attempts in the transgender community is high and all health measures, interventions and treatment in this field should be reviewed and reformulated. On the other hand, these results for researchers and clinical researchers can open the way for more research with better ideas in the field of suicide in transgender people.

Among the limitations of the present study, we can mention the small number of studies in some countries such as Australia, which can make it possible to

overestimate the overall result due to the small number of analyzed studies. Therefore, it is suggested to design and conduct survey studies with an appropriate sample size in these countries, considering all transgender groups in society in order to determine suicide prevalence.

Conclusion

The findings of this meta-analysis highlight the high prevalence of suicidal thoughts and attempts in the transgender community, and the alarming fact that about 50% of transgender individuals who reported suicidal thoughts actually committed suicide. These results emphasize the urgent need for effective measures to prevent suicide and promote mental health in the transgender population. To address this issue, it is important to develop patient-centered and community-centered interventions that are evidence-based and culturally sensitive. Such interventions should include the implementation of social, economic, and support programs, as well as the provision of necessary counseling and mental health services to both transgender individuals and their families. In addition, healthcare providers should be trained to provide comprehensive and inclusive care to transgender individuals, including the identification and management of suicide risk.

Abbreviations

FTM	Female to male
MTF	Male to female
NOS	Newcastle–Ottawa Quality Assessment
WHO	World Health Organization
CINHAL	The Cumulative Index to Nursing and Allied Health Literature
PRISMA	The Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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AR-001967

Foreword



The twentieth century will be remembered as a century marked by violence. It burdens us with its legacy of mass destruction, of violence inflicted on a scale never seen and never possible before in human history. But this legacy – the result of new technology in the service of ideologies of hate – is not the only one we carry, nor that we must face up to.

Less visible, but even more widespread, is the legacy of day-to-day, individual suffering. It is the pain of children who are abused by people who should protect them, women injured or humiliated by violent partners, elderly persons maltreated by their caregivers, youths who are bullied by other youths, and people of all ages who inflict violence on themselves. This suffering – and there are many more examples that I could give – is a legacy that reproduces itself, as new generations learn from the violence of generations past, as victims learn from victimizers, and as the social conditions that nurture violence are allowed to continue. No country, no city, no community is immune. But neither are we powerless against it.

Violence thrives in the absence of democracy, respect for human rights and good governance. We often talk about how a ''culture of violence'' can take root. This is indeed true – as a South African who has lived through apartheid and is living through its aftermath, I have seen and experienced it. It is also true that patterns of violence are more pervasive and widespread in societies where the authorities endorse the use of violence through their own actions. In many societies, violence is so dominant that it thwarts hopes of economic and social development. We cannot let that continue.

Many who live with violence day in and day out assume that it is an intrinsic part of the human condition. But this is not so. Violence can be prevented. Violent cultures can be turned around. In my own country and around the world, we have shining examples of how violence has been countered. Governments, communities and individuals can make a difference.

I welcome this first *World report on violence and health*. This report makes a major contribution to our understanding of violence and its impact on societies. It illuminates the different faces of violence, from the ''invisible'' suffering of society's most vulnerable individuals to the all-too-visible tragedy of societies in conflict. It advances our analysis of the factors that lead to violence, and the possible responses of different sectors of society. And in doing so, it reminds us that safety and security don't just happen: they are the result of collective consensus and public investment.

The report describes and makes recommendations for action at the local, national and international levels. It will thus be an invaluable tool for policy-makers, researchers, practitioners, advocates and volunteers involved in violence prevention. While violence traditionally has been the domain of the criminal justice system, the report strongly makes the case for involving all sectors of society in prevention efforts.

We owe our children – the most vulnerable citizens in any society – a life free from violence and fear. In order to ensure this, we must be tireless in our efforts not only to attain peace, justice and prosperity for countries, but also for communities and members of the same family. We must address the roots of violence. Only then will we transform the past century's legacy from a crushing burden into a cautionary lesson.

Nelson Mandela

Preface



Violence pervades the lives of many people around the world, and touches all of us in some way. To many people, staying out of harm's way is a matter of locking doors and windows and avoiding dangerous places. To others, escape is not possible. The threat of violence is behind those doors – well hidden from public view. And for those living in the midst of war and conflict, violence permeates every aspect of life.

This report, the first comprehensive summary of the problem on a global scale, shows not only the human toll of violence – over 1.6 million lives lost each year and countless more damaged in ways that are not always apparent – but exposes the many faces of interpersonal, collective and self-directed violence, as well as the settings in which violence occurs. It shows that where violence persists, health is seriously compromised.

The report also challenges us in many respects. It forces us to reach beyond our notions of what is acceptable and comfortable – to challenge notions that acts of violence are simply matters of family privacy, individual choice, or inevitable facets of life. Violence is a complex problem related to patterns of thought and behaviour that are shaped by a multitude of forces within our families and communities, forces that can also transcend national borders. The report urges us to work with a range of partners and to adopt an approach that is proactive, scientific and comprehensive.

We have some of the tools and knowledge to make a difference – the same tools that have successfully been used to tackle other health problems. This is evident throughout the report. And we have a sense of where to apply our knowledge. Violence is often predictable and preventable. Like other health problems, it is not distributed evenly across population groups or settings. Many of the factors that increase the risk of violence are shared across the different types of violence and are modifiable.

One theme that is echoed throughout this report is the importance of primary prevention. Even small investments here can have large and long-lasting benefits, but not without the resolve of leaders and support for prevention efforts from a broad array of partners in both the public and private spheres, and from both industrialized and developing countries.

Public health has made some remarkable achievements in recent decades, particularly with regard to reducing rates of many childhood diseases. However, saving our children from these diseases only to let them fall victim to violence or lose them later to acts of violence between intimate partners, to the savagery of war and conflict, or to self-inflicted injuries or suicide, would be a failure of public health.

While public health does not offer all of the answers to this complex problem, we are determined to play our role in the prevention of violence worldwide. This report will contribute to shaping the global response to violence and to making the world a safer and healthier place for all. I invite you to read the report carefully, and to join me and the many violence prevention experts from around the world who have contributed to it in implementing its vital call for action.

Gro Harlem Brundtland
Director-General
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AR-001973

Introduction

In 1996, the Forty-Ninth World Health Assembly adopted Resolution WHA49.25, declaring violence a major and growing public health problem across the world (see Box overleaf for full text).

In this resolution, the Assembly drew attention to the serious consequences of violence – both in the short-term and the long-term – for individuals, families, communities and countries, and stressed the damaging effects of violence on health care services.

The Assembly asked Member States to give urgent consideration to the problem of violence within their own borders, and requested the Director-General of the World Health Organization (WHO) to set up public health activities to deal with the problem.

This, the first *World report on violence and health*, is an important part of WHO's response to Resolution WHA49.25. It is aimed mainly at researchers and practitioners. The latter include health care workers, social workers, those involved in developing and implementing prevention programmes and services, educators and law enforcement officials. A summary of the report is also available.[1]

Goals

The goals of the report are to raise awareness about the problem of violence globally, and to make the case that violence is preventable and that public health has a crucial role to play in addressing its causes and consequences.

More specific objectives are to:

— describe the magnitude and impact of violence throughout the world;
— describe the key risk factors for violence;
— give an account of the types of intervention and policy responses that have been tried and summarize what is known about their effectiveness;
— make recommendations for action at local, national and international levels.

Topics and scope

This report examines the types of violence that are present worldwide, in the everyday lives of people, and that constitute the bulk of the health burden imposed by violence. Accordingly, the information has been arranged in nine chapters, covering the following topics:

1. Violence – a global public health problem
2. Youth violence
3. Child abuse and neglect by parents and other caregivers
4. Violence by intimate partners

[1] *World report on violence and health: a summary.* Geneva, World Health Organization, 2002.

Preventing violence: a public health priority (Resolution WHA49.25)

The Forty-ninth World Health Assembly,

Noting with great concern the dramatic worldwide increase in the incidence of intentional injuries affecting people of all ages and both sexes, but especially women and children;

Endorsing the call made in the Declaration of the World Summit for Social Development for the introduction and implementation of specific policies and programmes of public health and social services to prevent violence in society and mitigate its effect;

Endorsing the recommendations made at the International Conference on Population and Development (Cairo, 1994) and the Fourth World Conference on Women (Beijing, 1995) urgently to tackle the problem of violence against women and girls and to understand its health consequences;

Recalling the United Nations Declaration on the elimination of violence against women;

Noting the call made by the scientific community in the Melbourne Declaration adopted at the Third International Conference on Injury Prevention and Control (1996) for increased international cooperation in ensuring the safety of the citizens of the world;

Recognizing the serious immediate and future long-term implications for health and psychological and social development that violence represents for individuals, families, communities and countries;

Recognizing the growing consequences of violence for health care services everywhere and its detrimental effect on scarce health care resources for countries and communities;

Recognizing that health workers are frequently among the first to see victims of violence, having a unique technical capacity and benefiting from a special position in the community to help those at risk;

Recognizing that WHO, the major agency for coordination of international work in public health, has the responsibility to provide leadership and guidance to Member States in developing public health programmes to prevent self-inflicted violence and violence against others;

1. DECLARES that violence is a leading worldwide public health problem;
2. URGES Member States to assess the problem of violence on their own territory and to communicate to WHO their information about this problem and their approach to it;
3. REQUESTS the Director-General, within available resources, to initiate public health activities to address the problem of violence that will:
   (1) characterize different types of violence, define their magnitude and assess the causes and the public health consequences of violence using also a ''gender perspective'' in the analysis;
   (2) assess the types and effectiveness of measures and programmes to prevent violence and mitigate its effects, with particular attention to community-based initiatives;
   (3) promote activities to tackle this problem at both international and country level including steps to:
      (a) improve the recognition, reporting and management of the consequences of violence;
      (b) promote greater intersectoral involvement in the prevention and management of violence;
      (c) promote research on violence as a priority for public health research;
      (d) prepare and disseminate recommendations for violence prevention programmes in nations, States and communities all over the world;

AR-001975

(continued)

(4) ensure the coordinated and active participation of appropriate WHO technical programmes;

(5) strengthen the Organization's collaboration with governments, local authorities and other organizations of the United Nations system in the planning, implementation and monitoring of programmes of violence prevention and mitigation;

4. FURTHER REQUESTS the Director-General to present a report to the ninety-ninth session of the Executive Board describing the progress made so far and to present a plan of action for progress towards a science-based public health approach to violence prevention.

5. Abuse of the elderly
6. Sexual violence
7. Self-directed violence
8. Collective violence
9. The way forward: recommendations for action

Because it is impossible to cover all types of violence fully and adequately in a single document, each chapter has a specific focus. For example, the chapter on youth violence examines interpersonal violence among adolescents and young adults in the community. The chapter on child abuse discusses physical, sexual and psychological abuse, as well as neglect by parents and other caregivers; other forms of maltreatment of children, such as child prostitution and the use of children as soldiers, are covered in other parts of the report. The chapter on abuse of the elderly focuses on abuse by caregivers in domestic and institutional settings, while that on collective violence discusses violent conflict. The chapters on intimate partner violence and sexual violence focus primarily on violence against women, though some discussion of violence directed at men and boys is included in the chapter on sexual violence. The chapter on self-directed violence focuses primarily on suicidal behaviour. The chapter is included in the report because suicidal behaviour is one of the external causes of injury and is often the product of many of the same underlying social, psychological and environmental factors as other types of violence.

The chapters follow a similar structure. Each begins with a brief discussion of definitions for the specific type of violence covered in the chapter, followed by a summary of current knowledge about the extent of the problem in different regions of the world. Where possible, country-level data are presented, as well as findings from a range of research studies. The chapters then describe the causes and consequences of violence, provide summaries of the interventions and policy responses that have been tried, and make recommendations for future research and action. Tables, figures and boxes are included to highlight specific epidemiological patterns and findings, illustrate examples of prevention activities, and draw attention to specific issues.

The report concludes with two additional sections: a statistical annex and a list of Internet resources. The statistical annex contains global, regional and country data derived from the WHO mortality and morbidity database and from Version 1 of the WHO Global Burden of Disease project for 2000. A description of data sources and methods is provided in the annex to explain how these data were collected and analysed.

The list of Internet resources includes web site addresses for organizations involved in violence research, prevention and advocacy. The list includes metasites (each site offers access to hundreds of organizations involved in violence research, prevention and advocacy), web sites that focus on specific types of violence, web sites that address broader contextual issues related to violence, and web sites that offer surveillance tools for improving the understanding of violence.

How the report was developed

This report benefited from the participation of over 160 experts from around the world, coordinated by a small Editorial Committee. An Advisory Committee, comprising representatives of all the WHO regions, and members of WHO staff, provided guidance to the Editorial Committee at various stages during the writing of the report.

Chapters were peer-reviewed individually by scientists from different regions of the world. These reviewers were asked to comment not only on the scientific content of the chapter but also on the relevance of the chapter within their own culture.

As the report progressed, consultations were held with members of the WHO regional offices and diverse groups of experts from all over the world. Participants reviewed an early draft of the report, providing an overview of the problem of violence in their regions and making suggestions on what was needed to advance regional violence prevention activities.

Moving forward

This report, while comprehensive and the first of its kind, is only a beginning. It is hoped that the report will stimulate discussion at local, national and international levels and that it will provide a platform for increased action towards preventing violence.

AR-001977

CHAPTER 1

Violence — a global public health problem

AR-001978

Background

Violence has probably always been part of the human experience. Its impact can be seen, in various forms, in all parts of the world. Each year, more than a million people lose their lives, and many more suffer non-fatal injuries, as a result of self-inflicted, interpersonal or collective violence. Overall, violence is among the leading causes of death worldwide for people aged 15–44 years.

Although precise estimates are difficult to obtain, the cost of violence translates into billions of US dollars in annual health care expenditures worldwide, and billions more for national economies in terms of days lost from work, law enforcement and lost investment.

The visible and the invisible

The human cost in grief and pain, of course, cannot be calculated. In fact, much of it is almost invisible. While satellite technology has made certain types of violence – terrorism, wars, riots and civil unrest – visible to television audiences on a daily basis, much more violence occurs out of sight in homes, workplaces and even in the medical and social institutions set up to care for people. Many of the victims are too young, weak or ill to protect themselves. Others are forced by social conventions or pressures to keep silent about their experiences.

As with its impacts, some causes of violence are easy to see. Others are deeply rooted in the social, cultural and economic fabric of human life. Recent research suggests that while biological and other individual factors explain some of the predisposition to aggression, more often these factors interact with family, community, cultural and other external factors to create a situation where violence is likely to occur.

A preventable problem

Despite the fact that violence has always been present, the world does not have to accept it as an inevitable part of the human condition. As long as there has been violence, there have also been systems – religious, philosophical, legal and communal – which have grown up to prevent or limit it. None has been completely successful, but all have made their contribution to this defining mark of civilization.

Since the early 1980s, the field of public health has been a growing asset in this response. A wide range of public health practitioners, researchers and systems have set themselves the tasks of understanding the roots of violence and preventing its occurrence.

Violence can be prevented and its impact reduced, in the same way that public health efforts have prevented and reduced pregnancy-related complications, workplace injuries, infectious diseases, and illness resulting from contaminated food and water in many parts of the world. The factors that contribute to violent responses – whether they are factors of attitude and behaviour or related to larger social, economic, political and cultural conditions – can be changed.

Violence can be prevented. This is not an article of faith, but a statement based on evidence. Examples of success can be found around the world, from small-scale individual and community efforts to national policy and legislative initiatives.

What can a public health approach contribute?

By definition, public health is not about individual patients. Its focus is on dealing with diseases and with conditions and problems affecting health, and it aims to provide the maximum benefit for the largest number of people. This does not mean that public health ignores the care of individuals. Rather, the concern is to prevent health problems and to extend better care and safety to entire populations.

The public health approach to any problem is interdisciplinary and science-based (*1*). It draws upon knowledge from many disciplines, including medicine, epidemiology, sociology, psychology, criminology, education and economics. This has allowed the field of public health to be innovative and responsive to a wide range of diseases, illnesses and injuries around the world.

The public health approach also emphasizes collective action. It has proved time and again that

cooperative efforts from such diverse sectors as health, education, social services, justice and policy are necessary to solve what are usually assumed to be purely ''medical'' problems. Each sector has an important role to play in addressing the problem of violence and, collectively, the approaches taken by each have the potential to produce important reductions in violence (see Box 1.1).

The public health approach to violence is based on the rigorous requirements of the scientific method. In moving from problem to solution, it has four key steps (*1*):

- Uncovering as much basic knowledge as possible about all the aspects of violence – through systematically collecting data on the magnitude, scope, characteristics and consequences of violence at local, national and international levels.
- Investigating why violence occurs – that is, conducting research to determine:
  - — the causes and correlates of violence;
  - — the factors that increase or decrease the risk for violence;
  - — the factors that might be modifiable through interventions.
- Exploring ways to prevent violence, using the information from the above, by designing, implementing, monitoring and evaluating interventions.
- Implementing, in a range of settings, interventions that appear promising, widely disseminating information and determining the cost-effectiveness of programmes.

Public health is above all characterized by its emphasis on prevention. Rather than simply accepting or reacting to violence, its starting point

BOX 1.1

The public health approach in action: DESEPAZ in Colombia

In 1992, the mayor of Cali, Colombia – himself a public health specialist – helped the city set up a comprehensive programme aimed at reducing the high levels of crime there. Rates of homicide in Cali, a city of some 2 million inhabitants, had risen from 23 per 100 000 population in 1983 to 85 per 100 000 in 1991. The programme that ensued was called DESEPAZ, an acronym for *Desarrollo, Seguridad, Paz* (development, security, peace).

In the initial stages of the city's programme, epidemiological studies were conducted so as to identify the principal risk factors for violence and shape the priorities for action. Special budgets were approved to strengthen the police, the judicial system and the local human rights office.

DESEPAZ undertook education on civil rights matters for both the police and the public at large, including television advertising at peak viewing times highlighting the importance of tolerance for others and self-control. A range of cultural and educational projects were organized for schools and families in collaboration with local nongovernmental organizations, to promote discussions on violence and help resolve interpersonal conflicts. There were restrictions on the sale of alcohol, and the carrying of handguns was banned on weekends and special occasions.

In the course of the programme, special projects were set up to provide economic opportunities and safe recreational facilities for young people. The mayor and his administrative team discussed their proposals to tackle crime with local people, and the city administration ensured the continuing participation and commitment of the community.

With the programme in operation, the homicide rate in Cali declined from an all-time high of 124 per 100 000 to 86 per 100 000 between 1994 and 1997, a reduction of 30%. In absolute numbers, there were approximately 600 fewer homicides between 1994 and 1997 compared with the previous 3-year period, which allowed the law enforcement authorities to devote scarce resources to combating more organized forms of crime. Furthermore, public opinion in Cali shifted strongly from a passive attitude towards dealing with violence to a vociferous demand for more prevention activities.

AR-001981

is the strong conviction that violent behaviour and its consequences can be prevented.

Defining violence

Any comprehensive analysis of violence should begin by defining the various forms of violence in such a way as to facilitate their scientific measurement. There are many possible ways to define violence. The World Health Organization defines violence (*2*) as:

> The intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community, that either results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment or deprivation.

The definition used by the World Health Organization associates intentionality with the committing of the act itself, irrespective of the outcome it produces. Excluded from the definition are unintentional incidents – such as most road traffic injuries and burns.

The inclusion of the word ''power'', in addition to the phrase ''use of physical force'', broadens the nature of a violent act and expands the conventional understanding of violence to include those acts that result from a power relationship, including threats and intimidation. The ''use of power'' also serves to include neglect or acts of omission, in addition to the more obvious violent acts of commission. Thus, ''the use of physical force or power'' should be understood to include neglect and all types of physical, sexual and psychological abuse, as well as suicide and other self-abusive acts.

This definition covers a broad range of outcomes – including psychological harm, deprivation and maldevelopment. This reflects a growing recognition among researchers and practitioners of the need to include violence that does not necessarily result in injury or death, but that nonetheless poses a substantial burden on individuals, families, communities and health care systems worldwide. Many forms of violence against women, children and the elderly, for instance, can result in physical, psychological and social problems that do not necessarily lead to injury, disability or death. These consequences can be immediate, as well as latent, and can last for years after the initial abuse. Defining outcomes solely in terms of injury or death thus limits the understanding of the full impact of violence on individuals, communities and society at large.

Intentionality

One of the more complex aspects of the definition is the matter of intentionality. Two important points about this should be noted. First, even though violence is distinguished from unintended events that result in injuries, the presence of an intent to use force does not necessarily mean that there was an intent to cause damage. Indeed, there may be a considerable disparity between intended behaviour and intended consequence. A perpetrator may intentionally commit an act that, by objective standards, is judged to be dangerous and highly likely to result in adverse health effects, but the perpetrator may not perceive it as such.

As examples, a youth may be involved in a physical fight with another youth. The use of a fist against the head or the use of a weapon in the dispute certainly increases the risk of serious injury or death, though neither outcome may be intended. A parent may vigorously shake a crying infant with the intent to quieten it. Such an action, however, may instead cause brain damage. Force was clearly used, but without the intention of causing an injury.

A second point related to intentionality lies in the distinction between the intent to injure and the intent to ''use violence''. Violence, according to Walters & Parke (*3*), is culturally determined. Some people mean to harm others but, based on their cultural backgrounds and beliefs, do not perceive their acts as violent. The definition used by the World Health Organization, however, defines violence as it relates to the health or well-being of individuals. Certain behaviours – such as hitting a spouse – may be regarded by some people as acceptable cultural practices, but are considered violent acts with important health implications for the individual.

Other aspects of violence, though not explicitly stated, are also included in the definition. For example, the definition implicitly includes all acts of violence, whether they are public or private,

whether they are reactive (in response to previous events such as provocation) or proactive (instrumental for or anticipating more self-serving outcomes) (*4*), or whether they are criminal or non-criminal. Each of these aspects is important in understanding the causes of violence and in designing prevention programmes.

Typology of violence

In its 1996 resolution WHA49.25, declaring violence a leading public health problem, the World Health Assembly called on the World Health Organization to develop a typology of violence that characterized the different types of violence and the links between them. Few typologies exist already and none is very comprehensive (*5*).

Types of violence

The typology proposed here divides violence into three broad categories according to characteristics of those committing the violent act:

— self-directed violence;

— interpersonal violence;

— collective violence.

This initial categorization differentiates between violence a person inflicts upon himself or herself, violence inflicted by another individual or by a small group of individuals, and violence inflicted by larger groups such as states, organized political groups, militia groups and terrorist organizations (see Figure 1.1).

These three broad categories are each divided further to reflect more specific types of violence.

Self-directed violence

Self-directed violence is subdivided into suicidal behaviour and self-abuse. The former includes suicidal thoughts, attempted suicides – also called ''parasuicide'' or ''deliberate self-injury'' in some countries – and completed suicides. Self-abuse, in contrast, includes acts such as self-mutilation.

Interpersonal violence

Interpersonal violence is divided into two subcategories:

- Family and intimate partner violence – that is, violence largely between family members and intimate partners, usually, though not exclusively, taking place in the home.
- Community violence – violence between individuals who are unrelated, and who may or may not know each other, generally taking place outside the home.

The former group includes forms of violence such as child abuse, intimate partner violence and abuse of the elderly. The latter includes youth violence, random acts of violence, rape or sexual assault by strangers, and violence in institutional settings such as schools, workplaces, prisons and nursing homes.

Collective violence

Collective violence is subdivided into social, political and economic violence. Unlike the other two broad categories, the subcategories of collective violence suggest possible motives for violence committed by larger groups of individuals or by states. Collective violence that is committed to advance a particular social agenda includes, for example, crimes of hate committed by organized groups, terrorist acts and mob violence. Political violence includes war and related violent conflicts, state violence and similar acts carried out by larger groups. Economic violence includes attacks by larger groups motivated by economic gain – such as attacks carried out with the purpose of disrupting economic activity, denying access to essential services, or creating economic division and fragmentation. Clearly, acts committed by larger groups can have multiple motives.

The nature of violent acts

Figure 1.1 illustrates the nature of violent acts, which can be:

— physical;

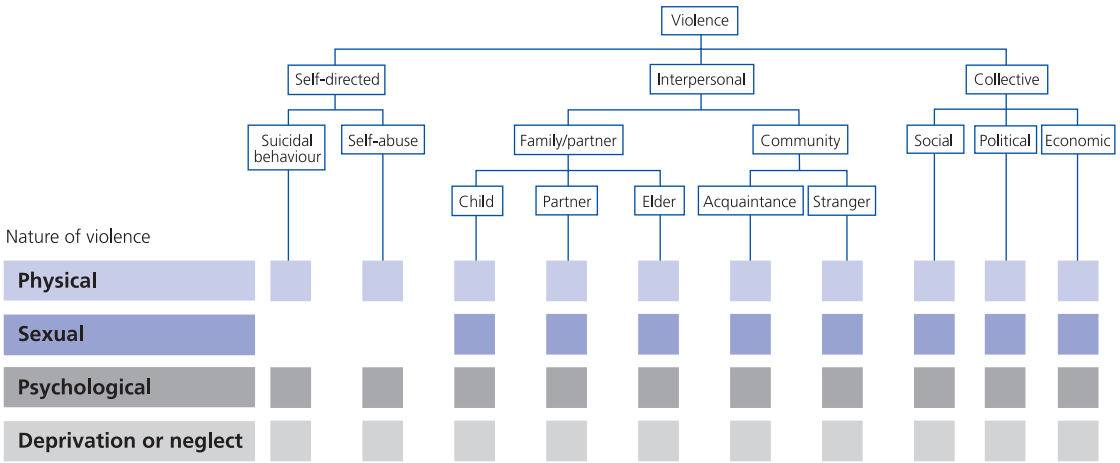
— sexual;

— psychological;

— involving deprivation or neglect.

The horizontal array in Figure 1.1 shows who is affected, and the vertical array describes how they are affected.

FIGURE 1.1
A typology of violence



These four types of violent acts occur in each of the broad categories and their subcategories described above – with the exception of self-directed violence. For instance, violence against children committed within the home can include physical, sexual and psychological abuse, as well as neglect. Community violence can include physical assaults between young people, sexual violence in the workplace and neglect of older people in long-term care facilities. Political violence can include such acts as rape during conflicts, and physical and psychological warfare.

This typology, while imperfect and far from being universally accepted, does provide a useful framework for understanding the complex patterns of violence taking place around the world, as well as violence in the everyday lives of individuals, families and communities. It also overcomes many of the limitations of other typologies by capturing the nature of violent acts, the relevance of the setting, the relationship between the perpetrator and the victim, and – in the case of collective violence – possible motivations for the violence. However, in both research and practice, the dividing lines between the different types of violence are not always so clear.

Measuring violence and its impact

Types of data

Different types of data are needed for different purposes, including:

— describing the magnitude and impact of violence;
— understanding which factors increase the risk for violent victimization and perpetration;
— knowing how effective violence prevention programmes are.

Some of these types of data and sources are described in Table 1.1.

Mortality data

Data on fatalities, particularly through homicide, and on suicide and war-related deaths can provide an indication of the extent of lethal violence in a particular community or country. When compared to statistics on other deaths, such data are useful indicators of the burden created by violence-related injuries. These data can also be used for monitoring changes over time in fatal violence, identifying groups and communities at high risk of violence, and making comparisons within and between countries.

Other types of data

Mortality figures, however, are only one possible type of data for describing the magnitude of the problem. Since non-fatal outcomes are much more common than fatal outcomes and because certain types of violence are not fully represented by mortality data, other types of information are

TABLE 1.1
Types of data and potential sources for collecting information

Type of data	Data sources	Examples of information collected
Mortality	Death certificates, vital statistics registries, medical examiners', coroners' or mortuary reports	Characteristics of the decedent, cause of death, location, time, manner of death
Morbidity and other health data	Hospital, clinic or other medical records	Diseases, injuries, information on physical, mental or reproductive health
Self-reported	Surveys, special studies, focus groups, media	Attitudes, beliefs, behaviours, cultural practices, victimization and perpetration, exposure to violence in the home or community
Community	Population records, local government records, other institutional records	Population counts and density, levels of income and education, unemployment rates, divorce rates
Crime	Police records, judiciary records, crime laboratories	Type of offence, characteristics of offender, relationship between victim and offender, circumstances of event
Economic	Programme, institutional or agency records, special studies	Expenditures on health, housing or social services, costs of treating violence-related injuries, use of services
Policy or legislative	Government or legislative records	Laws, institutional policies and practices

necessary. Such information can help in understanding the circumstances surrounding specific incidents and in describing the full impact of violence on the health of individuals and communities. These types of data include:

— health data on diseases, injuries and other health conditions;
— self-reported data on attitudes, beliefs, behaviours, cultural practices, victimization and exposure to violence;
— community data on population characteristics and levels of income, education and unemployment;
— crime data on the characteristics and circumstances of violent events and violent offenders;
— economic data related to the costs of treatment and social services;
— data describing the economic burden on health care systems and possible savings realized from prevention programmes;
— data on policy and legislation.

Sources of data

Potential sources of the various types of information include:

— individuals;
— agency or institutional records;
— local programmes;
— community and government records;
— population-based and other surveys;
— special studies.

Though not listed in Table 1.1, almost all sources include basic demographic information – such as a person's age and sex. Some sources – including medical records, police records, death certificates and mortuary reports – include information specific to the violent event or injury. Data from emergency departments, for instance, may provide information on the nature of an injury, how it was sustained, and when and where the incident occurred. Data collected by the police may include information on the relationship between the victim and the perpetrator, whether a weapon was involved, and other circumstances related to the offence.

Surveys and special studies can provide detailed information about the victim or perpetrator, and his or her background, attitudes, behaviours and possible previous involvement in violence. Such sources can also help uncover violence that is not reported to the police or other agencies. For example, a household survey in South Africa showed that between 50% and 80% of victims of violence received medical treatment for a violence-related injury without reporting the incident to the police (*6*). In another study, conducted in the United States of America, 46% of victims who sought emergency treatment did not make a report to the police (*7*).

Problems with collecting data

The availability, quality and usefulness of the different data sources for comparing types of

violence within and between countries vary considerably. Countries around the world are at very different stages with regard to their capacity for data collection.

Availability of data

Mortality data are the most widely collected and available of all sources of data. Many countries maintain birth and death registries and keep basic counts of homicides and suicides. Calculating rates from these basic counts, however, is not always possible because population data are often unavailable or unreliable. This is especially true where populations are in flux – in areas, for instance, experiencing conflict or continuous movements among population groups – or where populations are difficult to count, as is the case in densely populated or very remote areas.

Systematic data on non-fatal outcomes are not available in most countries of the world, though systems to collect such data are currently being developed. A number of documents providing guidance for measuring different types of violence in a range of settings have also been published in recent years (*8–14*).

Quality of data

Even when data are available, the quality of the information may be inadequate for research purposes and for identifying strategies for prevention. Given that agencies and institutions keep records for their own purposes, following their own internal procedures for record-keeping, their data may be incomplete or lack the kind of information necessary for a proper understanding of violence.

Data from health care facilities, for instance, are collected with a view to providing optimal treatment for the patient. The medical record may contain diagnostic information about the injury and course of treatment, but not the circumstances surrounding the injury. These data may also be confidential and thus not available for research purposes. Surveys, on the other hand, contain more detailed information about the person and his or her background and involvement in violence. They are limited, though, by the extent to which a person recalls events and admits to engaging in certain behaviours, and also by the manner in which questions are asked and by whom they are asked – as well as when, where and how well the interview is conducted.

Other obstacles

Linking data across sources is one of the more difficult problems in research on violence. Data on violence generally come from a variety of organizations that operate independently of one another. As such, data from medical examiners and coroners cannot usually be linked to data collected by the police. Also, there is a general lack of uniformity in the way data on violence are collected, which makes it very difficult to compare data across communities and nations.

Although they are beyond the scope of this discussion, a number of other problems in collecting violence-related data should be mentioned. They include:

- the difficulty of developing measures that are relevant and specific to subpopulation groups and different cultural contexts (*8, 9, 11, 14*);
- devising appropriate protocols to protect the confidentiality of victims and ensure their safety (*15*);
- a range of other ethical considerations associated with research into violence.

An overview of current knowledge

The prevention of violence, according to the public health approach, begins with a description of the magnitude and impact of the problem. This section describes what is currently known about global patterns of violence, using data compiled for this report from the World Health Organization's mortality database and Version 1 of the World Health Organization's Global Burden of Disease project for 2000, as well as data from surveys and special studies of violence.

Estimates of mortality

In 2000, an estimated 1.6 million people worldwide died as a result of self-inflicted, interpersonal or collective violence, for an overall age-adjusted rate of 28.8 per 100 000 population (see Table 1.2).

TABLE 1.2
Estimated global violence-related deaths, 2000

Type of violence	Number[a]	Rate per 100 000 population[b]	Proportion of total (%)
Homicide	520 000	8.8	31.3
Suicide	815 000	14.5	49.1
War-related	310 000	5.2	18.6
Total[c]	1 659 000	28.8	100.0
Low- to middle-income countries	1 510 000	32.1	91.1
High-income countries	149 000	14.4	8.9

Source: WHO Global Burden of Disease project for 2000, Version 1 (see Statistical annex).

[a] Rounded to the nearest 1000.

[b] Age-standardized.

[c] Includes 14 000 intentional injury deaths resulting from legal intervention.

The vast majority of these deaths occurred in low- to middle-income countries. Less than 10% of all violence-related deaths occurred in high-income countries.

Nearly half of these 1.6 million violence-related deaths were suicides, almost one-third were homicides and about one-fifth were war-related.

Mortality according to sex and age

Like many other health problems in the world, violence is not distributed evenly among sex or age groups. In 2000, there were an estimated 520 000 homicides, for an overall age-adjusted rate of 8.8 per 100 000 population (see Table 1.2). Males accounted for 77% of all homicides and had rates that were more than three times those of females (13.6 and 4.0, respectively, per 100 000) (see Table 1.3). The highest rates of homicide in the world are found among males aged 15–29 years (19.4 per 100 000), followed closely by males aged 30–44 years (18.7 per 100 000).

TABLE 1.3
Estimated global homicide and suicide rates by age group, 2000

Age group (years)	Homicide rate (per 100 000 population)		Suicide rate (per 100 000 population)	
	Males	Females	Males	Females
0–4	5.8	4.8	0.0	0.0
5–14	2.1	2.0	1.7	2.0
15–29	19.4	4.4	15.6	12.2
30–44	18.7	4.3	21.5	12.4
45–59	14.8	4.5	28.4	12.6
⩾60	13.0	4.5	44.9	22.1
Total[a]	13.6	4.0	18.9	10.6

Source: WHO Global Burden of Disease project for 2000, Version 1 (see Statistical annex).

[a] Age-standardized.

Worldwide, suicide claimed the lives of an estimated 815 000 people in 2000, for an overall age-adjusted rate of 14.5 per 100 000 (see Table 1.2). Over 60% of all suicides occurred among males, over half of these occurring among those aged 15–44 years. For both males and females, suicide rates increase with age and are highest among those aged 60 years and older (see Table 1.3). Suicide rates, though, are generally higher among males than females (18.9 per 100 000 as against 10.6 per 100 000). This is especially true among the oldest age groups, where worldwide, male suicide rates among those aged 60 years and older are twice as high as female suicide rates in the same age category (44.9 per 100 000 as against 22.1 per 100 000).

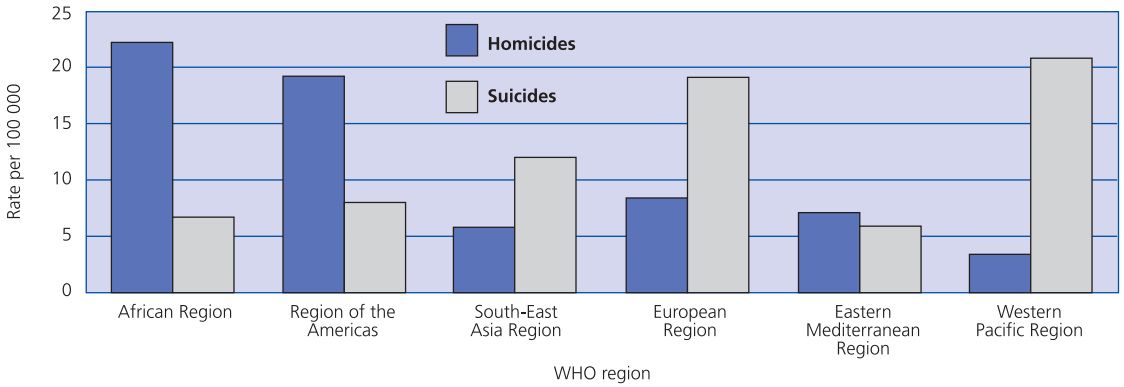
Mortality according to country income level and region

Rates of violent death vary according to country income levels. In 2000, the rate of violent death in low- to middle-income countries was 32.1 per 100 000 population, more than twice the rate in high-income countries (14.4 per 100 000) (see Table 1.2).

There are also considerable regional differences in rates of violent death. These differences are evident, for example, among the WHO regions (see Figure 1.2). In the African Region and the Region of the Americas, homicide rates are nearly three times greater than suicide rates. However, in the European and South-East Asia Regions, suicide rates are more than double homicide rates (19.1 per 100 000 as against 8.4 per 100 000 for the European Region, and 12.0 per 100 000 as against 5.8 per 100 000 for the South-East Asia Region), and in the Western Pacific Region, suicide rates are nearly six times greater than homicide rates (20.8 per 100 000 as against 3.4 per 100 000).

Within regions there are also large differences between countries. For example, in 1994 the homicide rate among males in Colombia was reported to be 146.5 per 100 000, while the corresponding rates in Cuba and Mexico were 12.6

FIGURE 1.2
Homicide and suicide rates by WHO region, 2000



and 32.3 per 100 000, respectively (*16*). Large differences within countries also exist between urban and rural populations, between rich and poor groups, and between different racial and ethnic groups. In the United States in 1999, for instance, African-American youths aged 15–24 years had a rate of homicide (38.6 per 100 000) more than twice that of their Hispanic counterparts (17.3 per 100 000), and over 12 times the rate of their Caucasian, non-Hispanic counterparts (3.1 per 100 000) (*17*).

Estimates of non-fatal violence

The above-mentioned mortality figures are almost certainly underestimates of the true burden of violence. In all parts of the world, deaths represent the ''tip of the iceberg'' as far as violence is concerned. Physical and sexual assaults occur daily, though precise national and international estimates of each are lacking. Not all assaults result in injuries severe enough to require medical attention and – even among those that do result in serious injuries – surveillance systems for reporting and compiling these injuries are in many countries either lacking or are still being developed.

Much of what is known about non-fatal violence comes from surveys and special studies of different population groups. For example, in national surveys, the percentage of women who reported ever being physically assaulted by an intimate partner ranged from 10% in Paraguay and the Philippines, to 22.1% in the United States, 29.0% in Canada and 34.4% in Egypt (*18–21*). The proportion of women from various cities or provinces around the world reporting ever having been sexually assaulted (including victims of attempted assault) varied from 15.3% in Toronto, Canada, to 21.7% in León, Nicaragua, 23.0% in London, England, and 25.0% in one province in Zimbabwe (*21–25*). Among adolescent males in secondary schools, the percentage reporting involvement in physical fighting in the past year ranged from 22.0% in Sweden and 44.0% in the United States to 76.0% in Jerusalem, Israel (*26–28*).

An important point here is that these data are based largely on self-reports. It is difficult to know whether they overestimate or underestimate the true extent of physical and sexual assaults among these population groups. Certainly, in those countries with strong cultural pressures to keep violence ''behind closed doors'' or simply to accept it as ''natural'', non-fatal violence is likely to be underreported. Victims may be reluctant to discuss violent experiences not only out of shame and because of taboos, but through fear. Admitting to having experienced certain violent events, such as rape, may in some countries result in death. In certain cultures, the preservation of family honour is a traditional motive for killing women who have been raped (so-called ''honour killings'').

The costs of violence

Violence exacts both a human and an economic toll on nations, and costs economies many billions of US dollars each year in health care, legal costs, absenteeism from work and lost productivity. In the United

States, a 1992 study estimated the direct and indirect annual costs of gunshot wounds at US$ 126 billion. Cutting or stab wounds cost an additional US$ 51 billion (*29*). In a 1996 study in the Canadian province of New Brunswick, the mean total cost per suicide death was over US$ 849 000. The total direct and indirect costs, including costs for health care services, autopsies, police investigations and lost productivity resulting from premature death, amounted to nearly US$ 80 million (*30*).

The high cost of violence is not unique to Canada and the United States. Between 1996 and 1997, the Inter-American Development Bank sponsored studies on the magnitude and economic impact of violence in six Latin American countries (*31*). Each study examined expenditures, as a result of violence, for health care services, law enforcement and judicial services, as well as intangible losses and losses from the transfer of assets. Expressed as a percentage of the gross domestic product (GDP) in 1997, the cost of health care expenditures arising from violence was 1.9% of the GDP in Brazil, 5.0% in Colombia, 4.3% in El Salvador, 1.3% in Mexico, 1.5% in Peru and 0.3% in Venezuela.

It is difficult to calculate the precise burden of all types of violence on health care systems, or their effects on economic productivity around the world. The available evidence shows that victims of domestic and sexual violence have more health problems, significantly higher health care costs and more frequent visits to emergency departments throughout their lives than those without a history of abuse (see Chapters 4 and 6). The same is true for victims of childhood abuse and neglect (see Chapter 3). These costs contribute substantially to annual health care expenditures.

Since national cost estimates are also generally lacking for other health problems, such as depression, smoking, alcohol and drug abuse, unwanted pregnancy, human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), other sexually transmitted diseases and other infections (all of which have been linked to violence in small-scale studies) (*32–37*), it is not yet possible to calculate the global economic burden of these problems as they relate to violence.

Examining the roots of violence: an ecological model

No single factor explains why some individuals behave violently toward others or why violence is more prevalent in some communities than in others. Violence is the result of the complex interplay of individual, relationship, social, cultural and environmental factors. Understanding how these factors are related to violence is one of the important steps in the public health approach to preventing violence.

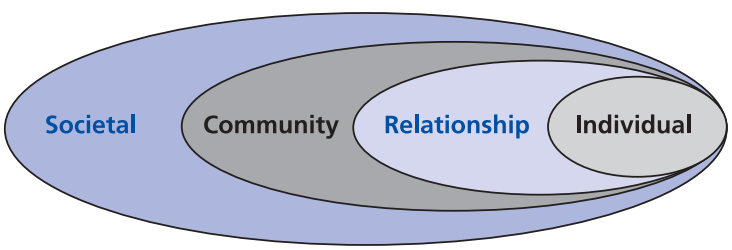
Multiple levels

The chapters in this report apply an ecological model to help understand the multifaceted nature of violence. First introduced in the late 1970s (*38, 39*), this ecological model was initially applied to child abuse (*38*) and subsequently to youth violence (*40, 41*). More recently, researchers have used it to understand intimate partner violence (*42, 43*) and abuse of the elderly (*44, 45*). The model explores the relationship between individual and contextual factors and considers violence as the product of multiple levels of influence on behaviour (see Figure 1.3).

Individual

The first level of the ecological model seeks to identify the biological and personal history factors that an individual brings to his or her behaviour. In addition

FIGURE 1.3
Ecological model for understanding violence



to biological and demographic factors, factors such as impulsivity, low educational attainment, substance abuse, and prior history of aggression and abuse are considered. In other words, this level of the ecological model focuses on the characteristics of the individual that increase the likelihood of being a victim or a perpetrator of violence.

Relationship

The second level of the ecological model explores how proximal social relationships – for example, relations with peers, intimate partners and family members – increase the risk for violent victimization and perpetration of violence. In the cases of partner violence and child maltreatment, for instance, interacting on an almost daily basis or sharing a common domicile with an abuser may increase the opportunity for violent encounters. Because individuals are bound together in a continuing relationship, it is likely in these cases that the victim will be repeatedly abused by the offender (*46*). In the case of interpersonal violence among youths, research shows that young people are much more likely to engage in negative activities when those behaviours are encouraged and approved by their friends (*47, 48*). Peers, intimate partners and family members all have the potential to shape an individual's behaviour and range of experience.

Community

The third level of the ecological model examines the community contexts in which social relationships are embedded – such as schools, workplaces and neighbourhoods – and seeks to identify the characteristics of these settings that are associated with being victims or perpetrators of violence. A high level of residential mobility (where people do not stay for a long time in a particular dwelling, but move many times), heterogeneity (highly diverse population, with little of the social ''glue'' that binds communities together) and high population density are all examples of such characteristics and each has been associated with violence. Similarly, communities characterized by problems such as drug trafficking, high levels of unemployment or widespread social isolation (for example, people not knowing their neighbours or having no involvement in the local community) are also more likely to experience violence. Research on violence shows that opportunities for violence are greater in some community contexts than others – for instance, in areas of poverty or physical deterioration, or where there are few institutional supports.

Societal

The fourth and final level of the ecological model examines the larger societal factors that influence rates of violence. Included here are those factors that create an acceptable climate for violence, those that reduce inhibitions against violence, and those that create and sustain gaps between different segments of society – or tensions between different groups or countries. Larger societal factors include:

- cultural norms that support violence as an acceptable way to resolve conflicts;
- attitudes that regard suicide as a matter of individual choice instead of a preventable act of violence;
- norms that give priority to parental rights over child welfare;
- norms that entrench male dominance over women and children;
- norms that support the use of excessive force by police against citizens;
- norms that support political conflict.

Larger societal factors also include the health, educational, economic and social policies that maintain high levels of economic or social inequality between groups in society (see Box 1.2).

The ecological framework highlights the multiple causes of violence and the interaction of risk factors operating within the family and broader community, social, cultural and economic contexts. Placed within a developmental context, the ecological model also shows how violence may be caused by different factors at different stages of life.

Complex linkages

While some risk factors may be unique to a particular type of violence, the various types of violence more commonly share a number of risk

BOX 1.2

Globalization: the implications for violence prevention

Through an ever more rapid and widespread movement and exchange of information, ideas, services and products, globalization has eroded the functional and political borders that separated people into sovereign states. On the one hand, this has driven a massive expansion in world trade accompanied by a demand for increased economic output, creating millions of jobs and raising living standards in some countries in a way previously unimaginable. On the other, the effects of globalization have been remarkably uneven. In some parts of the world, globalization has led to increased inequalities in income and helped destroy factors such as social cohesion that had protected against interpersonal violence.

The benefits and the obstacles for violence prevention arising from globalization can be summarized as follows.

The positive effects

The huge increase in information-sharing provoked by globalization has produced new international networks and alliances that have the potential to improve the scope and quality of data collected on violence. Where globalization has raised living standards and helped reduce inequalities, there is a greater possibility of economic interventions being used to lessen tensions and conflicts both within and between states. Furthermore, globalization creates new ways of using global mechanisms:

- To conduct research on violence – especially on social, economic and policy factors that transcend national boundaries.
- To stimulate violence prevention activities on a regional or global scale.
- To implement international laws and treaties designed to reduce violence.
- To support violence prevention efforts within countries, particularly those with a limited capacity to conduct such activities.

The negative effects

Societies with already high levels of inequality, which experience a further widening of the gap between rich and poor as a result of globalization, are likely to witness an increase in interpersonal violence. Rapid social change in a country in response to strong global pressures – as occurred, for instance, in some of the states of the former Soviet Union – can overwhelm existing social controls over behaviour and create conditions for a high level of violence. In addition, the removal of market constraints, and increased incentives for profit as a result of globalization can lead, for example, to much freer access to alcohol, drugs and firearms, despite efforts to reduce their use in violent incidents.

The need for global responses

Violence can no longer remain the preserve of national politics, but must be vigorously addressed also on the global level – through groupings of states, international agencies and international networks of governmental and nongovernmental organizations. Such international efforts must aim to harness the positive aspects of globalization for the greater good, while striving to limit the negative aspects.

factors. Prevailing cultural norms, poverty, social isolation and such factors as alcohol abuse, substance abuse and access to firearms are risk factors for more than one type of violence. As a result, it is not unusual for some individuals at risk of violence to experience more than one type of violence. Women

at risk of physical violence by intimate partners, for example, are also at risk of sexual violence (*18*).

It is also not unusual to detect links between different types of violence. Research has shown that exposure to violence in the home is associated with being a victim or perpetrator of violence in adolescence and adulthood (*49*). The experience of being rejected, neglected or suffering indifference at the hands of parents leaves children at greater risk for aggressive and antisocial behaviour, including abusive behaviour as adults (*50–52*). Associations have been found between suicidal behaviour and several types of violence, including child maltreatment (*53, 54*), intimate partner violence (*33*, *55*), sexual assault (*53*) and abuse of the elderly (*56, 57*). In Sri Lanka, suicide rates were shown to decrease during wartime, only to increase again after the violent conflict ended (*58*). In many countries that have suffered violent conflict, the rates of interpersonal violence remain high even after the cessation of hostilities – among other reasons because of the way violence has become more socially accepted and the availability of weapons.

The links between violence and the interaction between individual factors and the broader social, cultural and economic contexts suggest that addressing risk factors across the various levels of the ecological model may contribute to decreases in more than one type of violence.

How can violence be prevented?

The first two steps of the public health model provide important information about populations requiring preventive interventions, as well as on the risk and protective factors that need addressing. Putting this knowledge into practice is a central goal of public health.

Types of prevention

Public health interventions are traditionally characterized in terms of three levels of prevention:

- Primary prevention – approaches that aim to prevent violence before it occurs.
- Secondary prevention – approaches that focus on the more immediate responses to violence, such as pre-hospital care, emergency services or treatment for sexually transmitted diseases following a rape.
- Tertiary prevention – approaches that focus on long-term care in the wake of violence, such as rehabilitation and reintegration, and attempts to lessen trauma or reduce the long-term disability associated with violence.

These three levels of prevention are defined by their temporal aspect – whether prevention takes place before violence occurs, immediately afterwards or over the longer term. Although traditionally they are applied to victims of violence and within health care settings, secondary and tertiary prevention efforts have also been regarded as having relevance to the perpetrators of violence, and applied in judicial settings in response to violence.

Researchers in the field of violence prevention have increasingly turned to a definition of prevention that focuses on the target group of interest. This definition groups interventions as follows (*59*):

- Universal interventions – approaches aimed at groups or the general population without regard to individual risk; examples include violence prevention curricula delivered to all students in a school or children of a particular age and community-wide media campaigns.
- Selected interventions – approaches aimed at those considered at heightened risk for violence (having one or more risk factors for violence); an example of such an intervention is training in parenting provided to low-income, single parents.
- Indicated interventions – approaches aimed at those who have already demonstrated violent behaviour, such as treatment for perpetrators of domestic violence.

Many efforts to date, in both industrialized and developing countries, have focused on secondary and tertiary responses to violence. Understandably, priority is often given to dealing with the immediate consequences of violence, providing support to victims and punishing the offenders. Such responses, while important and in need of strengthening, should be accompanied by a greater investment in primary prevention. A comprehensive response to violence is one that not only protects and supports

victims of violence, but also promotes non-violence, reduces the perpetration of violence, and changes the circumstances and conditions that give rise to violence in the first place.

Multifaceted responses

Because violence is a multifaceted problem with biological, psychological, social and environmental roots, it needs to be confronted on several different levels at once. The ecological model serves a dual purpose in this regard: each level in the model represents a level of risk and each level can also be thought of as a key point for intervention.

Dealing with violence on a range of levels involves addressing all of the following:

- Addressing individual risk factors and taking steps to modify individual risk behaviours.
- Influencing close personal relationships and working to create healthy family environments, as well as providing professional help and support for dysfunctional families.
- Monitoring public places such as schools, workplaces and neighbourhoods and taking steps to address problems that might lead to violence.
- Addressing gender inequality, and adverse cultural attitudes and practices.
- Addressing the larger cultural, social and economic factors that contribute to violence and taking steps to change them, including measures to close the gap between the rich and poor and to ensure equitable access to goods, services and opportunities.

Documenting effective responses

A general ground rule for the public health approach to violence is that all efforts, whether large or small, should be rigorously evaluated. Documenting existing responses and encouraging a strictly scientific assessment of interventions in different settings is valuable for everyone. It is particularly needed by others trying to determine the most effective responses to violence and the strategies likely to make a difference.

Bringing together all available evidence and experience is also an extremely useful part of advocacy, as it assures decision-makers that something can be done. Even more importantly, it provides them with valuable guidance as to which efforts are likely to reduce violence.

Balancing public health action

Rigorous research takes time to produce results. The impulse to invest only in proven approaches should not be an obstacle to supporting promising ones. Promising approaches are those that have been evaluated but require more testing in a range of settings and with different population groups.

There is also wisdom in trying out and testing a variety of programmes, and in using the initiatives and ideas of local communities. Violence is far too pressing a problem to delay public health action while waiting to gain perfect knowledge.

Addressing cultural norms

In various parts of the world, cultural specificity and tradition are sometimes given as justifications for particular social practices that perpetuate violence. The oppression of women is one of the most widely quoted examples, but many others can also be given.

Cultural norms must be dealt with sensitively and respectfully in all prevention efforts – sensitively because of people's often passionate attachment to their traditions, and respectfully because culture is often a source of protection against violence. Experience has shown that it is important to conduct early and ongoing consultations with religious and traditional leaders, lay groups and prominent figures in the community, such as traditional healers, when designing and implementing programmes.

Actions against violence at all levels

Long-term successes in the prevention of violence will increasingly depend on comprehensive approaches at all levels.

Local level

At the local level, partners may include health care providers, police, educators, social workers, employers and government officials. Much can be

done here to promote violence prevention. Small-scale pilot programmes and research projects can provide a means for ideas to be tried out and – perhaps as important – for a range of partners to become used to working together. Structures such as working groups or commissions that draw together the different sectors and maintain both formal and informal contacts are essential for the success of this type of collaboration.

National level

Multisectoral partnerships are highly desirable at the national level as much as at the local level. A variety of government ministries – and not only those concerned with law enforcement, social services and health – have important contributions to make in preventing violence. Education ministries are obvious partners, given the importance of intervening in schools. Ministries of labour can do much to reduce violence in the workplace, especially in collaboration with trade unions and employers (see Box 1.3). Defence ministries can positively shape the attitudes towards violence of large numbers of young men under their control, by encouraging discipline, promoting codes of honour, and impressing a strong awareness of the lethalness of weapons. Religious leaders and organizations have a role to play in their pastoral work and, in appropriate cases, by offering their good offices to mediate in specific problems.

Global level

As has been shown, for instance, in the international response to AIDS and in the field of disaster relief, cooperation and exchange of information between organizations globally can produce significant benefits – in the same way as partnerships at the national and local levels. The World Health Organization clearly has an important global role to play in this respect as the United Nations agency responsible for health. Other international agencies, though, also have a considerable amount to offer in their specialized fields. These include the Office of the United Nations High Commissioner for Human Rights (in relation to human rights), the Office of the United Nations High Commissioner for Refugees (refugees), the United Nations Children's Fund (children's well-being), the United Nations Development Fund for Women and the United Nations Population Fund (women's health), the United Nations Development Programme (human development), the United Nations Interregional Crime and Justice Research Institute (crime) and the World Bank (financing and governance), to name just a few. A variety of international donors, bilateral programmes, nongovernmental organizations and religious organizations are already involved in violence prevention activities around the world.

Problems for national decision-makers

If violence is largely preventable, the question arises: why are there not more efforts to prevent it, particularly at national or provincial and state level?

A major obstacle is simply an absence of knowledge. For many decision-makers, the idea that violence is a public health problem is new – and indeed rather contrary to their belief that violence is a crime problem. This is particularly the case for the less visible forms of violence, such as abuse of children, women and the elderly. The notion that violence is preventable is also new or questionable for decision-makers. To many people in authority, a violence-free society seems unobtainable; an ''acceptable'' level of violence, especially on the streets where they live, appears far more realistic. To others, paradoxically, the inverse is true: since much of violence is hidden, distant or sporadic, peace and security seem to them the prevalent state. In the same way that clean air is taken for granted until the sky becomes full of smog, violence only has to be dealt with when it arrives on the doorstep. It is not surprising then that some of the most innovative solutions have come from the community and municipal levels of government – precisely those that are closest to the problem on a daily basis.

A second problem relates to the feasibility of policy options to tackle the problem. Not enough decision-makers have seen the evidence that many forms of violence are preventable. Too many of

BOX 1.3

A comprehensive approach to preventing violence at work

Violence in the workplace is a major contributor to death and injury in many parts of the world. In the United States of America, official statistics have placed homicide as the second single leading cause of death in the workplace – after road traffic injuries – for men, and the first for women. In the European Union, an estimated 3 million workers (2% of the labour force) have been subjected to physical violence at work. Studies on female migrant workers from the Philippines have shown that many, especially those working in domestic service or the entertainment industry, are disproportionately affected by violence within their work.

Violence at work involves not only physical but also psychological behaviour. Many workers are subjected to bullying, sexual harassment, threats, intimidation and other forms of psychological violence. Research in the United Kingdom has found that 53% of employees have suffered bullying at work and 78% have witnessed such behaviour. In South Africa, workplace hostilities have been reported as ''abnormally high'' and a recent study showed that 78% of those surveyed had at some time experienced bullying within the workplace.

Repeated acts of violence – from bullying, sexual harassment, and threats to humiliate and undermine workers – may also develop cumulatively into very serious cases. In Sweden, it is estimated that such behaviour has been a factor in 10–15% of suicides.

The costs

Violence in the workplace causes immediate and often long-term disruption to interpersonal relationships and to the whole working environment. The costs of such violence include:

- Direct costs – stemming from such things as:
  - accidents;
  - illness;
  - disability and death;
  - absenteeism;
  - turnover of staff.
- Indirect costs, including:
  - reduced work performance;
  - a lower quality of products or service and slower production;
  - decreased competitiveness.
- More intangible costs, including:
  - damage to the image of an organization;
  - decreased motivation and morale;
  - diminished loyalty to the organization;
  - lower levels of creativity;
  - an environment that is less conducive to work.

The responses

As in dealing with violence in other settings, a comprehensive approach is required. Violence at work is not simply an individual problem that happens from time to time, but a structural problem with much wider socioeconomic, cultural and organizational causes.

The traditional response to violence at work, based exclusively on the enforcement of regulations, fails to reach many situations in the workplace. A more comprehensive approach focuses on the causes of violence in the workplace. Its aim is to make the health, safety and well-being of workers integral parts of the development of the organization.

BOX 1.3 (continued)

The type of systematic and targeted package to prevent violence at work that is being increasingly adopted includes:

- the active collaboration of workers' and employers' organizations in formulating clear anti-violence workplace policies and programmes;
- supporting legislation and guidelines from national and local government;
- the dissemination of case studies of good practice in preventing violence at work;
- improvements to the working environment, styles of management and the organization of work;
- greater opportunities for training;
- counselling and support for those affected.

By directly linking health and safety with the management and development of an organization, this comprehensive approach offers the means of prompt and sustainable action to eliminate violence in the workplace.

them feel that the traditional approaches of the criminal justice system are the only ones that "work". Such a view fails to acknowledge the range of violence in society. It perpetuates the concentration on certain highly visible forms of violence – notably youth violence – while paying much less attention to other types, such as intimate partner violence and abuse of children and the elderly, where the criminal justice system is less responsive and less effective.

A third problem is one of determination. Violence is an extremely emotional issue and many countries tend to be reluctant to take initiatives challenging long-established attitudes or practices. It can take considerable political courage to try new approaches in areas such as policing and public security.

With all three of these problems, there is a strong role to be played by public health practitioners, academic institutions, nongovernmental organizations and international organizations, to help governments increase their knowledge of and confidence in workable interventions. Part of this role is advocacy, using education and science-based information. The other part is as a partner or consultant, helping to develop policies and design or implement interventions.

Conclusion

Public health is concerned with the health and well-being of populations as a whole. Violence imposes a major burden on that well-being. The objective of public health is to create safe and healthy communities around the world. A major priority today is to persuade all the various sectors – at the global, national and community levels – to commit themselves to this objective. Public health officials can do much to establish national plans and policies to prevent violence, building important partnerships between sectors and ensuring a proper allocation of resources to prevention efforts.

While public health leadership need not and indeed cannot direct all the actions to prevent and respond to violence, it has a significant role to play. The data at the disposal of public health and other agencies, the insights and understanding developed through scientific method, and the dedication to finding effective responses are important assets that the field of public health brings to the global response to violence.

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CHAPTER 2

Youth violence

Background

Violence by young people is one of the most visible forms of violence in society. Around the world, newspapers and the broadcast media report daily on violence by gangs, in schools or by young people on the streets. The main victims and perpetrators of such violence, almost everywhere, are themselves adolescents and young adults (*1*). Homicide and non-fatal assaults involving young people contribute greatly to the global burden of premature death, injury and disability (*1, 2*).

Youth violence deeply harms not only its victims, but also their families, friends and communities. Its effects are seen not only in death, illness and disability, but also in terms of the quality of life. Violence involving young people adds greatly to the costs of health and welfare services, reduces productivity, decreases the value of property, disrupts a range of essential services and generally undermines the fabric of society.

The problem of youth violence cannot be viewed in isolation from other problem behaviours. Violent young people tend to commit a range of crimes. They also often display other problems, such as truancy and dropping out of school, substance abuse, compulsive lying, reckless driving and high rates of sexually transmitted diseases. However, not all violent youths have significant problems other than their violence and not all young people with problems are necessarily violent (*3*).

There are close links between youth violence and other forms of violence. Witnessing violence in the home or being physically or sexually abused, for instance, may condition children or adolescents to regard violence as an acceptable means of resolving problems (*4, 5*). Prolonged exposure to armed conflicts may also contribute to a general culture of terror that increases the incidence of youth violence (*6–8*). Understanding the factors that increase the risk of young people being the victims or perpetrators of violence is essential for developing effective policies and programmes to prevent violence.

For the purposes of this report, youths are defined as people between the ages of 10 and 29 years. High rates of offending and victimization nevertheless often extend as far as the 30–35 years age bracket, and this group of older, young adults should also be taken into account in trying to understand and prevent youth violence.

The extent of the problem

Youth homicide rates

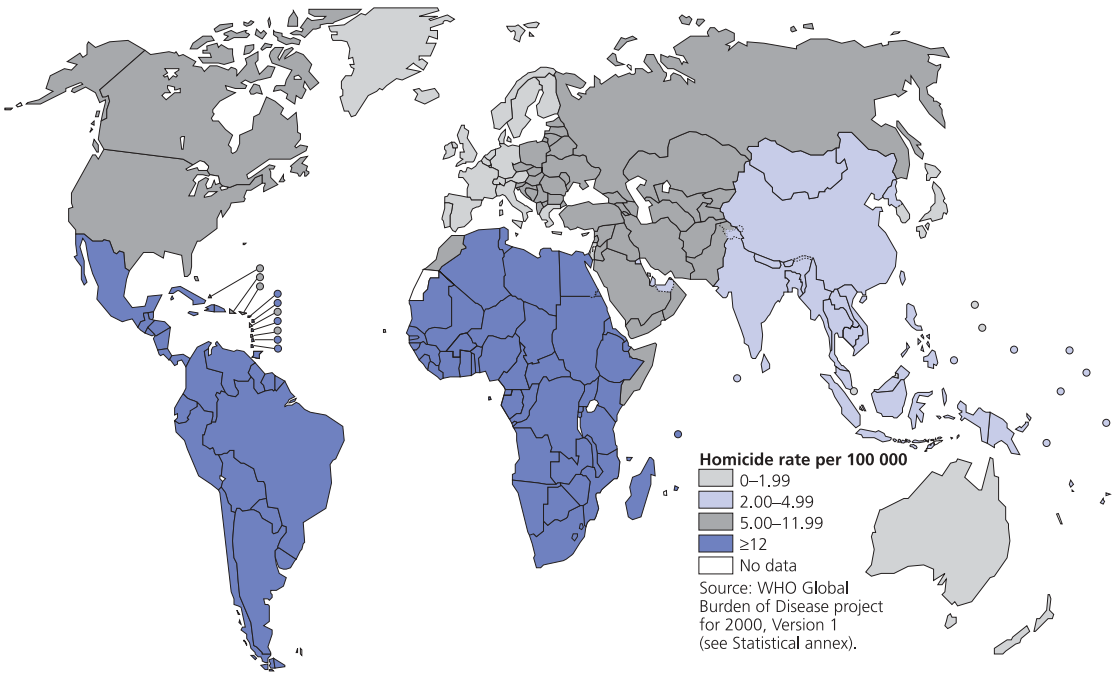
In 2000, an estimated 199 000 youth homicides (9.2 per 100 000 population) occurred globally. In other words, an average of 565 children, adolescents and young adults between the ages of 10 and 29 years die each day as a result of interpersonal violence. Homicide rates vary considerably by region, ranging from 0.9 per 100 000 in the high-income countries of Europe and parts of Asia and the Pacific, to 17.6 per 100 000 in Africa and 36.4 per 100 000 in Latin America (see Figure 2.1).

There are also wide variations between individual countries in youth homicide rates (see Table 2.1). Among the countries for which WHO data are available, the rates are highest in Latin America (for example, 84.4 per 100 000 in Colombia and 50.2 per 100 000 in El Salvador), the Caribbean (for example, 41.8 per 100 000 in Puerto Rico), the Russian Federation (18.0 per 100 000) and some countries of south-eastern Europe (for example, 28.2 per 100 000 in Albania). Apart from the United States of America, where the rate stands at 11.0 per 100 000, most of the countries with youth homicide rates above 10.0 per 100 000 are either developing countries or those experiencing rapid social and economic changes.

The countries with low rates of youth homicide tend to be in Western Europe – for example, France (0.6 per 100 000), Germany (0.8 per 100 000), and the United Kingdom (0.9 per 100 000) – or in Asia, such as Japan (0.4 per 100 000). Several countries have fewer than 20 youth homicides a year.

Almost everywhere, youth homicide rates are substantially lower among females than among males, suggesting that being a male is a strong demographic risk factor. The ratio of the male youth homicide rate to the female rate tends to be higher in those countries with high male rates. For example, the ratio is 13.1:1 in Colombia, 14.6:1 in El Salvador, 16.0:1 in the Philippines and 16.5:1 in Venezuela. Where male rates are lower, the ratio is usually lower

FIGURE 2.1
Estimated homicide rates among youths aged 10–29 years, 2000[a]



[a] Rates were calculated by WHO region and country income level and then grouped according to magnitude.

– such as in Hungary (0.9:1), and the Netherlands and the Republic of Korea (1.6:1). The variation between countries in the female homicide rate is considerably less than the variation in the male rate.

Epidemiological findings on youth homicide are scant in those countries and regions where WHO mortality data are lacking or incomplete. Where proper data on youth homicide do exist, such as in several studies in countries in Africa (including Nigeria, South Africa and the United Republic of Tanzania) and in Asia and the Pacific (such as China (including the Province of Taiwan) and Fiji) (*9–16*), similar epidemiological patterns have been reported, namely:

— a marked preponderance of male over female homicide victims;
— a substantial variation in rates between countries and between regions.

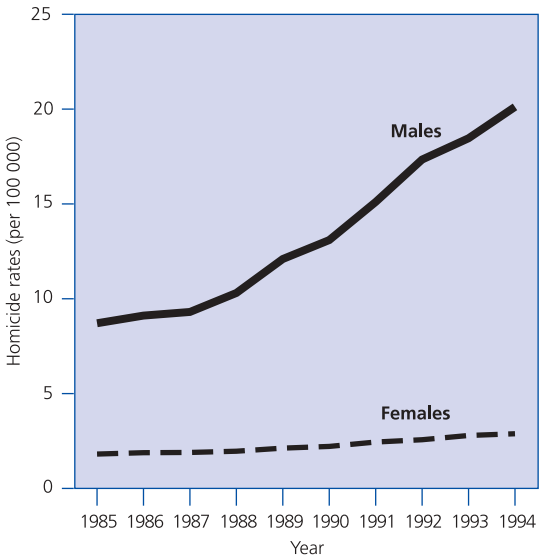
Trends in youth homicides

Between 1985 and 1994, youth homicide rates increased in many parts of the world, especially among youths in the 10–24-year-old age bracket. There were also important differences between the sexes, and between countries and regions. In general, rates of homicides among youths aged 15–19 and 20–24 years increased more than the rate among 10–14-year-olds. Male rates rose more than female rates (see Figure 2.2), and increases in youth homicide rates were more pronounced in developing countries and economies in transition. Furthermore, the increases in youth homicide rates were generally associated with increases in the use of guns as the method of attack (see Figure 2.3).

While youth homicide rates in Eastern Europe and the former Soviet Union increased dramatically after the collapse of communism there in the late 1980s and early 1990s, rates in Western Europe remained generally low and stable. In the Russian Federation, in the period 1985–1994, rates in the 10–24-year-old age bracket increased by over 150%, from 7.0 per 100 000 to 18.0 per 100 000, while in Latvia there was an increase of 125%, from 4.4 per 100 000 to 9.9 per 100 000. In the same period in many of these countries there was a steep increase in the proportion of deaths from gunshot wounds – the proportion

FIGURE 2.2

Global trends in youth homicide rates among males and females aged 10–24 years, 1985–1994[a]



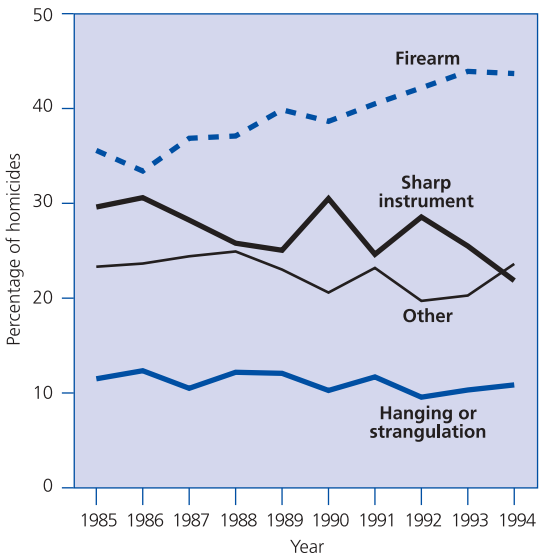
[a] Based on WHO mortality data from 66 countries.

more than doubling in Azerbaijan, Latvia and the Russian Federation.

In the United Kingdom, in contrast, homicide rates for 10–24-year-olds over the same 10-year period increased by 37.5% (from 0.8 per 100 000 to 1.1 per 100 000). In France, youth homicide rates increased by 28.6% over the same period (from 0.7 per 100 000 to 0.9 per 100 000). In Germany, youth homicide rates increased by 12.5% between 1990 and 1994 (from 0.8 per 100 000 to 0.9 per 100 000). While rates of youth homicide increased in these countries over the period, the proportion of youth homicides involving guns remained at around 30%.

FIGURE 2.3

Trends in method of attack in homicides among youths aged 10–24 years, 1985–1994[a]



[a] Based on WHO mortality data from 46 countries.

Remarkable differences in youth homicide trends for the period 1985–1994 were observed across the American continent. In Canada, where around one-third of youth homicides involve guns, rates fell by 9.5%, from 2.1 per 100 000 to 1.9 per 100 000. In the United States, the trend was exactly the reverse, with over 70% of youth homicides involving guns and an increase in homicides of 77%, from 8.8 per 100 000 to 15.6 per 100 000. In Chile, rates in the period remained low and stable, at around 2.4 per 100 000. In Mexico, where guns account for some 50% of all youth homicides, rates stayed high and stable, rising from 14.7 per 100 000 to 15.6 per 100 000. On the other hand, in Colombia, youth homicides increased by 159%, from 36.7 per 100 000 to 95.0 per 100 000 (with 80% of cases, at the end of this period, involving guns), and in Venezuela by 132%, from 10.4 per 100 000 to 24.1 per 100 000.

In Australia, the youth homicide rate declined from 2.0 per 100 000 in 1985 to 1.5 per 100 000 in 1994, while in neighbouring New Zealand it more than doubled in the same period, from 0.8 per 100 000 to 2.2 per 100 000. In Japan, rates in the period stayed low, at around 0.4 per 100 000.

Non-fatal violence

In some countries, data on youth homicide can be read alongside studies of non-fatal violence. Such comparisons give a more complete picture of the problem of youth violence. Studies of non-fatal violence reveal that for every youth homicide there are around 20–40 victims of non-fatal youth violence receiving hospital treatment. In some countries, including Israel, New Zealand and Nicaragua, the ratio is even greater (*17–19*). In Israel, among those under the age of 18 years, the annual incidence of

violent injuries receiving emergency room treatment is 196 per 100 000, compared with youth homicide rates of 1.3 per 100 000 in males and 0.4 per 100 000 in females (*19*).

As with fatal youth violence, the majority of victims of non-fatal violence treated in hospitals are males (*20–26*), although the ratio of male to female cases is somewhat lower than for fatalities. A study in Eldoret, Kenya, for instance, found the ratio of male to female victims of non-fatal violence to be 2.6:1 (*22*). Other research has found a ratio of around 3:1 in Jamaica, and of 4–5:1 in Norway (*23, 24*).

The rates of non-fatal violent injuries tend to increase dramatically during mid-adolescence and young adulthood. A survey of homes in Johannesburg, South Africa, found that 3.5% of victims of violence were 13 years old or younger, compared with 21.9% aged 14–21 years and 52.3% aged 22–35 years (*27*). Studies conducted in Jamaica, Kenya, Mozambique and a number of cities in Brazil, Chile, Colombia, Costa Rica, El Salvador and Venezuela also show high rates of non-fatal injuries from violence among adolescents and young adults (*22, 28, 29*).

Compared with fatal youth violence, non-fatal injuries resulting from violence involve substantially fewer firearm attacks and a correspondingly greater use of the fists and feet, and other weapons, such as knives or clubs. In Honduras, 52% of non-fatal attacks on youths involved weapons other

TABLE 2.1

Homicide rates among youths aged 10–29 years by country or area: most recent year available[a]

Country or area	Year	Total number of deaths	Homicide rate per 100 000 population aged 10–29 years			
			Total	Males	Females	Male:female ratio
Albania	1998	325	28.2	53.5	5.5	9.8
Argentina	1996	628	5.2	8.7	1.6	5.5
Armenia	1999	26	1.9	3.1	—[b]	—[c]
Australia	1998	88	1.6	2.2	1.0	2.3
Austria	1999	7	—[b]	—[b]	—[b]	—[c]
Azerbaijan	1999	194	6.7	12.1	—[b]	—[c]
Belarus	1999	267	8.8	13.2	4.3	3.1
Belgium	1995	37	1.4	1.8	—[b]	—[c]
Bosnia and Herzegovina	1991	2	—[b]	—[b]	—[b]	—[c]
Brazil	1995	20 386	32.5	59.6	5.2	11.5
Bulgaria	1999	51	2.2	3.2	—[b]	—[c]
Canada	1997	143	1.7	2.5	0.9	2.7
Chile	1994	146	3.0	5.1	—[b]	—[c]
China						
Hong Kong SAR	1996	16	—[b]	—[b]	—[b]	—[c]
Selected rural and urban areas	1999	778	1.8	2.4	1.2	2.1
Colombia	1995	12 834	84.4	156.3	11.9	13.1
Costa Rica	1995	75	5.5	8.4	—[b]	—[c]
Croatia	1999	21	1.6	—[b]	—[b]	—[c]
Cuba	1997	348	9.6	14.4	4.6	3.2
Czech Republic	1999	36	1.2	1.4	—[b]	—[c]
Denmark	1996	20	1.5	—[b]	—[b]	—[c]
Ecuador	1996	757	15.9	29.2	2.3	12.4
El Salvador	1993	1 147	50.2	94.8	6.5	14.6
Estonia	1999	33	7.7	13.3	—[b]	—[c]
Finland	1998	19	—[b]	—[b]	—[b]	—[c]
France	1998	91	0.6	0.7	0.4	1.9
Georgia	1992	4	—[b]	—[b]	—[b]	—[c]
Germany	1999	156	0.8	1.0	0.6	1.6
Greece	1998	25	0.9	1.4	—[b]	—[c]
Hungary	1999	41	1.4	1.4	1.5	0.9
Ireland	1997	10	—[b]	—[b]	—[b]	—[c]
Israel	1997	13	—[b]	—[b]	—[b]	—[c]
Italy	1997	210	1.4	2.3	0.5	4.5
Jamaica	1991	2	—[b]	—[b]	—[b]	—[c]
Japan	1997	127	0.4	0.5	0.3	1.7
Kazakhstan	1999	631	11.5	18.0	5.0	3.6
Kuwait	1999	14	—[b]	—[b]	—[b]	—[c]
Kyrgyzstan	1999	88	4.6	6.7	2.4	2.8
Latvia	1999	55	7.8	13.1	—[b]	—[c]
Lithuania	1999	59	5.4	8.4	—[b]	—[c]
Mauritius	1999	4	—[b]	—[b]	—[b]	—[c]
Mexico	1997	5 991	15.3	27.8	2.8	9.8
Netherlands	1999	60	1.5	1.8	1.2	1.6
New Zealand	1998	20	1.8	—[b]	—[b]	—[c]
Nicaragua	1996	139	7.3	12.5	—[b]	—[c]
Norway	1997	11	—[b]	—[b]	—[b]	—[c]
Panama (excluding Canal Zone)	1997	151	14.4	25.8	—[b]	—[c]
Paraguay	1994	191	10.4	18.7	—[b]	—[c]

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TABLE 2.1 *(continued)*

Country or area	Year	Total number of deaths	Homicide rate per 100 000 population aged 10–29 years			
			Total	Males	Females	Male:female ratio
Philippines	1993	3 252	12.2	22.7	1.4	16.0
Poland	1995	186	1.6	2.3	0.8	2.7
Portugal	1999	37	1.3	2.1	—[b]	—[c]
Puerto Rico	1998	538	41.8	77.4	5.3	14.5
Republic of Korea	1997	282	1.7	2.1	1.3	1.6
Republic of Moldova	1999	96	7.7	12.8	—[b]	—[c]
Romania	1999	169	2.3	3.5	1.1	3.1
Russian Federation	1998	7 885	18.0	27.5	8.0	3.4
Singapore	1998	15	—[b]	—[b]	—[b]	—[c]
Slovakia	1999	26	1.5	2.4	—[b]	—[c]
Slovenia	1999	4	—[b]	—[b]	—[b]	—[c]
Spain	1998	96	0.8	1.2	0.4	2.9
Sweden	1996	16	—[b]	—[b]	—[b]	—[c]
Switzerland	1996	17	—[b]	—[b]	—[b]	—[c]
Tajikistan	1995	124	5.5	9.7	—[b]	—[c]
Thailand	1994	1 456	6.2	10.0	2.2	4.4
The former Yugoslav Republic of Macedonia	1997	6	—[b]	—[b]	—[b]	—[c]
Trinidad and Tobago	1994	55	11.4	15.4	—[b]	—[c]
Turkmenistan	1998	131	6.9	12.4	—[b]	—[c]
Ukraine	1999	1 273	8.7	13.0	4.3	3.1
United Kingdom	1999	139	0.9	1.4	0.4	3.9
England and Wales	1999	91	0.7	1.0	0.3	3.4
Northern Ireland	1999	7	—[b]	—[b]	—[b]	—[c]
Scotland	1999	41	3.1	5.3	—[b]	—[c]
United States of America	1998	8 226	11.0	17.9	3.7	4.8
Uruguay	1990	36	3.6	4.5	—[b]	—[c]
Uzbekistan	1998	249	2.6	3.8	1.3	3.0
Venezuela	1994	2 090	25.0	46.4	2.8	16.5

SAR: Special Administrative Region.

[a] Most recent year available between 1990 and 2000 for countries with ⩾1 million population.

[b] Fewer than 20 deaths reported; rate not calculated.

[c] Rate ratio not calculated if fewer than 20 deaths reported for either males or females.

than guns, and in a Colombian study only 5% of non-fatal assaults were gun-related (compared with over 80% of youth homicides involving firearms) (*25, 30*). In South Africa, gunshot wounds account for some 16% of all violent injuries presenting at hospitals, as compared with 46% of all homicides (*31*). However, direct comparison between countries and subgroups within countries using data on non-fatal violence registered at health services can be misleading. Differences in the rates of emergency room presentation for gunshot wounds, for instance, may simply reflect the fact that pre-hospital and emergency medical care varies between different settings.

Risk behaviours for youth violence

Participating in physical fights, bullying and carrying of weapons are important risk behaviours for youth violence. Most studies examining these behaviours have involved primary and secondary school pupils, who differ considerably from children and adolescents who have left or dropped out of school. Consequently, the applicability of the results of these studies to youths who are no longer attending school is likely to be limited.

Involvement in physical fighting is very common among school-age children in many parts of the world (*32–38*). Around one-third of students report having been involved in fighting, with males 2–3 times more likely than females to have fought. Bullying is also prevalent among school-age children (*39, 40*). In a study of health behaviour among school-aged children in 27 countries, the majority of 13-year-olds in most countries were found to have engaged in bullying at least some of the time (see Table 2.2) (*40*). Apart from being forms of aggression, bullying and physical fighting can also lead to more serious forms of violence (*41*).

The carrying of weapons is both an important risk behaviour and a predominantly male activity among young people of school age. There are, however, major variations in the prevalence of weapon carrying as reported by adolescents in different countries. In Cape Town, South Africa, 9.8% of males and 1.3% of females in secondary schools reported carrying knives to school during the previous 4 weeks (*42*). In Scotland, 34.1% of males and 8.6% of females aged 11–16 years said that they had carried weapons at least once during

TABLE 2.2
Bullying behaviour among 13-year-olds, 1997–1998

Country	Engaged in bullying this school term?		
	Have not %	Sometimes %	Once a week %
Austria	26.4	64.2	9.4
Belgium (Flemish region)	52.2	43.6	4.1
Canada	55.4	37.3	7.3
Czech Republic	69.1	27.9	3.0
Denmark	31.9	58.7	9.5
England	85.2	13.6	1.2
Estonia	44.3	50.6	5.1
Finland	62.8	33.3	3.8
France	44.3	49.1	6.6
Germany	31.2	60.8	7.9
Greece	76.8	18.9	4.3
Greenland	33.0	57.4	9.6
Hungary	55.8	38.2	6.0
Israel	57.1	36.4	6.6
Latvia	41.2	49.1	9.7
Lithuania	33.3	57.3	9.3
Northern Ireland	78.1	20.6	1.3
Norway	71.0	26.7	2.3
Poland	65.1	31.3	3.5
Portugal	57.9	39.7	2.4
Republic of Ireland	74.2	24.1	1.7
Scotland	73.9	24.2	1.9
Slovakia	68.9	27.3	3.9
Sweden	86.8	11.9	1.2
Switzerland	42.5	52.6	5.0
United States of America	57.5	34.9	7.6
Wales	78.6	20.0	1.4

their lifetime, with drug users significantly more likely than non-drug users to have done so (*43*). In the Netherlands, 21% of secondary-school pupils admitted to possessing a weapon, and 8% had actually brought weapons to school (*44*). In the United States, a national survey of students in grades 9–12 found that 17.3% had carried a weapon in the previous 30 days and 6.9% had carried a weapon on the school premises (*32*).

The dynamics of youth violence

Patterns of behaviour, including violence, change over the course of a person's life. The period of adolescence and young adulthood is a time when violence, as well as other types of behaviours, are often given heightened expression (*45*). Understanding when and under what conditions violent behaviour typically occurs as a person develops can help in formulating interventions and policies for prevention that target the most critical age groups (*3*).

How does youth violence begin?

Youth violence can develop in different ways. Some children exhibit problem behaviour in early childhood that gradually escalates to more severe forms of aggression before and during adolescence. Between 20% and 45% of boys and 47% and 69% of girls who are serious violent offenders at the age of 16–17 years are on what is termed a ''life-course persistent developmental pathway'' (*3, 46–50*). Young people who fit into this category commit the most serious violent acts and often continue their violent behaviour into adulthood (*51–54*).

Longitudinal studies have examined in what ways aggression can continue from childhood to adolescence and from adolescence to adulthood to create a pattern of persistent offending throughout a person's life. Several studies have shown that childhood aggression is a good predictor of violence in adolescence and early adulthood. In a study in Örebro, Sweden (*55*), two-thirds of a sample of around 1000 young males who displayed violent behaviour up to the age of 26 years had already scored highly for aggressiveness at the ages of 10 and 13 years, compared with about one-third of all boys. Similarly, in a follow-up study in Jyväskylä, Finland, of nearly 400 youths (*56*), ratings by peers of aggression at the ages of 8 and 14 years significantly predicted violence up to the age of 20.

There is also evidence of a continuity in aggressive behaviour from adolescence to adulthood. In a study in Columbus, OH, United States, 59% of youths arrested for violent offences before the age of 18 years were rearrested as adults, and 42% of these adult offenders were charged with at least one serious violent offence, such as homicide, aggravated assault or rape (*57*). A greater proportion of those arrested as young people for offences involving serious violence were rearrested as adults than was the case for young people arrested for offences involving minor violence. A study on the development of delinquency in Cambridge, England, found that one-third of young males who had been convicted of offences involving violence

before the age of 20 years were convicted again between the ages of 21 and 40 years, compared with only 8% of those not convicted for violent offences during their teenage years (*58*).

The existence of a life-course persistent developmental pathway helps to explain the continuity over time in aggressive and violent behaviour. That is, there are certain individuals who persist in having a greater underlying tendency than others towards aggressive or violent behaviour. In other words, those who are relatively more aggressive at a given age also tend to be relatively more aggressive later on, even though their absolute levels of violence may vary.

There may also be progressions over time from one type of aggression to another. For instance, in a longitudinal study in Pittsburgh, PA, United States, of over 1500 boys originally studied at 7, 10 and 13 years of age, Loeber et al. reported that childhood aggression tended to develop into gang fighting and later into youth violence (*59*).

Lifetime offenders, though, represent only a small proportion of those committing violence. Most violent young people engage in violent behaviour over much shorter periods. Such people are termed ''adolescence-limited offenders''. Results from the National Youth Survey conducted in the United States – based on a national sample of young people aged 11–17 years in 1976, who were followed until the age of 27–33 years – show that although a small proportion of youths continued to commit violence into and through adulthood, some three-quarters of young people who had committed serious violence ceased their violent behaviour after around 1–3 years (*3*). The majority of young people who become violent are adolescence-limited offenders who, in fact, show little or no evidence of high levels of aggression or other problem behaviours during their childhood (*3*).

Situational factors

Among adolescence-limited offenders, certain situational factors may play an important role in causing violent behaviour. A situational analysis – explaining the interactions between the would-be perpetrator and victim in a given situation – describes how the potential for violence might develop into actual violence. Situational factors include:

- the motives for violent behaviour;
- where the behaviour occurs;
- whether alcohol or weapons are present;
- whether people other than the victim and offender are present;
- whether other actions (such as burglary) are involved that could be conducive to violence.

Motives for youth violence vary according to the age of the participants and whether others are present. A study of delinquency in Montreal, Canada, showed that, when the perpetrators were in their teenage years or early twenties, about half of violent personal attacks were motivated by the search for excitement, often with co-offenders, and half by rational or utilitarian objectives (*60*). For all crimes, however, the main motivation switched from being thrill-seeking in the perpetrators' teenage years to utilitarian – involving prior planning, psychological intimidation and the use of weapons – in their twenties (*61*).

The National Survey of Youth in the United States found that assaults were generally committed in retaliation for a previous attack, out of revenge, or because of provocation or anger (*61*). In the study in Cambridge mentioned above, the motives for physical fights depended on whether a boy fought alone or with a group (*62*). In individual fights, a boy was usually provoked, became angry and hit to hurt his opponent or to release internal tensions. In group fights, boys often became involved to help friends or because they were attacked – rarely because they were angry. The group fights, though, were on the whole more serious. They often escalated from minor incidents, typically occurred in bars or on the street, and were more likely to involve weapons, lead to injuries, and involve the police.

Drunkenness is an important immediate situational factor that can precipitate violence. In a Swedish study, about three-quarters of violent offenders and around half the victims of violence were intoxicated at the time of the incident, and in the Cambridge study, many of the boys fought after drinking (*62, 63*).

An interesting characteristic of young violent offenders that may make them more likely to become entangled in situations leading to violence is their tendency to be involved in a broad range of crimes, as well as their usually having a range of problem behaviours. Generally, young violent offenders are versatile rather than specialized in the types of crimes they commit. In fact, violent young people typically commit more non-violent offences than violent offences (*64–66*). In the Cambridge study, convicted violent delinquents up to the age of 21 years had nearly three times as many convictions for non-violent offences as for violent offences (*58*).

What are the risk factors for youth violence?

Individual factors

At the individual level, factors that affect the potential for violent behaviour include biological, psychological and behavioural characteristics. These factors may already appear in childhood or adolescence, and to varying degrees they may be influenced by the person's family and peers and by other social and cultural factors.

Biological characteristics

Among possible biological factors, there have been studies on injuries and complications associated with pregnancy and delivery, because of the suggestion that these might produce neurological damage, which in turn could lead to violence. In a study in Copenhagen, Denmark, Kandel & Mednick (*67*) followed up over 200 children born during 1959–1961. Their research showed that complications during delivery were a predictor for arrests for violence up to the age of 22 years. Eighty per cent of youths arrested for committing violent offences scored in the high range for delivery complications at birth, compared with 30% of those arrested for committing property-related offences and 47% of youths with no criminal record. Pregnancy complications, on the other hand, did not significantly predict violence.

Interestingly, delivery complications were strongly associated with future violence when a parent had a history of psychiatric illness (*68*). In these cases, 32% of males with significant delivery complications were arrested for violence, compared with 5% of those with only minor or no delivery complications. Unfortunately, these results were not replicated by Denno in the Philadelphia Biosocial Project (*69*) – a study of nearly 1000 African-American children in Philadelphia, PA, United States, who were followed from birth to 22 years of age. It may therefore be that pregnancy and delivery complications predict violence only or mainly when they occur in combination with other problems within the family.

Low heart rates – studied mainly in boys – are associated with sensation-seeking and risk-taking, both characteristics that may predispose boys to aggression and violence in an attempt to increase stimulation and arousal levels (*70–73*). High heart rates, however, especially in infants and young children, are linked to anxiety, fear and inhibitions (*71*).

Psychological and behavioural characteristics

Among the major personality and behavioural factors that may predict youth violence are hyperactivity, impulsiveness, poor behavioural control and attention problems. Nervousness and anxiety, though, are negatively related to violence. In a follow-up study of over 1000 children in Dunedin, New Zealand, boys with violent convictions up to the age of 18 years were significantly more likely to have had poor scores in behavioural control (for example, impulsiveness and lack of persistence) at the age of 3–5 years, compared with boys with no convictions or with convictions for non-violent offences (*74*). In the same study, personality factors of constraint (such as cautiousness and the avoidance of excitement) and of negative emotionality (such as nervousness and alienation) at the age of 18 years were significantly inversely correlated with convictions for violence (*75*).

Longitudinal studies conducted in Copenhagen, Denmark (*68*), Örebro, Sweden (*76*), Cambridge, England (*77*), and Pittsburgh, PA, United States (*77*), also showed links between these personality

traits and both convictions for violence and self-reported violence. Hyperactivity, high levels of daring or risk-taking behaviour, and poor concentration and attention difficulties before the age of 13 years all significantly predicted violence into early adulthood. High levels of anxiety and nervousness were negatively related to violence in the studies in Cambridge and in the United States.

Low intelligence and low levels of achievement in school have consistently been found to be associated with youth violence (*78*). In the Philadelphia project (*69*), poor intelligence quotient (IQ) scores in verbal and performance IQ tests at the ages of 4 and 7 years, and low scores in standard school achievement tests at 13–14 years, all increased the likelihood of being arrested for violence up to the age of 22 years. In a study in Copenhagen, Denmark, of over 12 000 boys born in 1953, low IQ at 12 years of age significantly predicted police-recorded violence between the ages of 15 and 22 years. The link between low IQ and violence was strongest among boys from lower socioeconomic groups.

Impulsiveness, attention problems, low intelligence and low educational attainment may all be linked to deficiencies in the executive functions of the brain, located in the frontal lobes. These executive functions include: sustaining attention and concentration, abstract reasoning and concept formation, goal formulation, anticipation and planning, effective self-monitoring and self-awareness of behaviour, and inhibitions regarding inappropriate or impulsive behaviours (*79*). Interestingly, in another study in Montreal – of over 1100 children initially studied at 6 years of age and followed onwards from the age of 10 years – executive functions at 14 years of age, measured with cognitive-neuropsychological tests, provided a significant means of differentiating between violent and non-violent boys (*80*). Such a link was independent of family factors, such as socioeconomic status, the parents' age at first birth, their educational level, or separation or divorce within the family.

Relationship factors

Individual risk factors for youth violence, such as the ones described above, do not exist in isolation from other risk factors. Factors associated with the interpersonal relations of young people – with their family, friends and peers – can also strongly affect aggressive and violent behaviour and shape personality traits that, in turn, can contribute to violent behaviour. The influence of families is usually the greatest in this respect during childhood, while during adolescence friends and peers have an increasingly important effect (*81*).

Family influences

Parental behaviour and the family environment are central factors in the development of violent behaviour in young people. Poor monitoring and supervision of children by parents and the use of harsh, physical punishment to discipline children are strong predictors of violence during adolescence and adulthood. In her study of 250 boys in Boston, MA, United States, McCord (*82*) found that poor parental supervision, parental aggression and harsh discipline at the age of 10 years strongly increased the risk of later convictions for violence up to 45 years of age.

Eron, Huesmann & Zelli (*83*) followed up almost 900 children in New York, NY, United States. They found that harsh, physical punishment by parents at the age of 8 years predicted not only arrests for violence up to the age of 30 years, but also – for boys – the severity of punishment of their own children and their own histories of spouse abuse. In a study of over 900 abused children and nearly 700 controls, Widom showed that recorded physical abuse and neglect as a child predicted later arrests for violence – independently of other predictors such as sex, ethnicity and age (*84*). Other studies have recorded similar findings (*77, 85, 86*).

Violence in adolescence and adulthood has also been strongly linked to parental conflict in early childhood (*77, 82*) and to poor attachment between parents and children (*87, 88*). Other factors include: a large number of children in the family (*65, 77*); a mother who had her first child at an early age, possibly as a teenager (*77, 89, 90*); and a low level of family cohesion (*91*). Many of these factors, in the absence of other social support, can affect children's social and emotional functioning and behaviour.

McCord (*87*), for example, showed that violent offenders were less likely than non-violent offenders to have experienced parental affection and good discipline and supervision.

Family structure is also an important factor for later aggression and violence. Findings from studies conducted in New Zealand, the United Kingdom and the United States show that children growing up in single-parent households are at greater risk for violence (*74, 77, 92*). In a study of 5300 children from England, Scotland and Wales, for example, experiencing parental separation between birth and the age of 10 years increased the likelihood of convictions for violence up to the age of 21 years (*92*). In the study in Dunedin, New Zealand, living with a single parent at the age of 13 years predicted convictions for violence up to the age of 18 years (*74*). The more restricted scope for support and probable fewer economic resources in these situations may be reasons why parenting often suffers and the risk of becoming involved in violence increases for youths.

In general, low socioeconomic status of the family is associated with future violence. For example, in a national survey of young people in the United States, the prevalence of self-reported assault and robbery among youths from low socioeconomic classes was about twice that among middle-class youths (*93*). In Lima, Peru, low educational levels of the mother and high housing density were both found to be associated with youth violence (*94*). A study of young adults in São Paulo, Brazil, found that, after adjusting for sex and age, the risk of being a victim of violence was significantly higher for youths from low socioeconomic classes compared with those from high socioeconomic classes (*95*). Similar results have been obtained from studies in Denmark (*96*), New Zealand (*74*) and Sweden (*97*).

Given the importance of parental supervision, family structure and economic status in determining the prevalence of youth violence, an increase in violence by young people would be expected where families have disintegrated through wars or epidemics, or because of rapid social change. Taking the case of epidemics, some 13 million children worldwide have lost one or both parents to AIDS, more than 90% of them in sub-Saharan Africa, where millions more children are likely to be orphaned in the next few years (*98*). The onslaught of AIDS on people of reproductive age is producing orphans at such a rate that many communities can no longer rely on traditional structures to care for these children. The AIDS epidemic is thus likely to have serious adverse implications for violence among young people, particularly in Africa, where rates of youth violence are already extremely high.

Peer influences

Peer influences during adolescence are generally considered positive and important in shaping interpersonal relationships, but they can also have negative effects. Having delinquent friends, for instance, is associated with violence in young people (*88*). The results of studies in developed countries (*78, 88*) are consistent with a study in Lima, Peru (*94*), which found a correlation between violent behaviour and having friends who used drugs. The causal direction in this correlation – whether having delinquent friends comes before or after being a violent offender – is, however, not clear (*99*). In their study, Elliott & Menard concluded that delinquency caused peer bonding and, at the same time, that bonding with delinquent peers caused delinquency (*100*).

Community factors

The communities in which young people live are an important influence on their families, the nature of their peer groups, and the way they may be exposed to situations that lead to violence. Generally speaking, boys in urban areas are more likely to be involved in violent behaviour than those living in rural areas (*77, 88, 93*). Within urban areas, those living in neighbourhoods with high levels of crime are more likely to be involved in violent behaviour than those living in other neighbourhoods (*77, 88*).

Gangs, guns and drugs

The presence of gangs (see Box 2.1), guns and drugs in a locality is a potent mixture, increasing

BOX 2.1

A profile of gangs

Youth gangs are found in all regions of the world. Although their size and nature may vary greatly – from mainly social grouping to organized criminal network – they all seem to answer a basic need to belong to a group and create a self-identity.

In the Western Cape region of South Africa, there are about 90 000 members of gangs, while in Guam, some 110 permanent gangs were recorded in 1993, around 30 of them hard-core gangs. In Port Moresby, Papua New Guinea, four large criminal associations with numerous subgroups have been reported. There are an estimated 30 000–35 000 gang members in El Salvador and a similar number in Honduras, while in the United States, some 31 000 gangs were operating in 1996 in about 4800 cities and towns. In Europe, gangs exist to varying extents across the continent, and are particularly strong in those countries in economic transition such as the Russian Federation.

Gangs are primarily a male phenomenon, though in countries such as the United States, girls are forming their own gangs. Gang members can range in age from 7 to 35 years, but typically are in their teens or early twenties. They tend to come from economically deprived areas, and from low-income and working-class urban and suburban environments. Often, gang members may have dropped out of school and hold low-skilled or low-paying jobs. Many gangs in high-income and middle-income countries consist of people from ethnic or racial minorities who may be socially very marginalized.

Gangs are associated with violent behaviour. Studies have shown that as youths enter gangs they become more violent and engage in riskier, often illegal activities. In Guam, over 60% of all violent crime reported to the police is committed by young people, much of it related to activities of the island's hard-core gangs. In Bremen, Germany, violence by gang members accounts for almost half of reported violent offences. In a longitudinal study of nearly 1000 youths in Rochester, NY, United States, some 30% of the sample were gang members, but they accounted for around 70% of self-reported violent crimes and 70% of drug dealing.

A complex interaction of factors leads young people to opt for gang life. Gangs seem to proliferate in places where the established social order has broken down and where alternative forms of shared cultural behaviour are lacking. Other socioeconomic, community and interpersonal factors that encourage young people to join gangs include:

- a lack of opportunity for social or economic mobility, within a society that aggressively promotes consumption;
- a decline locally in the enforcement of law and order;
- interrupted schooling, combined with low rates of pay for unskilled labour;
- a lack of guidance, supervision and support from parents and other family members;
- harsh physical punishment or victimization in the home;
- having peers who are already involved in a gang.

Actively addressing these underlying factors that encourage youth gangs to flourish, and providing safer, alternative cultural outlets for their prospective members, can help eliminate a significant proportion of violent crime committed by gangs or otherwise involving young people.

the likelihood of violence. In the United States, for example, the presence together in neighbourhoods of these three items would appear to be an important factor in explaining why the juvenile arrest rate for homicide more than doubled between 1984 and 1993 (from 5.4 per 100 000 to 14.5 per 100 000) (*97, 101, 102*). Blumstein suggested that this rise was linked to increases occurring over the same period in the carrying of guns, in the number of gangs and in battles fought over the selling of crack cocaine (*103*). In the Pittsburgh study already mentioned, initiation into

dealing in drugs coincided with a significant increase in carrying weapons, with 80% of 19-year-olds who sold hard drugs (such as cocaine), also carrying a gun (*104*). In Rio de Janeiro, Brazil, where the majority of victims and perpetrators of homicide are 25 years of age or younger, drug dealing is responsible for a large proportion of homicides, conflicts and injuries (*105*). In other parts of Latin America and the Caribbean, youth gangs involved in drug trafficking display higher levels of violence than those that are not (*106*).

Social integration

The degree of social integration within a community also affects rates of youth violence. Social capital is a concept that attempts to measure such community integration. It refers, roughly speaking, to the rules, norms, obligations, reciprocity and trust that exist in social relations and institutions (*107*). Young people living in places that lack social capital tend to perform poorly in school and have a greater probability of dropping out altogether (*108*).

Moser & Holland (*109*) studied five poor urban communities in Jamaica. They found a cyclical relationship between violence and the destruction of social capital. When community violence occurred, physical mobility in the particular locality was restricted, employment and educational opportunities were reduced, businesses were reluctant to invest in the area and local people were less likely to build new houses or repair or improve existing property. This reduction in social capital – the increased mistrust resulting from the destruction of infrastructure, amenities and opportunities – increased the likelihood of violent behaviour, especially among young people. A study on the relation between social capital and crime rates in a wide range of countries during the period 1980–1994, found that the level of trust among community members had a strong effect on the incidence of violent crimes (*107*). Wilkinson, Kawachi & Kennedy (*110*) showed that indices of social capital reflecting low social cohesion and high levels of interpersonal mistrust were linked with both higher homicide rates and greater economic inequality.

Societal factors

Several societal factors may create conditions conducive to violence among young people. Much of the evidence related to these factors, though, is based on cross-sectional or ecological studies and is mainly useful for identifying important associations, rather than direct causes.

Demographic and social changes

Rapid demographic changes in the youth population, modernization, emigration, urbanization and changing social policies have all been linked with an increase in youth violence (*111*). In places that have suffered economic crises and ensuing structural adjustment policies – such as in Africa and parts of Latin America – real wages have often declined sharply, laws intended to protect labour have been weakened or discarded, and a substantial decline in basic infrastructure and social services has occurred (*112, 113*). Poverty has become heavily concentrated in cities experiencing high population growth rates among young people (*114*).

In their demographic analysis of young people in Africa, Lauras-Locoh & Lopez-Escartin (*113*) suggest that the tension between a rapidly swelling population of young people and a deteriorating infrastructure has resulted in school-based and student revolts. Diallo Co-Trung (*115*) found a similar situation of student strikes and rebellions in Senegal, where the population under 20 years of age doubled between 1970 and 1988, during a period of economic recession and the implementation of structural adjustment policies. In a survey of youths in Algeria, Rarrbo (*116*) found that rapid demographic growth and accelerating urbanization together created conditions, including unemployment and grossly inadequate housing, that in turn led to extreme frustration, anger and pent-up tensions among youths. Young people, as a result, were more likely to turn to petty crime and violence, particularly under the influence of peers.

In Papua New Guinea, Dinnen (*117*) describes the evolution of ''raskolism'' (criminal gangs) in the broader context of decolonization and the ensuing social and political change, including rapid population growth unmatched by economic growth. Such a

phenomenon has also been cited as a concern in some of the former communist economies (*118*), where – as unemployment has soared, and the social welfare system been severely cut – young people have lacked legitimate incomes and occupations, as well as the necessary social support between leaving school and finding work. In the absence of such support, some have turned to crime and violence.

Income inequality

Research has shown links between economic growth and violence, and between income inequality and violence (*119*). Gartner, in a study of 18 industrialized countries during the period 1950–1980 (*6*), found that income inequality, as measured by the Gini coefficient, had a significant and positive effect on the homicide rate. Fajnzylber, Lederman & Loayza (*120*) obtained the same results in an investigation of 45 industrialized and developing countries between 1965 and 1995. The rate of growth of the GDP was also significantly negatively associated with the homicide rate, but this effect was in many cases offset by rising levels of income inequality. Unnithan & Whitt came to similar conclusions in their cross-national study (*121*), namely, that income inequality was strongly linked with homicide rates, and that such rates also decreased as the per capita GDP increased.

Political structures

The quality of governance in a country, both in terms of the legal framework and the policies offering social protection, is an important determinant of violence. In particular, the extent to which a society enforces its existing laws on violence, by arresting and prosecuting offenders, can act as a deterrent against violence. Fajnzylber, Lederman & Loayza (*120*) found that the arrest rate for homicides had a significant negative effect on the homicide rate. In their study, objective measures of governance (such as arrest rates) were negatively correlated with crime rates, while subjective measures (such as confidence in the judiciary and the perceived quality of governance) were only weakly correlated with crime rates.

Governance can therefore have an impact on violence, particularly as it affects young people. Noronha et al. (*122*), in their study on violence affecting various ethnic groups in Salvador, Bahia, Brazil, concluded that dissatisfaction with the police, the justice system and prisons increased the use of unofficial modes of justice. In Rio de Janeiro, Brazil, de Souza Minayo (*105*) found that the police were among the principal perpetrators of violence against young people. Police actions – particularly against young men from lower socioeconomic classes – involved physical violence, sexual abuse, rape and bribery. Sanjuán (*123*) suggested that a sense that justice depended on socioeconomic class was an important factor in the emergence of a culture of violence among marginalized youths in Caracas, Venezuela. Similarly, Aitchinson (*124*) concluded that in post-apartheid South Africa, impunity for former perpetrators of human rights abuses and the inability of the police to change their methods significantly, have contributed to a generalized feeling of insecurity and increased the number of extra-judicial actions involving violence.

Social protection by the state, another aspect of governance, is also important. In their study, Pampel & Gartner (*125*) used an indicator measuring the level of development of national institutions responsible for collective social protection. They were interested in the question of why different countries, whose 15–29-year-old age groups had grown at the same rate over a given period, nevertheless showed differing increases in their homicide rates. Pampel & Gartner concluded that strong national institutions for social protection had a negative effect on the homicide rate. Furthermore, having such institutions in place could counter the effects on homicide rates associated with increases in the 15–29-year-old age group, the group with traditionally high rates of being a victim or perpetrator of homicide.

Messner & Rosenfeld (*126*) examined the impact of efforts to protect vulnerable populations from market forces, including economic recession. Higher welfare expenditures were found to be associated with decreases in the homicide rate,

suggesting that societies with economic safety nets have fewer homicides. Briggs & Cutright (*7*), in a study of 21 countries over the period 1965–1988, found that spending on social insurance, as a proportion of the GDP, was negatively correlated with homicides of children up to 14 years of age.

Cultural influences

Culture, which is reflected in the inherited norms and values of society, helps determine how people respond to a changing environment. Cultural factors can affect the amount of violence in a society – for instance, by endorsing violence as a normal method to resolve conflicts and by teaching young people to adopt norms and values that support violent behaviour.

One important means through which violent images, norms and values are propagated is the media. Exposure of children and young people to the various forms of the media has increased dramatically in recent years. New forms of media – such as video games, video tapes and the Internet – have multiplied opportunities for young people to be exposed to violence. Several studies have shown that the introduction of television into countries was associated with increases in the level of violence (*127–131*), although these studies did not usually take into account other factors that may at the same time have influenced rates of violence (*3*). The preponderance of evidence to date indicates that exposure to violence on television increases the likelihood of immediate aggressive behaviour and has an unknown effect in the longer term on serious violence (*3*) (see Box 2.2). There is insufficient evidence on the impact of some of the newer forms of media.

Cultures which fail to provide non-violent alternatives to resolve conflicts appear to have higher rates of youth violence. In their study of gangs in Medellín, Colombia, Bedoya Marín & Jaramillo Martínez (*136*) describe how low-income youths are influenced by the culture of violence, in society in general and in their particular community. They suggest that a culture of violence is fostered at the community level through the growing acceptance of ''easy money'' (much of it related to drug trafficking) and of whatever means are necessary to obtain it, as well as through corruption in the police, judiciary, military and local administration.

Cultural influences across national boundaries have also been linked to rises in juvenile violence. In a survey of youth gangs in Latin America and the Caribbean, Rodgers (*106*) has shown that violent gangs, modelling themselves on those in Los Angeles, CA, United States, have emerged in northern and south-western Mexican towns, where immigration from the United States is highest. A similar process has been found in El Salvador, which has experienced a high rate of deportations of Salvadoran nationals from the United States since 1992, many of the deportees having been members of gangs in the United States.

What can be done to prevent youth violence?

In designing national programmes to prevent youth violence, it is important to address not only individual cognitive, social and behavioural factors, but also the social systems that shape these factors.

Tables 2.3 and 2.4 illustrate examples of youth violence prevention strategies as matrices, relating ecological systems through which violence can be prevented to developmental stages, from infancy to early adulthood, where violent behaviour or the risks for violent behaviour are likely to emerge. The prevention strategies in these tables are not exhaustive, nor do they necessarily represent strategies that have proved effective. Some, in fact, have been shown to be ineffective. Rather, the matrices are meant to illustrate the wide spectrum of possible solutions to the problem of youth violence, and to emphasize the need for a range of different strategies for various stages of development.

Individual approaches

The most common interventions against youth violence seek to increase the level of protective factors associated with individual skills, attitudes and beliefs.

One violence prevention strategy appropriate for early childhood – though it is not usually thought of as such – is the adoption of preschool enrichment programmes. These programmes introduce young

BOX 2.2

The impact of media on youth violence

Children and young people are important consumers of the mass media, including entertainment and advertising. Studies in the United States have found that television viewing often begins as early as 2 years of age, and that the average young person between 8 and 18 years of age watches some 10 000 violent acts a year on television. These patterns of exposure to the media are not necessarily evident in other parts of the world, especially where there is less access to television and film. All the same, there is little doubt that the exposure everywhere of children and young people to mass media is substantial and growing. It is therefore important to explore media exposure as a possible risk factor for interpersonal violence involving young people.

Researchers have been examining the impact of the media on aggressive and violent behaviour for over 40 years. Several meta-analyses of studies on the impact of the media on aggression and violence have tended to conclude that media violence is positively related to aggression toward others. However, evidence to confirm its effect on serious forms of violence (such as assault and homicide), is lacking.

A 1991 meta-analysis, involving 28 studies of children and adolescents exposed to media violence and observed in free social interaction, concluded that exposure to media violence increased aggressive behaviour towards friends, classmates and strangers (*132*). Another meta-analysis, conducted in 1994, examined 217 studies published between 1957 and 1990 concerned with the impact of media violence on aggressive behaviour, with 85% of the sample in the age range 6–21 years. The authors concluded that there was a significant positive correlation between exposure to media violence and aggressive behaviour, regardless of age (*133*).

Many of the studies included in these analytical reviews were either randomized experiments (laboratory and field) or cross-sectional surveys. Findings from the experimental studies show that brief exposure to violence on television or film, particularly dramatic presentations of violence, produces short-term increases in aggressive behaviour. Moreover, the effects seem to be greater for children and youths with aggressive tendencies and among those who have been aroused or provoked. The findings, however, may not extend to real-life situations. Indeed, real-life settings often include influences that cannot be ''controlled'' as in experiments – influences that might mitigate against aggressive and violent behaviour.

Findings from the cross-sectional studies also show a positive correlation between media violence and various measures of aggression – for instance, attitudes and beliefs, behaviour and emotions such as anger. The effects of media violence on the more serious forms of violent behaviour (such as assault and homicide), though, are rather small at best ($r = 0.06$) (*133*). Also, unlike experimental and longitudinal studies where causality can more easily be established, it is not possible to conclude from cross-sectional studies that exposure to media violence causes aggressive and violent behaviour.

There have also been longitudinal studies examining the link between television viewing and interpersonal aggression some years later. A 3-year longitudinal study of children aged 7–9 years in Australia, Finland, Israel, Poland and the United States produced inconsistent results (*134*), and a 1992 study of children in the Netherlands in the same age bracket failed to show any effect on aggressive behaviour (*135*). Other studies following up children in the United States over longer periods (10–15 years), however, have shown a positive correlation between television viewing in childhood and later aggression in young adulthood (*3*).

Studies examining the relationship between homicide rates and the introduction of television (primarily by looking at homicide rates in countries before and after television was introduced) have also found a positive correlation between the two (*127–131*). These studies, however, failed

BOX 2.2 (continued)

to control for confounding variables such as economic differences, social and political change, and a variety of other potential influences on homicide rates.

The scientific findings on the relationship between media violence and youth violence are thus conclusive with respect to short-term increases in aggression. The findings, however, are inconclusive with respect to longer-term effects and on the more serious forms of violent behaviour, and suggest that more research is needed. Apart from examining the extent to which media violence is a direct cause of serious physical violence, research is also required on the influence of the media on interpersonal relations and on individual traits such as hostility, callousness, indifference, lack of respect and the inability to identify with other people's feelings.

children early on to the skills necessary for success in school and they therefore increase the likelihood of future academic success. Such programmes can strengthen a child's bonds to the school and raise achievement and self-esteem (*137*). Long-term follow-up studies of prototypes of such programmes have found positive benefits for children, including less involvement in violent and other delinquent behaviours (*138–140*).

Social development programmes to reduce antisocial and aggressive behaviour in children and violence among adolescents adopt a variety of strategies. These commonly include improving competency and social skills with peers and generally promoting behaviour that is positive, friendly and cooperative (*141*). Such programmes can be provided universally or just to high-risk groups and are most frequently carried out in school settings (*142, 143*). Typically, they focus on one or more of the following (*143*):

— managing anger;
— modifying behaviour;
— adopting a social perspective;
— moral development;
— building social skills;
— solving social problems;
— resolving conflicts.

There is evidence that these social development programmes can be effective in reducing youth violence and improving social skills (*144–146*). Programmes that emphasize social and competency skills appear to be among the most effective among youth violence prevention strategies (*3*). They also appear to be more effective when delivered to children in preschool and primary school environments rather than to secondary school students.

An example of a social development programme that uses behavioural techniques in the classroom is a programme to prevent bullying introduced in elementary and junior secondary schools in Bergen, Norway. Incidents of bullying were reduced by a half within 2 years using this intervention (*147*). The programme has been reproduced in England, Germany and the United States with similar effects (*3*).

Other interventions targeting individuals that may be effective include the following, though further evidence is needed to confirm their effect on violent and aggressive behaviour (*137, 148*):

— programmes to prevent unintended pregnancies, so as to reduce child maltreatment and the risk it poses for later involvement in violent behaviour;
— for similar reasons, programmes to increase access to prenatal and postnatal care;
— academic enrichment programmes;
— incentives for youths at high risk for violence to complete secondary schooling and to pursue courses of higher education;
— vocational training for underprivileged youths and young adults.

Programmes that do not appear effective in reducing youth violence include (*3*):

— individual counselling;
— training in the safe use of guns;

TABLE 2.3
Violence prevention strategies by developmental stage (infancy to middle childhood) and ecological context

Ecological context	Developmental stage		
	Infancy (ages 0–3 years)	Early childhood (ages 3–5 years)	Middle childhood (ages 6–11 years)
Individual	• Preventing unintended pregnancies • Increasing access to prenatal and postnatal care	• Social development programmes[a] • Preschool enrichment programmes[a]	• Social development programmes[a] • Programmes providing information about drug abuse[b]
Relationship (e.g. family, peers)	• Home visitation[a] • Training in parenting[a]	• Training in parenting[a]	• Mentoring programmes • Home–school partnership programmes to promote parental involvement
Community	• Monitoring lead levels and removing toxins from homes • Increasing the availability and quality of child-care facilities	• Monitoring lead levels and removing toxins from homes • Increasing the availability and quality of preschool enrichment programmes	• Creating safe routes for children on their way to and from school or other community activities • Improving school settings, including teacher practices, school policies and security • Providing after-school programmes to extend adult supervision • Extracurricular activities
Societal	• Deconcentrating poverty • Reducing income inequality	• Deconcentrating poverty • Reducing income inequality • Reducing media violence • Public information campaigns	• Deconcentrating poverty • Reducing income inequality • Reducing media violence • Public information campaigns • Reforming educational systems

[a] Demonstrated to be effective in reducing youth violence or risk factors for youth violence.
[b] Shown to be ineffective in reducing youth violence or risk factors for youth violence.

— probation and parole programmes that include meetings with prison inmates who describe the brutality of prison life;
— trying young offenders in adult courts;
— residential programmes taking place in psychiatric institutions or correctional institutions;
— programmes providing information about drug abuse.

Programmes for delinquent young people modelled on basic military training (''boot camps'') have, in some studies, been found to lead to an increase in repeat offending (*3*).

Relationship approaches

Another common set of prevention strategies address youth violence by attempting to influence the type of relations that young people have with others with whom they regularly interact. These programmes address such problems as the lack of emotional relations between parents and children, powerful pressures brought to bear by peers to engage in violence and the absence of a strong relationship with a caring adult.

Home visitation

One type of family-based approach to preventing youth violence is home visitation. This is an intervention conducted in infancy (ages 0–3 years) involving regular visits by a nurse or other health care professional to the child's home. This type of programme is found in many parts of the world, including Australia, Canada, China (Hong Kong Special Administrative Region (SAR)), Denmark, Estonia, Israel, South Africa, Thailand and the United States. The objective is to provide training, support, counselling, monitoring and referrals to outside agencies for low-income mothers, for families who are expecting or have recently had their first child, and for families at increased risk of abusing their children or with other health problems (*137, 146*). Home visitation pro-

grammes have been found to have significant long-term effects in reducing violence and delinquency (*138, 149–152*). The earlier such programmes are delivered in the child's life and the longer their duration, the greater appear to be the benefits (*3*).

Training in parenting

Skill training programmes on parenting aim to improve family relations and child-rearing techniques and thereby to reduce youth violence. Their objectives include improving the emotional bonds between parents and their children, encouraging parents to use consistent child-rearing methods and helping them to develop self-control in bringing up children (*146*).

An example of a comprehensive training programme for parents is the Triple-P-Positive Parenting Programme in Australia (*153*). This programme includes a population-based media campaign to reach all parents and a health care component that uses consultations with primary care physicians to improve parenting practices. Intensive interventions are also offered to parents and families with children at risk for severe behavioural problems. The programme – or elements of it – have been or are being implemented in China (Hong Kong SAR), Germany, New Zealand, Singapore and the United Kingdom (*154*).

Several evaluation studies have found training in parenting to be successful and there is some evidence of a long-term effect in reducing antisocial behaviour (*155–158*). In a study on the cost-effectiveness of early interventions to prevent serious forms of crime in California, United States, training for parents whose children exhibited aggressive behaviour was estimated to have prevented 157 serious crimes (such as homicide, rape, arson and robbery) for every million US dollars spent (*159*). In fact, training in parenting was estimated to be about three times as cost-effective as the so-called ''three-strikes'' law in California – a law decreeing harsh sentences for those repeatedly offending.

Mentoring programmes

A warm and supportive relationship with a positive adult role model is thought to be a protective factor for youth violence (*3, 146*). Mentoring programmes based on this theory match a young person – particularly one at high risk for antisocial behaviour or growing up in a single-parent family – with a caring adult, a mentor, from outside the family (*160*). Mentors may be older classmates, teachers, counsellors, police officers or other members of the community. The objectives of such programmes are to help young people to develop skills and to provide a sustained relationship with someone who is their role model and guide (*143*). While not as widely evaluated as some of the other strategies to reduce youth violence, there is evidence that a positive mentoring relationship can significantly improve school attendance and performance, decrease the likelihood of drug use, improve relationships with parents and reduce self-reported forms of antisocial behaviour (*161*).

Therapeutic and other approaches

Therapeutic approaches have also been used with families to prevent youth violence. There are many forms of such therapy, but their common objectives are to improve communications and interactions between parents and children and to solve problems that arise (*143*). Some programmes also try to help families deal with environmental factors contributing to antisocial behaviour and make better use of resources in the community. Family therapy programmes are often costly, but there is substantial evidence that they can be effective in improving family functioning and reducing behavioural problems in children (*162–164*). Functional Family Therapy (*165*) and Multisystemic Therapy (*166*) are two particular approaches used in the United States that have been shown to have positive, long-term effects in reducing violent and delinquent behaviour of juvenile offenders at lower costs than other treatment programmes (*3*).

Other interventions targeting youth relationships that may be effective include (*3*):

— home–school partnership programmes to promote parental involvement;

— compensatory education, such as adult tutoring.

TABLE 2.4

Violence prevention strategies by developmental stage (adolescence and early adulthood) and ecological context

Ecological context	Developmental stage	
	Adolescence (ages 12–19 years)	Early adulthood (ages 20–29 years)
Individual	• Social development programmes[a] • Providing incentives for youths at high risk for violence to complete secondary schooling[a] • Individual counselling[b] • Probation or parole programmes that include meetings with prison inmates describing the brutality of prison life[b] • Residential programmes in psychiatric or correctional institutions[b] • Programmes providing information about drug abuse[b] • Academic enrichment programmes • Training in the safe use of guns[b] • Programmes modelled on basic military training[b] • Trying young offenders in adult courts[b]	• Providing incentives to pursue courses in higher education • Vocational training
Relationship (e.g. family, peers)	• Mentoring programmes[a] • Peer mediation or peer counselling[b] • Temporary foster care programmes for serious and chronic delinquents • Family therapy[a]	• Programmes to strengthen ties to family and jobs, and reduce involvement in violent behaviour
Community	• Creating safe routes for youths on their way to and from school or other community activities • Improving school settings, including teacher practices, school policies and security • Extracurricular activities • Gang prevention programmes[b] • Training health care workers to identify and refer youths at high risk for violence • Community policing • Reducing the availability of alcohol • Improving emergency response, trauma care and access to health services • Buying back guns[b]	• Establishing adult recreational programmes • Community policing • Reducing the availability of alcohol • Improving emergency response, trauma care and access to health services • Buying back guns[b]
Societal	• Deconcentrating poverty • Reducing income inequality • Public information campaigns • Reducing media violence • Enforcing laws prohibiting illegal transfers of guns to youths • Promoting safe and secure storage of firearms • Strengthening and improving police and judicial systems • Reforming educational systems	• Deconcentrating poverty • Reducing income inequality • Establishing job creation programmes for the chronically unemployed • Public information campaigns • Promoting safe and secure storage of firearms • Strengthening and improving police and judicial systems

[a] Demonstrated to be effective in reducing youth violence or risk factors for youth violence.
[b] Shown to be ineffective in reducing youth violence or risk factors for youth violence.

Programmes addressing youth relationships that do not appear to be effective in reducing adolescent violence include (*137*):

- Peer mediation – the involvement of students to help other students resolve disputes.
- Peer counselling.
- Redirecting youth behaviour and shifting peer group norms – both of these attempt to redirect youths at high risk of violence towards conventional activities, but have been shown to have negative effects on attitudes, achievement and behaviour (*3*).

Community-based efforts

Interventions addressing community factors are those that attempt to modify the environments in which young people interact with each other. A simple example is improving street lighting, where poorly-lit areas may increase the risk of violent assaults occurring. Less is known, unfortunately,

about the effectiveness of community-based strategies with regard to youth violence than of those focusing on individual factors or on the relationships that young people have with others.

Community policing

Community or problem-oriented policing has become an important law enforcement strategy for addressing youth violence and other criminal problems in many parts of the world (*167*). It can take many forms, but its core ingredients are building community partnerships and solving community problems (*168*). In some programmes, for instance, police collaborate with mental health professionals to identify and refer youths who have witnessed, experienced or committed violence (*169*). This type of programme builds on the fact that police come into daily contact with young victims or perpetrators of violence. It then provides them with special training and links them – at an early stage in the youth's development – with the appropriate mental health professionals (*168*). The effectiveness of this type of programme has not yet been determined, though it appears to be a useful approach.

Community policing programmes have been implemented with some success in Rio de Janeiro, Brazil, and San José, Costa Rica (*170, 171*). In Costa Rica, an evaluation of the programme found an association with a decline in both crime and perceived personal insecurity (*171*). Such programmes need to be more rigorously evaluated, but they do offer local residents better protection and make up for a lack of regular police services (*170*).

Availability of alcohol

Another community strategy to address crime and violence is to reduce the availability of alcohol. As already mentioned, alcohol is an important situational factor that can precipitate violence. The effect of reducing alcohol availability on rates of offending was examined in a 4-year longitudinal study conducted in a small provincial region of New Zealand (*172*). The rates of serious criminal offences (homicide and rape) and other offences (related to property and traffic) were compared in two experimental towns and four control towns over the study period. While both types of offence decreased in the experimental towns and increased relative to national trends in the control towns, crime rates fell significantly for 2 years in areas of reduced alcohol availability. It is not clear, though, to what extent the intervention affected violent behaviour among young people or how well such an approach might work in other settings.

Extracurricular activities

Extracurricular activities – such as sports and recreation, art, music, drama and producing newsletters – can provide adolescents with opportunities to participate in and gain recognition for constructive group activities (*3*). In many communities, though, either such activities are lacking or there are no places where children can safely go outside school hours to practise them (*173*). After-school programmes provide these facilities for children and young people. Ideally, such programmes should be (*174*):

- comprehensive – addressing the whole range of risk factors for youth violence and delinquency;
- developmentally appropriate;
- of long duration.

Essor, in Maputo, Mozambique (*175*), is an example of a community programme designed to address adolescent delinquency in two low-income neighbourhoods. The programme, which targets adolescents between the ages of 13 and 18 years, offers sports and leisure activities to promote self-expression and team-building. Programme staff also maintain contact with youths through regular home visits. An evaluation of the programme showed significant improvements in constructive behaviour and communications with parents over an 18-month period, along with a significant drop in antisocial behaviour.

Suppressing gang violence

Community programmes to prevent gang violence have taken on several forms. Preventive strategies have included attempts to suppress gangs or to

organize communities affected by gang violence in such a way that youth gangs operate differently and with less criminal activities (*106*). Rehabilitative or corrective strategies include outreach and counselling programmes for gang members as well as programmes that seek to channel gang activities into socially productive directions (*106*). There is little evidence that programmes to suppress gangs, organize communities, or provide outreach or counselling services are effective. In Nicaragua, wide-ranging police efforts in 1997 to suppress gang activity met with only temporary success and may have in the end exacerbated the problem (*176*). Attempts at community organization in the United States, in Boston, MA, and Chicago, IL, have not been successful in reducing gang violence either, possibly because the affected communities were insufficiently integrated or cohesive to sustain organized efforts (*177*). Outreach and counselling efforts have had the unwanted, and unexpected, consequence of increasing gang cohesion (*178*). In Medellín, Colombia, programmes have been successfully used to encourage gang members to involve themselves in local politics and social development projects (*179*), while in Nicaragua and the United States such ''opportunity'' programmes have met with only limited success (*106*).

Other strategies

Other interventions targeting communities that may prove effective include (*148, 180*):

- Monitoring lead levels and removing toxins from the home environment so as to reduce the risk of brain damage in children, something that may lead indirectly to youth violence.
- Increasing the availability and quality of child-care facilities and preschool enrichment programmes to promote healthy development and facilitate success in school.
- Attempts to improve school settings – including changing teaching practices and school policies and rules, and increasing security (for instance, by installing metal detectors or surveillance cameras).
- Creating safe routes for children on their way to and from school or other community activities.

Health care systems can contribute considerably both to responding to and preventing youth violence, by:

— improving the response and performance of emergency services;
— improving access to health services;
— training health care workers to identify and refer young people at high risk.

One type of programme that appears to be ineffective in reducing adolescent violence is where money is offered as a reward for handing in firearms to the police or other community agencies – in what is known as a ''gun buy-back programme''. There is some evidence that the types of guns handed in are not the types usually used in youth homicides (*3*).

Societal approaches

Changing the social and cultural environment to reduce violence is the strategy that is least frequently employed to prevent youth violence. Such an approach seeks to reduce economic or social barriers to development – for instance, by creating job programmes or strengthening the criminal justice system – or to modify the embedded cultural norms and values that stimulate violence.

Addressing poverty

Policies to reduce the concentration of poverty in urban areas may be effective in combating youth violence. This was shown in a housing and mobility experiment, ''Moving to Opportunity'', conducted in Maryland, United States (*181*). In a study of the impact of this programme, families from high-poverty neighbourhoods in the city of Baltimore were divided into three groups:

— families that had received subsidies, counselling and other assistance specifically to move to communities with lower levels of poverty;
— families that had received subsidies only, but with no restrictions on where they could move;

— families that had received no special assistance.

The study found that providing families with the opportunity to move to neighbourhoods with lower poverty levels substantially reduced violent behaviour by adolescents (*181*). A better understanding of the mechanisms through which neighbourhoods and peer groups influence youth violence is needed, though, in order fully to understand the implications of these results.

Tackling gun violence among youths

Changing the social environment so as to keep guns and other lethal weapons out of the hands of children and unsupervised young people may be a viable strategy for reducing the number of deaths arising from youth violence. Young people and others who should not possess guns will inevitably get hold of them. Some of these people will do so intending to commit crimes, while others – whose judgements are impaired by alcohol or drugs – will lack the proper care and responsibility that should accompany the possession of firearms.

In many countries, the means by which young people can obtain guns are already illegal. Here, a stricter enforcement of existing laws regulating illegal transfers of guns may have a high return in reducing firearm-related violence among adolescents (*182*). Very little is known, though, about the effectiveness of such an approach.

Another approach to the problem of young people possessing lethal weapons is to legislate for and enforce the safe and secure storage of firearms. This may have the effect of limiting inappropriate access directly, by making it more difficult for young people to take guns out of their homes, and indirectly, by reducing the ability of people to steal guns. Theft is a major source of guns for illegal markets, and theft and burglary are the ultimate (though not always the most recent) source through which juveniles obtain guns (*182, 183*). A longer-term strategy for reducing unauthorized access to guns on the part of children and adolescents would be to develop ''smart'' guns that do not function if anyone other than their rightful owner tries to use them (*184*). Such guns might operate by being able to recognize the owner's palm print or by needing to be in close proximity to a holster or special ring in order to function.

Some other interventions designed to control the misuse of guns have been evaluated. In 1977, a restrictive licensing law prohibiting handgun ownership by everyone except police officers, security guards and existing gun owners was introduced in Washington, DC, United States. Subsequently, the incidence of firearm-related homicides and suicides declined by 25% (*185*). The impact of this law on reducing gun-related violence specifically among young people is, however, unknown. In Cali and Bogotá, Colombia, during the 1990s, the carrying of guns was banned during periods that were known from past experience to have higher homicide rates (*186*). These included weekends after pay-days, weekends linked to holidays and election days. An evaluation found that the incidence of homicide was lower during periods when the ban on carrying firearms was in effect (*186*). The authors of the study suggested that intermittent city-wide bans on carrying of guns could be useful in preventing homicide, particularly in regions of the world with very high rates of homicide.

Other approaches

Other strategies addressing socioeconomic and cultural factors that might be effective for youth violence prevention, but that have not been adequately evaluated, include (*148, 170*):

— public information campaigns to change social norms and promote pro-social behaviour;
— efforts to reduce media violence;
— programmes to reduce income inequality;
— activities and policies to mitigate the effects of rapid social change;
— efforts to strengthen and improve police and judicial systems;
— institutional reforms of educational systems.

As is evident from the review of risk factors and prevention strategies, youth violence is caused by a complex interaction among multiple factors, and efforts to reduce this problem in a substantial way will

need to be multifaceted. As the preceding discussions have shown, there are a number of factors – some residing in the individual, others in the family and social environment – that increase the probability of aggression and violence during childhood, adolescence and early adulthood. Ideally, programmes should approach youths through multiple systems of influence (individual, family, community and society) and provide a continuum of interventions and activities spanning the stages of development. Such programmes can address co-occurring risk factors, such as low educational attainment, teenage pregnancy, unsafe sex and drug use, and thereby address the needs of youths in many spheres of their lives.

Recommendations

Deaths and injuries from youth violence constitute a major public health problem in many parts of the world. Significant variations in the magnitude of this problem exist within and between countries and regions of the world. There are a broad range of viable strategies for preventing youth violence, some of which have been shown to be particularly effective. However, no single strategy is on its own likely to be sufficient to reduce the health burden of youth violence. Instead, multiple concurrent approaches will be required and they will need to be relevant to the particular place where they are implemented. What is successful in preventing youth violence in Denmark, for instance, will not necessarily be effective in Colombia or South Africa.

Over the past two decades, a great amount has been learnt about the nature and causes of youth violence and how to prevent it. This knowledge, although based mainly on research from developed countries, provides a foundation from which to develop successful programmes to prevent youth violence. There is, however, much more to be learned about prevention. Based on the present state of knowledge, the following recommendations, if implemented, should lead to greater understanding and more effective prevention of youth violence.

Establishing data collection systems

Developing data systems for routine monitoring of trends in violent behaviour, in injuries and in deaths should form the basis of prevention efforts. Such data will provide valuable information for formulating public policies and programmes to prevent youth violence and for evaluating them. Simple approaches to the surveillance of youth violence are needed that can be applied in a wide range of cultural settings. In this regard, the following points should be given priority.

- Uniform standards for defining and measuring youth violence should be developed and incorporated into injury and violence surveillance systems. These standards should include age categories that accurately reflect the different risks among young people of being victims or perpetrators of youth violence.
- Priority should be given to developing systems to monitor deaths from violence in regions where homicide data are currently inadequate or lacking. These regions include Africa, South-East Asia and the Eastern Mediterranean, and parts of both the Americas and the Western Pacific, especially the poorer parts of these two regions.
- In parallel with surveillance, there should be special studies to establish the ratio of fatal to non-fatal cases of violence-related injuries, classified by the method of attack, age and sex of the victim. Such data can then be used to estimate the magnitude of the youth violence problem where only one type of data – such as mortality or morbidity – is available.
- All countries and regions should be encouraged to establish centres where routine information available from the health services (including emergency departments), the police and other authorities, relevant to violence, can be collated and compared. This will greatly help in formulating and implementing prevention programmes.

More scientific research

Scientific evidence on the patterns and causes of youth violence, both qualitative and quantitative, is essential for developing rational and effective responses to the problem. While an understanding of the phenomenon of violence has greatly

progressed, significant gaps remain which research in the following areas could help to fill:

— cross-culturally, on the causes, development and prevention of youth violence, in order to explain the large variations worldwide in levels of youth violence;
— on the validity and relative advantages of using official records, hospital records and self-reports to measure youth violence;
— comparing youths who commit violent offences with both youths who commit non-violent offences and those who are not involved in violent or delinquent behaviour;
— to determine which risk factors have differential effects on the persistence, escalation, de-escalation and terminating of violent offending at various ages;
— to identify factors that protect against youth violence;
— on female involvement in youth violence;
— cross-culturally, on the societal and cultural influences on youth violence;
— in longitudinal studies measuring a broad range of risk and protective factors, so as to further the knowledge of developmental pathways to youth violence;
— to provide a better understanding of how social and macroeconomic factors might effectively be modified to reduce youth violence.

In addition to the research needs listed above:

- Estimates are needed of the total cost to society of youth violence, so as better to assess the cost-effectiveness of prevention and treatment programmes.
- Institutions should be established to organize, coordinate and fund global research on youth violence.

Developing prevention strategies

Up to now, most of the resources committed to prevention have been in untested programmes. Many of these programmes have been based on questionable assumptions and delivered with little consistency or quality control. The ability effectively to prevent and control youth violence requires, above all, systematic evaluation of interventions. In particular, the following aspects relating to youth violence prevention programmes need much more research:

— longitudinal studies evaluating the long-term impact of interventions conducted in infancy or childhood;
— evaluations of the impact of interventions on the social factors associated with youth violence, such as income inequality and the concentration of poverty;
— studies on the cost-effectiveness of prevention programmes and policies.

Consistent standards are needed for evaluation studies assessing the effectiveness of youth violence programmes and policies. These standards should include:

— the application of an experimental design;
— evidence of a statistically significant reduction in the incidence of violent behaviour or in violence-related injuries;
— replication across different sites and different cultural contexts;
— evidence that the impact is sustained over time.

Disseminating knowledge

Greater efforts need to be made to apply what has been learnt about the causes and prevention of youth violence. Currently, knowledge on this subject is disseminated to practitioners and policy-makers worldwide with great difficulty, mainly because of a poor infrastructure of communication. The following areas in particular should receive greater attention:

- Global coordination is needed to develop networks of organizations that focus on information sharing, training and technical assistance.
- Resources should be allocated to the application of Internet technology. In parts of the world where this presents problems, other non-electronic forms of information-sharing should be promoted.
- International clearing houses should be set up to identify and translate relevant information

from all parts of the world, in particular from lesser-known sources.

- Research is needed on how best to implement youth violence prevention strategies and policies. Simply knowing which strategies have proved effective is not enough to ensure they will be successful when implemented.
- Youth violence prevention programmes should be integrated, wherever possible, with programmes to prevent child abuse and other forms of violence within the family.

Conclusion

The volume of information about the causes and prevention of youth violence is growing rapidly, as is the demand worldwide for this information. Meeting the huge demand will require substantial investment – to improve the mechanisms for conducting public health surveillance, to carry out all the necessary scientific research, and to create the global infrastructure for disseminating and applying what has been learnt. If the world can meet the challenge and provide the resources required, youth violence can, in the foreseeable future, begin to be regarded as a preventable public health problem.

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CHAPTER 3

Child abuse and neglect by parents and other caregivers

Background

Child abuse has for a long time been recorded in literature, art and science in many parts of the world. Reports of infanticide, mutilation, abandonment and other forms of violence against children date back to ancient civilizations (*1*). The historical record is also filled with reports of unkempt, weak and malnourished children cast out by families to fend for themselves and of children who have been sexually abused.

For a long time also there have existed charitable groups and others concerned with children's well-being who have advocated the protection of children. Nevertheless, the issue did not receive widespread attention by the medical profession or the general public until 1962, with the publication of a seminal work, *The battered child syndrome*, by Kempe et al. (*2*).

The term ''battered child syndrome'' was coined to characterize the clinical manifestations of serious physical abuse in young children (*2*). Now, four decades later, there is clear evidence that child abuse is a global problem. It occurs in a variety of forms and is deeply rooted in cultural, economic and social practices. Solving this global problem, however, requires a much better understanding of its occurrence in a range of settings, as well as of its causes and consequences in these settings.

How are child abuse and neglect defined?

Cultural issues

Any global approach to child abuse must take into account the differing standards and expectations for parenting behaviour in the range of cultures around the world. Culture is a society's common fund of beliefs and behaviours, and its concepts of how people should conduct themselves. Included in these concepts are ideas about what acts of omission or commission might constitute abuse and neglect (*3, 4*). In other words, culture helps define the generally accepted principles of child-rearing and care of children.

Different cultures have different rules about what are acceptable parenting practices. Some researchers have suggested that views on child-rearing across cultures might diverge to such an extent that agreement on what practices are abusive or neglectful may be extremely difficult to reach (*5, 6*). Nonetheless, differences in how cultures define what is abusive have more to do with emphasizing particular aspects of parental behaviour. It appears that there is general agreement across many cultures that child abuse should not be allowed, and virtual unanimity in this respect where very harsh disciplinary practices and sexual abuse are concerned (*7*).

Types of abuse

The International Society for the Prevention of Child Abuse and Neglect recently compared definitions of abuse from 58 countries and found some commonality in what was considered abusive (*7*). In 1999, the WHO Consultation on Child Abuse Prevention drafted the following definition (*8*):

> ''Child abuse or maltreatment constitutes all forms of physical and/or emotional ill-treatment, sexual abuse, neglect or negligent treatment or commercial or other exploitation, resulting in actual or potential harm to the child's health, survival, development or dignity in the context of a relationship of responsibility, trust or power.''

Some definitions focus on the behaviours or actions of adults while others consider abuse to take place if there is harm or the threat of harm to the child (*8–13*). The distinction between behaviour – regardless of the outcome – and impact or harm is a potentially confusing one if parental intent forms part of the definition. Some experts consider as abused those children who have been inadvertently harmed through the actions of a parent, while others require that harm to the child be intended for the act to be defined as abusive. Some of the literature on child abuse explicitly includes violence against children in institutional or school settings (*14–17*).

The definition given above (*8*) covers a broad spectrum of abuse. This chapter focuses primarily on acts of commission and omission by parents or caregivers that result in harm to the child. In particular, it explores the prevalence, causes and consequences of four types of child maltreatment by caregivers, namely:

— physical abuse;
— sexual abuse;
— emotional abuse;
— neglect.

Physical abuse of a child is defined as those acts of commission by a caregiver that cause actual physical harm or have the potential for harm. Sexual abuse is defined as those acts where a caregiver uses a child for sexual gratification.

Emotional abuse includes the failure of a caregiver to provide an appropriate and supportive environment, and includes acts that have an adverse effect on the emotional health and development of a child. Such acts include restricting a child's movements, denigration, ridicule, threats and intimidation, discrimination, rejection and other non-physical forms of hostile treatment.

Neglect refers to the failure of a parent to provide for the development of the child – where the parent is in a position to do so – in one or more of the following areas: health, education, emotional development, nutrition, shelter and safe living conditions. Neglect is thus distinguished from circumstances of poverty in that neglect can occur only in cases where reasonable resources are available to the family or caregiver.

The manifestations of these types of abuse are further described in Box 3.1.

The extent of the problem

Fatal abuse

Information on the numbers of children who die each year as a result of abuse comes primarily from death registries or mortality data. According to the World Health Organization, there were an estimated 57 000 deaths attributed to homicide among children under 15 years of age in 2000. Global estimates of child homicide suggest that infants and very young children are at greatest risk, with rates for the 0–4-year-old age group more than double those of 5–14-year-olds (see Statistical annex).

The risk of fatal abuse for children varies according to the income level of a country and region of the world. For children under 5 years of age living in high-income countries, the rate of homicide is 2.2 per 100 000 for boys and 1.8 per 100 000 for girls. In low- to middle-income countries the rates are 2–3 times higher – 6.1 per 100 000 for boys and 5.1 per 100 000 for girls. The highest homicide rates for children under 5 years of age are found in the WHO African Region – 17.9 per 100 000 for boys and 12.7 per 100 000 for girls. The lowest rates are seen in high-income countries in the WHO European, Eastern Mediterranean and Western Pacific Regions (see Statistical annex).

Many child deaths, however, are not routinely investigated and postmortem examinations are not carried out, which makes it difficult to establish the precise number of fatalities from child abuse in any given country. Even in wealthy countries there are problems in properly recognizing cases of infanticide and measuring their incidence. Significant levels of misclassification in the cause of death as reported on death certificates have been found, for example, in several states of the United States of America. Deaths attributed to other causes – for instance, sudden infant death syndrome or accidents – have often been shown on reinvestigation to be homicides (*18, 19*).

Despite the apparent widespread misclassification, there is general agreement that fatalities from child abuse are far more frequent than official records suggest in every country where studies of infant deaths have been undertaken (*20–22*). Among the fatalities attributed to child abuse, the most common cause of death is injury to the head, followed by injury to the abdomen (*18, 23, 24*). Intentional suffocation has also been extensively reported as a cause of death (*19, 22*).

Non-fatal abuse

Data on non-fatal child abuse and neglect come from a variety of sources, including official statistics, case reports and population-based surveys. These sources, however, differ as regards their usefulness in describing the full extent of the problem.

Official statistics often reveal little about the patterns of child abuse. This is partly because, in many countries, there are no legal or social systems with specific responsibility for recording, let alone responding to, reports of child abuse and neglect (*7*). In addition, there are differing legal and

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BOX 3.1

Manifestations of child abuse and neglect

Injuries inflicted by a caregiver on a child can take many forms. Serious damage or death in abused children is most often the consequence of a head injury or injury to the internal organs. Head trauma as a result of abuse is the most common cause of death in young children, with children in the first 2 years of life being the most vulnerable. Because force applied to the body passes through the skin, patterns of injury to the skin can provide clear signs of abuse. The skeletal manifestations of abuse include multiple fractures at different stages of healing, fractures of bones that are very rarely broken under normal circumstances, and characteristic fractures of the ribs and long bones.

The shaken infant

Shaking is a prevalent form of abuse seen in very young children. The majority of shaken children are less than 9 months old. Most perpetrators of such abuse are male, though this may be more a reflection of the fact that men, being on average stronger than women, tend to apply greater force, rather than that they are more prone than women to shake children. Intracranial haemorrhages, retinal haemorrhages and small ''chip'' fractures at the major joints of the child's extremities can result from very rapid shaking of an infant. They can also follow from a combination of shaking and the head hitting a surface. There is evidence that about one-third of severely shaken infants die and that the majority of the survivors suffer long-term consequences such as mental retardation, cerebral palsy or blindness.

The battered child

One of the syndromes of child abuse is the ''battered child''. This term is generally applied to children showing repeated and devastating injury to the skin, skeletal system or nervous system. It includes children with multiple fractures of different ages, head trauma and severe visceral trauma, with evidence of repeated infliction. Fortunately, though the cases are tragic, this pattern is rare.

Sexual abuse

Children may be brought to professional attention because of physical or behavioural concerns that, on further investigation, turn out to result from sexual abuse. It is not uncommon for children who have been sexually abused to exhibit symptoms of infection, genital injury, abdominal pain, constipation, chronic or recurrent urinary tract infections or behavioural problems. To be able to detect child sexual abuse requires a high index of suspicion and familiarity with the verbal, behavioural and physical indicators of abuse. Many children will disclose abuse to caregivers or others spontaneously, though there may also be indirect physical or behavioural signs.

Neglect

There exist many manifestations of child neglect, including non-compliance with health care recommendations, failure to seek appropriate health care, deprivation of food resulting in hunger, and the failure of a child physically to thrive. Other causes for concern include the exposure of children to drugs and inadequate protection from environmental dangers. In addition, abandonment, inadequate supervision, poor hygiene and being deprived of an education have all been considered as evidence of neglect.

cultural definitions of abuse and neglect between countries. There is also evidence that only a small proportion of cases of child maltreatment are reported to authorities, even where mandatory reporting exists (*25*).

Case series have been published in many countries. They are important for guiding local action on child abuse, and raising awareness and concern among the public and professionals (*26–32*). Case series can reveal similarities between the experiences in different countries and suggest new hypotheses. However, they are not particularly helpful in assessing the relative importance of possible risk or protective factors in different cultural contexts (*33*).

Population-based surveys are an essential element for determining the true extent of non-fatal child abuse. Recent surveys of this type have been completed in a number of countries, including Australia, Brazil, Canada, Chile, China, Costa Rica, Egypt, Ethiopia, India, Italy, Mexico, New Zealand, Nicaragua, Norway, Philippines, the Republic of Korea, Romania, South Africa, the United States and Zimbabwe (*12, 14–17, 26, 34–43*).

Physical abuse

Estimates of physical abuse of children derived from population-based surveys vary considerably. A 1995 survey in the United States asked parents how they disciplined their children (*12*). An estimated rate of physical abuse of 49 per 1000 children was obtained from this survey when the following behaviours were included: hitting the child with an object, other than on the buttocks; kicking the child; beating the child; and threatening the child with a knife or gun.

Available research suggests that the rates for many other countries are no lower, and may be indeed higher than the estimates of physical abuse in the United States. The following findings, among others around the world, have emerged recently:

- In a cross-sectional survey of children in Egypt, 37% reported being beaten or tied up by their parents and 26% reported physical injuries such as fractures, loss of consciousness or permanent disability as a result of being beaten or tied up (*17*).
- In a recent study in the Republic of Korea, parents were questioned about their behaviour towards their children. Two-thirds of the parents reported whipping their children and 45% confirmed that they had hit, kicked or beaten them (*26*).
- A survey of households in Romania found that 4.6% of children reported suffering severe and frequent physical abuse, including being hit with an object, being burned or being deprived of food. Nearly half of Romanian parents admitted to beating their children ''regularly'' and 16% to beating their children with objects (*34*).
- In Ethiopia, 21% of urban schoolchildren and 64% of rural schoolchildren reported bruises or swellings on their bodies resulting from parental punishment (*14*).

Data that are more comparable come from the World Studies of Abuse in the Family Environment (WorldSAFE) project, a cross-national collaborative study. Investigators from Chile, Egypt, India and the Philippines administered a common core protocol to population-based samples of mothers in each country to establish comparable incidence rates for harsh and more moderate forms of child discipline. Specifically, the researchers measured the frequency of parental discipline behaviours, without labelling harsh discipline as abusive, using the Parent–Child Conflict Tactics Scale (*9–12, 40*). Other data to determine risk and protective factors were also routinely collected in these studies.

Table 3.1 presents the findings, from the four countries involved in this study, on the relative incidence of self-reported parental discipline behaviours. Identically worded questions were used in each country. The results are compared to those from a national survey conducted in the United States using the same instrument (*12*). It is clear that harsh parental punishment is not confined to a few places or a single region of the world. Parents in Egypt, rural areas of India, and the Philippines frequently reported, as a punishment, hitting their children with an object on a part of the

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TABLE 3.1

Rates of harsh or moderate forms of physical punishment in the previous 6 months as reported by mothers, WorldSAFE study

Type of punishment	Incidence (%)				
	Chile	Egypt	India[a]	Philippines	USA
Severe physical punishment					
Hit the child with an object (not on buttocks)	4	26	36	21	4
Kicked the child	0	2	10	6	0
Burned the child	0	2	1	0	0
Beat the child	0	25	—[b]	3	0
Threatened the child with a knife or gun	0	0	1	1	0
Choked the child	0	1	2	1	0
Moderate physical punishment					
Spanked buttocks (with hand)	51	29	58	75	47
Hit the child on buttocks (with object)	18	28	23	51	21
Slapped the child's face or head	13	41	58	21	4
Pulled the child's hair	24	29	29	23	—[b]
Shook the child[c]	39	59	12	20	9
Hit the child with knuckles	12	25	28	8	—[b]
Pinched the child	3	45	17	60	5
Twisted the child's ear	27	31	16	31	—[b]
Forced the child to kneel or stand in an uncomfortable position	0	6	2	4	—[b]
Put hot pepper in the child's mouth	0	2	3	1	—[b]

[a] Rural areas.
[b] Question not asked in the survey.
[c] Children aged 2 years or older.

body other than the buttocks at least once during the previous 6 months. This behaviour was also reported in Chile and the United States, though at a much lower rate. Harsher forms of violence – such as choking children, burning them or threatening them with a knife or gun – were much less frequently reported.

Similar parental self-reports from other countries confirm that harsh physical punishment of children by their parents exists in significant amounts wherever it has been examined. In Italy, based on the Conflict Tactics Scales, the incidence of severe violence was 8% (*39*). Tang indicated an annual rate of severe violence against children, as reported by the parents, of 461 per 1000 in China (Hong Kong SAR) (*43*).

Another study, comparing rates of violence against primary school-aged children in China and the Republic of Korea, also used the Conflict Tactics Scales, though with the questions being directed at the children rather than their parents (*41*). In China, the rate of severe violence reported by the children was 22.6%, while in the Republic of Korea it was 51.3%.

Data from the WorldSAFE study are also illuminating about patterns of more ''moderate'' forms of physical discipline in different countries (see Table 3.1). Moderate discipline is not universally agreed to be abusive, though some professionals and parents regard such forms of discipline as unacceptable. In this area, the WorldSAFE study suggested a wider divergence among societies and cultures. Spanking children on the buttocks was the most common disciplinary measure reported in each country, with the exception of Egypt, where other measures such as shaking children, pinching them, or slapping them on the face or head were more frequently used as punishment. Parents in rural areas of India, though, reported slapping their children on the face or head about as often as slapping them on the buttocks, while in the other countries slapping children on the face or head occurred less often.

Severe and more moderate forms of discipline are not limited to the family or home environment. A substantial amount of harsh punishment occurs in schools and other institutions at the hands of teachers and others responsible for the care of children (see Box 3.2).

Sexual abuse

Estimates of the prevalence of sexual abuse vary greatly depending on the definitions used and the way in which information is collected. Some surveys are conducted with children, others with adolescents and adults reporting on their childhood, while others question parents about what their children may have experienced. These three different methods can produce very different results. For example, the survey of Romanian

BOX 3.2

Corporal punishment

Corporal punishment of children — in the form of hitting, punching, kicking or beating — is socially and legally accepted in most countries. In many, it is a significant phenomenon in schools and other institutions and in penal systems for young offenders.

The United Nations Convention on the Rights of the Child requires states to protect children from ''all forms of physical or mental violence'' while they are in the care of parents and others, and the United Nations Committee on the Rights of the Child has underlined that corporal punishment is incompatible with the Convention.

In 1979, Sweden became the first country to prohibit all forms of corporal punishment of children. Since then, at least 10 further states have banned it. Judgements from constitutional or supreme courts condemning corporal punishment in schools and penal systems have also been handed down — including in Namibia, South Africa and Zimbabwe — and, in 2000, Israel's supreme court declared all corporal punishment unlawful. Ethiopia's 1994 constitution asserts the right of children to be free of corporal punishment in schools and institutions of care. Corporal punishment in schools has also been banned in New Zealand, the Republic of Korea, Thailand and Uganda.

Nevertheless, surveys indicate that corporal punishment remains legal in at least 60 countries for juvenile offenders, and in at least 65 countries in schools and other institutions. Corporal punishment of children is legally acceptable in the home in all but 11 countries. Where the practice has not been persistently confronted by legal reform and public education, the few existing prevalence studies suggest that it remains extremely common.

Corporal punishment is dangerous for children. In the short term, it kills thousands of children each year and injures and handicaps many more. In the longer term, a large body of research has shown it to be a significant factor in the development of violent behaviour, and it is associated with other problems in childhood and later life.

families already mentioned found that 0.1% of parents admitted to having sexually abused their children, while 9.1% of children reported having suffered sexual abuse (*34*). This discrepancy might be explained in part by the fact that the children were asked to include sexual abuse by people other than their parents.

Among published studies of adults reporting retrospectively on their own childhood, prevalence rates of childhood sexual abuse among men range from 1% (*44*) – using a narrow definition of sexual contact involving pressure or force – to 19% (*38*), where a broader definition was employed. Lifetime prevalence rates for childhood sexual victimization among adult women range from 0.9% (*45*), using rape as the definition of abuse, to 45% (*38*) with a much wider definition. Findings reported in international studies conducted since 1980 reveal a mean lifetime prevalence rate of childhood sexual victimization of 20% among women and of 5–10% among men (*46, 47*).

These wide variations in published prevalence estimates could result either from real differences in risk prevailing in different cultures or from differences in the way the studies were conducted (*46*). Including abuse by peers in the definition of child sexual abuse can increase the resulting prevalence by 9% (*48*) and including cases where physical contact does not occur can raise the rates by around 16% (*49*).

Emotional and psychological abuse

Psychological abuse against children has been allotted even less attention globally than physical and sexual abuse. Cultural factors appear strongly to influence the non-physical techniques that parents

choose to discipline their children – some of which may be regarded by people from other cultural backgrounds as psychologically harmful. Defining psychological abuse is therefore very difficult. Furthermore, the consequences of psychological abuse, however defined, are likely to differ greatly depending on the context and the age of the child.

There is evidence to suggest that shouting at children is a common response by parents across many countries. Cursing children and calling them names appears to vary more greatly. In the five countries of the WorldSAFE study, the lowest incidence rate of calling children names in the previous 6 months was 15% (see Table 3.2). The practices of threatening children with abandonment or with being locked out of the house, however, varied widely among the countries. In the Philippines, for example, threats of abandonment were frequently reported by mothers as a disciplinary measure. In Chile, the rate of using such threats was much lower, at about 8%.

TABLE 3.2

Rates of verbal or psychological punishment in the previous 6 months as reported by mothers, WorldSAFE study

Verbal or psychological punishment	Incidence (%)				
	Chile	Egypt	India[a]	Philippines	USA
Yelled or screamed at the child	84	72	70	82	85
Called the child names	15	44	29	24	17
Cursed at the child	3	51	—[b]	0	24
Refused to speak to the child	17	48	31	15	—[b]
Threatened to kick the child out of the household	5	0	—[b]	26	6
Threatened abandonment	8	10	20	48	—b
Threatened evil spirits	12	6	20	24	—[b]
Locked the child out of the household	2	1	—[b]	12	—[b]

[a] Rural areas.

[b] Question not asked in the survey.

Data on the extent that non-violent and non-abusive disciplinary methods are employed by caregivers in different cultures and parts of the world are extremely scarce. Limited data from the WorldSAFE project suggest that the majority of parents use non-violent disciplinary practices. These include explaining to children why their behaviour was wrong and telling them to stop, withdrawing privileges and using other non-violent methods to change problem behaviour (see Table 3.3). Elsewhere, in Costa Rica, for instance, parents acknowledged using physical punishment to discipline children, but reported it as their least preferred method (*50*).

Neglect

Many researchers include neglect or harm caused by a lack of care on the part of parents or other caregivers as part of the definition of abuse (*29, 51–53*). Conditions such as hunger and poverty are sometimes included within the definition of neglect. Because definitions vary and laws on reporting abuse do not always require the mandatory reporting of neglect, it is difficult to estimate the global dimensions of the problem or meaningfully to compare rates between countries. Little research, for instance, has been done on how children and parents or other caregivers may differ in defining neglect.

In Kenya, abandonment and neglect were the most commonly cited aspects of child abuse when adults in the community were questioned on the subject (*51*). In this study, 21.9% of children reported that they had been neglected by their parents. In Canada, a national study of cases reported to child welfare services found that, among the substantiated cases of neglect, 19% involved physical neglect, 12% abandonment, 11% educational neglect, and 48% physical harm resulting from a parent's failure to provide adequate supervision (*54*).

What are the risk factors for child abuse and neglect?

A variety of theories and models have been developed to explain the occurrence of abuse within families. The most widely adopted explanatory model is the ecological model, described in Chapter 1. As applied to child abuse and neglect, the ecological model considers a number of factors, including the characteristics of the individual child and his or her family, those of the caregiver or perpetrator, the

TABLE 3.3
Rates of non-violent disciplinary practices in the previous 6 months as reported by mothers, WorldSAFE study

Non-violent discipline	Incidence (%)				
	Chile	Egypt	India[a]	Philippines	USA
Explained why the behaviour was wrong	91	80	94	90	94
Took privileges away	60	27	43	3	77
Told child to stop	88	69	—[b]	91	—[b]
Gave child something to do	71	43	27	66	75
Made child stay in one place	37	50	5	58	75

[a] Rural areas.
[b] Question not asked in the survey.

nature of the local community, and the social, economic and cultural environment (*55, 56*).

The limited research in this area suggests that some factors are fairly consistent, over a range of countries, in conferring risk. It is important to note, though, that these factors, which are listed below, may be only statistically associated and not causally linked (*6*).

Factors increasing a child's vulnerability

A number of studies, mostly from the developed world, have suggested that certain characteristics of children increase the risk for abuse.

Age

Vulnerability to child abuse – whether physical, sexual or through neglect – depends in part on a child's age (*14, 17, 57, 58*). Fatal cases of physical abuse are found largely among young infants (*18, 20, 21, 28*). In reviews of infant deaths in Fiji, Finland, Germany and Senegal, for instance, the majority of victims were less than 2 years of age (*20, 24, 28, 59*).

Young children are also at risk for non-fatal physical abuse, though the peak ages for such abuse vary from country to country. For example, rates of non-fatal physical abuse peak for children at 3–6 years of age in China, at 6–11 years of age in India and between 6 and 12 years of age in the United States (*11, 40, 43*). Sexual abuse rates, on the other hand, tend to rise after the onset of puberty, with the highest rates occurring during adolescence (*15, 47, 60*). Sexual abuse, however, can also be directed at young children.

Sex

In most countries, girls are at higher risk than boys for infanticide, sexual abuse, educational and nutritional neglect, and forced prostitution (see also Chapter 6). Findings from several international studies show rates of sexual abuse to be 1.5–3 times higher among girls than boys (*46*). Globally, more than 130 million children between the ages of 6 and 11 years are not in school, 60% of whom are girls (*61*). In some countries, girls are either not allowed to receive schooling or else are kept at home to help look after their siblings or to assist the family economically by working.

Male children appear to be at greater risk of harsh physical punishment in many countries (*6, 12, 16, 40, 62*). Although girls are at increased risk for infanticide in many places, it is not clear why boys are subjected to harsher physical punishment. It may be that such punishment is seen as a preparation for adult roles and responsibilities, or else that boys are considered to need more physical discipline. Clearly, the wide cultural gaps that exist between different societies with respect to the role of women and the values attached to male and female children could account for many of these differences.

Special characteristics

Premature infants, twins and handicapped children have been shown to be at increased risk for physical abuse and neglect (*6, 53, 57, 63*). There are conflicting findings from studies on the importance of mental retardation as a risk factor. It is believed that low birth weight, prematurity, illness, or physical or mental handicaps in the infant or child interfere with attachment and bonding and may make the child more vulnerable to abuse (*6*). However, these characteristics do not appear to be major risk factors for abuse when other factors are considered, such as parental and societal variables (*6*).

Caregiver and family characteristics

Research has linked certain characteristics of the caregiver, as well as features of the family environ-

ment, to child abuse and neglect. While some factors – including demographic ones – are related to variation in risk, others are related to the psychological and behavioural characteristics of the caregiver or to aspects of the family environment that may compromise parenting and lead to child maltreatment.

Sex

Whether abusers are more likely to be male or female, depends, in part, on the type of abuse. Research conducted in China, Chile, Finland, India and the United States suggests that women report using more physical discipline than men (*12, 40, 43, 64, 65*). In Kenya, reports from children also show more violence by mothers than fathers (*51*). However, men are the most common perpetrators of life-threatening head injuries, abusive fractures and other fatal injuries (*66–68*).

Sexual abusers of children, in the cases of both female and male victims, are predominantly men in many countries (*46, 69, 70*). Studies have consistently shown that in the case of female victims of sexual abuse, over 90% of the perpetrators are men, and in the case of male victims, between 63% and 86% of the perpetrators are men (*46, 71, 72*).

Family structure and resources

Physically abusive parents are more likely to be young, single, poor and unemployed and to have less education than their non-abusing counterparts. In both developing and industrialized countries, poor, young, single mothers are among those at greatest risk for using violence towards their children (*6, 12, 65, 73*). In the United States, for instance, single mothers are three times more likely to report using harsh physical discipline than mothers in two-parent families (*12*). Similar findings have been reported in Argentina (*73*).

Studies from Bangladesh, Colombia, Italy, Kenya, Sweden, Thailand and the United Kingdom have also found that low education and a lack of income to meet the family's needs increase the potential of physical violence towards children (*39, 52, 62, 67, 74–76*), though exceptions to this pattern have been noted elsewhere (*14*). In a study of Palestinian families, lack of money for the child's needs was one of the primary reasons given by parents for psychologically abusing their children (*77*).

Family size and household composition

The size of the family can also increase the risk for abuse. A study of parents in Chile, for example, found that families with four or more children were three times more likely to be violent towards their children than parents with fewer children (*78*). However, it is not always simply the size of the family that matters. Data from a range of countries indicate that household overcrowding increases the risk of child abuse (*17, 41, 52, 57, 74, 79*). Unstable family environments, in which the composition of the household frequently changes as family members and others move in and out, are a feature particularly noted in cases of chronic neglect (*6, 57*).

Personality and behavioural characteristics

A number of personality and behavioural characteristics have been linked, in many studies, to child abuse and neglect. Parents more likely to abuse their children physically tend to have low self-esteem, poor control of their impulses, mental health problems, and to display antisocial behaviour (*6, 67, 75, 76, 79*). Neglectful parents have many of these same problems and may also have difficulty planning important life events such as marriage, having children or seeking employment. Many of these characteristics compromise parenting and are associated with disrupted social relationships, an inability to cope with stress and difficulty in reaching social support systems (*6*).

Abusive parents may also be uninformed and have unrealistic expectations about child development (*6, 57, 67, 80*). Research has found that abusive parents show greater irritation and annoyance in response to their children's moods and behaviour, that they are less supportive, affectionate, playful and responsive to their children, and that they are more controlling and hostile (*6, 39*).

Prior history of abuse

Studies have shown that parents maltreated as children are at higher risk of abusing their own

children (*6, 58, 67, 81, 82*). The relationship here is complex, though (*81–83*), and some investigations have suggested that the majority of abusing parents were not, in fact, themselves abused (*58*). While empirical data suggest that there is indeed a relationship, the importance of this risk factor may have been overstated. Other factors that have been linked to child abuse – such as young parental age, stress, isolation, overcrowding in the home, substance abuse and poverty – may be more predictive.

Violence in the home

Increasing attention is being given to intimate partner violence and its relationship to child abuse. Data from studies in countries as geographically and culturally distinct as China, Colombia, Egypt, India, Mexico, the Philippines, South Africa and the United States have all found a strong relationship between these two forms of violence (*6, 15, 17, 37, 40, 43, 67*). In a recent study in India, the occurrence of domestic violence in the home doubled the risk of child abuse (*40*). Among known victims of child abuse, 40% or more have also reported domestic violence in the home (*84*). In fact, the relationship may be even stronger, since many agencies charged with protecting children do not routinely collect data on other forms of violence in families.

Other characteristics

Stress and social isolation of the parent have also been linked to child abuse and neglect (*6, 39, 57, 73, 85*). It is believed that stress resulting from job changes, loss of income, health problems or other aspects of the family environment can heighten the level of conflict in the home and the ability of members to cope or find support. Those better able to find social support may be less likely to abuse children, even when other known risk factors are present. In a case–control study in Buenos Aires, Argentina, for instance, children living in single-parent families were at significantly greater risk for abuse than those in two-parent families. The risk for abuse was lower, though, among those who were better able to gain access to social support (*73*).

Child abuse has also been linked in many studies to substance abuse (*6, 37, 40, 67, 76*), though further research is needed to disentangle the independent effects of substance abuse from the related issues of poverty, overcrowding, mental disorders and health problems associated with this behaviour.

Community factors

Poverty

Numerous studies across many countries have shown a strong association between poverty and child maltreatment (*6, 37, 40, 62, 86–88*). Rates of abuse are higher in communities with high levels of unemployment and concentrated poverty (*89–91*). Such communities are also characterized by high levels of population turnover and overcrowded housing. Research shows that chronic poverty adversely affects children through its impact on parental behaviour and the availability of community resources (*92*). Communities with high levels of poverty tend to have deteriorating physical and social infrastructures and fewer of the resources and amenities found in wealthier communities.

Social capital

Social capital represents the degree of cohesion and solidarity that exists within communities (*85*). Children living in areas with less ''social capital'' or social investment in the community appear to be at greater risk of abuse and have more psychological or behavioural problems (*85*). On the other hand, social networks and neighbourhood connections have been shown to be protective of children (*4, 58, 93*). This is true even for children with a number of risk factors – such as poverty, violence, substance abuse and parents with low levels of educational achievement – who appear to be protected by high levels of social capital (*85*).

Societal factors

A range of society-level factors are considered to have important influences on the well-being of children and families. These factors – not examined to date in most countries as risk factors for child abuse – include:

- The role of cultural values and economic forces in shaping the choices facing families and shaping their response to these forces.
- Inequalities related to sex and income – factors present in other types of violence and likely to be related to child maltreatment as well.
- Cultural norms surrounding gender roles, parent–child relationships and the privacy of the family.
- Child and family policies – such as those related to parental leave, maternal employment and child care arrangements.
- The nature and extent of preventive health care for infants and children, as an aid in identifying cases of abuse in children.
- The strength of the social welfare system – that is, the sources of support that provide a safety net for children and families.
- The nature and extent of social protection and the responsiveness of the criminal justice system.
- Larger social conflicts and war.

Many of these broader cultural and social factors can affect the ability of parents to care for children – enhancing or lessening the stresses associated with family life and influencing the resources available to families.

The consequences of child abuse

Health burden

Ill health caused by child abuse forms a significant portion of the global burden of disease. While some of the health consequences have been researched (*21, 35, 72, 94–96*), others have only recently been given attention, including psychiatric disorders and suicidal behaviour (*53, 97, 98*). Importantly, there is now evidence that major adult forms of illness – including ischaemic heart disease, cancer, chronic lung disease, irritable bowel syndrome and fibromyalgia – are related to experiences of abuse during childhood (*99–101*). The apparent mechanism to explain these results is the adoption of behavioural risk factors such as smoking, alcohol abuse, poor diet and lack of exercise. Research has also highlighted important direct acute and long-term consequences (*21, 23, 99–103*) (see Table 3.4).

TABLE 3.4
Health consequences of child abuse

Physical
Abdominal/thoracic injuries
Brain injuries
Bruises and welts
Burns and scalds
Central nervous system injuries
Disability
Fractures
Lacerations and abrasions
Ocular damage
Sexual and reproductive
Reproductive health problems
Sexual dysfunction
Sexually transmitted diseases, including HIV/AIDS
Unwanted pregnancy
Psychological and behavioural
Alcohol and drug abuse
Cognitive impairment
Delinquent, violent and other risk-taking behaviours
Depression and anxiety
Developmental delays
Eating and sleep disorders
Feelings of shame and guilt
Hyperactivity
Poor relationships
Poor school performance
Poor self-esteem
Post-traumatic stress disorder
Psychosomatic disorders
Suicidal behaviour and self-harm
Other longer-term health consequences
Cancer
Chronic lung disease
Fibromyalgia
Irritable bowel syndrome
Ischaemic heart disease
Liver disease
Reproductive health problems such as infertility

Similarly, there are many studies demonstrating short-term and long-term psychological damage (*35, 45, 53, 94, 97*). Some children have a few symptoms that do not reach clinical levels of concern, or else are at clinical levels but not as high as in children generally seen in clinical settings. Other survivors have serious psychiatric symptoms, such as depression, anxiety, substance abuse, aggression, shame or cognitive impairments. Finally, some children meet the full criteria for psychiatric illnesses that include post-traumatic

stress disorder, major depression, anxiety disorders and sleep disorders (*53, 97, 98*). A recent longitudinal cohort study in Christchurch, New Zealand, for instance, found significant associations between sexual abuse during childhood and subsequent mental health problems such as depression, anxiety disorders and suicidal thoughts and behaviour (*97*).

Physical, behavioural and emotional manifestations of abuse vary between children, depending on the child's stage of development when the abuse occurs, the severity of the abuse, the relationship of the perpetrator to the child, the length of time over which the abuse continues and other factors in the child's environment (*6, 23, 72, 95–101*).

Financial burden

The financial costs associated with both the short-term and long-term care of victims form a significant proportion of the overall burden created by child abuse and neglect. Included in the calculation are the direct costs associated with treatment, visits to the hospital and doctor, and other health services. A range of indirect costs are related to lost productivity, disability, decreased quality of life and premature death. There are also costs borne by the criminal justice system and other institutions, including:

- — expenditures related to apprehending and prosecuting offenders;
- — the costs to social welfare organizations of investigating reports of maltreatment and protecting children from abuse;
- — costs associated with foster care;
- — costs to the education system;
- — costs to the employment sector arising from absenteeism and low productivity.

Available data from a few developed countries illustrate the potential financial burden. In 1996, the financial cost associated with child abuse and neglect in the United States was estimated at some US$12.4 billion (*8*). This figure included estimates for future lost earnings, educational costs and adult mental health services. In the United Kingdom, an estimated annual cost of nearly US$1.2 billion has been cited for immediate welfare and legal services alone (*104*). The costs of preventive interventions are likely to be exceeded many times over by the combined total of short-term and long-term costs of child abuse and neglect to individuals, families and society.

What can be done to prevent child abuse and neglect?

While the prevention of child abuse is almost universally proclaimed to be an important social policy, surprisingly little work has been done to investigate the effectiveness of preventive interventions. Careful work has been done on a few interventions, such as home visitation (*105–107*), but many more interventions in this field lack adequate evaluation (*108*).

The majority of programmes focus on victims or perpetrators of child abuse and neglect. Very few emphasize primary prevention approaches aimed at preventing child abuse and neglect from occurring in the first place. The more common responses are described below.

Family support approaches

Training in parenting

A number of interventions for improving parenting practices and providing family support have been developed. These types of programmes generally educate parents on child development and help them improve their skills in managing their children's behaviour. While most of these programmes are intended for use with high-risk families or those families in which abuse has already occurred, it is increasingly considered that providing education and training in this area for all parents or prospective parents can be beneficial. In Singapore, for instance, education and training in parenting begins in secondary school, with ''preparation for parenthood'' classes. Students learn about child care and development, and gain direct experience by working with young children at preschool and child care centres (*8*).

For families in which child abuse has already occurred, the principal aim is to prevent further abuse, as well as other negative outcomes for the child, such as emotional problems or delayed development. While evaluations of programmes

on education and training in parenting have shown promising results in reducing youth violence, few studies have specifically examined the impact of such programmes on rates of child abuse and neglect. Instead, for many of the interventions, proximal outcomes – such as parental competence and skills, parent–child conflict and parental mental health – have been used to measure their effectiveness.

As an example, Wolfe et al. evaluated a behavioural intervention to provide training in parenting, specifically designed for families considered at risk (*109*). Mother–child pairs were randomly assigned to either the intervention or a comparison group. Mothers who received the training in parenting reported fewer behavioural problems with their children and fewer adjustment problems associated with potential maltreatment compared with mothers in the comparison group. Furthermore, a follow-up evaluation by the caseworkers showed that there was a lower risk of maltreatment by the mothers who had received the training in parenting.

Home visitation and other family support programmes

Home visitation programmes bring community resources to families in their homes. This type of intervention has been identified as one of the most promising for preventing a number of negative outcomes, including youth violence (see Chapter 2) and child abuse (*105–107*). During the home visits, information, support and other services to improve the functioning of the family are offered. A number of different models for home visitation have been developed and studied. In some, home visits are provided to all families, regardless of their risk status, whereas others focus on families at risk for violence, such as first-time parents or single and adolescent parents living in communities with high rates of poverty.

In a survey of more than 1900 home visitation programmes, Wasik & Roberts (*110*) identified 224 that primarily provided services for abused and neglected children. Among these, the enhancement of parenting skills and raising the parents' level of coping were considered the most important services, followed by emotional support. Families were generally visited weekly or every 2 weeks, with the services provided over a period ranging from 6 months to 2 years.

An example of such a programme is the one run by the Parent Centre in Cape Town, South Africa. Home visitors are recruited from the community, trained by the centre and supervised by professional social workers. Families are visited monthly during the prenatal period, weekly for the first 2 months after birth, from then on once every 2 weeks up to 2 months of age and then monthly until the baby reaches 6 months. At that time, visits may continue or be terminated, depending on the supervisor's assessment. Families may be referred to other agencies for services where this is felt appropriate.

One of the few studies on the long-term effects of home visitation on child abuse and neglect was conducted by Olds et al. (*106*). They concluded that, throughout the 15-year period after the birth of a first child, women who were visited by nurses during their pregnancy and during their child's infancy were less likely to be identified as perpetrators of child abuse than women who were not visited.

Intensive family preservation services

This type of service is designed to keep the family together and to prevent children from being placed in substitute care. Targeted towards families in which child maltreatment has been confirmed, the intervention is short (lasting a few weeks or months) and intense, with generally 10–30 hours a week devoted to a particular family, either in the home or somewhere else that is familiar to the child. A broad array of services are usually offered, according to the needs of the family, including various forms of therapy and more practical services such as temporary rent subsidies.

An example of such a programme in the United States is Homebuilders, an intensive in-home family crisis intervention and education programme (*111*). Families who have one or more children in imminent danger of being placed in

care are referred to this programme by state workers. Over a period of 4 months, the families receive intensive services from therapists who are on call 24 hours a day. The wide range of services being offered includes help with basic needs such as food and shelter and with learning new skills.

Evaluations of this type of intervention have been limited and their findings somewhat inconclusive, mainly because of the fact that programmes offer a large variety of services and relatively few studies have included a control group. There is some evidence suggesting that programmes to preserve the family unit may help avoid placing children in care, at least in the short term. However, there is little to suggest that the underlying family dysfunction at the root of the problem can be resolved with short, intensive services of this type. One meta-analysis of several different intensive family preservation programmes found that those with high levels of participant involvement, using an approach that built on the strengths of the family and involved an element of social support, produced better results than programmes without these components (*112*).

Health service approaches

Screening by health care professionals

Health care professionals have a key part to play in identifying, treating and referring cases of abuse and neglect and in reporting suspected cases of maltreatment to the appropriate authorities. It is vital that cases of child maltreatment are detected early on, so as to minimize the consequences for the child and to launch the necessary services as soon as possible.

Screening, traditionally, is the identification of a health problem before signs and symptoms appear. In the case of child abuse and neglect, screening could present problems, since it would need to rely on information obtained directly from the perpetrator or from observers. For this reason, relatively few approaches to screening have been described, and for the most part the focus has been on improving the early recognition by health care providers of child abuse and neglect, primarily through greater levels of training and education.

Training for health care professionals

Studies in various countries have highlighted the need for the continuing education of health care professionals on the detection and reporting of early signs and symptoms of child abuse and neglect (*113–115*). Consequently, a number of health care organizations have developed training programmes so as to improve both the detection and reporting of abuse and neglect, and the knowledge among health care workers of available community services. In the United States, for example, the American Medical Association and the American Academy of Pediatrics have produced diagnostic and treatment guidelines for child maltreatment (*116*) and sexual abuse (*117*). In New York state, health care professionals are required to take a 2-hour course on identifying and reporting child abuse and neglect as a prerequisite to gain a licence (*118*). There have also been moves in several European countries and elsewhere to increase such training for health care professionals (*7, 119–121*).

The detection of child abuse and neglect, however, is not always straightforward (*122–124*). Specific interview techniques and types of physical examination are generally required. Medical professionals should also be alert to the presence of family or other risk factors that might suggest child abuse.

To maintain a continuing and dynamic process of education, some researchers have suggested multicomponent, structured curricula for health professionals, according to their particular level of involvement with child abuse cases (*125*). Under this proposal, separate but integrated courses of training would be developed for medical students and physicians in training, on the one hand, and for those with a specific interest in child abuse on the other.

Evaluations of training programmes have focused principally on the health care worker's knowledge of child abuse and behaviour. The impact of training programmes on other outcomes, such as improved care and referral for children, is not known.

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Therapeutic approaches

Responses to child abuse and neglect depend on many factors, including the age and developmental level of the child and the presence of environmental stress factors. For this reason, a broad range of therapeutic services have been designed for use with individuals. Therapeutic programmes have been set up throughout the world, including in Argentina, China (Hong Kong SAR), Greece, Panama, the Russian Federation, Senegal and Slovakia (*7*).

Services for victims

A review of treatment programmes for physically abused children found that therapeutic day care – with an emphasis on improving cognitive and developmental skills – was the most popular approach (*126*). Therapeutic day care has been advocated for a range of conditions related to abuse, such as emotional, behavioural or attachment-related problems and cognitive or developmental delays. The approach incorporates therapy and specific treatment methods in the course of the child's daily activities at a child care facility. Most programmes of this type also include therapy and education for the parents.

An example of a specific treatment method for socially withdrawn, abused children has been described by Fantuzzo et al. (*127*). Maltreated preschool children who were highly withdrawn socially were placed in playgroups together with children with higher levels of social functioning. The better-functioning children were taught to act as role models for the more withdrawn children and to encourage them to participate in play sessions. Their tasks included making appropriate verbal and physical overtures to the withdrawn children – for instance, offering a toy. Improvements in the social behaviour of the withdrawn children were observed, though the long-term effects of this strategy were not assessed. Most of the other treatment programmes described in the review mentioned above have also had little or no evaluation (*126*).

As with physical abuse, the manifestations of sexual abuse can vary considerably, depending on a number of factors, such as the individual characteristics of the victim, the relationship of the perpetrator to the victim and the circumstances of the abuse. Consequently, a wide variety of intervention approaches and treatment methods have been adopted to treat child victims of sexual abuse, including individual, group and family therapy (*128–131*). Although limited research suggests that the mental health of victims is improved as a result of such interventions, there is considerably less information on other benefits.

Services for children who witness violence

One of the more recent additions to the collection of intervention strategies is services for children who witness domestic violence (*132–134*). Research has shown that such exposure may have numerous negative consequences. For instance, children who witness violence are more likely to reproduce, as adults, dysfunctional relationships within their own families.

As with cases of direct physical or sexual assault, children who witness violence may exhibit a range of symptoms, including behavioural, emotional or social problems and delays in cognitive or physical development, although some may not develop problems at all. Given this variability, different intervention strategies and treatment methods have been developed, taking into account the developmental age of the child. The evidence to date for the effectiveness of these programmes is limited and often contradictory. Two evaluations, for example, of the same 10-week group counselling programme produced differing results. In one, the children in the intervention group were able to describe more skills and strategies to avoid getting involved in violent conflicts between their parents and to seek out support than the children in the comparison group, while in the other, no differences between treatment and comparison groups were observed (*135, 136*).

Services for adults abused as children

A number of studies have found a link between a history of child abuse and a range of conditions, including substance abuse, mental health problems

and alcohol dependence (*96–99, 137*). In addition, victims of child abuse may not be identified as such until later in life and may not have symptoms until long after the abuse has occurred. For these reasons, there has been a recent increase in services for adults who were abused as children, and particularly in referrals to mental health services. Unfortunately, few evaluations have been published on the impact of interventions for adults who were abused during childhood. Most of the studies that have been conducted have focused on girls who were abused by their fathers (*138*).

Legal and related remedies

Mandatory and voluntary reporting

The reporting by health professionals of suspected child abuse and neglect is mandated by law in various countries, including Argentina, Finland, Israel, Kyrgyzstan, the Republic of Korea, Rwanda, Spain, Sri Lanka and the United States. Even so, relatively few countries have mandatory reporting laws for child abuse and neglect. A recent worldwide survey found that, of the 58 countries that responded, 33 had mandatory reporting laws in place and 20 had voluntary reporting laws (*7*).

The reasoning behind the introduction of mandatory reporting laws was that early detection of abuse would help forestall the occurrence of serious injuries, increase the safety of victims by relieving them of the necessity to make reports, and foster coordination between legal, health care and service responses.

In Brazil, there is mandatory reporting to a five-member ''Council of Guardians'' (*8*). Council members, elected to serve a 2-year term, have the duty to protect victims of child abuse and neglect by all social means, including temporary foster care and hospitalization. The legal aspects of child abuse and neglect – such as the prosecution of perpetrators and revoking parental rights – are not handled by the Council.

Mandatory laws are potentially useful for data gathering purposes, but it is not known how effective they are in preventing cases of abuse and neglect. Critics of this approach have raised various concerns, such as whether underfunded social agencies are in a position to benefit the child and his or her family, and whether instead they may do more harm than good by raising false hopes (*139*).

Various types of voluntary reporting systems exist around the world, in countries such as Barbados, Cameroon, Croatia, Japan, Romania and the United Republic of Tanzania (*7*). In the Netherlands, suspected cases of child abuse can be reported voluntarily to one of two separate public agencies – the Child Care and Protection Board and the Confidential Doctor's Office. Both these bodies exist to protect children from abuse and neglect, and both act to investigate suspected reports of maltreatment. Neither agency provides direct services to the child or the family, instead referring children and family members elsewhere for appropriate services (*140*).

Child protection services

Child protection service agencies investigate and try to substantiate reports of suspected child abuse. The initial reports may come from a variety of sources, including health care personnel, police, teachers and neighbours.

If the reports are verified, then staff of the child protection services have to decide on appropriate treatment and referral. Such decisions are often difficult, since a balance has to be found between various potentially competing demands – such as the need to protect the child and the wish to keep a family intact. The services offered to children and families thus vary widely. While some research has been published on the process of decision-making with regard to appropriate treatment, as well as on current shortcomings – such as the need for specific, standard criteria to identify families and children at risk of child abuse – there has been little investigation of the effectiveness of child protection services in reducing rates of abuse.

Child fatality review teams

In the United States, increased awareness of severe violence against children has led to the establishment of teams to review child fatalities in many states (*141*). These multidisciplinary teams review deaths among children, drawing on data and resources of the police, prosecution lawyers, health care profes-

sionals, child protection services and coroners or medical examiners. Researchers have found that these specialized review teams are more likely to detect signs of child abuse and neglect than those without relevant training. One of the objectives of this type of intervention, therefore, is to improve the accuracy of classification of child deaths.

Improved accuracy of classification, in turn, may contribute to more successful prosecutions through the collection of better evidence. In an analysis of data gathered from child fatality reviews in the state of Georgia, United States (*142*), researchers found that child fatality reviews were most sensitive for investigating death from maltreatment and sudden infant death syndrome. After investigation by the child fatality review team, 2% of deaths during the study year not initially classified as related to abuse or neglect were later reclassified as due to maltreatment.

Other review team objectives include preventing future child deaths from maltreatment through the review, analysis and putting in place of corrective actions, and promoting better coordination between the various agencies and disciplines involved.

Arrest and prosecution policies

Criminal justice policies vary markedly, reflecting different views about the role of the justice system with regard to child maltreatment. The decision whether to prosecute alleged perpetrators of abuse depends on a number of factors, including the seriousness of the abuse, the strength of evidence, whether the child would make a competent witness and whether there are any viable alternatives to prosecution (*143*). One review of the criminal prosecution of child sexual abuse cases (*144*) found that 72% of 451 allegations filed during a 2-year period were considered probable sexual abuse cases. Formal charges, however, were filed in a little over half of these cases. In another study of allegations of child sexual abuse (*145*), prosecutors accepted 60% of the cases referred to them.

Mandatory treatment for offenders

Court-mandated treatment for child abuse offenders is an approach recommended in many countries. There is a debate among researchers, though, as to whether treatment mandated through the court system is preferable to voluntary enrolment in treatment programmes. Mandatory treatment follows from the belief that, in the absence of legal repercussions, some offenders will refuse to undergo treatment. Against that, there is the view that enforced treatment imposed by a court could actually create resistance to treatment on the part of the offenders, and that the willing participation of offenders is essential for successful treatment.

Community-based efforts

Community-based interventions often focus on a selected population group or are implemented in a specific setting, such as in schools. They may also be conducted on a wider scale – over a number of population segments, for instance, or even the entire community – with the involvement of many sectors.

School programmes

School-based programmes to prevent child sexual abuse are one of the most widely applied preventive strategies and have been incorporated into the regular school curriculum in several countries. In Ireland, for example, the Stay Safe primary prevention programme is now implemented in almost all primary schools, with the full support of the Department of Education and religious leaders (*146*).

These programmes are generally designed to teach children how to recognize threatening situations and to provide them with skills to protect themselves against abuse. The concepts underlying the programmes are that children own and can control access to their bodies and that there are different types of physical contact. Children are taught how to tell an adult if they are asked to do something they find uncomfortable. School programmes vary widely in terms of their content and presentation and many also involve parents or caregivers.

Although there is agreement among researchers that children can develop knowledge and acquire skills to protect themselves against abuse, questions have been asked about whether these skills are retained over time and whether they would protect a child in an abusive situation, particularly if the

perpetrator was someone well known to and trusted by the child. In an evaluation of the Irish Stay Safe programme mentioned above, for instance, children in the programme showed significant improvements in knowledge and skills (*146*). The skills were maintained at a follow-up after 3 months.

One recent meta-analysis (*147*) concluded that programmes to prevent victimization were fairly effective in teaching children concepts and skills related to protection against sexual abuse. The authors also found that retention of this information was satisfactory. However, they concluded that proof of the ultimate effectiveness of these programmes would require showing that the skills learned had been successfully transferred to real-life situations.

Prevention and educational campaigns

Widespread prevention and educational campaigns are another approach to reducing child abuse and neglect. These interventions stem from the belief that increasing awareness and understanding of the phenomenon among the general population will result in a lower level of abuse. This could occur directly – with perpetrators recognizing their own behaviour as abusive and wrong and seeking treatment – or indirectly, with increased recognition and reporting of abuse either by victims or third parties.

In 1991–1992, a multimedia campaign was conducted in the Netherlands (*148, 149*). The goal was to increase disclosure of child abuse, both by victims and those in close contact with children, such as teachers. The campaign included a televised documentary, short films and commercials, a radio programme and printed materials such as posters, stickers, booklets and newspaper articles. Regional training sessions were provided for teachers. In an evaluation of this intervention, Hoefnagels & Baartman (*149*) concluded that the mass media campaign increased the level of disclosure, as measured by the rate of telephone calls to the National Child Line service before and after the campaign. The effect of increased disclosure on rates of child abuse and on the mental health of the victims, however, needs to be studied further.

Interventions to change community attitudes and behaviour

Another approach to prevent child abuse and neglect is to develop coordinated interventions to change community attitudes and behaviour, effective across a range of sectors. One example of such a programme is the comprehensive response to child abuse and neglect in Kenya (see Box 3.3).

In Zimbabwe, the Training and Research Support Centre set up a participatory, multisectoral programme to address child sexual abuse (*8*). The Centre convened a diverse group of individuals, including some professionals, from rural and urban areas across the country. Role plays, drama, paintings and discussion sessions were used to bring out the experiences and perceptions of child sexual abuse and to consider what could be done to prevent and detect the problem.

Following on from this first stage, the group of participants subsequently set up and implemented two action programmes. The first, a school programme developed in collaboration with the Ministries of Education and Culture, covered training, capacity building and the development of materials for school psychologists, teachers, administrative staff and children. The second was a legal programme developed jointly with the Ministry of Justice, Legal and Parliamentary Affairs. This programme – designed for nurses, nongovernmental organization workers, police and other law enforcement officials – set up training courses on how to manage young sexual offenders. The training also dealt with the issue of creating victim-friendly courts for vulnerable witnesses. Guidelines for reporting were also developed.

Societal approaches

National policies and programmes

Most prevention efforts for child maltreatment focus on victims and perpetrators without necessarily addressing the root causes of the problem. It is believed, though, that by successfully tackling poverty, improving educational levels and employment opportunities, and increasing the availability and quality of child care, rates of child abuse and neglect can be significantly reduced. Research from

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BOX 3.3

Preventing child abuse and neglect in Kenya

In 1996, a coalition was formed in Kenya with the goal of raising public awareness of child abuse and neglect, and improving the provision of services to victims. An earlier study in four areas of Kenya had shown that child abuse and neglect were relatively prevalent in the country, though no organized response systems existed. Members of the coalition came initially from key government ministries as well as from nongovernmental organizations with community-based programmes. They were subsequently joined by representatives from the private sector, the police and judicial system, and the main hospitals.

All coalition members received training on child abuse and neglect. Three working groups were established, one to deal with training, one with advocacy and the third with child protection. Each group collaborated with specific governmental and nongovernmental bodies. The working group on training, for instance, worked in conjunction with the Ministries of Education, Health, Home Affairs and Labour, running workshops for school staff, health professionals, lawyers, social workers and the police. The advocacy group worked with the Ministry of Information and Broadcasting and various nongovernmental organizations, producing radio and television programmes, and also collaborated with the press in rural areas.

Importantly, children themselves became involved in the project through drama, music and essay competitions. These were held initially at the local level and subsequently at district, provincial and national levels. These competitions are now a regular activity within the Kenyan school system.

The coalition also worked to strengthen the reporting and management of cases of child abuse and neglect. It assisted the Department for Children of the Ministry of Home Affairs in setting up a database on child abuse and neglect and helped create a legal network for abused children, the ''Children Legal Action Network''. In 1998 and 1999, the coalition organized national and regional conferences to bring together researchers and practitioners in the field of child abuse and neglect.

As a result of these various efforts, more Kenyans are now aware of the problem of child abuse and neglect, and a system has been established to address the needs of victims and their families.

several countries in Western Europe, as well as Canada, Colombia and parts of Asia and the Pacific, indicates that the availability of high-quality early-childhood programmes may offset social and economic inequalities and improve child outcomes (*150*). Evidence directly linking the availability of such programmes to a decrease in child maltreatment, though, is lacking. Studies of these programmes have usually measured outcomes such as child development and school success.

Other policies that can indirectly affect levels of child abuse and neglect are those related to reproductive health. It has been suggested that liberal policies on reproductive health provide families with a greater sense of control over the size of their families and that this, in turn, benefits women and children. Such policies, for instance, have allowed for more flexibility in maternal employment and child care arrangements.

The nature and scope of these policies is, however, also important. Some researchers have claimed that policies limiting the size of families, such as the ''one-child'' policy in China, have had the indirect effect of reducing rates of child abuse and neglect (*151*), though others point to the increased numbers of abandoned girls in China as evidence that such policies may actually increase the incidence of abuse.

International treaties

In November 1989, the United Nations General Assembly adopted the Convention on the Rights of

the Child. A guiding principle of the Convention is that children are individuals with equal rights to those of adults. Since children are dependent on adults, though, their views are rarely taken into account when governments set out policies. At the same time, children are often the most vulnerable group as regards government-sponsored activities relating to the environment, living conditions, health care and nutrition. The Convention on the Rights of the Child provides clear standards and obligations for all signatory nations for the protection of children.

The Convention on the Rights of the Child is one of the most widely ratified of all the international treaties and conventions. Its impact, though, in protecting children from abuse and neglect has yet to be fully realized (see Box 3.4).

Recommendations

There are several major areas for action that need to be addressed by governments, researchers, health care and social workers, the teaching and legal professions, nongovernmental organizations and other groups with an interest in preventing child abuse and neglect.

Better assessment and monitoring

Governments should monitor cases of child abuse and neglect and the harm they cause. Such monitoring may consist of collecting case reports, conducting periodic surveys or using other appropriate methods, and may be assisted by academic institutions, the health care system and nongovernmental organizations. Because in many countries professionals are not trained in the subject and because government programmes are generally lacking, reliance on official reports will probably not be sufficient in most places to raise public concern about child abuse and neglect. Instead, periodic population-based surveys of the public are likely to be needed.

Better response systems

It is essential that systems for responding to child abuse and neglect are in place and are operational. In the Philippines, for example, private and public hospitals provide the first line of response to child abuse, followed by the national criminal justice system (*152*). Clearly, it is vital that children should receive expert and sensitively conducted services at all stages. Investigations, medical evaluations, medical and mental health care, family interventions and legal services all need to be completely safe for the children and families concerned. In countries where there is a tradition of private children's aid societies providing these services, it may be necessary to monitor only the child's care. It is important, though, for governments to guarantee the quality and availability of services, and to provide them if no other provider is available.

Policy development

Governments should assist local agencies to implement effective protection services for children. New policies may be needed:

- to ensure a well-trained workforce;
- to develop responses using a range of disciplines;
- to provide alternative care placements for children;
- to ensure access to health resources;
- to provide resources for families.

An important policy area that needs to be addressed is the way the justice system operates with regard to victims of child abuse and neglect. Some countries have put resources into improving juvenile courts, finding ways to minimize the need for testimony from children, and ensuring that when a child does give evidence in court, there are supportive people present.

Better data

Lack of good data on the extent and consequences of abuse and neglect has held back the development of appropriate responses in most parts of the world. Without good local data, it is also difficult to develop a proper awareness of child abuse and neglect and expertise in addressing the problem within the health care, legal and social service professions. While a systematic study of child abuse and neglect within each country is essential, researchers should be encouraged to use the

BOX 3.4

The Convention on the Rights of the Child

The Convention on the Rights of the Child recognizes and urges respect for the human rights of children. In particular, Article 19 calls for legislative, administrative, social and educational actions to protect children from all forms of violence, including abuse and neglect.

It is difficult, however, to assess the precise impact of the Convention on levels of child abuse. Most countries include the protection of children from violence within family law, making it difficult to extract detailed information on the progress that signatories to the Convention have made in preventing child abuse. Furthermore, no global study has tried specifically to determine the impact of the Convention on the prevention of abuse.

All the same, the Convention has stimulated legal reform and the setting up of statutory bodies to oversee issues affecting children. In Latin America, a pioneer in the global process of ratifying the Convention and reforming legislation accordingly, national parliaments have passed laws stipulating that children must be protected from situations of risk, including neglect, violence and exploitation. Incorporating the Convention into national law has led to official recognition of the key role of the family in child care and development. In the case of child abuse, it has resulted in a shift from the institutionalization of abused children to policies of increased support for the family and of removing perpetrators of abuse from the family environment.

In Europe, Poland is one of the countries that have integrated the stipulations of the Convention into their domestic law. Local government bodies in that country now have a responsibility to provide social, psychiatric and legal aid for children. In Africa, Ghana has also amended its criminal code, raised the penalties for rape and molestation, and abolished the option of fines for offences involving sexual violence. The government has also conducted educational campaigns on issues relating to the rights of children, including child abuse.

Only a few countries, though, have legal provisions covering all forms of violence against children. Furthermore, lack of coordination between different government departments and between authorities at the national and local level, as well as other factors, have resulted in the often fragmented implementation of those measures that have been ratified. In Ecuador, for example, a national body to protect minors has been set up, but reform of the child protection system is required before the proper enforcement of children's rights is possible. In Ghana, the legal reforms have had only a limited effect, as funds to disseminate information and provide the necessary training are lacking.

Nongovernmental organizations have expended considerable efforts on behalf of the rights of children and have campaigned for the Convention to be strongly supported. Child protection bodies in a number of countries, including the Gambia, Pakistan and Peru, have used the Convention to justify calls for greater state investment in child protection and for increased governmental and nongovernmental involvement generally in preventing child abuse. In Pakistan, for example, the Coalition for Child Rights works in North-West Frontier Province, training community activists on child rights and carrying out research on issues such as child abuse. Using its own findings and the legal framework of the Convention, it tries to make other community-based organizations more sensitive to the issue of abuse.

There is a need for more countries to incorporate the rights of children in their social policies and to mandate local government institutions to implement these rights. Specific data on violence against children and on interventions addressing the issue are also needed, so that existing programmes can be monitored and new ones implemented effectively.

measuring techniques already successfully employed elsewhere, so that cross-cultural comparisons can meaningfully be made and the reasons behind variations between countries examined.

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More research

Disciplinary practices

More research is needed to explore variations across cultures in the definition of acceptable disciplinary behaviours. Patterns of cultural variations in child discipline can help all countries develop workable definitions of abuse and attend to issues of cultural variations within countries. Such cultural variations may indeed be the underlying reason for some of the unusual manifestations of child abuse reported in the medical literature (*153*). Some of the data cited above suggest that there may well be more general agreement than previously thought across cultures on what disciplinary practices are considered unacceptable and abusive. Research is needed, though, to explore further whether a broader consensus can also be reached concerning very harsh discipline.

Neglect

There is also a great need for more study of the problem of neglect of children. Because neglect is so closely associated with low education and low income, it is important to discover how best to distinguish neglect by parents from deprivation through poverty.

Risk factors

Many risk factors appear to operate similarly across all societies, yet there are some, requiring further research, that seem dependent on culture. While there appears to be a clear association between the risk of abuse and the age of the child, the peak rates of physical abuse occur at different ages in different countries. This phenomenon requires further investigation. In particular, it is necessary to understand more about how parental expectations of child behaviour vary across cultures, as well as what role child characteristics play in the occurrence of abuse.

Other factors that have been suggested as either risk factors or protective factors in child abuse – including stress, social capital, social support, the availability of an extended family to help with the care of children, domestic violence and substance abuse – also need further research.

Equally necessary is a better understanding of how broader social, cultural and economic factors influence family life. Such forces are believed to interact with individual and family factors to produce coercive and violent patterns of behaviour. Most of them, however, have been largely neglected in studies of child maltreatment.

Documentation of effective responses

Relatively few studies have been carried out on the effectiveness of responses to prevent child abuse and neglect. There is thus an urgent need, in both industrialized and developing countries, for the rigorous evaluation of many of the preventive responses described above. Other existing interventions should also be assessed with regard to their potential for preventing abuse – for instance, child-support payments, paid paternity and maternity leave, and early childhood programmes. Finally, new approaches should be developed and tested, especially those focusing on primary prevention.

Improved training and education for professionals

Health and education professionals have a special responsibility. Researchers in the fields of medicine and public health must have the skills to design and conduct investigations of abuse. Curricula for medical and nursing students, graduate training programmes in the social and behavioural sciences, and teacher training programmes should all include the subject of child abuse and the development within organizations of responses to it. Leading professionals in all these fields should actively work to attract resources to enable such curricula to be properly implemented.

Conclusion

Child abuse is a serious global health problem. Although most studies on it have been conducted in developed countries, there is compelling evidence that the phenomenon is common throughout the world.

Much more can and should be done about the problem. In many countries, there is little recognition of child abuse among the public or health

professionals. Recognition and awareness, although essential elements for effective prevention, are only part of the solution. Prevention efforts and policies must directly address children, their caregivers and the environments in which they live in order to prevent potential abuse from occurring and to deal effectively with cases of abuse and neglect that have taken place. The concerted and coordinated efforts of a whole range of sectors are required here, and public health researchers and practitioners can play a key role by leading and facilitating the process.

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CHAPTER 4

Violence by intimate partners

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Background

One of the most common forms of violence against women is that performed by a husband or an intimate male partner. This is in stark contrast to the situation for men, who in general are much more likely to be attacked by a stranger or acquaintance than by someone within their close circle of relationships (*1–5*). The fact that women are often emotionally involved with and economically dependent on those who victimize them has major implications for both the dynamics of abuse and the approaches to dealing with it.

Intimate partner violence occurs in all countries, irrespective of social, economic, religious or cultural group. Although women can be violent in relationships with men, and violence is also sometimes found in same-sex partnerships, the overwhelming burden of partner violence is borne by women at the hands of men (*6, 7*). For that reason, this chapter will deal with the question of violence by men against their female partners.

Women's organizations around the world have long drawn attention to violence against women, and to intimate partner violence in particular. Through their efforts, violence against women has now become an issue of international concern. Initially viewed largely as a human rights issue, partner violence is increasingly seen as an important public health problem.

The extent of the problem

Intimate partner violence refers to any behaviour within an intimate relationship that causes physical, psychological or sexual harm to those in the relationship. Such behaviour includes:

- Acts of physical aggression – such as slapping, hitting, kicking and beating.
- Psychological abuse – such as intimidation, constant belittling and humiliating.
- Forced intercourse and other forms of sexual coercion.
- Various controlling behaviours – such as isolating a person from their family and friends, monitoring their movements, and restricting their access to information or assistance.

When abuse occurs repeatedly in the same relationship, the phenomenon is often referred to as ''battering''.

In 48 population-based surveys from around the world, between 10% and 69% of women reported being physically assaulted by an intimate male partner at some point in their lives (see Table 4.1). The percentage of women who had been assaulted by a partner in the previous 12 months varied from 3% or less among women in Australia, Canada and the United States to 27% of ever-partnered women (that is, women who have ever had an ongoing sexual partnership) in León, Nicaragua, 38% of currently married women in the Republic of Korea, and 52% of currently married Palestinian women in the West Bank and Gaza Strip. For many of these women, physical assault was not an isolated event but part of a continuing pattern of abusive behaviour.

Research suggests that physical violence in intimate relationships is often accompanied by psychological abuse, and in one-third to over one-half of cases by sexual abuse (*3, 8–10*). Among 613 women in Japan who had at any one time been abused, for example, 57% had suffered all three types of abuse – physical, psychological and sexual. Less than 10% of these women had experienced only physical abuse (*8*). Similarly, in Monterrey, Mexico, 52% of physically assaulted women had also been sexually abused by their partners (*11*). Figure 4.1 graphically illustrates the overlap between types of abuse among ever-partnered women in León, Nicaragua (*9*).

Most women who are targets of physical aggression generally experience multiple acts of aggression over time. In the León study, for instance, 60% of women abused during the previous year had been attacked more than once, and 20% had experienced severe violence more than six times. Among women reporting physical aggression, 70% reported severe abuse (*12*). The average number of physical assaults during the previous year among women currently suffering abuse, according to a survey in London, England, was seven (*13*), while in the United States, in a national study in 1996, it was three (*5*).

TABLE 4.1

Physical assault on women by an intimate male partner, selected population-based studies, 1982–1999

Country or area	Year of study	Coverage	Sample			Proportion of women physically assaulted by a partner (%)		
			Size	Study population[a]	Age (years)	During the previous 12 months	In current relationship	Ever
Africa								
Ethiopia	1995	Meskanena Woreda	673	II	⩾15	10[b]		45
Kenya	1984–1987	Kisii District	612	VI	⩾15		42	
Nigeria	1993	Not stated	1 000	I	—			31[c]
South Africa	1998	Eastern Cape	396	III	18–49	11		27
		Mpumalanga	419	III	18–49	12		28
		Northern Province	464	III	18–49	5		19
		National	10 190	III	15–49	6		13
Zimbabwe	1996	Midlands Province	966	I	⩾18			17[d]
Latin America and the Caribbean								
Antigua	1990	National	97	I	29–45			30[d]
Barbados	1990	National	264	I	20–45			30[c,e]
Bolivia	1998	Three districts	289	I	⩾20	17[c]		
Chile	1993	Santiago province	1 000	II	22–55		26/11[f]	
	1997	Santiago	310	II	15–49	23		
Colombia	1995	National	6 097	II	15–49		19	
Mexico	1996	Guadalajara	650	III	⩾15			27
		Monterrey	1 064	III	⩾15			17
Nicaragua	1995	León	360	III	15–49	27/20[f]		52/37[f]
	1997	Managua	378	III	15–49	33/28		69
	1998	National	8 507	III	15–49	12/8[f]		28/21[f]
Paraguay	1995–1996	National, except Chaco region	5 940	III	15–49			10
Peru	1997	Metro Lima (middle-income and low-income)	359	II	17–55	31		
Puerto Rico	1995–1996	National	4 755	III	15–49			13[g]
Uruguay	1997	Two regions	545	II[h]	22–55	10[e]		
North America								
Canada	1991–1992	Toronto	420	I	18–64			27[c]
	1993	National	12 300	I	⩾18	3[d,e]		29[d,e]
United States	1995–1996	National	8 000	I	⩾18	1.3[c]		22[c]
Asia and Western Pacific								
Australia	1996	National	6 300	I	—	3[d]	8[d]	
Bangladesh	1992	National (villages)	1 225	II	<50	19		47
	1993	Two rural regions	10 368	II	15–49		42	
Cambodia	1996	Six regions	1 374	III	—			16
India	1993–1994	Tamil Nadu	859	II	15–39		37	
	1993–1994	Uttar Pradesh	983	II	15–39		45	
	1995–1996	Uttar Pradesh, five districts	6 695	IV	15–65		30	
	1998–1999	National	89 199	III	15–49	11[i]		19[i]
	1999	Six states	9 938	III	15–49	14		40/26
Papua New Guinea	1982	National, rural villages	628	III[h]	—			67
	1984	Port Moresby	298	III[h]	—			56
Philippines	1993	National	8 481	V	15–49			10
	1998	Cagayan de Oro City and Bukidnon Province	1 660	II	15–49			26[j]
Republic of Korea	1989	National	707	II	⩾20	38/12[f]		
Thailand	1994	Bangkok	619	IV	—		20	

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TABLE 4.1 *(continued)*

Country or area	Year of study	Coverage	Sample			Proportion of women physically assaulted by a partner (%)		
			Size	Study population[a]	Age (years)	During the previous 12 months	In current relationship	Ever
Europe								
Netherlands	1986	National	989	I	20–60			21/11[c,f]
Norway	1989	Trondheim	111	III	20–49			18
Republic of Moldova	1997	National	4 790	III	15–44	⩾7		⩾14
Switzerland	1994–1996	National	1 500	II	20–60	6[e]		21[e]
Turkey	1998	East and south-east Anatolia	599	I	14–75			58[c]
United Kingdom	1993	North London	430	I	⩾16	12[c]		30[c]
Eastern Mediterranean								
Egypt	1995–1996	National	7 121	III	15–49	16[j]		34[g]
Israel	1997	Arab population	1 826	II	19–67	32		
West Bank and Gaza Strip	1994	Palestinian population	2 410	II	17–65	52/37[f]		

Source: reproduced from reference *6* with the permission of the publisher.

[a] Study population: I = all women; II = currently married/partnered women; III = ever-married/partnered women; IV = married men reporting on own use of violence against spouse; V = women with a pregnancy outcome; VI = married women – half with pregnancy outcome, half without.

[b] In past 3 months.

[c] Sample group included women who had never been in a relationship and therefore were not at risk of partner violence.

[d] Although sample includes all women, rate of abuse is shown for ever-married/partnered women (number not given).

[e] Physical or sexual assault.

[f] Any physical abuse/severe physical abuse only.

[g] Rate of partner abuse among ever-married/partnered women recalculated from author's data.

[h] Non-random sampling techniques used.

[i] Includes assault by others.

[j] Perpetrator could be a family member or close friend.

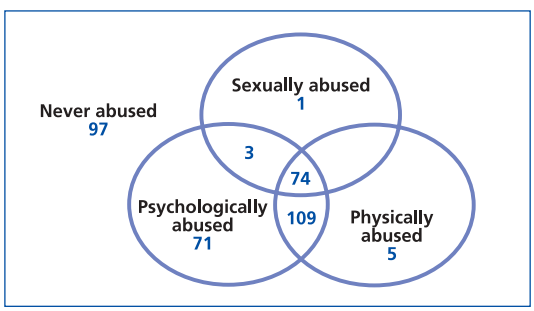
Various types of abuse generally coexist in the same relationship. However, prevalence studies of domestic violence are a new area of research and data on the various types of partner violence, other than physical abuse, are generally not yet available. The figures in Table 4.1, therefore, refer exclusively to physical assault. Even so, because of methodological differences, the data from these well-designed studies are not directly comparable. Reported estimates of abuse are highly sensitive to the particular definitions used, the manner in which questions are asked, the degree of privacy in interviews and the nature of the population being studied (*14*) (see Box 4.1). Differences between countries, therefore – especially fairly small differences – may well reflect methodological variations rather than real differences in prevalence rates.

Measuring partner violence

In surveys of partner violence, women are usually asked whether they have experienced any abuse from a list of specific acts of aggression, including being slapped or hit, kicked, beaten or threatened

FIGURE 4.1

Overlap between sexual, physical and psychological abuse experienced by women in León, Nicaragua (*N* = 360 ever-partnered women)



Source: reference *9*.

BOX 4.1

Making data on intimate partner violence more comparable

Various factors affect the quality and comparability of data on intimate partner violence, including:

— inconsistencies in the way violence and abuse are defined;
— variations in the selection criteria for study participants;
— differences resulting from the sources of data;
— the willingness of respondents to talk openly and honestly about experiences with violence.

Because of these factors, most prevalence figures on partner violence from different studies cannot be compared directly. For instance, not all studies separate different kinds of violence, so that it is not always possible to distinguish between acts of physical, sexual and psychological violence. Some studies examine only violent acts from the previous 12 months or 5 years, while others measure lifetime experiences.

There is also considerable variation in the study populations used for research. Many studies on partner violence include all women within a specific age range, while other studies interview only women who are currently married or who have been married. Both age and marital status are associated with a woman's risk of suffering partner abuse. The selection criteria for participants can therefore considerably affect estimates of the prevalence of abuse in a population.

Prevalence estimates are also likely to vary according to the source of data. Several national studies have produced estimates of the prevalence of partner violence — estimates that are generally lower than those obtained from smaller in-depth studies of women's experiences with violence. Smaller in-depth studies tend to concentrate more on the interaction between interviewers and respondents. These studies also tend to cover the subject matter in much greater detail than most national surveys. Prevalence estimates between the two types of studies may also vary because of some of the factors previously mentioned — including differences in the study populations and definitions of violence.

Improving disclosure

All studies on sensitive topics such as violence face the problem of how to achieve openness from people about intimate aspects of their lives. Success will depend partly on the way in which the questions are framed and delivered, as well as on how comfortable interviewees feel during the interview. The latter depends on such factors as the sex of the interviewer, the length of the interview, whether others are present, and how interested and non-judgemental the interviewer appears.

Various strategies can improve disclosure. These include:

- Giving the interviewee several opportunities during an interview in which to disclose violence.
- Using behaviourally specific questions, rather than subjective questions such as ''Have you ever been abused?''.
- Carefully selecting interviewers and training them to develop a good rapport with the interviewees.
- Providing support for interviewees, to help avoid retaliation by an abusive partner or family member.

The safety of both respondents and interviewers must always be taken into account in all strategies for improving research into violence.

The World Health Organization has recently published guidelines addressing ethical and safety issues in research into violence against women (*15*). Guidelines for defining and measuring partner violence and sexual assault are being developed to help improve the comparability of data. Some of these guidelines are currently available (*16*) (see also Resources).

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with a weapon. Research has shown that behaviourally specific questions such as ''Have you ever been forced to have sexual intercourse against your will?'' produce greater rates of positive response than questions asking women whether they have been ''abused'' or ''raped'' (*17*). Such behaviourally specific questions also allow researchers to gauge the relative severity and frequency of the abuse suffered. Physical acts that are more severe than slapping, pushing or throwing an object at a person are generally defined in studies as ''severe violence'', though some observers object to defining severity solely according to the act (*18*).

A focus on acts alone can also hide the atmosphere of terror that sometimes permeates violent relationships. In a national survey of violence against women in Canada, for example, one-third of all women who had been physically assaulted by a partner said that they had feared for their lives at some time in the relationship (*19*). Although international studies have concentrated on physical violence because it is more easily conceptualized and measured, qualitative studies suggest that some women find the psychological abuse and degradation even more intolerable than the physical violence (*1, 20, 21*).

Partner violence and murder

Data from a wide range of countries suggest that partner violence accounts for a significant number of deaths by murder among women. Studies from Australia, Canada, Israel, South Africa and the United States of America show that 40–70% of female murder victims were killed by their husbands or boyfriends, frequently in the context of an ongoing abusive relationship (*22–25*). This contrasts starkly with the situation of male murder victims. In the United States, for example, only 4% of men murdered between 1976 and 1996 were killed by their wives, ex-wives or girlfriends (*26*). In Australia between 1989 and 1996, the figure was 8.6% (*27*).

Cultural factors and the availability of weapons define the profiles of murders of intimate partners in different countries. In the United States, more murders of women are committed by guns than by all other types of weapons combined (*28*). In India, guns are rare but beatings and death by fire are common. A frequent ploy is to douse a woman with kerosene and then to claim that she died in a ''kitchen accident''. Indian public health officials suspect that many actual murders of women are concealed in official statistics as ''accidental burns''. One study in the mid-1980s found that among women aged 15–44 years in Greater Bombay and other urban areas of Maharashtra state, one out of five deaths were ascribed to ''accidental burns'' (*29*).

Traditional notions of male honour

In many places, notions of male honour and female chastity put women at risk (see also Chapter 6). For example, in parts of the Eastern Mediterranean, a man's honour is often linked to the perceived sexual ''purity'' of the women in his family. If a woman is ''defiled'' sexually – either through rape or by engaging voluntarily in sex outside marriage – she is thought to disgrace the family honour. In some societies, the only way to cleanse the family honour is by killing the ''offending'' woman or girl. A study of female deaths by murder in Alexandria, Egypt, found that 47% of the women were killed by a relative after they had been raped (*30*).

The dynamics of partner violence

Recent research from industrialized countries suggests that the forms of partner violence that occur are not the same for all couples who experience violent conflict. There would seem to be at least two patterns (*31, 32*):

- A severe and escalating form of violence characterized by multiple forms of abuse, terrorization and threats, and increasingly possessive and controlling behaviour on the part of the abuser.
- A more moderate form of relationship violence, where continuing frustration and anger occasionally erupt into physical aggression.

Researchers hypothesize that community-based surveys are better-suited to detecting the second, more moderate form of violence – also called ''common couple violence'' – than the severe type of abuse known as battering. This may help explain

why community-based surveys of violence in industrialized countries frequently find substantial evidence of physical aggression by women, even though the vast majority of victims that come to the attention of service providers (in shelters, for instance) and the police or the courts are women. Although there is evidence from industrialized countries that women engage in common couple violence, there are few indications that women subject men to the same type of severe and escalating violence frequently seen in clinical samples of battered women (*32, 33*).

Similarly, research suggests that the consequences of partner violence differ between men and women, and so do the motivations for perpetrating it. Studies in Canada and the United States have shown that women are far more likely to be injured during assaults by intimate partners than are men, and that women suffer more severe forms of violence (*5, 34–36*). In Canada, female victims of partner violence are three times more likely to suffer injury, five times more likely to receive medical attention and five times more likely to fear for their lives than are male victims (*36*). Where violence by women occurs it is more likely to be in the form of self-defence (*32, 37, 38*).

In more traditional societies, wife beating is largely regarded as a consequence of a man's right to inflict physical punishment on his wife – something indicated by studies from countries as diverse as Bangladesh, Cambodia, India, Mexico, Nigeria, Pakistan, Papua New Guinea, the United

TABLE 4.2

Percentage of respondents who approve of using physical violence against a spouse, by rationale, selected studies, 1995–1999

Country or area	Year	Respondent	Rationale for physical abuse			
			She neglects children or house	She refuses him sex	He suspects her of adultery	She answers back or disobeys
Brazil (Salvador, Bahia)	1999	M	—	—	19[a]	—
		F	—	—	11[a]	—
Chile (Santiago)	1999	M	—	—	12[a]	—
		F	—	—	14[a]	—
Colombia (Cali)	1999	M	—	—	14[a]	—
		F	—	—	13[a]	—
Egypt	1996	Urban F	40	57	—	59
		Rural F	61	81	—	78
El Salvador (San Salvador)	1999	M	—	—	5[a]	—
		F	—	—	9[a]	—
Ghana[b]	1999	M	—	43	—	—
		F	—	33	—	—
India (Uttar Pradesh)	1996	M	—	—	—	10–50
New Zealand	1995	M	1	1	5[c]	1[d]
Nicaragua[e]	1999	Urban F	15	5	22	—
		Rural F	25	10	32	—
Singapore	1996	M	—	5	33[f]	4
Venezuela (Caracas)	1999	M	—	—	8[a]	—
		F	—	—	8[a]	—
West Bank and Gaza Strip[g]	1996	M[h]	—	28	71	57

Source: reproduced from reference *6* with the permission of the publisher.

M = male; F = female; — indicates question was not asked.

[a] ''An unfaithful woman deserves to be beaten.''

[b] Also, 51% of men and 43% of women agreed ''a husband is justified in beating his wife if she uses family planning without his knowledge.''

[c] ''He catches her in bed with another man.''

[d] ''She won't do as she is told.''

[e] Also, 11% of urban women and 23% of rural women agreed ''a husband is justified in beating his wife if she goes out without his permission.''

[f] ''She is sexually involved with another man.''

[g] Also, 23% of men agreed ''wife-beating is justified if she does not respect her husband's relatives.''

[h] Palestinian population.

Republic of Tanzania and Zimbabwe (*39–47*). Cultural justifications for violence usually follow from traditional notions of the proper roles of men and women. In many settings women are expected to look after their homes and children, and show their husbands obedience and respect. If a man feels that his wife has failed in her role or overstepped her limits – even, for instance, by asking for household money or stressing the needs of the children – then violence may be his response. As the author of the study from Pakistan notes, ''Beating a wife to chastise or to discipline her is seen as culturally and religiously justified . . . Because men are perceived as the 'owners' of their wives, it is necessary to show them who is boss so that future transgressions are discouraged.''

A wide range of studies from both industrialized and developing countries have produced a remarkably consistent list of events that are said to trigger partner violence (*39–44*). These include:

- not obeying the man;
- arguing back;
- not having food ready on time;
- not caring adequately for the children or home;
- questioning the man about money or girlfriends;
- going somewhere without the man's permission;
- refusing the man sex;
- the man suspecting the woman of infidelity.

In many developing countries, women often agree with the idea that men have the right to discipline their wives, if necessary by force (see Table 4.2). In Egypt, over 80% of rural women share the view that beatings are justified in certain circumstances (*48*). Significantly, one of the reasons that women cite most often as just cause for beatings is refusing a man sex (*48–51*). Not surprisingly, denying sex is also one of the reasons women cite most often as a trigger for beatings (*40, 52–54*). This clearly has implications for the ability of women to protect themselves from unwanted pregnancy and sexually transmitted infections.

Societies often distinguish between ''just'' and ''unjust'' reasons for abuse and between ''acceptable'' and ''unacceptable'' levels of violence. In this way, certain individuals – usually husbands or older family members – are given the right to punish a woman physically, within limits, for certain transgressions. Only if a man oversteps these bounds – for example, by becoming too violent or for beating a woman without an accepted cause – will others intervene (*39, 43, 55, 56*).

This notion of ''just cause'' is found in much qualitative data on violence from the developing world. One indigenous woman in Mexico observed, ''I think that if the wife is guilty, the husband has the right to hit her . . . If I have done something wrong . . . nobody should defend me. But if I have not done something wrong, I have a right to be defended'' (*43*). Similar sentiments are found among focus group participants in north and south India. ''If it is a great mistake,'' noted one woman in Tamil Nadu, ''then the husband is justified in beating his wife. Why not? A cow will not be obedient without beatings'' (*47*).

Even where culture itself grants men substantial control over female behaviour, abusive men generally exceed the norm (*49, 57, 58*). Statistics from the Demographic and Health Survey in Nicaragua, for instance, show that among women who were physically abused, 32% had husbands scoring high on a scale of ''marital control'', compared with only 2% among women who were not physically abused. The scale included a range of behaviours on the part of the husband, including continually accusing the wife of being unfaithful and limiting her access to family and friends (*49*).

How do women respond to abuse?

Qualitative studies have confirmed that most abused women are not passive victims but rather adopt active strategies to maximize their safety and that of their children. Some women resist, others flee, while still others attempt to keep the peace by giving in to their husbands' demands (*3, 59–61*). What may seem to an outside observer to be a lack of positive response by the woman may in fact be a calculated assessment of what is needed to survive in the marriage and to protect herself and her children.

A woman's response to abuse is often limited by the options available to her (*60*). In-depth qualitative studies of women in the United States and Africa, Latin America, Asia and Europe show that various factors can keep women in abusive relationships. These commonly include: fear of retribution, a lack of alternative means of economic support, concern for the children, emotional dependence, a lack of support from family and friends, and an abiding hope that the man will change (*9, 40, 42, 62, 63*). In developing countries, women also cite the stigmatization associated with being unmarried as an additional barrier to leaving abusive relationships (*40, 56, 64*).

TABLE 4.3

Proportion of physically abused women who sought help from different sources, selected population-based studies

Country or area	Sample (*M*)	Proportion of physically abused women who:			
		Never told anyone (%)	Contacted police (%)	Told friends (%)	Told family (%)
Australia[a]	6 300	18	19	58	53
Bangladesh	10 368	68	—	—	30
Canada	12 300	22	26	45	44
Cambodia	1 374	34	1	33	22
Chile	1 000	30	16	14	32[b]/21[c]
Egypt	7 121	47	—	3	44
Ireland	679	—	20	50	37
Nicaragua	8 507	37	17	28	34
Republic of Moldova	4 790	—	6	30	31
United Kingdom	430	38	22	46	31

Source: reproduced from reference *6* with the permission of the publisher.

[a] Women who were physically assaulted in the past 12 months.

[b] Refers to the proportion of women who told their family.

[c] Refers to the proportion of women who told their partners' family.

Denial and the fear of being socially ostracized often prevent women from reaching out for help. Studies have shown that around 20–70% of abused women never told another person about the abuse until they were interviewed for the study (see Table 4.3). Those who do reach out do so mainly to family members and friends, rather than to institutions. Only a minority ever contact the police.

Despite the obstacles, many abused women eventually do leave violent partners, sometimes only after many years, once the children have grown up. In the study in León, Nicaragua, for example, 70% of the women eventually left their abusive partners (*65*). The median time that women spent in a violent relationship was around 6 years, although younger women were more likely to leave sooner (*9*). Studies suggest that there is a consistent set of factors leading women to separate from their abusive partners permanently. Usually this occurs when the violence becomes severe enough to trigger the realization that the partner is not going to change, or when the situation starts noticeably to affect the children. Women have also mentioned emotional and logistical support from family or friends as being pivotal in their decision to end the relationship (*61, 63, 66–68*).

According to research, leaving an abusive relationship is a process, not a ''one-off'' event. Most women leave and return several times before finally deciding to end the relationship. The process includes periods of denial, self-blame and suffering before women come to recognize the reality of the abuse and to identify with other women in similar situations. At this point, disengagement and recovery from the abusive relationship begin (*69*). Recognizing that this process exists can help people to be more understanding and less judgemental about women who return to abusive situations.

Unfortunately, leaving an abusive relationship does not of itself always guarantee safety. Violence can sometimes continue and may even escalate after a woman leaves her partner (*70*). In fact in Australia, Canada and the United States, a significant proportion of intimate partner homicides involving women occur around the time that a woman is trying to leave an abusive partner (*22, 27, 71, 72*).

What are the risk factors for intimate partner violence?

Researchers have only recently begun to look for individual and community factors that might affect the rate of partner violence. Although violence against women is found to exist in most places, it turns out that there are examples of pre-industrial

societies where partner violence is virtually absent (*73, 74*). These societies stand as testament to the fact that social relations can be organized in such a way as to minimize violence against women.

In many countries the prevalence of domestic violence varies substantially between neighbouring areas. These local differences are often greater than differences across national boundaries. For example, in the state of Uttar Pradesh, India, the percentage of men who admitted beating their wives varied from 18% in Naintal district to 45% in Banda district. The proportion that physically forced their wives to have sex varied from 14% to 36% among the districts (see Table 4.4). Such variations raise an interesting and compelling question: what is it about these settings that can account for the large differences in physical and sexual assault?

TABLE 4.4

Variations in men's attitudes and reported use of violence, selected districts in Uttar Pradesh, India, 1995–1996

District	Sample size (*N*)	Proportion of men who:			
		Admit to forcing wife to have sex (%)	Agree that if wife disobeys, she should be beaten (%)	Admit to hitting wife (%)	Hit wife in past year (%)
Aligarh	323	31	15	29	17
Banda	765	17	50	45	33
Gonda	369	36	27	31	20
Kanpur Nagar	256	14	11	22	10
Naintal	277	21	10	18	11

Source: reproduced from reference *6* with the permission of the publisher.

Recently, researchers have become more interested in exploring such questions, although the current research base is inadequate for the task. Our present understanding of factors affecting the prevalence of partner violence is based largely on studies conducted in North America, which may not necessarily be relevant to other settings. A number of population-based studies are available from developing countries, but their usefulness in investigating risk and protective factors is limited by their cross-sectional design and by the limited number of predictive factors that they explore. In general, the current research base is highly skewed towards investigating individual factors rather than community or societal factors that may affect the likelihood of abuse.

Indeed, while there is an emerging consensus that an interplay of personal, situational, social and cultural factors combine to cause abuse (*55, 75*), there is still only limited information on which factors are the most important. Table 4.5 summarizes the factors that have been put forward as being related to the risk of perpetrating violence against an intimate partner. This information should, however, be viewed as both incomplete and highly tentative. Several important factors may be missing because no studies have examined their significance, while other factors may prove simply to be correlates of partner aggression rather than true causal factors.

Individual factors

Black et al. recently reviewed the social science literature from North America on risk factors for physically assaulting an intimate partner (*76*). They reviewed only studies they considered to be methodologically sound and that employed either a representative community sample or a clinical sample with an appropriate control group. A number of demographic, personal history and personality factors emerged from this analysis, as consistently linked to a man's likelihood of physically assaulting an intimate partner. Among the demographic factors, young age and low income were consistently found to be factors linked to the likelihood of a man committing physical violence against a partner.

Some studies have found a relationship between physical assault and composite measures of socio-economic status and educational level, although the data are not fully consistent. The Health and Development Study in Dunedin, New Zealand – one of the few longitudinal, birth cohort studies to explore partner violence – found that family poverty in childhood and adolescence, low academic achievement and aggressive delinquency at the age of 15 years all strongly predicted physical abuse of partners by men at the age of 21 years

TABLE 4.5
Factors associated with a man's risk for abusing his partner

Individual factors	Relationship factors	Community factors	Societal factors
• Young age • Heavy drinking • Depression • Personality disorders • Low academic achievement • Low income • Witnessing or experiencing violence as a child	• Marital conflict • Marital instability • Male dominance in the family • Economic stress • Poor family functioning	• Weak community sanctions against domestic violence • Poverty • Low social capital	• Traditional gender norms • Social norms supportive of violence

(*77*). This study was one of the few that evaluated whether the same risk factors predict aggression by both women and men against a partner.

History of violence in family

Among personal history factors, violence in the family of origin has emerged as an especially powerful risk factor for partner aggression by men. Studies in Brazil, Cambodia, Canada, Chile, Colombia, Costa Rica, El Salvador, Indonesia, Nicaragua, Spain, the United States and Venezuela all found that rates of abuse were higher among women whose husbands had either themselves been beaten as children or had witnessed their mothers being beaten (*12, 57, 76, 78–81*). Although men who physically abuse their wives frequently have violence in their background, not all boys who witness or suffer abuse grow up to become abusive themselves (*82*). An important theoretical question here is: what distinguishes those men who are able to form healthy, non-violent relationships despite childhood adversity from those who become abusive?

Alcohol use by men

Another risk marker for partner violence that appears especially consistent across different settings is alcohol use by men (*81, 83–85*). In the meta-analysis by Black et al. mentioned earlier, every study that examined alcohol use or excessive drinking as a risk factor for partner violence found a significant association, with correlation coefficients ranging from $r = 0.21$ to $r = 0.57$. Population-based surveys from Brazil, Cambodia, Canada, Chile, Colombia, Costa Rica, El Salvador, India, Indonesia, Nicaragua, South Africa, Spain and Venezuela also found a relationship between a woman's risk of suffering violence and her partner's drinking habits (*9, 19, 79–81, 86, 87*).

There is, however, a considerable debate about the nature of the relationship between alcohol use and violence and whether it is truly causal. Many researchers believe that alcohol operates as a situational factor, increasing the likelihood of violence by reducing inhibitions, clouding judgement and impairing an individual's ability to interpret cues (*88*). Excessive drinking may also increase partner violence by providing ready fodder for arguments between couples. Others argue that the link between violence and alcohol is culturally dependent, and exists only in settings where the collective expectation is that drinking causes or excuses certain behaviours (*89, 90*). In South Africa, for example, men speak of using alcohol in a premeditated way to gain the courage to give their partners the beatings they feel are socially expected of them (*91*).

Despite conflicting opinions about the causal role played by alcohol abuse, the evidence is that women who live with heavy drinkers run a far greater risk of physical partner violence, and that men who have been drinking inflict more serious violence at the time of an assault (*57*). According to the survey of violence against women in Canada, for example, women who lived with heavy drinkers were five times more likely to be assaulted by their partners than those who lived with non-drinkers (*19*).

Personality disorders

A number of studies have attempted to identify whether certain personality factors or disorders are

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consistently related to partner violence. Studies from Canada and the United States show that men who assault their wives are more likely to be emotionally dependent, insecure and low in self-esteem, and are more likely to find it difficult to control their impulses (*33*). They are also more likely than their non-violent peers to exhibit greater anger and hostility, to be depressed and to score high on certain scales of personality disorder, including antisocial, aggressive and borderline personality disorders (*76*). Although rates of psychopathology generally appear higher among men who abuse their wives, not all physically abusive men show such psychological disorders. The proportion of partner assaults linked to psychopathology is likely to be relatively low in settings where partner violence is common.

Relationship factors

At an interpersonal level, the most consistent marker to emerge for partner violence is marital conflict or discord in the relationship. Marital conflict is moderately to strongly related to partner assault by men in every study reviewed by Black et al. (*76*). Such conflict has also been found to be predictive of partner violence in a population-based study of women and men in South Africa (*87*) and a representative sample of married men in Bangkok, Thailand (*92*). In the study in Thailand, verbal marital conflict remained significantly related to physical assault of the wife, even after controlling for socioeconomic status, the husband's stress level and other aspects related to the marriage, such as companionship and stability (*92*).

Community factors

A high socioeconomic status has generally been found to offer some protection against the risk of physical violence against an intimate partner, although exceptions do exist (*39*). Studies from a wide range of settings show that, while physical violence against partners cuts across all socio-economic groups, women living in poverty are disproportionately affected (*12, 19, 49, 78, 79, 81, 92–96*).

It is as yet unclear why poverty increases the risk of violence – whether it is because of low income in itself or because of other factors that accompany poverty, such as overcrowding or hopelessness. For some men, living in poverty is likely to generate stress, frustration and a sense of inadequacy for having failed to live up to their culturally expected role of providers. It may also work by providing ready material for marital disagreements or by making it more difficult for women to leave violent or otherwise unsatisfactory relationships. Whatever the precise mechanisms, it is probable that poverty acts as a ''marker'' for a variety of social conditions that combine to increase the risk faced by women (*55*).

How a community responds to partner violence may affect the overall levels of abuse in that community. In a comparative study of 16 societies with either high or low rates of partner violence, Counts, Brown & Campbell found that societies with the lowest levels of partner violence were those that had community sanctions against partner violence and those where abused women had access to sanctuary, either in the form of shelters or family support (*73*). The community sanctions, or prohibitions, could take the form either of formal legal sanctions or the moral pressure for neighbours to intervene if a woman was beaten. This ''sanctions and sanctuary'' framework suggests the hypothesis that intimate partner violence will be highest in societies where the status of women is in a state of transition. Where women have a very low status, violence is not ''needed'' to enforce male authority. On the other hand, where women have a high status, they will probably have achieved sufficient power collectively to change traditional gender roles. Partner violence is thus usually highest at the point where women begin to assume non-traditional roles or enter the workforce.

Several other community factors have been suggested as possibly affecting the overall incidence of partner violence, but few of these have been tested empirically. An ongoing multi-country study sponsored by the World Health Organization in eight countries (Bangladesh, Brazil, Japan, Namibia, Peru, Samoa, Thailand and the United Republic of Tanzania) is collecting data on a number of community-

level factors to examine their possible relationship to partner violence. These factors include:

- Rates of other violent crime.
- Social capital (see Chapter 2).
- Social norms to do with family privacy.
- Community norms related to male authority over women.

The study will shed light on the relative contributions of individual and community-level factors to rates of partner violence.

Societal factors

Research studies across cultures have come up with a number of societal and cultural factors that might give rise to higher levels of violence. Levinson, for example, used statistical analysis of coded ethnographic data from 90 societies to examine the cultural patterns of wife beating – exploring the factors that consistently distinguish societies where wife beating is common from those where the practice is rare or absent (*74*). Levinson's analysis suggests that wife beating occurs more often in societies in which men have economic and decision-making power in the household, where women do not have easy access to divorce, and where adults routinely resort to violence to resolve their conflicts. The second strongest predictor in this study of the frequency of wife beating was the absence of all-women workgroups. Levinson advances the hypothesis that the presence of female workgroups offers protection from wife beating because they provide women with a stable source of social support as well as economic independence from their husbands and families.

Various researchers have proposed a number of additional factors that might contribute to higher rates of partner violence. It has been argued, for example, that partner violence is more common in places where war or other conflicts or social upheavals are taking place or have recently taken place. Where violence has become commonplace and individuals have easy access to weapons, social relations – including the roles of men and women – are frequently disrupted. During these times of economic and social disruption, women are often more independent and take on greater economic responsibility, whereas men may be less able to fulfil their culturally expected roles as protectors and providers. Such factors may well increase partner violence, but evidence for this remains largely anecdotal.

Others have suggested that structural inequalities between men and women, rigid gender roles and notions of manhood linked to dominance, male honour and aggression, all serve to increase the risk of partner violence (*55*). Again, although these hypotheses seem reasonable, they remain to be proved by firm evidence.

The consequences of intimate partner violence

The consequences of abuse are profound, extending beyond the health and happiness of individuals to affect the well-being of entire communities. Living in a violent relationship affects a woman's sense of self-esteem and her ability to participate in the world. Studies have shown that abused women are routinely restricted in the way they can gain access to information and services, take part in public life, and receive emotional support from friends and relatives. Not surprisingly, such women are often unable properly to look after themselves and their children or to pursue jobs and careers.

Impact on health

A growing body of research evidence is revealing that sharing her life with an abusive partner can have a profound impact on a woman's health. Violence has been linked to a host of different health outcomes, both immediate and long-term. Table 4.6 draws on the scientific literature to summarize the consequences that have been associated with intimate partner violence. Although violence can have direct health consequences, such as injury, being a victim of violence also increases a woman's risk of future ill health. As with the consequences of tobacco and alcohol use, being a victim of violence can be regarded as a risk factor for a variety of diseases and conditions.

Studies show that women who have experienced physical or sexual abuse in childhood or

TABLE 4.6
Health consequences of intimate partner violence

Physical
Abdominal/thoracic injuries
Bruises and welts
Chronic pain syndromes
Disability
Fibromyalgia
Fractures
Gastrointestinal disorders
Irritable bowel syndrome
Lacerations and abrasions
Ocular damage
Reduced physical functioning
Sexual and reproductive
Gynaecological disorders
Infertility
Pelvic inflammatory disease
Pregnancy complications/miscarriage
Sexual dysfunction
Sexually transmitted diseases, including HIV/AIDS
Unsafe abortion
Unwanted pregnancy
Psychological and behavioural
Alcohol and drug abuse
Depression and anxiety
Eating and sleep disorders
Feelings of shame and guilt
Phobias and panic disorder
Physical inactivity
Poor self-esteem
Post-traumatic stress disorder
Psychosomatic disorders
Smoking
Suicidal behaviour and self-harm
Unsafe sexual behaviour
Fatal health consequences
AIDS-related mortality
Maternal mortality
Homicide
Suicide

adulthood experience ill-health more frequently than other women – with regard to physical functioning, psychological well-being and the adoption of further risk behaviours, including smoking, physical inactivity, and alcohol and drug abuse (*85, 97–103*). A history of being the target of violence puts women at increased risk of:

— depression;
— suicide attempts;
— chronic pain syndromes;
— psychosomatic disorders;
— physical injury;
— gastrointestinal disorders;
— irritable bowel syndrome;
— a variety of reproductive health consequences (see below).

In general, the following are conclusions emerging from current research about the health consequences of abuse:

- The influence of abuse can persist long after the abuse itself has stopped (*103, 104*).
- The more severe the abuse, the greater its impact on a woman's physical and mental health (*98*).
- The impact over time of different types of abuse and of multiple episodes of abuse appears to be cumulative (*85, 99, 100, 103, 105*).

Reproductive health

Women who live with violent partners have a difficult time protecting themselves from unwanted pregnancy or disease. Violence can lead directly to unwanted pregnancy or sexually transmitted infections, including HIV infection, through coerced sex, or else indirectly by interfering with a woman's ability to use contraceptives, including condoms (*6, 106*). Studies consistently show that domestic violence is more common in families with many children (*5, 47, 49, 50, 78, 93, 107*). Researchers have therefore long assumed that the stress of having many children increases the risk of violence, but recent data from Nicaragua, in fact, suggests that the relationship may be the opposite. In Nicaragua, the onset of violence largely precedes having many children (80% of violence beginning within the first 4 years of marriage), suggesting that violence may be a risk factor for having many children (*9*).

Violence also occurs during pregnancy, with consequences not only for the woman but also for the developing fetus. Population-based studies from Canada, Chile, Egypt and Nicaragua have found that 6–15% of ever-partnered women have been physically or sexually abused during pregnancy, usually by their partners (*9, 48, 49, 57, 78*). In the United States, estimates of abuse during pregnancy range from 3% to 11% among adult

women and up to 38% among low-income, teenage mothers (*108–112*).

Violence during pregnancy has been associated with (*6, 110, 113–117*):

— miscarriage;
— late entry into prenatal care;
— stillbirth;
— premature labour and birth;
— fetal injury;
— low birth weight, a major cause of infant death in the developing world.

Intimate partner violence accounts for a substantial but largely unrecognized proportion of maternal mortality. A recent study among 400 villages and seven hospitals in Pune, India, found that 16% of all deaths during pregnancy were the result of partner violence (*118*). The study also showed that some 70% of maternal deaths in this region generally went unrecorded and that 41% of recorded deaths were misclassified. Being killed by a partner has also been identified as an important cause of maternal deaths in Bangladesh (*119*) and in the United States (*120, 121*).

Partner violence also has many links with the growing AIDS epidemic. In six countries in Africa, for instance, fear of ostracism and consequent violence in the home was an important reason for pregnant women refusing an HIV test, or else not returning for their results (*122*). Similarly, in a recent study of HIV transmission between heterosexuals in rural Uganda, women who reported being forced to have sex against their will in the previous year had an eightfold increased risk of becoming infected with HIV (*123*).

Physical health

Obviously, violence can lead to injuries, ranging from cuts and bruises to permanent disability and death. Population-based studies suggest that 40–72% of all women who have been physically abused by a partner are injured at some point in their life (*5, 9, 19, 62, 79, 124*). In Canada, 43% of women injured in this way received medical care and 50% of those injured had to take time off from work (*19*).

Injury, however, is not the most common physical outcome of partner abuse. More common are ''functional disorders'' – a host of ailments that frequently have no identifiable medical cause, such as irritable bowel syndrome, fibromyalgia, gastrointestinal disorders and various chronic pain syndromes. Studies consistently link such disorders with a history of physical or sexual abuse (*98, 125–127*). Women who have been abused also experience reduced physical functioning, more physical symptoms and a greater number of days in bed than non-abused women (*97, 98, 101, 124, 125, 128*).

Mental health

Women who are abused by their partners suffer more depression, anxiety and phobias than non-abused women, according to studies in Australia, Nicaragua, Pakistan and the United States (*129–132*). Research similarly suggests that women abused by their partners are at heightened risk for suicide and suicide attempts (*25, 49, 133–136*).

Use of health services

Given the long-term impact of violence on women's health, women who have suffered abuse are more likely to be long-term users of health services, thereby increasing health care costs. Studies in Nicaragua, the United States and Zimbabwe indicate that women who have experienced physical or sexual assault, either in childhood or adulthood, use health services more frequently than their non-abused peers (*98, 100, 137–140*). On average, abuse victims experience more operative surgery, visits by doctors, hospital stays, visits to pharmacies and mental health consultations over their lifetime than non-victims, even after controlling for potential confounding factors.

Economic impact of violence

In addition to its human costs, violence places an enormous economic burden on societies in terms of lost productivity and increased use of social services. Among women in a survey in Nagpur, India, for example, 13% had to forgo paid work because of abuse, missing an average of 7 workdays per inci-

dent, and 11% had been unable to perform household chores because of an incident of violence (*141*).

Although partner violence does not consistently affect a woman's overall probability of being employed, it does appear to influence a woman's earnings and her ability to keep a job (*139, 142, 143*). A study in Chicago, IL, United States, found that women with a history of partner violence were more likely to have experienced spells of unemployment, to have had a high turnover of jobs, and to have suffered more physical and mental health problems that could affect job performance. They also had lower personal incomes and were significantly more likely to receive welfare assistance than women who did not report a history of partner violence (*143*). Similarly, in a study in Managua, Nicaragua, abused women earned 46% less than women who did not report suffering abuse, even after controlling for other factors that could affect earnings (*139*).

Impact on children

Children are often present during domestic altercations. In a study in Ireland (*62*), 64% of abused women said that their children routinely witnessed the violence, as did 50% of abused women in Monterrey, Mexico (*11*).

Children who witness marital violence are at a higher risk for a whole range of emotional and behavioural problems, including anxiety, depression, poor school performance, low self-esteem, disobedience, nightmares and physical health complaints (*9, 144–146*). Indeed, studies from North America indicate that children who witness violence between their parents frequently exhibit many of the same behavioural and psychological disturbances as children who are themselves abused (*145, 147*).

Recent evidence suggests that violence may also directly or indirectly affect child mortality (*148, 149*). Researchers in León, Nicaragua, found that after controlling for other possible confounding factors, the children of women who were physically and sexually abused by a partner were six times more likely to die before the age of 5 years than children of women who had not been abused. Partner abuse accounted for as much as one-third of deaths among children in this region (*149*). Another study in the Indian states of Tamil Nadu and Uttar Pradesh found that women who had been beaten were significantly more likely than non-abused women to have experienced an infant death or pregnancy loss (abortion, miscarriage or stillbirth), even after controlling for well-established predictors of child mortality such as the woman's age, level of education and the number of previous pregnancies that had resulted in a live birth (*148*).

What can be done to prevent intimate partner violence?

The majority of work carried out to date on partner violence has been spearheaded by women's organizations, with occasional funding and assistance from governments. Where governments have become involved – as in Australia, Latin America, North America and parts of Europe – it has generally been in response to demands by civil society for constructive action. The first wave of activity has generally involved elements of legal reform, police training and the establishment of specialized services for victims. Scores of countries have now passed laws on domestic violence, although many officials are either still unaware of the new laws or unwilling to implement them. Those within the system (in the police or the legal system, for instance) frequently share the same prejudices that predominate in society as a whole. Experience has repeatedly shown that without sustained efforts to change institutional culture and practice, most legal and policy reforms have little effect.

Despite over 20 years of activism in the field of violence against women, remarkably few interventions have been rigorously evaluated. Indeed, the recent review of programmes to prevent family violence in the United States by the National Research Council found only 34 studies that attempted to evaluate interventions related to partner abuse. Of those, 19 focused on law enforcement, reflecting the strong preference among government officials towards using the criminal justice system to deal with violence (*150*). Research on interventions in developing countries is even more limited. Only a

handful of studies exist that attempt critically to examine current interventions. Among these are a review of programmes on violence against women in four states of India. In addition, the United Nations Development Fund for Women has reviewed seven projects across five regions funded by the United Nations Violence Against Women Trust Fund, with the aim of disseminating the lessons learnt from these projects (*151*).

Support for victims

In the developed world, women's crisis centres and battered women's shelters have been the cornerstone of programmes for victims of domestic violence. In 1995, there were approximately 1800 such programmes in the United States, 1200 of which provided emergency shelter in addition to emotional, legal and material support to women and their children (*152*). Such centres generally provide support groups and individual counselling, job training, programmes for children, assistance in dealing with social services and with legal matters, and referrals for treatment for drug and alcohol abuse. Most shelters and crisis centres in Europe and the United States were originally set up by women activists, though many are now run by professionals and receive government funding.

Since the early 1980s, shelters and crisis centres for women have also sprung up in many developing countries. Most countries have at least a few nongovernmental organizations offering specialized services for victims of abuse and campaigning on their behalf. Some countries have hundreds of such organizations. However, maintaining shelters is expensive, and many developing countries have avoided this model, instead setting up telephone hotlines or non-residential crisis centres that provide some of the same services as residential ones.

Where running a formal shelter is not possible, women have often found other ways to deal with emergencies related to domestic abuse. One approach is to set up an informal network of ''safe homes'', where women in distress can seek temporary shelter in the homes of neighbours. Some communities have designated their local place of worship – a temple or church, for instance – as a sanctuary where women can stay with their children overnight to escape drunken or violent partners.

Legal remedies and judicial reforms

Criminalizing abuse

The 1980s and 1990s saw a wave of legal reforms relating to physical and sexual abuse by an intimate partner (*153, 154*). In the past 10 years, for example, 24 countries in Latin America and the Caribbean have passed specific legislation on domestic violence (*154*). The most common reforms involve criminalizing physical, sexual and psychological abuse by intimate partners, either through new laws on domestic violence or by amending existing penal codes.

The intended message behind such legislation is that partner violence is a crime and will not be tolerated in society. Bringing it into the open is also a way to dispel the idea that violence is a private, family matter. Aside from introducing new laws or extending existing ones, there have been experiments in some developed countries to back up legislation by introducing special domestic violence courts, training police and court officials and prosecution lawyers, and providing special advisers to help women deal with the criminal justice system. Although rigorous evaluation of these measures has so far been sparse, the recent review of family violence interventions by the United States National Academy of Sciences concludes: ''Anecdotal evidence suggests that specialized units and comprehensive reforms in police departments, prosecutors' offices and specialized courts have improved the experience of abused children and women'' (*150*).

Similar experiments are under way elsewhere. In India, for example, state governments have established legal aid cells, family courts, *lok adalat* (people's courts) and *mahilla lok adalat* (women's courts). A recent evaluation notes that these bodies are primarily conciliatory mechanisms, relying exclusively on mediation and counselling to promote family reconciliation. It has, however, been suggested that these institutions are less than satisfactory even as conciliatory mechanisms, and

that the mediators tend to place the well-being of women below the state's interest in keeping families together (*155*).

Laws and policies on arrest

After support services for victims, efforts to reform police practice are the next most common form of intervention against domestic violence. Early on, the focus was on training the police, but when training alone proved largely ineffective in changing police behaviour, efforts shifted to seeking laws requiring mandatory arrest for domestic violence and policies that forced police officers to take a more active stand.

Support for arrest as a means of reducing domestic violence was boosted by a 1984 research experiment in Minneapolis, MN, United States, that suggested that arrest halved the risk of future assaults over a 6-month period, compared with the strategies of separating couples or advising them to seek help (*156*). These results were widely publicized and led to a dramatic shift in police policies toward domestic violence throughout the United States.

Efforts to duplicate the Minneapolis findings in five other areas of the United States, however, failed to confirm the deterrent value of arrest. These new studies found that, on average, arrest was no more effective in reducing violence than other police responses such as issuing warnings or citations, providing counselling to the couples or separating them (*157, 158*). Detailed analysis of these studies also produced some other interesting findings. When the perpetrator of the violence was married, employed or both, arrest reduced repeat assaults, but for unemployed and unattached men, arrest actually led to increased abuse in some cities. The impact of arrest also varied by community. Men living in communities with low unemployment were deterred by arrest regardless of their individual employment status; suspects living in areas of high unemployment, however, were more violent following an arrest than they were after simply receiving a warning (*159*). These findings have led some to question the wisdom of mandatory arrest laws in areas of concentrated poverty (*160*).

Alternative sanctions

As alternatives to arrest, some communities are experimenting with other methods of deterring violent behaviour. One civil law approach is to issue court orders that prohibit a man from contacting or abusing his partner, mandate that he leave the home, order him to pay maintenance or child support, or require him to seek counselling or treatment for substance abuse.

Researchers have found that although victims generally find protection orders useful, the evidence for their effectiveness in deterring violence is mixed (*161, 162*). In a study in the cities of Denver and Boulder, CO, United States, Harrell & Smith (*163*) found that protection orders were effective for at least a year in preventing a reoccurrence of domestic violence, compared with similar situations where there was no protection order. However, studies have shown that arrests for violation of a protection order are rare, which tends to undermine their effectiveness in preventing violence (*164*). Other research shows that protection orders can enhance a woman's self-esteem but have little effect on men with serious criminal records (*165, 166*).

Elsewhere, communities have explored techniques such as public shaming, picketing an abuser's home or workplace, or requiring community service as a punishment for abusive behaviour. Activists in India frequently stage *dharna*, a form of public shaming and protest, in front of the homes or workplaces of abusive men (*155*).

All-women police stations

Some countries have experimented with all-women police stations, an innovation that started in Brazil and has now spread throughout Latin America and parts of Asia (*167, 168*). Although commendable in theory, evaluations show that this initiative has to date experienced many problems (*155, 168–172*). While the presence of a police station staffed entirely by women does increase the number of abused women coming forward, frequently the services that abused women require – such as legal advice and counselling – are not available at the stations. Furthermore, the assumption that female

police officers will be more sympathetic to victims has not always proved true, and in some places, the creation of specialized police cells for crimes against women has made it easier for other police units to dismiss women's complaints. A review of all-women police stations in India observes that ''women victims are forced to travel great distances to register their complaints with all-women police stations and cannot be assured of speedy neighbourhood police protection.'' To be viable, the strategy must be accompanied by sensitivity-training for police officers, incentives to encourage such work and the provision of a wider range of services (*155, 168, 170*).

Treatment for abusers

Treatment programmes for perpetrators of partner violence are an innovation that has spread from the United States to Australia, Canada, Europe and a number of developing countries (*173–175*). Most of the programmes use a group format to discuss gender roles and teach skills, including how to cope with stress and anger, take responsibility for one's actions and show feelings for others.

In recent years, there have been efforts to evaluate these programmes, although they have been hindered by methodological difficulties that continue to pose problems in interpreting the results. Research from the United States suggests that the majority of men (53–85%) who complete treatment programmes remain physically non-violent for up to 2 years, with lower rates for longer follow-up periods (*176, 177*). These success rates, however, should be seen in the light of the high drop-out rate that such programmes encounter; overall, between one-third and one-half of all men who enrol in these programmes fail to complete them (*176*) and many who are referred to programmes never formally enrol (*178*). An evaluation of the United Kingdom's flagship Violence Prevention Programme, for example, showed that 65% of men did not show up for the first session, 33% attended fewer than six sessions, and only 33% went on to the second stage (*179*).

A recent evaluation of programmes in four cities in the United States found that most abused women felt ''better off'' and ''safe'' after their partners had entered treatment (*177*). Nevertheless, this study found that after 30 months, nearly half the men had used violence once, and 23% of the men had been repeatedly violent and continued to inflict serious injuries, while 21% of the men were neither physically nor verbally abusive. A total of 60% of couples had split up and 24% were no longer in contact.

According to a recent international review by researchers at the University of North London, England (*179*), evaluations collectively suggest that treatment programmes work best if they:

- continue for longer rather than shorter periods;
- change men's attitudes enough for them to discuss their behaviour;
- sustain participation in the programme;
- work in tandem with a criminal justice system that acts strictly when there are breaches of the conditions of the programme.

In Pittsburgh, PA, United States, for example, the non-attendance rate dropped from 36% to 6% between 1994 and 1997 when the justice system began issuing arrest warrants for men who failed to appear at the programme's initial interview session (*179*).

Health service interventions

In recent years attention has turned towards reforming the response of health care providers to victims of abuse. Most women come into contact with the health system at some point in their lives – when they seek contraception, for instance, or give birth or seek care for their children. This makes the health care setting an important place where women undergoing abuse can be identified, provided with support and referred if necessary to specialized services. Unfortunately, studies show that in most countries, doctors and nurses rarely enquire of women whether they are being abused, or even check for obvious signs of violence (*180–186*).

Existing interventions have focused on sensitizing health care providers, encouraging routine screening for abuse and drawing up protocols for

the proper management of abuse. A growing number of countries – including Brazil, Ireland, Malaysia, Mexico, Nicaragua, the Philippines and South Africa – have begun pilot projects training health workers to identify and respond to abuse (*187–189*). Several countries in Latin America have also incorporated guidelines to address domestic violence in their health sector policies (*190*).

Research suggests that making procedural changes in patient care – such as stamping a reminder for the provider on the patient's chart or incorporating questions on abuse in the standard intake forms – have the greatest effect on the behaviour of health care providers (*191, 192*).

Confronting deep-rooted beliefs and attitudes is also important. In South Africa, the Agisanang Domestic Abuse Prevention and Training Project and its partner, the Health Systems Development Unit of the University of Witwatersrand, have developed a reproductive health and gender course for nurses that has a strong domestic violence component. In these courses, popular sayings, wedding songs and role-plays are used in an exercise to dissect commonly held notions on violence and the expected roles of men and women. Following the exercise, there is a discussion on the responsibility of nurses as health professionals. Analysis of a survey completed after one of these courses found that participants no longer believed that beating a woman was justified and that most accepted that a woman could be raped by her husband.

Active screening for abuse – questioning patients about their possible histories of suffering violence by intimate partners – is generally considered good practice in this field. However, while studies repeatedly show that women welcome being queried about violence in a non-judgemental way (*181, 182, 193*), little systematic evaluation has been carried out on whether screening for abuse can improve the safety of women or their health-seeking behaviour – and if it does, under what conditions (*194*).

Community-based efforts

Outreach work

Outreach work has been a major part of the response to partner violence from nongovernmental organizations. Outreach workers – who are often peer educators – visit victims of violence in their homes and communities. Nongovernmental organizations frequently recruit and train peer workers from the ranks of former clients, themselves earlier victims of partner violence.

Both governmental and nongovernmental projects have been known to employ ''advocates'' – individuals who provide abused women with information and advice, particularly with help in negotiating the intricacies of the legal system and of family welfare and other benefits. These people focus on the rights and entitlements of victims of violence and carry out their work from institutions as diverse as police stations, legal prosecutors' offices and hospitals.

Several outreach schemes have been evaluated. The Domestic Violence Matters project in Islington, London, England, placed civilian advocates in local police stations, with the task of contacting all victims of partner violence within 24 hours of their calling the police. Another initiative in London, the Domestic Violence Intervention project in Hammersmith and Fulham, combined an education programme for violent men with appropriate interventions for their partners. A recent review of these programmes found that the Islington project had reduced the number of repeated calls to the police and – by inference – had reduced the reoccurrence of domestic violence. At the same time, it had increased the use by women of new services, including shelters, legal advice and support groups. The second project had managed to reach greater numbers of women from ethnic minority groups and professional women than other services for victims of domestic violence (*195*).

Coordinated community interventions

Coordinating councils or interagency forums are an increasingly popular means of monitoring and improving responses towards intimate partner violence at the community level (*166*). Their aim is to:

— exchange information;

— identify and address problems in the provision of services;

— promote good practice through training and drawing up guidelines;
— track cases and carry out institutional audits to assess the practice of various agencies;
— promote community awareness and prevention work.

Adapted from the original pilot programmes in California, Massachusetts and Minnesota in the United States, this type of intervention has spread widely throughout the rest of the United States, Canada, the United Kingdom and parts of Latin America.

The Pan American Health Organization (PAHO), for instance, has set up pilot projects in 16 Latin American countries to test this approach in both urban and rural settings. In rural settings, the coordinating councils include individuals such as the local priest, the mayor, community health promoters, magistrates and representatives of women's groups. The PAHO project began with a qualitative research study – known as *La Ruta Crítica* – to examine what happens to women in rural communities when they seek help, and the results are summarized in Box 4.2.

These types of community interventions have seldom been evaluated. One study found a statistically significant increase in the proportion of police calls that resulted in arrests, as well as in the proportion of arrests that resulted in prosecution, after the implementation of a community intervention project (*196*). The study also found a significant increase in the proportion of men sent for mandatory counselling in each of the communities, though it is unclear what impact, if any, these actions had on rates of abuse.

Qualitative evaluations have noted that many of these interventions focus primarily on coordinating refuges and the criminal justice system, at the expense of wider involvement of religious communities, schools, the health system, or other social service agencies. A recent review of interagency forums in the United Kingdom concluded that while coordinating councils can improve the quality of services offered to women and children, interagency work can act as a smokescreen, concealing the fact that little actually changes. The review suggested that organizations should identify firm criteria for self-evaluation that cover user satisfaction and real changes in policies and practices (*197*).

Prevention campaigns

Women's organizations have long used communication campaigns, small-scale media and other events in an attempt to raise awareness of partner violence and change behaviour. There is evidence that such campaigns reach a large number of people, although only a few campaigns have been evaluated for their effectiveness in changing attitudes or behaviour. During the 1990s, for instance, a network of women's groups in Nicaragua mounted an annual mass media campaign to raise awareness of the impact of violence on women (*198*). Using slogans such as "*Quiero vivir sin violencia*" (I want to live free of violence), the campaigns mobilized communities against abuse. Similarly, the United Nations Development Fund for Women, together with several other United Nations agencies, has been sponsoring a series of regional campaigns against gender violence around the slogan, "A life free of violence: it's our right" (*199*). One communication project that has been evaluated is the multimedia health project known as *Soul City*, in South Africa – a project that combines prime-time television and radio dramas with other educational activities. One component is specifically devoted to domestic violence (see Box 9.1 in Chapter 9). The evaluation found increased knowledge and awareness of domestic violence, changed attitudes and norms, and greater willingness on the part of the project's audience to take appropriate action.

School programmes

Despite a growing number of initiatives aimed at young people on preventing violence, only a small number specifically address the problem of violence in intimate relationships. There is considerable scope, though, to integrate material that explores relationships, gender roles and coercion and control into existing programmes for reducing school violence, bullying, delinquency and other problem behaviours, as well as into reproductive and sexual health programmes.

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BOX 4.2

La Ruta Crítica: a study of responses to domestic violence

In 1995, the Pan American Health Organization launched a community study in 10 countries in Latin America (Belize, Bolivia, Costa Rica, Ecuador, El Salvador, Guatemala, Honduras, Nicaragua, Panama and Peru). Its purpose was to record the process that a woman who has suffered domestic violence goes through after making a decision to end her silence and seek assistance. The Spanish name for this process was *La Ruta Crítica* — the critical path — referring to the unfolding series of decisions and actions taken by the woman as she comes to terms with the violent situation and the responses she encounters from others in her search for help. Each action and decision by the woman along the path affects the actions of others, including service providers and members of the community, and what they do, in turn, has an influence on the next step the woman takes.

The questions investigated by the study were therefore concerned with the consequences of a woman deciding to seek help, the sources she approached for assistance, her motivations, and the attitudes and responses, both of institutional service providers and individuals. The qualitative study involved over 500 in-depth interviews with women who had been abused and more than 1000 interviews with service providers, as well as some 50 focus group sessions.

Women who had been victims of violence identified several factors that can act as triggers for action. These included an increase in the severity or frequency of the violence, causing a recognition that the abuser was not going to change. One important factor motivating action was the realization that the life of the woman or those of her children were in danger. As with the factors that precipitated action, the factors inhibiting a woman from seeking help were multiple and interconnected.

The study found that economic considerations seemed to carry more weight than emotional ones. Many women, for instance, expressed concern about their ability to support themselves and their children. The women interviewed also frequently expressed feelings of guilt, self-blame or being abnormal. Corruption and stereotyping by gender in the judicial system and among the police were also mentioned. The greatest inhibiting factor, though, was fear — that the consequences of telling someone or of leaving would be worse than staying in the relationship.

From the *Ruta Crítica* study, it is clear that there are many factors, both internal and external, that have a bearing on an abused woman's decision to take action to stop the violence. The process is often a long one — many years in some cases — involving several attempts at seeking help from a number of sources. Rarely is there just a single event that precipitates action. The evidence indicates that, despite facing formidable obstacles, abused women are often resourceful in seeking help and in finding ways of mitigating the violence inflicted on them.

The programmes for young people that do explicitly address abuse within intimate relationships tend to be independent initiatives sponsored by bodies working to end violence against women (see Box 4.3). Only a handful of these programmes have been evaluated, including one in Canada (*200*) and two in the United States (*201, 202*). Using experimental designs, these evaluations found positive changes in knowledge and attitudes toward relationship violence (see also *203*). One of the programmes in the United States demonstrated a reduction in the perpetration of violence at 1 month. Although its effect on behaviour had vanished after 1 year, its effects on norms of violence within an intimate relationship, on skills for resolving conflict and on knowledge were all maintained (*201*).

Principles of good practice

A growing body of wisdom on partner violence, accumulated over many years by large numbers of service providers, advocates and researchers, suggests a set of principles to help guide ''good

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BOX 4.3

Promoting non-violence: some examples of primary prevention programmes

The following are a few of the many examples from around the world of innovative programmes to prevent violence between intimate partners.

In Calabar, Nigeria, the Girl's Power Initiative is aimed at young girls. The girls meet weekly over a period of 3 years to discuss frankly a range of issues related to sexuality, women's health and rights, relationships and domestic violence. Specific topics in the programme, designed to build self-esteem and teach skills for self-protection, have included societal attitudes that put women at risk of rape, and distinguishing between love and infatuation.

Education Wife Assault in Toronto, Canada, works with immigrant and refugee women, helping them develop violence prevention campaigns that are culturally appropriate for their communities by means of special ''skill shops''. Education Wife Assault provides technical assistance, enabling women to conduct their own campaigns. At the same time, it also offers emotional support to the women organizers to help them overcome the discrimination often directed at women campaigning against domestic violence because they are seen as threatening their community's cohesiveness.

In Mexico, the nongovernmental organization Instituto Mexicano de Investigación de Familia y Población has created a workshop for adolescents to help prevent violence in dating and within relationships between friends. Entitled ''Faces and Masks of Violence'', the project uses participatory techniques to help young people explore expectations and feelings about love, desire and sex, and to understand how traditional gender roles can inhibit behaviour, both in men and women.

In Trinidad and Tobago, the nongovernmental organization SERVOL (Service Volunteered for All) conducts workshops over 14 weeks for adolescents to assist them in developing healthy relationships and learning parenting skills. The project helps these young people understand how their own parenting contributed towards shaping what they are and teaches them how not to repeat the mistakes their parents and other relatives may have made in bringing up their families. As a result, the students discover how to recognize and handle their emotions, and become more sensitive to how early physical and psychological traumas can lead to destructive behaviour later in life.

practice'' in this field. These principles include the following:

- Actions to address violence should take place at both national and local level.
- The involvement of women in the development and implementation of projects and the safety of women should guide all decisions relating to interventions.
- Efforts to reform the response of institutions – including the police, health care workers and the judiciary – should extend beyond training to changing institutional cultures.
- Interventions should cover and be coordinated between a range of different sectors.

Action at all levels

An important lesson to emerge from efforts to prevent violence is that actions should take place at both national and local levels. At the national level, priorities include improving the status of women, establishing appropriate norms, policies and laws on abuse, and creating a social environment that is conducive to non-violent relationships.

Many countries, industrialized as well as developing, have found it useful to set up a formal mechanism for developing and implementing national plans of action. Such plans should include clear objectives, lines of responsibility and time schedules, and be backed by adequate resources.

Experience nevertheless suggests that national efforts alone are insufficient to transform the landscape of intimate violence. Even in those industrialized countries where national movements against partner violence have existed for more than 25 years, the options for help available to a woman who has suffered abuse, and the reactions she is likely to meet from institutions such as the police, still vary greatly according to the particular locality. Where there have been efforts in the community to prevent violence, and where there are established groups to conduct training and monitor the activities of formal institutions, victims of abuse fare considerably better than where these are lacking (*204*).

Women's involvement

Interventions should be designed to work with women – who are usually the best judges of their situation – and to respect their decisions. Recent reviews of a range of domestic violence programmes in the Indian states of Gujarat, Karnataka, Madhya Pradesh and Maharashtra, for instance, have consistently shown that the success or failure of projects was determined largely by the attitudes of organizers towards intimate partner violence and their priorities for including the interests of women during the planning and implementation of interventions (*205*).

Women's safety should also be carefully considered when planning and implementing interventions. Those that make women's safety and autonomy a priority have generally proved more successful than those that do not. For example, concern has been raised about laws requiring health care workers to report suspected cases of abuse to the police. These types of interventions take control away from women and have usually proved counterproductive. They may well put a woman's safety at risk and make it less likely that she will come forward for care (*206–208*). Such laws also transform health workers into arms of the judicial system and work against the emotional protection that the environment of the clinic is meant to provide (*150*).

Changing institutional cultures

Little enduring change is usually achieved by short-term efforts to sensitize institutional actors, unless there are also real efforts to engage the whole institution. The nature of the organization's leadership, the way in which performances are evaluated and rewarded, and the embedded cultural biases and beliefs are all of prime importance in this respect (*209, 210*). In the case of reforming health care practice, training alone has seldom been sufficient to change institutional behaviour toward victims of violence (*211, 212*). Although training can improve knowledge and practice in the short term, its impact generally wears off quickly unless accompanied by institutional changes in policies and performance (*211, 213*).

A multisectoral approach

Various sectors such as the police, health services, judiciary and social support services should work together in tackling the problem of intimate partner violence. Historically, the tendency of programmes has been to concentrate on a single sector, which has been shown by experience very often to produce poor results (*155*).

Recommendations

The evidence available shows violence against women by intimate partners to be a serious and widespread problem in all parts of the world. There is also a growing documentation of the damaging impact of violence on the physical and mental health of women and their overall well-being. The following are the main recommendations for action:

- Governments and other donors should be encouraged to invest much more in research on violence by intimate partners over the next decade.
- Programmes should place greater emphasis on enabling families, circles of friends and community groups, including religious communities, to deal with the problem of partner violence.
- Programmes on partner violence should be integrated with other programmes, such as those tackling youth violence, teenage pregnancies, substance abuse and other forms of family violence.

- Programmes should focus more on the primary prevention of intimate partner violence.

Research on intimate partner violence

The lack of a clear theoretical understanding of the causes of intimate partner violence and its relationship to other forms of interpersonal violence has frustrated efforts to build an effective global response. Studies to advance the understanding of violence are needed on a variety of fronts, including:

- Studies that examine the prevalence, consequences and risk and protective factors of violence by intimate partners in different cultural settings, using standardized methodologies.
- Longitudinal research on the trajectory of violent behaviour by intimate partners over time, examining whether and how it differs from the development of other violent behaviours.
- Studies that explore the impact of violence over the course of a person's life, investigating the relative impact of different types of violence on health and well-being, and whether the effects are cumulative.
- Studies that examine the life history of adults who are in healthy, non-violent relationships despite past experiences that are known to increase the risk of partner violence.

In addition, much more research is needed on interventions, both for the purpose of lobbying policy-makers for more investment as well as to improve the design and implementation of programmes. In the next decade, priority should be given to the following:

- Documentation of the various strategies and interventions around the world for combating intimate partner violence.
- Studies assessing the economic costs of intimate partner violence.
- Evaluation of the short-term and long-term effects of programmes to prevent and respond to partner violence – including school education programmes, legal and policy changes, services for victims of violence, programmes that target perpetrators of violence, and campaigns to change social attitudes and behaviour.

Strengthening informal sources of support

Many women do not seek assistance from the official services or systems that are available to them. Expanding the informal sources of support through neighbourhood networks and networks of friends, religious and other community groups, and workplaces is therefore vital (*6, 61, 183, 214*). How these informal groups and individuals respond will determine whether a victim of partner violence takes action or else retreats into isolation and self-blame (*214*).

There is plenty of room for programmes that can create constructive responses on the part of family and friends. An innovative programme in Iztacalco, Mexico, for instance, used community events, small-scale media (such as posters, pamphlets and audio cassettes) and workshops to help victims of violence discuss the abuse they had undergone and to demonstrate to friends and other family members how best to deal with such situations (*215*).

Making common cause with other social programmes

There is a considerable overlap between the factors that increase the risk of various problem behaviours (*216*). There also appears to be a significant continuity between aggressive behaviour in childhood and a range of problem behaviours in youth and early adulthood (see Chapter 2). The insights gained from research on these types of violence overlap as well. There is an evident need to intervene early with high-risk families and to provide support and other services before dysfunctional patterns of behaviour within the family set in, preparing the stage for abusive behaviour in adolescence or adulthood.

Unfortunately, there is at present little coordination between programmes or research agendas on youth violence, child abuse, substance abuse and partner violence, despite the fact that all these problems regularly coexist in families. If true progress is to be made, attention must be paid to the development of aggressive behaviour patterns – patterns that often begin in childhood. Integrated

prevention responses that address the links between different types of violence have the potential to reduce some of these forms of violence.

Investing in primary prevention

The importance of primary prevention of violence by intimate partners is often overshadowed by the importance of the large number of programmes that, understandably, seek to deal with the immediate and numerous consequences of violence.

Both policy-makers and activists in this field must give greater priority to the admittedly immense task of creating a social environment that allows and promotes equitable and non-violent personal relationships. The foundation for such an environment must be the new generation of children, who should come of age with better skills than their parents generally had for managing their relationships and resolving the conflicts within them, with greater opportunities for their future, and with more appropriate notions on how men and women can relate to each other and share power.

Conclusion

Violence by intimate partners is an important public health problem. Resolving it requires the involvement of many sectors working together at community, national and international levels. At each level, responses must include empowering women and girls, reaching out to men, providing for the needs of victims and increasing the penalties for abusers. It is vital that responses should involve children and young people, and focus on changing community and societal norms. The progress made in each of these areas will be the key to achieving global reductions in violence against intimate partners.

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CHAPTER 5

Abuse of the elderly

Background

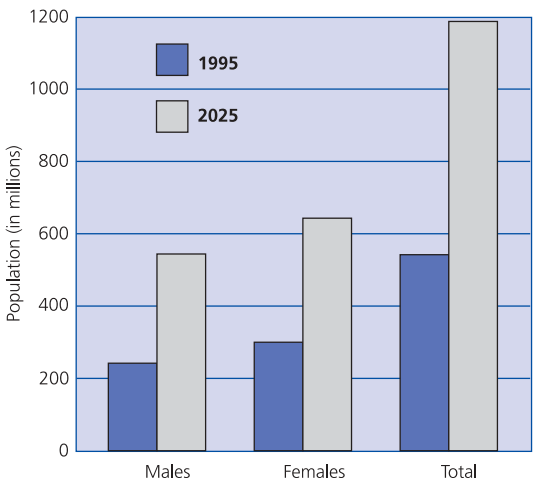
The abuse of older people by family members dates back to ancient times. Until the advent of initiatives to address child abuse and domestic violence in the last quarter of the 20th century, it remained a private matter, hidden from public view. Initially seen as a social welfare issue and subsequently a problem of ageing, abuse of the elderly, like other forms of family violence, has developed into a public health and criminal justice concern. These two fields – public health and criminal justice – have therefore dictated to a large extent how abuse of the elderly is viewed, how it is analysed, and how it is dealt with. This chapter focuses on abuse of older people by family members or others known to them, either in their homes or in residential or other institutional settings. It does not cover other types of violence that may be directed at older people, such as violence by strangers, street crime, gang warfare or military conflict.

Mistreatment of older people – referred to as ''elder abuse'' – was first described in British scientific journals in 1975 under the term ''granny battering'' (*1, 2*). As a social and political issue, though, it was the United States Congress that first seized on the problem, followed later by researchers and practitioners. During the 1980s scientific research and government actions were reported from Australia, Canada, China (Hong Kong SAR), Norway, Sweden and the United States, and in the following decade from Argentina, Brazil, Chile, India, Israel, Japan, South Africa, the United Kingdom and other European countries. Although elder abuse was first identified in developed countries, where most of the existing research has been conducted, anecdotal evidence and other reports from some developing countries have shown that it is a universal phenomenon. That elder abuse is being taken far more seriously now reflects the growing worldwide concern about human rights and gender equality, as well as about domestic violence and population ageing.

Where ''older age'' begins is not precisely defined, which makes comparisons between studies and between countries difficult. In Western societies, the onset of older age is usually considered to coincide with the age of retirement, at 60 or 65 years of age. In most developing countries, however, this socially constructed concept based on retirement age has little significance. Of more significance in these countries are the roles assigned to people in their lifetime. Old age is thus regarded as that time of life when people, because of physical decline, can no longer carry out their family or work roles.

Concern over the mistreatment of older people has been heightened by the realization that in the coming decades, in both developed and developing countries, there will be a dramatic increase in the population in the older age segment – what in French is termed *''le troisième âge''* (the third age). It is predicted that by the year 2025, the global population of those aged 60 years and older will more than double, from 542 million in 1995 to about 1.2 billion (see Figure 5.1). The total number of older people living in developing countries will also more than double by 2025, reaching 850 million (*3*) – 12% of the overall population of the developing world – though in some countries, including Colombia, Indonesia, Kenya and Thailand, the increase is expected to be more than fourfold. Throughout the world, 1 million people

FIGURE 5.1
Projected growth in the global population aged 60 years and older, 1995–2025



Source: United Nations Population Division, 2002.

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reach the age of 60 years every month, 80% of whom are in the developing world.

Women outlive men in nearly all countries of the world, rich and poor (*3*). This gender gap is, however, considerably narrower in developing countries, mainly because of higher rates of maternal mortality and, in recent years, also because of the AIDS epidemic.

These demographic changes are taking place in developing countries alongside increasing mobility and changing family structures. Industrialization is eroding long-standing patterns of interdependence between the generations of a family, often resulting in material and emotional hardship for the elderly. The family and community networks in many developing countries that had formerly provided support to the older generation have been weakened, and often destroyed, by rapid social and economic change. The AIDS pandemic is also significantly affecting the lives of older people. In many parts of sub-Saharan Africa, for instance, children are being orphaned in large numbers as their parents die from the disease. Older people who had anticipated support from their children in old age are finding themselves to be the main caregivers and without a family to help them in the future.

Only 30% of the world's elderly are covered by pension schemes. In Eastern Europe and the countries of the former Soviet Union, for instance, as a result of the changes from planned to market economies, many older people have been left without a retirement income and the health and welfare services that were provided by the former communist regimes. In the economies of both developed and developing countries, structural inequalities have often been the cause among the general population of low wages, high unemployment, poor health services, lack of educational opportunities and discrimination against women – all of which have tended to make the elderly poorer and more vulnerable.

Older people in developing countries still face a significant risk from communicable diseases. As life expectancy increases in these countries, the elderly will be subject to the same long-term, largely incurable and often disabling diseases associated with old age that are currently most prevalent in developed countries. They will also face environmental dangers and the likelihood of violence in their societies. Nevertheless, advances in medical science and in social welfare will ensure that many older people will enjoy longer periods of disability-free old age. Diseases will be avoided or their impact lessened through better health care strategies. The resulting large number of older people will be a boon for society, constituting a great reservoir of experience and knowledge.

How is elder abuse defined?

It is generally agreed that abuse of older people is either an act of commission or of omission (in which case it is usually described as ''neglect''), and that it may be either intentional or unintentional. The abuse may be of a physical nature, it may be psychological (involving emotional or verbal aggression), or it may involve financial or other material maltreatment. Regardless of the type of abuse, it will certainly result in unnecessary suffering, injury or pain, the loss or violation of human rights, and a decreased quality of life for the older person (*4*). Whether the behaviour is termed abusive, neglectful or exploitative will probably depend on how frequently the mistreatment occurs, its duration, severity and consequences, and above all, the cultural context. Among the Navajo people in the United States, for instance, what had appeared to an outside researcher to be economic exploitation by family members was regarded instead by the tribal elders concerned as their cultural duty, and indeed privilege, to share material belongings with their families (*5*). Other Indian tribes in the United States viewed elder abuse as a community problem rather than an individual one (*6*).

The definition developed by Action on Elder Abuse in the United Kingdom (*7*) and adopted by the International Network for the Prevention of Elder Abuse states that: ''Elder abuse is a single or repeated act, or lack of appropriate action, occurring within any relationship where there is an expectation of trust which causes harm or distress to an older

person.'' Such abuse is generally divided into the following categories:

- Physical abuse – the infliction of pain or injury, physical coercion, or physical or drug-induced restraint.
- Psychological or emotional abuse – the infliction of mental anguish.
- Financial or material abuse – the illegal or improper exploitation or use of funds or resources of the older person.
- Sexual abuse – non-consensual sexual contact of any kind with the older person.
- Neglect – the refusal or failure to fulfil a caregiving obligation. This may or may not involve a conscious and intentional attempt to inflict physical or emotional distress on the older person.

This definition of elder abuse has been heavily influenced by the work done in Canada, the United Kingdom and the United States. Studies conducted in China (Hong Kong SAR), Finland, Greece, India, Ireland, Israel, Norway, Poland and South Africa have approached the topic in distinctly different ways (*8*). Norwegian researchers, for instance, identified abuse with a ''triangle of violence'' that includes a victim, a perpetrator and others, who – directly or indirectly – observe the principal players. In countries such as China, that emphasize harmony and respect within society, neglecting the care of an older person is considered an act of elder abuse. If family members fail to fulfil their kinship obligations to provide food and housing, this also constitutes neglect.

Traditional societies

Many traditional societies of the past considered family harmony to be an important factor governing family relationships. This reverence for the family was reinforced by philosophical traditions and public policy. In Chinese society, it was embedded in a value system that stressed ''filial piety''. Mistreatment of older people was unrecognized and certainly unreported. These traditions are still influential today. Studies in the United States of attitudes towards elder abuse revealed that citizens of Korean origin believed in the primacy of family harmony over individual well-being as a yardstick for determining whether a particular behaviour was regarded as abusive or not (*9*). Similarly, people of Japanese origin considered the ''group'' to be paramount, and that an individual's well-being should be sacrificed for the good of the group (*10*).

Displacing older people as heads of households and depriving them of their autonomy in the name of affection are cultural norms even in countries where the family is the central institution and the sense of filial obligation is strong (*11*). Such infantilization and overprotection can leave the older person isolated, depressed and demoralized, and can be considered a form of abuse. In some traditional societies, older widows are abandoned and their property seized. Mourning rites of passage for widows in parts of Africa and India include practices that elsewhere would certainly be considered cruel, for example sexual violence, forced levirate marriages (where a man is obliged by custom to marry the childless widow of his brother) and expulsion from their homes (*12*). In some places, accusations of witchcraft, often connected with unexplained events in the local community, such as a death or crop failure, are directed at isolated, older women (*13*). In sub-Saharan Africa, accusations of the practice of witchcraft have driven many older women from their homes and their communities to live in poverty in urban areas. In the United Republic of Tanzania, an estimated 500 older women accused of witchcraft are murdered every year (*14*). These acts of violence have become firmly entrenched as social customs and may not be considered locally as ''elder abuse'' (see Box 5.1).

A workshop on elder abuse held in South Africa in 1992 drew a distinction between *mistreatment* (such as verbal abuse, passive and active neglect, financial exploitation and overmedication) and *abuse* (including physical, psychological and sexual violence, and theft) (*8*). Since then, focus groups have been held with older people recruited from three historically ''black'' townships in South Africa to determine the level of knowledge and understanding of elder abuse within these communities. In addition to the typical Western schema that

comprises physical, verbal, financial and sexual abuse, and neglect, the participants wished to add to the definition:

— loss of respect for elders, which was equated with neglect;
— accusations of witchcraft;
— abuse by systems (mistreatment at health clinics and by bureaucratic bodies).

The focus groups produced the following definitions (*15*):

- Physical abuse – beating and physical manhandling.

BOX 5.1

Witchcraft: the threat of violence in the United Republic of Tanzania

In the United Republic of Tanzania, some 500 older women are murdered each year following accusations against them of witchcraft. The problem is particularly serious in Sukumaland in the north of the country. Large numbers of older women are driven from their homes and communities in fear of being accused of witchcraft, and end up living destitute in urban areas.

Belief in witchcraft has existed in Sukumaland for centuries, though the violence surrounding it has increased sharply in recent years. This may in part be due to increased poverty caused by too many people living off too little land, as well as an overall lack of education. As poor and uneducated people try to explain the misfortunes that befall them — illness and death, crop failures and dried-up wells — they search for a scapegoat, and witchcraft appears to explain events they cannot otherwise understand or control.

Men are sometimes accused of witchcraft, though the low status of women in society means that women are overwhelmingly the main target. Among some of the particular ways in this region in which women are accused of witchcraft are the following:

- *Land disputes* are a common underlying cause of violence against widows. According to inheritance laws, widows may continue to live on their husbands' land, without owning the property. When they die, the land becomes the property of their husbands' sons. Accusations of witchcraft are thus used to get rid of widows living on the land as tenants, and blocking the inheritance of others.
- *Traditional healers* are frequently urged by family members or neighbours to make accusations of witchcraft against women. One young boy killed his mother after a traditional healer told him that she was the cause of his problems.
- *Myths* about the physical appearance of witches — that they have red eyes, for instance — also often give rise to accusations of witchcraft. The eyes of many older women are red from a lifetime of cooking over smoky stoves, or from medical conditions such as conjunctivitis.

Community leaders in Sukumaland are calling for a strong lead from the Government. One was quoted as saying: "It is a question of educating the people. In other areas of the country where people are better educated, we don't face this problem."

Until recently, the Government was reluctant to acknowledge that belief in witchcraft still existed. Now the subject is being widely discussed and officially condemned. In 1999, the Tanzanian Government made witchcraft the theme for International Women's Day.

A local nongovernmental organization and HelpAge International are also taking measures to improve the security of older women in the United Republic of Tanzania. They aim to change attitudes and beliefs surrounding witchcraft and to address some of the practical matters, such as poverty and poor housing, that have helped to keep such beliefs alive.

Source: reproduced from reference *14* with the permission of the publisher.

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- Emotional and verbal abuse – discrimination on the basis of age, insults and hurtful words, denigration, intimidation, false accusations, psychological pain and distress.
- Financial abuse – extortion and control of pension money, theft of property, and exploitation of older people to force them to care for grandchildren.
- Sexual abuse – incest, rape and other types of sexual coercion.
- Neglect – loss of respect for elders, withholding of affection, and lack of interest in the older person's well-being.
- Accusations of witchcraft – stigmatization and ostracization.
- Abuse by systems – the dehumanizing treatment older people are liable to suffer at health clinics and pension offices, and marginalization by the government.

These definitions, produced by the participants and classified by the researchers, were the result of an initial effort in South Africa to obtain information on elder abuse directly from older people. They are also the first attempt to classify elder abuse in a developing country, building on the Western model but bringing in factors that are relevant to the indigenous population.

The extent of the problem

Domestic settings

With most developing nations only recently becoming aware of the problem, information on the frequency of elder abuse has relied on five surveys conducted in the past decade in five developed countries (*16–20*). The results show a rate of abuse of 4–6% among older people if physical, psychological and financial abuse, and neglect are all included. One difficulty in making comparisons between studies is the variation in their time frames. The studies conducted in Canada, the Netherlands and the United States refer to the ''preceding year''. The study in Finland investigated abuse since the ''age of retirement'', while the study in Great Britain examined cases from ''the past few years''. The first set of studies (from Canada, the Netherlands and the United States) found no significant difference in prevalence rates of abuse by age or by sex, the study in Finland found a higher proportion of female victims (7.0%) than male victims (2.5%), while no breakdown by age or sex was given in the British study. Because of the differences in the methodology used in the five surveys and the relatively small numbers of victims, further comparative analysis is not justified.

A recent survey of family violence in Canada found that 7% of older people had experienced some form of emotional abuse, 1% financial abuse, and 1% physical abuse or sexual assault, at the hands of children, caregivers or partners during the previous 5 years (*21*). Men (9%) were more likely than women (6%) to report suffering emotional or financial abuse. Because of differences in the survey questions and time frame, these findings cannot be compared with the earlier study in Canada which had found a much smaller proportion of emotional abuse (1.4%) and a larger rate of financial abuse (2.5%) (*17*).

Institutional settings

A quarter of a century ago, the proportion of older people living in institutions in developed countries had reached an estimated 9% (*22*). Since that time, there has been a shift in emphasis towards care in the community and the use of less restrictive residential settings. Current rates of use of nursing homes are in the range of 4–7% in countries such as Canada (6.8%), Israel (4.4%), South Africa (4.5%) and the United States (4%). In most African countries, older people can be found in long-stay hospital wards, homes for the destitute and disabled, and – in some sub-Saharan countries – in witches' camps. Social, economic and cultural changes taking place in some of the developing societies will leave families less able to care for their frail relatives and thus portend an increasing demand for institutional care. In China, the expectation of institutional care for older people is becoming the norm. In Taiwan, China, institutional care has rapidly overtaken family care for the elderly (AY Kwan, unpublished data, 2000).

In Latin America, the rates of institutionalization of older people range from 1% to 4%. Institutional care is no longer considered unacceptable for an older person but is seen as an alternative for families. The government-sponsored *asilos*, large institutions resembling the early English workhouses, have been converted into smaller facilities with professional staff from many disciplines. Other homes are operated by religious communities of immigrant origin. Figures for rates of institutionalization are not available in the countries of the former Eastern European bloc, because the authorities at the time did not allow publication of such information.

Despite the fact that a vast literature exists on the quality of care in institutional settings, and that cases of elder abuse have been well documented in reports of governmental inquiries, ethnographic studies and personal histories, there are no national data on the prevalence or incidence of abuse available, but only local data from smaller-scale studies. A survey of nursing-home personnel in one state of the United States disclosed that 36% of the nursing and general staff reported having witnessed at least one incident of physical abuse by other staff members in the preceding year, while 10% admitted having committed at least one act of physical abuse themselves. At least one incident of psychological abuse against a resident had been observed by 81% of the sample in the preceding year, and 40% admitted to having also committed such an act (*23*). The findings suggest that mistreatment of older residents in institutions may be even more extensive than generally believed.

The likely rates of elder abuse both in the community and in institutional settings may be greater than the general statistics collected by countries on violent acts would indicate. Some of the disparity stems from the fact that elder abuse had gone unrecognized until the 1970s. Deaths of older people, both in institutional settings and the community, have often been attributed to natural, accidental or undetermined causes when in fact they were the consequences of abusive or neglectful behaviour.

What are the risk factors for elder abuse?

Most of the early work on abuse of the elderly was limited to domestic settings and carried out in developed countries. In seeking explanations for elder abuse, researchers drew from the literature in the fields of psychology, sociology, gerontology and the study of family violence. To accommodate the complexity of elder abuse and the many factors associated with it, researchers have turned to the ecological model, which was first applied to the study of child abuse and neglect (*24*) and has been applied more recently to elder abuse (*25, 26*). The ecological model can take into account the interactions that take place across a number of systems. As described in Chapter 1, the model consists of a nested hierarchy of four levels of the environment: individual, relationship, community and society.

Individual factors

Early researchers in the field played down individual personality disturbances as causal agents of family violence in favour of social and cultural factors (*27*). More recently, though, research on family violence has shown that abusers who are physically aggressive are more likely to have personality disorders and alcohol-related problems than the general population (*28*). Similarly, studies restricted to violence against older people in domestic settings have found that aggressors are more likely to have mental health and substance abuse problems than family members or caregivers who are not violent or otherwise abusive (*29–31*).

Cognitive and physical impairments of the abused older person were strongly identified in the early studies as risk factors for abuse. However, a later study of a range of cases from a social service agency revealed that the older people who had been mistreated were not more debilitated than their non-abused peers and may even have been less so, particularly in cases of physical and verbal abuse (*32*). In other studies, a comparison of samples of patients with Alzheimer disease showed that the degree of impairment was not a risk factor for being abused (*33, 34*). However, among cases of abuse reported to the authorities, those involving the very

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old and the most impaired generally constitute a large proportion.

Gender has been proposed by some as a defining factor in elder abuse on the grounds that older women may have been subject to oppression and economically disadvantaged all of their lives (*35*). However, according to community-based prevalence studies, it appears that older men are at risk of abuse by spouses, adult children and other relatives in about the same proportions as women (*16, 17*).

Although the income of the older person was not a significant factor in a study of the prevalence of elder abuse in the United States, financial difficulties on the part of the abuser did appear to be an important risk factor. Sometimes this was related to an adult child's substance abuse problem, leading him or her to extort money, possibly a pension cheque, from the older person. Resentment by family members at having to spend money on the care of the older person may also have played a part in abuse of this nature.

Relationship factors

In the early theoretical models, the level of stress of caregivers was seen as a risk factor that linked elder abuse with care of an elderly relative (*36, 37*). While the popular image of abuse depicts a dependent victim and an overstressed caregiver, there is growing evidence that neither of these factors properly accounts for cases of abuse. Although researchers do not deny the component of stress, they tend now to look at it in a wider context in which the quality of the overall relationship is a causal factor (*30, 34, 38*). Some of the studies involving caregiver stress, Alzheimer disease and elder abuse suggest that the nature of the relationship between the caregiver and the care recipient before abuse begins may be an important predictor of abuse (*34, 39, 40*). Today, therefore, the belief is that stress may be a contributing factor in cases of abuse but does not by itself account for the phenomenon.

Work with patients with dementia has shown that violent acts carried out by a care recipient can act as ''triggers'' for reciprocal violence by the caregiver (*41*). It may be that the violence is a result of the interplay of several factors, including stress, the relationship between the carer and the care recipient, the existence of disruptive behaviour and aggression by the care recipient, and depression in the caregiver (*42*).

Living arrangements, particularly overcrowded conditions and a lack of privacy, have been associated with conflict within families. Although abuse can occur when the abuser and the older person suffering abuse live apart, the older person is more at risk when living with the caregiver.

The early theories on the subject also sought to associate dependency with increased risk of abuse. At first the emphasis focused on the dependency of the victim on the caregiver or abuser, though later case work identified abusers who were dependent on the older person – usually adult children dependent on elderly parents for housing and financial assistance (*32*). In some of these cases a ''web of interdependency'' was evident – a strong emotional attachment between the abused and abuser that often hindered efforts at intervention.

Community and societal factors

In almost all studies of risk factors, the community factor of social isolation emerges as a significant one in elder mistreatment (*17, 29, 43, 44*). As with battered women, isolation of older people can be both a cause and a consequence of abuse. Many older people are isolated because of physical or mental infirmities. Furthermore, loss of friends and family members reduces the opportunities for social interaction.

Although there is as yet little solid empirical evidence, societal factors are currently considered important as risk factors for elder abuse in both developing and industrialized countries; in the past the emphasis was generally on individual or interpersonal attributes as potential causal factors for elder abuse. Cultural norms and traditions – such as ageism, sexism and a culture of violence – are also now recognized as playing an important underlying role. Older people are often depicted as being frail, weak and dependent, something that has made them appear less worthy of government

investment or even of family care than other groups, and has presented them as ready targets for exploitation.

As regards sub-Saharan Africa in particular, societal and community factors include (*12*):

— the systems of patrilineal and matrilineal inheritance and land rights, affecting the distribution of power;
— the way societies view the role of women;
— the erosion of the close bonds between generations of a family, caused by rural–urban migration and the growth in formal education;
— the loss, through modernization, of the traditional domestic, ritual and family arbitration roles of older people.

According to the focus group study in South Africa mentioned earlier, much of the abuse – and particularly domestic violence – occurred as a result of social disorder, exacerbated by crime, alcohol and drugs. Similar conclusions came from an exercise conducted by seven male community leaders of the Tamaho squatter camp in Katlehong, South Africa (*15*). Drawing a link between poverty and violence, they described how dysfunctional family life, a lack of money for essentials, and a lack of education and job opportunities have all contributed to a life of crime, drug peddling and prostitution by young people. In this society, older people are viewed as targets for abuse and exploitation, their vulnerability being a result of poverty distinguished by a lack of pension support and job opportunities, poor hygiene, disease and malnutrition.

The political transformations within post-communist Eastern Europe have also produced conditions heightening the risk of elder abuse. The factors suggested there as having affected the overall health and psychosocial well-being of people, particularly the elderly, whose vulnerability to mistreatment has thereby increased, include:

— the growing pauperization of significant parts of society;
— high unemployment;
— a lack of stability and social security;
— the outward expression of aggressiveness, especially among the young.

In Chinese societies several reasons have been suggested (*45*) for the mistreatment of older people, including:

— a lack of respect by the younger generation;
— tension between traditional and new family structures;
— restructuring of the basic support networks for the elderly;
— migration of young couples to new towns, leaving elderly parents in deteriorating residential areas within town centres.

Studies on elder abuse have tended to focus on interpersonal and family problems. However, an integrated model encompassing individual, interpersonal, community and societal perspectives is more appropriate, and reduces some of the bias evident in the earlier studies. Such a model takes into account the difficulties faced by older people, especially older women. These people often live in poverty, without the basic necessities of life and without family support – factors that increase their risk of abuse, neglect and exploitation.

The consequences of elder abuse

For older people, the consequences of abuse can be especially serious. Older people are physically weaker and more vulnerable than younger adults, their bones are more brittle and convalescence takes longer. Even a relatively minor injury can cause serious and permanent damage. Many older people survive on limited incomes, so that the loss of even a small sum of money can have a significant impact. They may be isolated, lonely or troubled by illness, in which case they are more vulnerable as targets for fraudulent schemes.

Domestic settings

Very few empirical studies have been conducted to determine the consequences of mistreatment, even though clinical and case study reports about the severe emotional distress experienced by mistreated older people are plentiful. There is some evidence from studies in developed countries to show that a higher proportion of abused elderly people suffer

from depression or psychological distress than do their non-abused peers (*31, 46, 47*). Since these studies were cross-sectional in design, it is not possible to tell whether the condition existed before or was a consequence of the mistreatment. Other symptoms that have been proposed as being associated with cases of abuse include feelings of helplessness, alienation, guilt, shame, fear, anxiety, denial and post-traumatic stress (*48, 49*). Emotional effects were also cited by the participants in the focus group study in South Africa, along with health problems and, in the words of one participant, ''illness of the heart'' (*15*).

In a seminal study in New Haven, CT, United States, data from a comprehensive annual health and welfare study of a representative sample of 2812 older people were merged with the database of the local agency concerned with adult abuse for each year over a 9-year period (*50*). Information for the health survey was recorded by nurses, who saw the older people at a hospital for the first year's data collection and every third year after that. In the intervening years, data were updated by telephone. Information about abuse and neglect was obtained by case workers using existing protocols after investigating claims of mistreatment, usually by a home visit. The merged database allowed the researchers to identify those people from the sample who were confirmed during the 9-year survey as having experienced physical abuse or neglect. Mortality rates were then calculated, beginning with the first year of the survey and for 12 years thereafter, both for those who had been abused or neglected as well as for the non-abused group. When mortality rates for the two groups were compared, 13 years after the study began, 40% of the group where no abuse or neglect had been reported were still alive, compared with 9% of those who had been physically abused or neglected. After controlling for all possible factors that might affect mortality (for example, age, sex, income, functional and cognitive conditions, diagnosis and degree of social support) and finding no significant relationships in these additional factors, the researchers concluded that mistreatment causes extreme interpersonal stress that may confer an additional risk of death.

Institutions

Mistreatment of older people has been identified in facilities for continuing care (such as nursing homes, residential care, hospitals and day care facilities) in almost every country where such institutions exist. Various people may be responsible for the abuse: a paid member of the staff, another resident, a voluntary visitor, or relatives or friends. An abusive or neglectful relationship between the older person and their caregiver at home may not necessarily end once the older person has entered institutional care; the abuse may sometimes continue in a new setting.

A distinction must be made between individual acts of abuse or neglect in institutional settings and institutionalized abuse – where the prevailing regime of the institution itself is abusive or negligent. In practice, though, it is often difficult to say whether the reasons for abuse or neglect found in an institutional setting have been caused by individual acts or through institutional failings, since the two are frequently found together.

The spectrum of abuse and neglect within institutions spans a considerable range (*51*), and may be related to any of the following:

- The provision of care – for example, resistance to changes in geriatric medicine, erosion of individuality in the care, inadequate nutrition and deficient nursing care (such as lack of attention to pressure sores).
- Problems with staffing – for example, work-related stress and staff burnout, poor physical working conditions, insufficient training and psychological problems among staff.
- Difficulties in staff–resident interactions – for example, poor communication, aggressiveness on the part of residents and cultural differences.
- Environment – for example, a lack of basic privacy, dilapidated facilities, the use of restraints, inadequate sensory stimulation, and a proneness to accidents within the institution.

- Organizational policies – for example, those that operate for the benefit of the institution, giving residents few choices over daily living; bureaucratic or unsympathetic attitudes towards residents; staff shortages or high staff turnover; fraud involving residents' possessions or money; and lack of a residents' council or residents' family council.

Anecdotal evidence from India suggests that institutional abuse is often perpetuated by staff through a system of unquestioning regimentation – in the name of discipline or imposed protective care – and exploitation of the dependence of the older people, and is aggravated by a lack of professionally trained management.

With the present state of knowledge, it is impossible to know how pervasive such conditions are. The leading ten deficiencies, cited in broad categories by the United States Government in its 1997 survey of 15 000 nursing homes (*52*), were:

1. Food preparation (21.8%).
2. Comprehensive assessment – a documented assessment of all care needs, including medical, nursing and social care (17.3%).
3. Comprehensive care plans – usually in the form of a document specifying the day-to-day care needs of an individual and stating who is responsible for delivering them, with comments on progress and changes required (17.1%).
4. Accidents (16.6%).
5. Pressure sores (16.1%).
6. Quality of care (14.4%).
7. Physical restraints (13.3%).
8. Housekeeping (13.3%).
9. Lack of dignity (13.2%).
10. Accident prevention (11.9%).

Abuse and neglect can occur in many types of institution, including those that seem to provide high-quality care to patients. A key finding from an examination of inquiries into scandals in residential care suggested that an acceptable or good regime of care could be transformed into an abusive one relatively easily and quickly, with little detectable change in the outward situation (*53*).

What can be done to prevent elder abuse?

The impact that physical and psychological violence have on the health of an older person is exacerbated by the ageing process and diseases of old age. It is more difficult for the elderly to leave an abusive relationship or to make correct decisions because of the physical and cognitive impairments that usually come with old age. In some places, kinship obligations and the use of the extended family network to resolve difficulties may also lessen the ability of older people, particularly women, to escape from dangerous situations. Often, the abuser may be the abused person's only source of companionship. Because of these and other considerations, preventing elder abuse presents a whole host of problems for practitioners. In most cases, the greatest dilemma is how to balance the older person's right to self-determination with the need to take action to end the abuse.

Responses at national level

Efforts to galvanize social action against elder abuse at a national level and to develop legislation and other policy initiatives are at varying stages of development around the world. Some authors (*54, 55*) have used Blumer's model (*56*) of social problems to describe the stages of the process:

— emergence of a problem;
— legitimization of the problem;
— mobilization of action;
— formulation of an official plan;
— implementation of the plan.

The United States is furthest advanced in terms of a national-level response, with a fully developed system for reporting and treating cases of elder abuse. This system operates at the state level, the federal government's involvement being limited to supporting the National Center on Elder Abuse, which gives technical assistance and a small amount of funding to the states for their elder abuse prevention services. A focus at national level is also provided by the National Committee for the Prevention of Elder Abuse, a non-profit organization formed in 1988, and the National Association

of State Adult Protective Services Administrators, established in 1989.

In Australia and Canada, some provinces or states have set up systems to deal with cases of elder abuse, but no official federal policy has been announced. New Zealand has established a series of pilot projects throughout the country. All three of these countries have national groups. The New Zealand National Elder Abuse and Neglect Advisory Council was formed in the early 1990s to provide a national perspective on strategies for the care and protection of older people. The Australian Network for the Prevention of Elder Abuse was set up in 1998, as a point of contact and information-sharing for those working with older people in abusive situations. In 1999, the Canadian Network for the Prevention of Elder Abuse was created with similar aims – to find ways to develop policies, programmes and services to eliminate elder abuse.

In the United Kingdom, Action on Elder Abuse, a national nongovernmental organization, has helped focus government attention on the abuse of older people, giving rise to policy documents from the Department of Health and the Social Services Inspectorate. Norway leads among the Scandinavian countries, having obtained parliamentary approval for a service project in Oslo and a resource centre for information and research on violence, the latter largely as a result of action by campaigners against elder abuse. Other European countries – including France, Germany, Italy and Poland – are at the ''legitimization'' stage of Blumer's model. Activities for the prevention of elder abuse in these countries are limited mainly to individual researchers and to some local programmes.

The Latin American Committee for the Prevention of Elder Abuse has actively campaigned to draw attention to the problem of abuse of the elderly within Latin American and Caribbean countries, and it offers training at regional and national meetings. For some countries – including Cuba, Peru, Uruguay and Venezuela – awareness of the problem is still emerging, and activities consist mainly of meetings of professionals and research studies. Other countries in the region, such as Argentina, Brazil and Chile, have moved on to legitimization and action.

In Buenos Aires, Argentina, the organization ''Proteger'', dealing exclusively with elder abuse cases, was established in 1998 as one of the programmes of the Department for the Promotion of Social Welfare and Old Age. Professionals and other workers in this programme receive a 6-month training in gerontology, focusing mainly on the prevention of violence and intervention in cases of elder abuse. Proteger also runs a free telephone helpline.

In Brazil, official support for training on elder abuse has been provided by the Ministry of Justice, Health and Welfare. In Chile, as a result of the work of the Interministerial Commission for the Prevention of Intrafamiliar Violence, a law against violence in the family was passed in 1994 (*57*). The law covered all acts of family violence, including those directed at the elderly.

In Asia, studies by researchers in China (Hong Kong SAR), India, Japan and the Republic of Korea have drawn attention to the problem of elder abuse, but no official action, in terms of policies or programme development, has followed so far.

Reports about elder abuse in South Africa first surfaced in 1981. In 1994 a preventive programme on institutional abuse was established jointly by the state and private sector (*58*). Activists working to prevent elder abuse strongly promoted the idea of a national strategy on elder abuse, which the government is now considering, and pushed for the inclusion of elder abuse in the final declaration of the Southern African Development Community Conference on the Prevention of Violence Against Women, held in Maseru, Lesotho, in December 2000. The Nigerian Coalition on Prevention of Elder Abuse brings together all agencies and groups working with and for the elderly. For many other African nations, efforts to deal with elder abuse are overshadowed by other seemingly more pressing concerns – such as conflicts, poverty and debt.

With a rapid expansion of activities worldwide on elder abuse, the International Network for the Prevention of Elder Abuse (INPEA) was formed in 1997, with representation from all six continents.

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INPEA's aims are to: increase public awareness; promote education and training; campaign on behalf of abused and neglected older people; and promote research into the causes, consequences, treatment and prevention of elder abuse. During INPEA's early stage of development, workshops have been the main medium of training, and have been conducted at professional meetings in Australia, Brazil, Canada, Cuba, the United Kingdom and the United States. A quarterly newsletter and a web site have been set up. INPEA was also the inspiration for both the Australian and the Canadian networks.

Local responses

Most of the programmes set up to tackle the problem of abuse of the elderly are found in high-income countries. They are generally conducted under the auspices of the social services, health care or legal systems or in conjunction with programmes to combat family violence. Although elder abuse has been proven to exist in several low-income or middle-income countries, few specific programmes have been established. In these countries, cases of elder abuse are generally handled by governmental or nongovernmental social service agencies, even though the staff of such agencies might not always be knowledgeable about the subject. Costa Rica, where there is a strong local programme in place, is an exception (*11*). In some countries, there are no social services or health care systems to deal with elder abuse.

Social services

In general, countries that deliver services to abused, neglected or exploited older people have done so through the existing health and social services network. Such cases frequently involve medical, legal, ethical, psychological, financial, law enforcement and environmental issues. Guidelines and protocols have been developed to help case workers and special training is usually available to them. Care is generally planned by consulting teams drawn from a wide range of disciplines. Typically, these services operate in close collaboration with task forces, usually representing statutory bodies and voluntary, private and charitable organizations, that offer consultation services, provide training, develop model legislation and identify weak points in the system. Telephone helplines to receive reports of mistreatment are often a feature of such systems (*59, 60*) and are currently operating in the United Kingdom and in local communities in France, Germany and Japan (see Box 5.2). Only the United States and a number of Canadian provinces have created a system solely for handling reports of adult mistreatment. In these adult protection services, as they are known, the case workers investigate and assess cases, develop plans for appropriate care and monitor the cases until they can be handed over to existing social service agencies for the elderly.

There is a growing interest in providing services for victims of elder abuse along the lines of those developed for battered women. Emergency shelters and support groups specifically aimed at older abused people are relatively new. They provide an environment where victims of abuse can share experiences, develop the psychological strength to cope with their fears, self-doubt, stress and anxiety, and raise their self-esteem. One example of how the domestic violence model has been adapted for elder abuse is the programme set up by the Finnish Federation of Mother and Child Homes and Shelters in collaboration with a local nursing home and the Finnish health care system. This project provides emergency shelter beds in the nursing home, a telephone helpline offering advice and an opportunity for older people to talk about their problems, and a biweekly victim support group meeting. Other such emergency shelters exist in Canada, Germany, Japan and the United States.

In low-income countries lacking the social service infrastructure to undertake these types of programmes, local projects can be established to help older people plan programmes and develop their own services, as well as to campaign for change. Such activities will also give the older people strength and self-esteem. In Guatemala, for instance, blind older people who had been ejected from their homes by their families formed their own committee, created a safe house for themselves, and set up local handicraft and other

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BOX 5.2

The Japan Elder Abuse Prevention Centre

In 1993, the Society for the Study of Elder Abuse (SSEA) in Japan, an independent group consisting largely of social workers and academics, carried out a national survey of community care centres. Their study confirmed the existence of elder abuse in Japan. Based on the results, SSEA decided that a telephone counselling service, similar to that run in the United Kingdom by Action on Elder Abuse, was the best way to confront the problem of elder abuse (*60*).

With financial help from a national nongovernmental organization, the Japan Elder Abuse Prevention Centre was set up in 1996 as a non-profit body, offering a volunteer-operated telephone counselling service known simply as *Helpline*. One of the SSEA's members, a director of a nursing home, made a room available in the nursing home for use as an office and provided other help. The counselling service was advertised in newspapers, support centres and other agencies.

Helpline now offers a wide range of information as well as legal counselling to anyone — including health care and welfare professionals — with a problem related to elder abuse.

Initially, *Helpline* counsellors were all members of the SSEA, but three outside volunteers were subsequently added to the staff. On any particular day, one or two counsellors are in attendance. Extensive training is given to new counsellors, and all counsellors attend monthly meetings at the SSEA, to exchange information on elder abuse and review their case studies. Outside professionals may be called in, if required, to help deal with special cases.

Helpline is exclusively a telephone service. If a caller needs counselling in person, rather than by telephone, their case is handed over to a local home service support centre. Privacy, confidentiality and the anonymity of the callers are key concerns of *Helpline.*

income-generating projects to help fund the safe house (*61*).

Health care

In some Latin American and European countries, as well as in Australia, the medical profession has played a leading role in raising public concern about elder abuse. In other countries, including Canada and the United States, physicians have lagged many years behind the social work and nursing professions. Few intervention programmes for abused older people are housed in hospital settings. Where these do exist, they are usually consultation teams who are on call in the event a suspected case of abuse is reported. Those involved in the provision of health care have an important role to play in programmes that screen for and detect abuse.

While it may be thought that doctors are best placed to notice cases of abuse – partly because of the trust that most elderly people have in them – many doctors do not diagnose abuse because it is not part of their formal or professional training and hence does not feature in their list of differential diagnoses.

In emergency rooms, too, it would seem, scant attention is usually paid to the special needs of elderly people. Health care professionals often feel more comfortable dealing with younger people than they do with elderly ones, and the concerns of older patients are frequently ignored. Most emergency departments do not use protocols to detect and deal with elder abuse, and rarely attempt to address the mental health or behavioural signs of elder abuse, such as depression, attempted suicide, or drug or alcohol abuse (*62*).

There should be an investigation of a patient's condition for possible abuse (*63, 64*) if a doctor or other health care worker notices any of the following signs:

— delays between injuries or illness and seeking medical attention;

— implausible or vague explanations for injuries or ill-health, from either the patient or his or her caregiver;
— differing case histories from the patient and the caregiver;
— frequent visits to emergency departments because a chronic condition has worsened, despite a care plan and resources to deal with this in the home;
— functionally impaired older patients who arrive without their main caregivers;
— laboratory findings that are inconsistent with the history provided.

When conducting an examination (*65*), the doctor or health care worker should:

— interview the patient alone, asking directly about possible physical violence, restraints or neglect;
— interview the suspected abuser alone;
— pay close attention to the relationship between, and the behaviour of, the patient and his or her suspected abuser;
— conduct a comprehensive geriatric assessment of the patient, including medical, functional, cognitive and social factors;
— document the patient's social networks, both formal and informal.

Table 5.1 contains a list of indicators that may serve as a useful guide if mistreatment is suspected. The presence of any indicator in this table, though, should not be taken as proof that abuse has actually taken place.

Legal action

Despite a growing interest in the problem, most countries have not introduced specific legislation on elder abuse. Particular aspects of abuse are usually covered either by criminal law, or by laws dealing with civil rights, property rights, family violence or mental health. Specific and comprehensive legislation on the abuse of older people would imply a much stronger commitment to eradicating the problem. However, even where such laws exist, cases of elder abuse have only rarely been prosecuted. This is principally because older people are usually reluctant – or unable – to press charges against family members, because older people are often regarded as being unreliable witnesses, or because of the inherently hidden nature of elder abuse. As long as elder abuse is viewed solely as a caregiver issue, legal action is not likely to be an effective measure.

Only the Atlantic provinces of Canada, Israel, and a number of states in the United States have legislation for the mandatory reporting of abuse of the elderly. In the United States, 43 states require professionals and others working with older people to report possible cases of elder abuse to a state-designated agency, should they have ''reason to believe'' that abuse, neglect or exploitation has taken place. The first of these states passed its legislation in 1976, and the most recent in 1999. The Canadian province of Newfoundland passed its adult protection law as early as 1973, with the last of the four Atlantic provinces, Prince Edward Island, following in 1988. Israel's law dates from 1989. As with child abuse reporting laws, all these laws on elder abuse were introduced to prevent evidence of abuse from going unnoticed. Mandatory reporting was considered a valuable tool, particularly in situations where victims were unable to report and professionals were reluctant to refer cases. While research on the impact of existing mandatory reporting does not as yet provide a conclusive answer, the indications are that whether a case is reported or not has less to do with legal requirements than with other organizational, ethical, cultural and professional factors (*66*).

Education and public awareness campaigns

Education and public awareness campaigns have been vital for informing people in industrialized countries about elder abuse. Education involves not only teaching new information but also changing attitudes and behaviour, and is thus a fundamental preventive strategy. It can be conducted in a wide variety of ways – for instance, in training sessions, seminars, continuing educational programmes, workshops, and scientific meetings and conferences. Those targeted will include not only practitioners in the various relevant disciplines – from medicine, mental health and nursing to social

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TABLE 5.1
Indicators of elder abuse

Indicators relating to the elderly person				Indicators relating to the caregiver
Physical	Behavioural and emotional	Sexual	Financial	
• Complaints of being physically assaulted • Unexplained falls and injuries • Burns and bruises in unusual places or of an unusual type • Cuts, finger marks or other evidence of physical restraint • Excessive repeat prescriptions or under-usage of medication • Malnourishment or dehydration without an illness-related cause • Evidence of inadequate care or poor standards of hygiene • Person seeks medical attention from a variety of doctors or medical centres	• Change in eating pattern or sleep problems • Fear, confusion or air of resignation • Passivity, withdrawal or increasing depression • Helplessness, hopelessness or anxiety • Contradictory statements or other ambivalence not resulting from mental confusion • Reluctance to talk openly • Avoidance of physical, eye or verbal contact with caregiver • Older person is isolated by others	• Complaints of being sexually assaulted • Sexual behaviour that is out of keeping with the older person's usual relationships and previous personality • Unexplained changes in behaviour, such as aggression, withdrawal or self-mutilation • Frequent complaints of abdominal pain, or unexplained vaginal or anal bleeding • Recurrent genital infections, or bruises around the breasts or genital area • Torn, stained or bloody underclothes	• Withdrawals of money that are erratic, or not typical of the older person • Withdrawals of money that are inconsistent with the older person's means • Changing a will or property title to leave house or assets to "new friends or relatives" • Property is missing • Older person "can't find" jewellery or personal belongings • Suspicious activity on credit card account • Lack of amenities, when the older person could afford them • Untreated medical or mental health problems • Level of care is not commensurate with the older person's income or assets	• Caregiver appears tired or stressed • Caregiver seems excessively concerned or unconcerned • Caregiver blames the older person for acts such as incontinence • Caregiver behaves aggressively • Caregiver treats the older person like a child or in a dehumanized way • Caregiver has a history of substance abuse or abusing others • Caregiver does not want the older person to be interviewed alone • Caregiver responds defensively when questioned; may be hostile or evasive • Caregiver has been providing care to the older person for a long period of time

work, criminal justice and religion – but also researchers, educators, policy-makers and decision-makers. A typical basic syllabus suitable for most disciplines includes an introduction to the topic of elder abuse, consideration of the signs and symptoms of abuse, and details of local organizations that can provide assistance. More specialized training courses will concentrate on developing skills in interviewing, assessment of abuse cases, and planning care programmes. Even more advanced teaching from specialists in the field is needed to cover ethical and legal matters. Courses in how to work with other professionals and in multidisciplinary teams have also become part of advanced training curricula on elder abuse.

Public education and awareness raising are equally important elements in preventing abuse and neglect. As in public education on child abuse and intimate partner violence, the aim is to inform the general public about the various types of abuse, how to identify the signs and where help can be obtained. People who come into frequent contact with the elderly are a particular target for such education. Apart from family members and friends,

they include postal workers, bank tellers, and electricity and gas meter readers. Educational programmes aimed at older people themselves are usually more successful if the information on abuse is woven into wider topics such as successful ageing or health care. Organizations for the elderly, community centres, day-care programmes, schools (see Box 5.3), and self-help and support groups can all help this educational effort.

The media are a powerful tool for raising public awareness. More positive images and a greater prominence for older people in the media can work towards changing attitudes and reducing the stereotyping that exists around the elderly. The participants in the focus group study in South Africa stressed the importance of the media in raising public awareness (*15*), suggesting that awareness of the problem of elder abuse should also be promoted through community workshops with government involvement. In other developing countries with limited resources, local associations can provide basic education along with health care.

To date, few intervention programmes have been evaluated and it is therefore not possible to say which approaches have had the most success. Efforts to assess the effectiveness of various projects have been hindered by a lack of common definitions, a variety of theoretical explanations, a low level of interest on the part of the scientific community and a lack of funding for rigorous studies to be conducted.

A literature review of studies on elder abuse interventions found that 117 such studies had been published, in English, between 1989 and 1998 (G. Bolen, J. Ploeg & B. Hutchinson, unpublished data, 1999). Not one of them, however, included a comparison group or met standard criteria for a valid evaluation study. Based on these findings, the authors of the review felt that there was insufficient evidence in favour of any specific intervention. Six of the studies reviewed were singled out as most closely meeting the necessary criteria, but they too contained serious methodological weaknesses. Among these six studies, the proportion of cases

BOX 5.3

A Canadian school curriculum to prevent elder abuse

A nongovernmental organization, Health Canada, has developed a two-part educational project on elder abuse for children and young people. The project is intended to make children aware of and sensitive to old age and what it entails, and to create opportunities for young people to foster relationships across the generations. In so doing, it is hoped that children and young people will develop greater respect for the elderly and will be much less inclined, now and in the future, to mistreat them.

The first part of the project is an interactive story-telling kit for children aged 3–7 years, involving games and stories. While not directly addressing the subject of elder abuse, the kit provides positive images of old age. It has also proved effective with older children with a limited knowledge of English.

A formal school curriculum is at the core of the second part of the project, developed after extensive consultations with a range of people — including teachers, youth workers, religious leaders, health care providers, young people, those working with the elderly and older people themselves. The curriculum — appropriate mainly for adolescents — aims to change the deeply-rooted negative attitudes in society about older people and ageing, and to reduce the level of elder abuse.

Also in Canada, schools in Ontario have included the topic of conflict resolution in their curricula, and teachers there have found that a discussion of elder abuse can easily be introduced in this subject.

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successfully resolved following a particular intervention ranged from 22% to 75%.

Recommendations

Although abuse of the elderly by family members, caregivers and others is better understood today than it was 25 years ago, a firmer base of knowledge is needed for policy, planning and programming purposes. Many aspects of the problem remain unknown, including its causes and consequences, and even the extent to which it occurs. Research on the effectiveness of interventions has to date yielded almost no useful or reliable results.

Perhaps the most insidious form of abuse against the elderly lies in the negative attitudes towards, and stereotypes of, older people and the process of ageing itself, attitudes that are reflected in the frequent glorification of youth. As long as older people are devalued and marginalized by society, they will suffer from loss of self-identity and remain highly susceptible to discrimination and all forms of abuse.

Among the priorities for confronting and eradicating the problem of elder abuse are:

— greater knowledge about the problem;
— stronger laws and policies;
— more effective prevention strategies.

Greater knowledge

Better knowledge about elder abuse is a top priority worldwide. In 1990 the Council of Europe convened a broad-ranging conference on the subject that looked at definitions, statistics, laws and policies, prevention and treatment, as well as the available sources of information on elder abuse (*67*). A global working group on elder abuse should be set up to deal with all these subjects. Among other things, such a body could bring together and standardize global statistics, and work out the requirements for a common data-reporting form. The precise role of different cultures in elder abuse should also be researched and better explained.

Research leading to effective interventions is urgently needed. Studies should be conducted to ascertain how older people can play a greater part in designing and participating in prevention programmes, something that has already been started in Canada. This could be particularly relevant in developing countries, where involving older people in the design and implementation of programmes can help raise awareness about their rights, address the problems related to social exclusion and help to empower them (*3*).

More rigorous standards are needed in scientific research on elder abuse. Too much past research has involved small samples and weak methodology, sometimes producing conflicting results. Some studies have shown that the mental state of the abuser and substance abuse are risk factors, but exactly how these factors contribute to abuse or neglect in some cases but not in others has not been investigated. Further work is also needed to resolve the currently contradictory data about cognitive and physical impairment in older people as risk factors for abuse.

Causes of abuse

More research is needed on the role of stress among caregivers, originally considered a primary cause of elder abuse. With the increasing prevalence of Alzheimer disease worldwide and the greater level of abusive behaviour found in families where a family member suffers from the disease, more attention should be given to the relationship between the caregiver and the care recipient. While it may be obvious that social isolation or lack of support can contribute to abuse or neglect, the sufferers of abuse in these situations are generally unwilling to join programmes that encourage social interaction, such as centres for the elderly or day-care activities. Research on who these victims are and on their situations might produce better solutions.

The role of ageism – discrimination against and stigmatization of older people – as a possible cause of elder abuse has yet to be properly investigated, although some specialists in the field have suggested that the marginalization of the elderly is a contributory factor. Cross-cultural studies would probably be helpful in understanding this effect.

Clearly there are certain social and cultural factors in some developing countries that are directly linked to abuse, such as a belief in witchcraft and the abandonment of widows. Other practices, which are also often quoted as being important causal factors, need to be examined, since there has been no research to confirm the claims.

Other cultural and socioeconomic factors, such as poverty, modernization and inheritance systems, may be indirect causes of abuse. The use of the ecological model to explain elder abuse is still new and more research is needed on the factors operating at different levels of the model.

Impact of abuse

The aspect of elder abuse that has perhaps received least attention is the impact on the older person. Longitudinal studies that track both abused and non-abused people over a long period of time should therefore form part of the research agenda. In particular, few studies have looked at the psychological impact on an abused person. Except for depression, little is known about the emotional damage caused to the victims.

Evaluation of interventions

A variety of interventions have been developed, including interventions related to mandatory reporting, protective service units, social service protocols, emergency shelters, support and self-help groups, and consultation teams. Very few of these, however, have been evaluated using an experimental or quasi-experimental research design, and evaluative research of a high standard is urgently required. Unfortunately, the topic of elder abuse has not attracted the attention of many established researchers, whose expertise is nonetheless much needed. A greater investment of resources in studies on elder abuse would encourage such research.

Stronger laws

Basic rights

The human rights of older people must be guaranteed worldwide. To this end:

- Existing laws on domestic or intrafamily violence should be extended to include older people as a group.
- Relevant existing criminal and civil laws should explicitly cover the abuse, neglect and exploitation of older people.
- Governments should introduce new laws specifically to protect older people.

Abusive traditions

Many existing traditions are abusive towards older women, including belief in witchcraft and the practice of abandoning widows. Ending these customs will require a high degree of collaboration among many groups, probably over a long period of time. To help this process:

- Advocacy groups, consisting of older people as well as younger people, should be formed at local, provincial and national levels to campaign for change.
- Governmental health and welfare programmes should actively seek to mitigate the negative impact that many modernization processes and the consequent changes in family structure have on older people.
- National governments should establish an adequate pension system, in all countries where it does not exist.

More effective prevention strategies

At the most basic level, greater importance must be attached to primary prevention. This requires building a society in which older people are allowed to live out their lives in dignity, adequately provided with the necessities of life and with genuine opportunities for self-fulfilment. For those societies overwhelmed by poverty, the challenge is enormous.

Prevention starts with awareness. One important way to raise awareness – both among the public and concerned professionals – is through education and training. Those providing health care and social services at all levels, both in the community and in institutional settings, should receive basic training on the detection of elder abuse. The media are a second powerful tool for raising awareness of the

problem and its possible solutions, among the general public as well as the authorities.

Programmes, in which older people themselves play a leading role, for preventing abuse of the elderly in their homes include:

— recruiting and training older people to serve as visitors or companions to other older people who are isolated;
— creating support groups for victims of elder abuse;
— setting up community programmes to stimulate social interaction and participation among the elderly;
— building social networks of older people in villages, neighbourhoods or housing units;
— working with older people to create ''self-help'' programmes that enable them to be productive.

Preventing elder abuse by helping abusers, particularly adult children, to resolve their own problems is a difficult task. Measures that may be useful include:

— offering services for the treatment of mental health problems and substance abuse;
— making jobs and education available;
— finding new ways of resolving conflict, especially where the traditional role of older people in conflict resolution has been eroded.

Much can also be done to prevent abuse of the elderly in institutional settings. Measures that may be useful include:

— the development and implementation of comprehensive care plans;
— training for staff;
— policies and programmes to address work-related stress among staff;
— the development of policies and programmes to improve the physical and social environment of the institution.

Conclusion

The problem of elder abuse cannot be properly solved if the essential needs of older people – for food, shelter, security and access to health care – are not met. The nations of the world must create an environment in which ageing is accepted as a natural part of the life cycle, where anti-ageing attitudes are discouraged, where older people are given the right to live in dignity – free of abuse and exploitation – and are given opportunities to participate fully in educational, cultural, spiritual and economic activities (*3*).

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CHAPTER 6

Sexual violence

Background

Sexual violence occurs throughout the world. Although in most countries there has been little research conducted on the problem, available data suggest that in some countries nearly one in four women may experience sexual violence by an intimate partner (*1–3*), and up to one-third of adolescent girls report their first sexual experience as being forced (*4–6*).

Sexual violence has a profound impact on physical and mental health. As well as causing physical injury, it is associated with an increased risk of a range of sexual and reproductive health problems, with both immediate and long-term consequences (*4, 7–16*). Its impact on mental health can be as serious as its physical impact, and may be equally long lasting (*17–24*). Deaths following sexual violence may be as a result of suicide, HIV infection (*25*) or murder – the latter occurring either during a sexual assault or subsequently, as a murder of ''honour'' (*26*). Sexual violence can also profoundly affect the social well-being of victims; individuals may be stigmatized and ostracized by their families and others as a consequence (*27, 28*).

Coerced sex may result in sexual gratification on the part of the perpetrator, though its underlying purpose is frequently the expression of power and dominance over the person assaulted. Often, men who coerce a spouse into a sexual act believe their actions are legitimate because they are married to the woman.

Rape of women and of men is often used as a weapon of war, as a form of attack on the enemy, typifying the conquest and degradation of its women or captured male fighters (*29*). It may also be used to punish women for transgressing social or moral codes, for instance, those prohibiting adultery or drunkenness in public. Women and men may also be raped when in police custody or in prison.

While sexual violence can be directed against both men and women, the main focus of this chapter will be on the various forms of sexual violence against women, as well as those directed against young girls by people other than caregivers.

How is sexual violence defined?

Sexual violence is defined as:

> any sexual act, attempt to obtain a sexual act, unwanted sexual comments or advances, or acts to traffic, or otherwise directed, against a person's sexuality using coercion, by any person regardless of their relationship to the victim, in any setting, including but not limited to home and work.

Coercion can cover a whole spectrum of degrees of force. Apart from physical force, it may involve psychological intimidation, blackmail or other threats – for instance, the threat of physical harm, of being dismissed from a job or of not obtaining a job that is sought. It may also occur when the person aggressed is unable to give consent – for instance, while drunk, drugged, asleep or mentally incapable of understanding the situation.

Sexual violence includes *rape*, defined as physically forced or otherwise coerced penetration – even if slight – of the vulva or anus, using a penis, other body parts or an object. The attempt to do so is known as *attempted rape*. Rape of a person by two or more perpetrators is known as *gang rape*.

Sexual violence can include other forms of assault involving a sexual organ, including coerced contact between the mouth and penis, vulva or anus.

Forms and contexts of sexual violence

A wide range of sexually violent acts can take place in different circumstances and settings. These include, for example:

- rape within marriage or dating relationships;
- rape by strangers;
- systematic rape during armed conflict;
- unwanted sexual advances or sexual harassment, including demanding sex in return for favours;
- sexual abuse of mentally or physically disabled people;
- sexual abuse of children;
- forced marriage or cohabitation, including the marriage of children;
- denial of the right to use contraception or to adopt other measures to protect against sexually transmitted diseases;
- forced abortion;

— violent acts against the sexual integrity of women, including female genital mutilation and obligatory inspections for virginity;
— forced prostitution and trafficking of people for the purpose of sexual exploitation.

There is no universally accepted definition of trafficking for sexual exploitation. The term encompasses the organized movement of people, usually women, between countries and within countries for sex work. Such trafficking also includes coercing a migrant into a sexual act as a condition of allowing or arranging the migration.

Sexual trafficking uses physical coercion, deception and bondage incurred through forced debt. Trafficked women and children, for instance, are often promised work in the domestic or service industry, but instead are usually taken to brothels where their passports and other identification papers are confiscated. They may be beaten or locked up and promised their freedom only after earning – through prostitution – their purchase price, as well as their travel and visa costs (*30–33*).

The extent of the problem

Sources of data

Data on sexual violence typically come from police, clinical settings, nongovernmental organizations and survey research. The relationship between these sources and the global magnitude of the problem of sexual violence may be viewed as corresponding to an iceberg floating in water (*34*) (see Figure 6.1). The small visible tip represents cases reported to police. A larger section may be elucidated through survey research and the work of nongovernmental organizations. But beneath the surface remains a substantial although unquantified component of the problem.

In general, sexual violence has been a neglected area of research. The available data are scanty and fragmented. Police data, for instance, are often incomplete and limited. Many women do not report sexual violence to police because they are ashamed, or fear being blamed, not believed or otherwise mistreated. Data from medico-legal clinics, on the other hand, may be biased towards the more violent incidents of sexual abuse. The proportion of women who seek medical services for immediate problems related to sexual violence is also relatively small.

Although there have been considerable advances over the past decade in measuring the phenomenon through survey research, the definitions used have varied considerably across studies. There are also significant differences across cultures in the willingness to disclose sexual violence to researchers. Caution is therefore needed when making global comparisons of the prevalence of sexual violence.

Estimates of sexual violence

Surveys of victims of crime have been undertaken in many cities and countries, using a common methodology to aid comparability, and have generally included questions on sexual violence. Table 6.1 summarizes data from some of these surveys on the prevalence of sexual assault over the preceding 5 years (*35, 36*). According to these

FIGURE 6.1
Magnitude of the problem of sexual violence

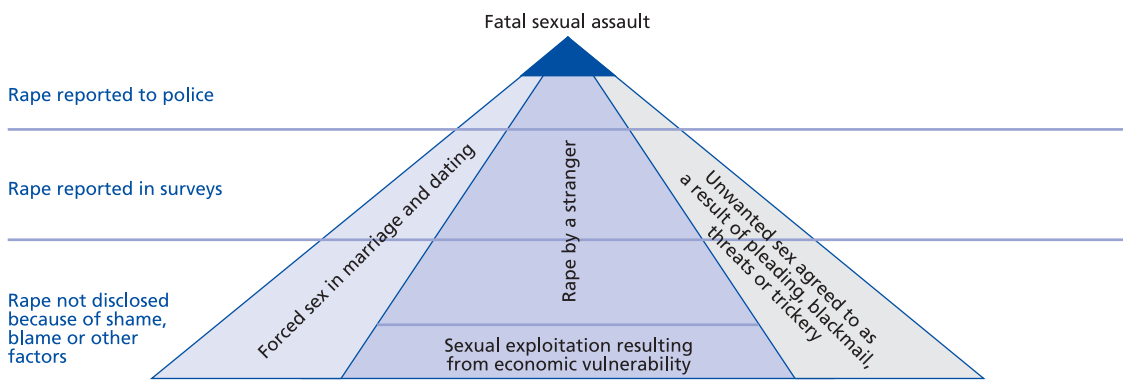

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TABLE 6.1

Percentage of women aged 16 years and older who report having been sexually assaulted in the previous 5 years, selected cities, 1992–1997

Country	Study population	Year	Sample size	Percentage of women (aged 16 years and older) sexually assaulted in the previous 5 years (%)
Africa				
Botswana	Gaborone	1997	644	0.8
Egypt	Cairo	1992	1000	3.1
South Africa	Johannesburg	1996	1006	2.3
Tunisia	Grand-Tunis	1993	1087	1.9
Uganda	Kampala	1996	1197	4.5
Zimbabwe	Harare	1996	1006	2.2
Latin America				
Argentina	Buenos Aires	1996	1000	5.8
Bolivia	La Paz	1996	999	1.4
Brazil	Rio de Janiero	1996	1000	8.0
Colombia	Bogotá	1997	1000	5.0
Costa Rica	San José	1996	1000	4.3
Paraguay	Asunción	1996	587	2.7
Asia				
China	Beijing	1994	2000	1.6
India	Bombay	1996	1200	1.9
Indonesia	Jakarta and Surabaya	1996	1400	2.7
Philippines	Manila	1996	1500	0.3
Eastern Europe				
Albania	Tirana	1996	1200	6.0
Hungary	Budapest	1996	756	2.0
Lithuania	Ðiauliai, Kaunas, Klaipêda, Panevêžys, Vilnius	1997	1000	4.8
Mongolia	Ulaanbaatar, Zuunmod	1996	1201	3.1

Source: references *35* and *36*.

studies, the percentage of women reporting having been a victim of sexual assault ranges from less than 2% in places such as La Paz, Bolivia (1.4%), Gaborone, Botswana (0.8%), Beijing, China (1.6%), and Manila, Philippines (0.3%), to 5% or more in Tirana, Albania (6.0%), Buenos Aires, Argentina (5.8%), Rio de Janeiro, Brazil (8.0%), and Bogotá, Colombia (5.0%). It is important to note that no distinction has been made in these figures between rape by strangers and that by intimate partners. Surveys that fail to make this distinction or those that only examine rape by strangers usually underestimate substantially the prevalence of sexual violence (*34*).

Apart from crime surveys, there have been a small number of surveys, with representative samples, that have asked women about sexual violence. For instance, in a national survey conducted in the United States of America, 14.8% of women over 17 years of age reported having been raped in their lifetime (with an additional 2.8% having experienced attempted rape) and 0.3% of the sample reported having been raped in the previous year (*37*). A survey of a representative sample of women aged 18–49 years in three provinces of South Africa found that in the previous year 1.3% of women had been forced, physically or by means of verbal threats, to have non-consensual sex (*34*). In a survey of a representative sample of the general population over 15 years of age in the Czech Republic (*38*), 11.6% of women reported forced sexual contact in their lifetime, 3.4% reporting that this had occurred more than once. The most common form of contact was forced vaginal intercourse.

Sexual violence by intimate partners

In many countries a substantial proportion of women experiencing physical violence also experience sexual abuse. In Mexico and the United States, studies estimate that 40–52% of women experiencing physical violence by an intimate partner have also been sexually coerced by that partner (*39, 40*). Sometimes, sexual violence occurs without physical violence (*1*). In the Indian state of Uttar Pradesh, in a representative sample of over 6000 men, 7% reported having sexually and physically abused their wives, 22% reported using sexual violence without physical violence and 17% reported that they had used physical violence alone (*41*).

Table 6.2 summarizes some of the available data on the prevalence of sexual coercion by intimate partners (*1–3, 37, 42–53*). Findings from these

TABLE 6.2

Percentage of adult women reporting sexual victimization by an intimate partner, selected population-based surveys, 1989–2000

Country	Study population	Year	Sample size	Percentage assaulted in past 12 months	Percentage ever assaulted	
				Attempted or completed forced sex (%)	Attempted or completed forced sex (%)	Completed forced sex (%)
Brazil[a]	Sao Paulo	2000	941[a]	2.8	10.1	
	Pernambuco	2000	1 188[a]	5.6	14.3	
Canada	National	1993	12 300		8.0	
	Toronto	1991–1992	420		15.3[b]	
Chile	Santiago	1997	310	9.1		
Finland	National	1997–1998	7 051	2.5	5.9	
Japan[a]	Yokohama	2000	1 287[a]	1.3	6.2	
Indonesia	Central Java	1999–2000	765	13.0		22.0
Mexico	Durango	1996	384		42.0	
	Guadalajara	1996	650	15.0	23.0	
Nicaragua	León	1993	360		21.7	
	Managua	1997	378	17.7		
Peru[a]	Lima	2000	1 086[a]	7.1	22.5	
	Cusco	2000	1 534[a]	22.9	46.7	
Puerto Rico	National	1993–1996	7 079			5.7[b]
Sweden	Teg, Umeå	1991	251		7.5[c]	
Switzerland	National	1994–1995	1 500		11.6	
Thailand[a]	Bangkok	2000	1 051[a]	17.1	29.9	
	Nakornsawan	2000	1 027[a]	15.6	28.9	
Turkey	East and south-east Anatolia	1998	599			51.9[b]
United Kingdom	England, Scotland and Wales	1989	1 007			14.2[d]
	North London, England	1993	430	6.0[b]	23.0[b]	
United States	National	1995–1996	8 000	0.2[b]	7.7[b]	
West Bank and Gaza Strip	Palestinians	1995	2 410	27.0		
Zimbabwe	Midlands Province	1996	966		25.0	

Sources: references *1–3, 37, 42–53*.

[a] Preliminary results from the *WHO multi-country study on women's health and domestic violence*. Geneva, World Health Organization, 2000 (unpublished). Sample size reported is the denominator for the prevalence rate and not the total sample size of the study.

[b] Sample group included women who had never been in a relationship and therefore were not at risk of being assaulted by an intimate partner.

[c] Offenders reported to be husbands, boyfriends and acquaintances.

[d] Weighted estimate; unweighted prevalence rate was 13.9%.

studies show that sexual assault by an intimate partner is neither rare nor unique to any particular region of the world. For instance, 23% of women in North London, England, reported having been the victim of either an attempted or completed rape by a partner in their lifetime. Similar figures have been reported for Guadalajara, Mexico (23.0%), León, Nicaragua (21.7%), Lima, Peru (22.5%), and for the Midlands Province in Zimbabwe (25.0%). The prevalence of women sexually assaulted by an intimate partner in their lifetime (including attempted assaults) has also been estimated in a few national surveys (for example, Canada 8.0%, England, Wales and Scotland (combined) 14.2%, Finland 5.9%, Switzerland 11.6% and the United States 7.7%).

Forced sexual initiation

A growing number of studies, particularly from sub-Saharan Africa, indicate that the first sexual experience of girls is often unwanted and forced. In a

case–control study, for example, of 191 adolescent girls (mean age 16.3 years) attending an antenatal clinic in Cape Town, South Africa, and 353 non-pregnant adolescents matched for age and neighbourhood or school, 31.9% of the study cases and 18.1% of the controls reported that force was used during their sexual initiation. When asked about the consequences of refusing sex, 77.9% of the study cases and 72.1% of the controls said that they feared being beaten if they refused to have sex (*4*).

Forced sexual initiation and coercion during adolescence have been reported in many studies of young women and men (see Table 6.3 and Box 6.1). Where studies have included both men and women in the sample, the prevalence of reported rape or sexual coercion has been higher among the women than the men (*5, 6, 54–60*). For example, nearly half of the sexually active adolescent women in a multi-country study in the Caribbean reported that their first sexual intercourse was forced, compared with one-third of the adolescent men (*60*). In Lima, Peru, the percentage of young women reporting forced sexual initiation was almost four times that reported by the young men (40% against 11%, respectively) (*56*).

Gang rape

Rape involving at least two or more perpetrators is widely reported to occur in many parts of the world. Systematic information on the extent of the problem, however, is scant. In Johannesburg, South Africa, surveillance studies of women attending medico-legal clinics following a rape found that one-third of the cases had been gang rapes (*61*). National data on rape and sexual assault in the United States reveal that about 1 out of 10 sexual assaults involve multiple perpetrators. Most of these assaults are committed by people unknown to their victims (*62*). This pattern, though, differs from that in South Africa where boyfriends are often involved in gang rapes.

Sexual trafficking

Each year hundreds of thousands of women and girls throughout the world are bought and sold into prostitution or sexual slavery (*30–32, 63, 64*). Research in Kyrgyzstan has estimated that around 4000 people were trafficked from the country in 1999, with the principal destinations being China, Germany, Kazakhstan, the Russian Federation, Turkey and the United Arab Emirates. Of those trafficked, 62% reported being forced to work without pay, while over 50% reported being physically abused or tortured by their employers (*31*). A World Organization against Torture (OMCT) report suggested that more than 200 000 Bangladeshi women had been trafficked between 1990 and 1997 (*65*). Some 5000–7000 Nepali

TABLE 6.3

Percentage of adolescents reporting forced sexual initiation, selected population-based surveys, 1993–1999

Country or area	Study population	Year	Sample		Percentage reporting first sexual intercourse as forced (%)	
			Size[a]	Age group (years)	Females	Males
Cameroon	Bamenda	1995	646	12–25	37.3	29.9
Caribbean	Nine countries[b]	1997–1998	15 695	10–18	47.6[c]	31.9[c]
Ghana	Three urban towns	1996	750	12–24	21.0	5.0
Mozambique	Maputo	1999	1 659	13–18	18.8	6.7
New Zealand	Dunedin	1993–1994	935	Birth cohort[d]	7.0	0.2
Peru	Lima	1995	611	16–17	40.0	11.0
South Africa	Transkei	1994–1995	1 975	15–18	28.4	6.4
United Republic of Tanzania	Mwanza	1996	892	12–19	29.1	6.9
United States	National	1995	2 042	15–24	9.1	–

Source: references *5, 6* and *54–60*.

[a] Total number of adolescents in the study. Rates are based on those who have had sexual intercourse.

[b] Antigua, Bahamas, Barbados, British Virgin Islands, Dominica, Grenada, Guyana, Jamaica and Saint Lucia.

[c] Percentage of adolescents responding that their first intercourse was forced or ''somewhat'' forced.

[d] Longitudinal study of a cohort born in 1972–1973. Subjects were questioned at 18 years of age and again at 21 years of age about their current and previous sexual behaviour.

BOX 6.1

Sexual violence against men and boys

Sexual violence against men and boys is a significant problem. With the exception of childhood sexual abuse, though, it is one that has largely been neglected in research. Rape and other forms of sexual coercion directed against men and boys take place in a variety of settings, including in the home, the workplace, schools, on the streets, in the military and during war, as well as in prisons and police custody.

In prisons, forced sex can occur among inmates to establish hierarchies of respect and discipline. Sexual violence by prison officials, police and soldiers is also widely reported in many countries. Such violence may take the form of prisoners being forced to have sex with others as a form of ''entertainment'', or to provide sex for the officers or officials in command. Elsewhere, men who have sex with other men may be ''punished'', by rape, for their behaviour which is perceived to transgress social norms.

The extent of the problem

Studies conducted mostly in developed countries indicate that 5–10% of men report a history of childhood sexual abuse. In a few population-based studies conducted with adolescents in developing countries, the percentage of males reporting ever having been the victim of a sexual assault ranges from 3.6% in Namibia and 13.4% in the United Republic of Tanzania to 20% in Peru. Studies from both industrialized and developing countries also reveal that forced first intercourse is not rare. Unfortunately, there are few reliable statistics on the number of boys and men raped in settings such as schools, prisons and refugee camps.

Most experts believe that official statistics vastly under-represent the number of male rape victims. The evidence available suggests that males may be even less likely than female victims to report an assault to the authorities. There are a variety of reasons why male rape is under-reported, including shame, guilt and fear of not being believed or of being denounced for what has occurred. Myths and strong prejudices surrounding male sexuality also prevent men from coming forward.

Consequences of sexual violence

As is the case with female victims of sexual assault, research suggests that male victims are likely to suffer from a range of psychological consequences, both in the immediate period after the assault and over the longer term. These include guilt, anger, anxiety, depression, post-traumatic stress disorder, sexual dysfunction, somatic complaints, sleep disturbances, withdrawal from relationships and attempted suicide. In addition to these reactions, studies of adolescent males have also found an association between suffering rape and substance abuse, violent behaviour, stealing and absenteeism from school.

Prevention and policy responses

Prevention and policy responses to sexual violence against men need to be based on an understanding of the problem, its causes and the circumstances in which it occurs. In many countries the phenomenon is not adequately addressed in legislation. In addition, male rape is frequently not treated as an equal offence with rape of women.

Many of the considerations relating to support for women who have been raped — including an understanding of the healing process, the most urgent needs following an assault and the effectiveness of support services — are also relevant for men. Some countries have progressed in their response to male sexual assault, providing special telephone hotlines, counselling, support

BOX 6.1 (continued)

groups and other services for male victims. In many places, though, such services are either not available or else are very limited — for instance, focusing primarily on women, with few, if any, counsellors on hand who are experienced in discussing problems with male victims.

In most countries, there is much to be done before the issue of sexual violence against men and boys can be properly acknowledged and discussed, free of denial or shame. Such a necessary development, though, will enable more comprehensive prevention measures and better support for the victims to be implemented.

women and girls are illegally traded to India each year and trafficking of Thai women to Japan has also been reported (*32*). Trafficking of women also takes place internally within some countries, often from rural areas to cities.

North America is also an important destination for international trafficking. A study undertaken under the auspices of the United States Central Intelligence Agency, estimated that 45 000–50 000 women and children are trafficked annually to the United States (*63*). Over 150 cases of trafficking were prosecuted between 1996 and 1999 by the United States Department of Justice (*63*). The problem also exists in Europe. A study conducted by the International Organization for Migration estimated that 10–15% of 2000 known foreign prostitutes in Belgium had been forcibly sold from abroad (*30*). In Italy, a study of some 19 000–25 000 foreign prostitutes estimated that 2000 of them had been trafficked (*66*). Most of these women were under 25 years of age, many of them between 15 and 18 years (*30, 66*). Their origin was mainly central and eastern Europe, particularly Albania, as well as Colombia, Nigeria and Peru (*66*).

Sexual violence against sex workers

Whether trafficked or not, sex workers are at high risk for both physical and sexual violence, particularly where sex work is illegal (*67*). A survey of female sex workers in Leeds, England, and Glasgow and Edinburgh, Scotland, revealed that 30% had been slapped, punched or kicked by a client while working, 13% had been beaten, 11% had been raped and 22% had experienced an attempted rape (*68*). Only 34% of those who had suffered violence at the hands of a client reported it to police. A survey of sex workers in Bangladesh revealed that 49% of the women had been raped and 59% beaten by police in the previous year; the men reported much lower levels of violence (*69*). In Ethiopia, a study of sex workers also found high rates of physical and sexual violence from clients, especially against the child sex workers (*70*).

Sexual violence in schools, health care settings, armed conflicts and refugee settings

Schools

For many young women, the most common place where sexual coercion and harassment are experienced is in school. In an extreme case of violence in 1991, 71 teenage girls were raped by their classmates and 19 others were killed at a boarding school in Meru, Kenya (*71*). While much of the research in this field comes from Africa, it is not clear whether this reflects a particularly high prevalence of the problem or simply the fact that the problem has had a greater visibility there than in other parts of the world.

Harassment of girls by boys is in all likelihood a global problem. In Canada, for example, 23% of girls had experienced sexual harassment while attending school (*72*). The research done in Africa, however, has highlighted the role of teachers there in facilitating or perpetrating sexual coercion. A report by Africa Rights (*28*) found cases of schoolteachers attempting to gain sex, in return for good grades or for not failing pupils, in the Democratic Republic of the Congo, Ghana, Nigeria, Somalia, South Africa, Sudan, Zambia and Zimbabwe. A recent national survey in South Africa that included questions about experience of rape before the age of 15 years found that schoolteachers were

responsible for 32% of disclosed child rapes (*34*). In Zimbabwe, a retrospective study of reported cases of child sexual abuse over an 8-year period (1990–1997) found high rates of sexual abuse committed by teachers in rural primary schools. Many of the victims were girls between 11 and 13 years of age and penetrative sex was the most prevalent type of sexual abuse (*73*).

Health care settings

Sexual violence against patients in health facilities has been reported in many places (*74–79*). A study of physicians disciplined for sexual offences in the United States, for instance, found that the number of cases had increased from 42 in 1989 to 147 in 1996, with the proportion of all disciplinary action that was sex-related rising from 2.1% to 4.4% over the same period (*76*). This increase, though, could reflect a greater readiness to lodge complaints.

Other documented forms of sexual violence against female patients include the involvement of medical staff in the practice of clitoridectomy in Egypt (*80*), forced gynaecological examinations and the threat of forced abortions in China (*81*), and inspections of virginity in Turkey (*82*). Sexual violence is part of the broader problem of violence against women patients perpetrated by health workers that has been reported in a large number of countries and until recently has been much neglected (*83–87*). Sexual harassment of female nurses by male doctors has also been reported (*88, 89*).

Armed conflicts and refugee settings

Rape has been used as a strategy in many conflicts, including in Korea during the Second World War and in Bangladesh during the war of independence, as well as in a range of armed conflicts such as those in Algeria (*90*), India (Kashmir) (*91*), Indonesia (*92*), Liberia (*29*), Rwanda and Uganda (*93*). In some armed conflicts – for example, the ones in Rwanda and the states of the former Yugoslavia – rape has been used as a deliberate strategy to subvert community bonds and thus the perceived enemy, and furthermore as a tool of ''ethnic cleansing''. In East Timor, there were reports of extensive sexual violence against women by the Indonesian military (*94*).

A study in Monrovia, Liberia, found that women under 25 years were more likely than those aged 25 years and over to report experiencing attempted rape and sexual coercion during the conflict (18% compared with 4%) (*29*). Women who were forced to cook for a warring faction were at significantly higher risk.

Another inevitable consequence of armed conflicts is the ensuing economic and social disruption which can force large numbers of people into prostitution (*94*), an observation that applies equally to the situation of refugees, whether they are fleeing armed conflicts or natural disasters such as floods, earthquakes or powerful storms.

Refugees fleeing conflicts and other threatening conditions are often at risk of rape in their new setting. Data from the Office of the United Nations High Commissioner for Refugees, for instance, indicated that among the ''boat people'' who fled Viet Nam in the late 1970s and early 1980s, 39% of the women were abducted or raped by pirates while at sea – a figure that is likely to be an underestimate (*27*). In many refugee camps as well, including those in Kenya and the United Republic of Tanzania, rape has been found to be a major problem (*95, 96*).

''Customary'' forms of sexual violence

Child marriage

Marriage is often used to legitimize a range of forms of sexual violence against women. The custom of marrying off young children, particularly girls, is found in many parts of the world. This practice – legal in many countries – is a form of sexual violence, since the children involved are unable to give or withhold their consent. The majority of them know little or nothing about sex before they are married. They therefore frequently fear it (*97*) and their first sexual encounters are often forced (*98*).

Early marriage is most common in Africa and South Asia, though it also occurs in the Middle East and parts of Latin America and Eastern Europe (*99, 100*). In Ethiopia and parts of West Africa, for instance, marriage at the age of 7 or 8 years is not

uncommon. In Nigeria, the mean age at first marriage is 17 years, but in the Kebbi State of northern Nigeria, the average age at first marriage is just over 11 years (*100*). High rates of child marriage have also been reported in the Democratic Republic of the Congo, Mali, Niger and Uganda (*99, 100*).

In South Asia, child marriage is especially common in rural areas, but exists also in urban areas (*100–102*). In Nepal, the average age at first marriage is 19 years. Seven per cent of girls, though, are married before the age of 10 years, and 40% by the age of 15 years (*100*). In India, the median age at first marriage for women is 16.4 years. A survey of 5000 women in the Indian state of Rajasthan found that 56% of the women had married before the age of 15 years, and of these, 17% were married before they were 10 years old. Another survey, conducted in the state of Madhya Pradesh, found that 14% of girls were married between the ages of 10 and 14 years (*100*).

Elsewhere, in Latin America for instance, early age at first marriage has been reported in Cuba, Guatemala, Honduras, Mexico and Paraguay (*99, 100*). In North America and Western Europe, less than 5% of marriages involve girls younger than 19 years of age (for example, 1% in Canada, Switzerland and the United Kingdom, 2% in Belgium and Germany, 3% in Spain, and 4% in the United States) (*103*).

Other customs leading to violence

In many places, there are customs other than child marriage that result in sexual violence towards women. In Zimbabwe, for instance, there is the custom of *ngozi*, whereby a girl can be given to a family as compensation for a death of a man caused by a member of the girl's family. On reaching puberty the girl is expected to have sexual intercourse with the brother or father of the deceased person, so as to produce a son to replace the one who died. Another custom is *chimutsa mapfiwa* – wife inheritance – according to which, when a married woman dies, her sister is obliged to replace her in the matrimonial home.

What are the risk factors for sexual violence?

Explaining sexual violence against women is complicated by the multiple forms it takes and contexts in which it occurs. There is considerable overlap between forms of sexual violence and intimate partner violence; many of the causes are similar to those already discussed in Chapter 4. There are factors increasing the risk of someone being coerced into sex, factors increasing the risk of an individual man forcing sex on another person, and factors within the social environment – including peers and family – influencing the likelihood of rape and the reaction to it. Research suggests that the various factors have an additive effect, so that the more factors present, the greater the likelihood of sexual violence. In addition, a particular factor may vary in importance according to the life stage.

Factors increasing women's vulnerability

One of the most common forms of sexual violence around the world is that which is perpetrated by an intimate partner, leading to the conclusion that one of the most important risk factors for women – in terms of their vulnerability to sexual assault – is being married or cohabiting with a partner. Other factors influencing the risk of sexual violence include:

- being young;
- consuming alcohol or drugs;
- having previously been raped or sexually abused;
- having many sexual partners;
- involvement in sex work;
- becoming more educated and economically empowered, at least where sexual violence perpetrated by an intimate partner is concerned;
- poverty.

Age

Young women are usually found to be more at risk of rape than older women (*24, 62, 104*). According to data from justice systems and rape crisis centres in Chile, Malaysia, Mexico, Papua New Guinea, Peru and the United States, between

one-third and two-thirds of all victims of sexual assault are aged 15 years or less (*62, 104*). Certain forms of sexual violence, for instance, are very closely associated with a young age, in particular violence taking place in schools and colleges, and trafficking in women for sexual exploitation.

Alcohol and drug consumption

Increased vulnerability to sexual violence also stems from the use of alcohol and other drugs. Consuming alcohol or drugs makes it more difficult for women to protect themselves by interpreting and effectively acting on warning signs. Drinking alcohol may also place women in settings where their chances of encountering a potential offender are greater (*105*).

Having previously been raped or sexually abused

There is some evidence linking experiences of sexual abuse in childhood or adolescence with patterns of victimization during adulthood (*24, 37, 105–108*). A national study of violence against women in the United States found that women who were raped before the age of 18 years were twice as likely to be raped as adults, compared with those who were not raped as children or adolescents (18.3% and 8.7%, respectively) (*37*). The effects of early sexual abuse may also extend to other forms of victimization and problems in adulthood. For instance, a case–control study in Australia on the long-term impact of abuse reported significant associations between child sexual abuse and experiencing rape, sexual and mental health problems, domestic violence and other problems in intimate relationships – even after accounting for various family background characteristics (*108*). Those who had experienced abuse involving intercourse had more negative outcomes than those suffering other types of coercion.

Having many sexual partners

Young women who have many sexual partners are at increased risk of sexual violence (*105, 107, 109*). It is not clear, though, if having more sexual partners is a cause or consequence of abuse, including childhood sexual abuse. For example, findings from a representative sample of men and women in León, Nicaragua, found that women who had experienced attempted or completed rape during childhood or adolescence were more likely to have a higher number of sexual partners in adulthood, compared with non-abused or moderately abused women (*110*). Similar findings have been reported in longitudinal studies of young women in New Zealand and Norway (*107, 109*).

Educational level

Women are at increased risk of sexual violence, as they are of physical violence by an intimate partner, when they become more educated and thus more empowered. Women with no education were found in a national survey in South Africa to be much less likely to experience sexual violence than those with higher levels of education (*34*). In Zimbabwe, women who were working were much more likely to report forced sex by a spouse than those who were not (*42*). The likely explanation is that greater empowerment brings with it more resistance from women to patriarchal norms (*111*), so that men may resort to violence in an attempt to regain control. The relationship between empowerment and physical violence is an inverted U-shape – with greater empowerment conferring greater risk up to a certain level, beyond which it starts to become protective (*105, 112*). It is not known, though, whether this is also the case for sexual violence.

Poverty

Poor women and girls may be more at risk of rape in the course of their daily tasks than those who are better off, for example when they walk home on their own from work late at night, or work in the fields or collect firewood alone. Children of poor women may have less parental supervision when not in school, since their mothers may be at work and unable to afford child care. The children themselves may, in fact, be working and thus vulnerable to sexual exploitation.

Poverty forces many women and girls into occupations that carry a relatively high risk of sexual violence (*113*), particularly sex work (*114*). It also creates enormous pressures for them to find

TABLE 6.4
Factors increasing men's risk of committing rape

Individual factors	Relationship factors	Community factors	Societal factors
• Alcohol and drug use • Coercive sexual fantasies and other attitudes and beliefs supportive of sexual violence • Impulsive and antisocial tendencies • Preference for impersonal sex • Hostility towards women • History of sexual abuse as a child • Witnessed family violence as a child	• Associate with sexually aggressive and delinquent peers • Family environment characterized by physical violence and few resources • Strongly patriarchal relationship or family environment • Emotionally unsupportive family environment • Family honour considered more important than the health and safety of the victim	• Poverty, mediated through forms of crisis of male identity • Lack of employment opportunities • Lack of institutional support from police and judicial system • General tolerance of sexual assault within the community • Weak community sanctions against perpetrators of sexual violence	• Societal norms supportive of sexual violence • Societal norms supportive of male superiority and sexual entitlement • Weak laws and policies related to sexual violence • Weak laws and policies related to gender equality • High levels of crime and other forms of violence

or maintain jobs, to pursue trading activities and, if studying, to obtain good grades – all of which render them vulnerable to sexual coercion from those who can promise these things (*28*). Poorer women are also more at risk of intimate partner violence, of which sexual violence is often a manifestation (*41, 115*).

Factors increasing men's risk of committing rape

Data on sexually violent men are somewhat limited and heavily biased towards apprehended rapists, except in the United States, where research has also been conducted on male college students. Despite the limited amount of information on sexually violent men, it appears that sexual violence is found in almost all countries (though with differences in prevalence), in all socioeconomic classes and in all age groups from childhood onwards. Data on sexually violent men also show that most direct their acts at women whom they already know (*116, 117*). Among the factors increasing the risk of a man committing rape are those related to attitudes and beliefs, as well as behaviour arising from situations and social conditions that provide opportunities and support for abuse (see Table 6.4).

Alcohol and drug consumption

Alcohol has been shown to play a disinhibiting role in certain types of sexual assault (*118*), as have some drugs, notably cocaine (*119*). Alcohol has a psychopharmacological effect of reducing inhibitions, clouding judgements and impairing the ability to interpret cues (*120*). The biological links between alcohol and violence are, however, complex (*118*). Research on the social anthropology of alcohol consumption suggests that connections between violence, drinking and drunkenness are socially learnt rather than universal (*121*). Some researchers have noted that alcohol may act as a cultural ''break time'', providing the opportunity for antisocial behaviour. Thus men are more likely to act violently when drunk because they do not consider that they will be held accountable for their behaviour. Some forms of group sexual violence are also associated with drinking. In these settings, consuming alcohol is an act of group bonding, where inhibitions are collectively reduced and individual judgement ceded in favour of that of the group.

Psychological factors

There has been considerable research in recent times on the role of cognitive variables among the set of factors that can lead to rape. Sexually violent men have been shown to be more likely to consider victims responsible for the rape and are less knowledgeable about the impact of rape on victims (*122*). Such men may misread cues given out by women in social situations and may lack the inhibitions that act to suppress associations between

sex and aggression (*122, 123*). They have coercive sexual fantasies (*122, 123*), generally encouraged by access to pornography (*124*), and overall are more hostile towards women than men who are not sexually violent (*106, 125, 126*). In addition to these factors, sexually violent men are believed to differ from other men in terms of impulsivity and antisocial tendencies (*105*). They also tend to have an exaggerated sense of masculinity.

Sexual violence is also associated with a preference for impersonal sexual relationships as opposed to emotional bonding, with having many sexual partners and with the inclination to assert personal interests at the expense of others (*125, 127*). A further association is with adversarial attitudes on gender, that hold that women are opponents to be challenged and conquered (*128*).

Peer and family factors

Gang rape

Some forms of sexual violence, such as gang rape, are predominantly committed by young men (*129*). Sexual aggression is often a defining characteristic of manhood in the group and is significantly related to the wish to be held in high esteem (*130*). Sexually aggressive behaviour among young men has been linked with gang membership and having delinquent peers (*126, 131*). Research also suggests that men with sexually aggressive peers are also much more likely to report coercive or enforced intercourse outside the gang context than men lacking sexually aggressive peers (*132*).

Gang rape is often viewed by the men involved, and sometimes by others too, as legitimate, in that it is seen to discourage or punish perceived ''immoral'' behaviour among woman – such as wearing short skirts or frequenting bars. For this reason, it may not be equated by the perpetrators with the idea of a crime. In several areas in Papua New Guinea, women can be punished by public gang rape, often sanctioned by elders (*133*).

Early childhood environments

There is evidence to suggest that sexual violence is also a learnt behaviour in some men, particularly as regards child sexual abuse. Studies on sexually abused boys have shown that around one in five continue in later life to molest children themselves (*134*). Such experiences may lead to a pattern of behaviour where the man regularly justifies being violent, denies doing wrong, and has false and unhealthy notions about sexuality.

Childhood environments that are physically violent, emotionally unsupportive and characterized by competition for scarce resources have been associated with sexual violence (*105, 126, 131, 135*). Sexually aggressive behaviour in young men, for instance, has been linked to witnessing family violence, and having emotionally distant and uncaring fathers (*126, 131*). Men raised in families with strongly patriarchal structures are also more likely to become violent, to rape and use sexual coercion against women, as well as to abuse their intimate partners, than men raised in homes that are more egalitarian (*105*).

Family honour and sexual purity

Another factor involving social relationships is a family response to sexual violence that blames women without punishing men, concentrating instead on restoring ''lost'' family honour. Such a response creates an environment in which rape can occur with impunity.

While families will often try to protect their women from rape and may also put their daughters on contraception to prevent visible signs should it occur (*136*), there is rarely much social pressure to control young men or persuade them that coercing sex is wrong. Instead, in some countries, there is frequently support for family members to do whatever is necessary – including murder – to alleviate the ''shame'' associated with a rape or other sexual transgression. In a review of all crimes of honour occurring in Jordan in 1995 (*137*), researchers found that in over 60% of the cases, the victim died from multiple gunshot wounds – mostly at the hands of a brother. In cases where the victim was a single pregnant female, the offender was either acquitted of murder or received a reduced sentence.

Even though poverty is often the driving force behind child marriage, factors such as maintaining

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the sexual purity of a young girl and protecting her from premarital sex, HIV infection and unwelcome sexual advances are also reasons commonly given by families to justify such marriages (*100*).

Community factors

Poverty

Poverty is linked to both the perpetration of sexual violence and the risk of being a victim of it. Several authors have argued that the relationship between poverty and perpetration of sexual violence is mediated through forms of crisis of masculine identity (*95, 112, 138–140*). Bourgois, writing about life in East Harlem, New York, United States (*138*), described how young men felt pressured by models of ''successful'' masculinity and family structure passed down from their parents' and grandparents' generations, together with modern-day ideals of manhood that also place an emphasis on material consumption. Trapped in their slums, with little or no available employment, they are unlikely to attain either of these models or expectations of masculine ''success''. In these circumstances, ideals of masculinity are reshaped to emphasize misogyny, substance abuse and participation in crime (*138*) – and often also xenophobia and racism. Gang rape and sexual conquest are normalized, as men turn their aggression against women they can no longer control patriarchally or support economically.

Physical and social environment

While fear of rape is typically associated with being outside the home (*141, 142*), the great majority of sexual violence actually occurs in the home of the victim or the abuser. Nonetheless, abduction by a stranger is quite often the prelude to a rape and the opportunities for such an abduction are influenced by the physical environment.

The social environment within a community is, however, usually more important than the physical surrounding. How deeply entrenched in a community beliefs in male superiority and male entitlement to sex are will greatly affect the likelihood of sexual violence taking place, as will the general tolerance in the community of sexual assault and the strength of sanctions, if any, against perpetrators (*116, 143*). For instance, in some places, rape can even occur in public, with passers-by refusing to intervene (*133*). Complaints of rape may also be treated leniently by the police, particularly if the assault is committed during a date or by the victim's husband. Where police investigations and court cases do proceed, the procedures may well be either extremely lax or else corrupt – for instance, with legal papers being ''lost'' in return for a bribe.

Societal factors

Factors operating at a societal level that influence sexual violence include laws and national policies relating to gender equality in general and to sexual violence more specifically, as well as norms relating to the use of violence. While the various factors operate largely at local level, within families, schools, workplaces and communities, there are also influences from the laws and norms working at national and even international level.

Laws and policies

There are considerable variations between countries in their approach to sexual violence. Some countries have far-reaching legislation and legal procedures, with a broad definition of rape that includes marital rape, and with heavy penalties for those convicted and a strong response in supporting victims. Commitment to preventing or controlling sexual violence is also reflected in an emphasis on police training and an appropriate allocation of police resources to the problem, in the priority given to investigating cases of sexual assault, and in the resources made available to support victims and provide medico-legal services. At the other end of the scale, there are countries with much weaker approaches to the issue – where conviction of an alleged perpetrator on the evidence of the women alone is not allowed, where certain forms or settings of sexual violence are specifically excluded from the legal definition, and where rape victims are strongly deterred from bringing the matter to court through the fear of being punished for filing an ''unproven'' rape suit.

Social norms

Sexual violence committed by men is to a large extent rooted in ideologies of male sexual entitlement. These belief systems grant women extremely few legitimate options to refuse sexual advances (*139, 144, 145*). Many men thus simply exclude the possibility that their sexual advances towards a woman might be rejected or that a woman has the right to make an autonomous decision about participating in sex. In many cultures women, as well as men, regard marriage as entailing the obligation on women to be sexually available virtually without limit (*34, 146*), though sex may be culturally proscribed at certain times, such as after childbirth or during menstruation (*147*).

Societal norms around the use of violence as a means to achieve objectives have been strongly associated with the prevalence of rape. In societies where the ideology of male superiority is strong – emphasizing dominance, physical strength and male honour – rape is more common (*148*). Countries with a culture of violence, or where violent conflict is taking place, experience an increase in almost all forms of violence, including sexual violence (*148–151*).

Global trends and economic factors

Many of the factors operating at a national level have an international dimension. Global trends, for instance towards free trade, have been accompanied by an increase in the movement around the world of women and girls for labour, including for sex work (*152*). Economic structural adjustment programmes, drawn up by international agencies, have accentuated poverty and unemployment in a number of countries, thereby increasing the likelihood of sexual trafficking and sexual violence (*153*) – something particularly noted in Central America, the Caribbean (*114*) and parts of Africa (*113*).

The consequences of sexual violence

Physical force is not necessarily used in rape, and physical injuries are not always a consequence. Deaths associated with rape are known to occur, though the prevalence of fatalities varies considerably across the world. Among the more common consequences of sexual violence are those related to reproductive, mental health and social well-being.

Pregnancy and gynaecological complications

Pregnancy may result from rape, though the rate varies between settings and depends particularly on the extent to which non-barrier contraceptives are being used. A study of adolescents in Ethiopia found that among those who reported being raped, 17% became pregnant after the rape (*154*), a figure which is similar to the 15–18% reported by rape crisis centres in Mexico (*155, 156*). A longitudinal study in the United States of over 4000 women followed for 3 years found that the national rape-related pregnancy rate was 5.0% per rape among victims aged 12–45 years, producing over 32 000 pregnancies nationally among women from rape each year (*7*). In many countries, women who have been raped are forced to bear the child or else put their lives at risk with back-street abortions.

Experience of coerced sex at an early age reduces a woman's ability to see her sexuality as something over which she has control. As a result, it is less likely that an adolescent girl who has been forced into sex will use condoms or other forms of contraception, increasing the likelihood of her becoming pregnant (*4, 16, 157, 158*). A study of factors associated with teenage pregnancy in Cape Town, South Africa, found that forced sexual initiation was the third most strongly related factor, after frequency of intercourse and use of modern contraceptives (*4*). Forced sex can also result in unintended pregnancy among adult women. In India, a study of married men revealed that men who admitted forcing sex on their wives were 2.6 times more likely to have caused an unintended pregnancy than those who did not admit to such behaviour (*41*).

Gynaecological complications have been consistently found to be related to forced sex. These include vaginal bleeding or infection, fibroids, decreased sexual desire, genital irritation, pain during intercourse, chronic pelvic pain and urinary tract infections (*8–15*). Women who experience

both physical and sexual abuse from intimate partners are at higher risk of health problems generally than those experiencing physical violence alone (*8, 14*).

Sexually transmitted diseases

HIV infection and other sexually transmitted diseases are recognized consequences of rape (*159*). Research on women in shelters has shown that women who experience both sexual and physical abuse from intimate partners are significantly more likely to have had sexually transmitted diseases (*160*). For women who have been trafficked into sex work, the risks of HIV and other sexually transmitted diseases are likely to be particularly high. The links between HIV and sexual violence, and the relevant prevention strategies, are discussed in Box 6.2.

Mental health

Sexual violence has been associated with a number of mental health and behavioural problems in adolescence and adulthood (*17–20, 22, 23, 161*). In one population-based study, the prevalence of symptoms or signs suggestive of a psychiatric disorder was 33% in women with a history of sexual abuse as adults, 15% in women with a history of physical violence by an intimate partner and 6% in non-abused women (*162*). Sexual violence by an intimate partner aggravates the effects of physical violence on mental health.

Abused women reporting experiences of forced sex are at significantly greater risk of depression and post-traumatic stress disorder than non-abused women (*14, 18, 22, 23*). Post-traumatic stress disorder after rape is more likely if there is injury during the rape, or a history of depression or alcohol abuse (*24*). A study of adolescents in France also found a relationship between having been raped and current sleep difficulties, depressive symptoms, somatic complaints, tobacco consumption and behavioural problems (such as aggressive behaviour, theft and truancy) (*163*). In the absence of trauma counselling, negative psychological effects have been known to persist for at least a year following a rape, while physical health problems and symptoms tend to decrease over such a period (*164*). Even with counselling, up to 50% of women retain symptoms of stress (*165–167*).

Suicidal behaviour

Women who experience sexual assault in childhood or adulthood are more likely to attempt or commit suicide than other women (*21, 168–173*). The association remains, even after controlling for sex, age, education, symptoms of post-traumatic stress disorder and the presence of psychiatric disorders (*168, 174*). The experience of being raped or sexually assaulted can lead to suicidal behaviour as early as adolescence. In Ethiopia, 6% of raped schoolgirls reported having attempted suicide (*154*). A study of adolescents in Brazil found prior sexual abuse to be a leading factor predicting several health risk behaviours, including suicidal thoughts and attempts (*161*).

Experiences of severe sexual harassment can also result in emotional disturbances and suicidal behaviour. A study of female adolescents in Canada found that 15% of those experiencing frequent, unwanted sexual contact had exhibited suicidal behaviour in the previous 6 months, compared with 2% of those who had not had such harassment (*72*).

Social ostracization

In many cultural settings it is held that men are unable to control their sexual urges and that women are responsible for provoking sexual desire in men (*144*). How families and communities react to acts of rape in such settings is governed by prevailing ideas about sexuality and the status of women.

In some societies, the cultural ''solution'' to rape is that the woman should marry the rapist, thereby preserving the integrity of the woman and her family by legitimizing the union (*175*). Such a ''solution'' is reflected in the laws of some countries, which allow a man who commits rape to be excused his crime if he marries the victim (*100*). Apart from marriage, families may put pressure on the woman not to report or pursue a case or else to concentrate on

BOX 6.2

Sexual violence and HIV/AIDS

Violent or forced sex can increase the risk of transmitting HIV. In forced vaginal penetration, abrasions and cuts commonly occur, thus facilitating the entry of the virus — when it is present — through the vaginal mucosa. Adolescent girls are particularly susceptible to HIV infection through forced sex, and even through unforced sex, because their vaginal mucous membrane has not yet acquired the cellular density providing an effective barrier that develops in the later teenage years. Those who suffer anal rape — boys and men, as well as girls and women — are also considerably more susceptible to HIV than would be the case if the sex were not forced, since anal tissues can be easily damaged, again allowing the virus an easier entry into the body.

Being a victim of sexual violence and being susceptible to HIV share a number of risk behaviours. Forced sex in childhood or adolescence, for instance, increases the likelihood of engaging in unprotected sex, having multiple partners, participating in sex work, and substance abuse. People who experience forced sex in intimate relationships often find it difficult to negotiate condom use — either because using a condom could be interpreted as mistrust of their partner or as an admission of promiscuity, or else because they fear experiencing violence from their partner. Sexual coercion among adolescents and adults is also associated with low self-esteem and depression — factors that are associated with many of the risk behaviours for HIV infection.

Being infected with HIV or having an HIV-positive family member can also increase the risk of suffering sexual violence, particularly for women. Because of the stigma attached to HIV and AIDS in many countries, an infected woman may be evicted from her home. In addition, an AIDS-related illness or death in a poor household may make the economic situation desperate. Women may be forced into sex work and consequently be at increased risk for both HIV/AIDS and sexual violence. Children orphaned by AIDS, impoverished and with no one to care for them, may be forced to live on the streets, at considerable risk of sexual abuse.

Among the various ways of reducing the incidence of both sexual violence and HIV infection, education is perhaps the foremost. For young people, above all, there must be comprehensive interventions in schools and other educational institutes, youth groups and workplaces. School curricula should cover relevant aspects of sexual and reproductive health, relationships and violence. They should also teach life skills, including how to avoid risky or threatening situations — related to such things as violence, sex or drugs — and how to negotiate safe sexual behaviour.

For the adult population in general there should be full and accessible information on sexual health and the consequences of specific sexual practices, as well as interventions to change harmful patterns of behaviour and social norms that hinder communication on sexual matters.

It is important that health care workers and other service providers receive integrated training on gender and reproductive health, including gender-based violence and sexually transmitted diseases such as HIV infection.

For rape victims, there should be screening and referral for HIV infection. Also, the use of postexposure prophylaxis for HIV — given soon after the assault, together with counselling — may be considered. Similarly, women with HIV should be screened for a possible history of sexual violence. Voluntary counselling programmes for HIV should consider incorporating violence prevention strategies.

obtaining financial ''damages'' from the rapist's family (*42, 176*). Men may reject their wives if they have been raped (*27*) and in some countries, as mentioned previously, restoring lost honour calls for the woman to be cast out – or in extreme cases, murdered (*26*).

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What can be done to prevent sexual violence?

The number of initiatives addressing sexual violence is limited and few have been evaluated. Most interventions have been developed and implemented in industrialized countries. How relevant they may be in other settings is not well known. The interventions that have been developed can be categorized as follows.

Individual approaches

Psychological care and support

Counselling, therapy and support group initiatives have been found to be helpful following sexual assaults, especially where there may be complicating factors related to the violence itself or the process of recovery. There is some evidence that a brief cognitive-behavioural programme administered shortly after assault can hasten the rate of improvement of psychological damage arising from trauma (*177, 178*). As already mentioned, victims of sexual violence sometimes blame themselves for the incident, and addressing this in psychological therapy has also been shown to be important for recovery (*179*). Short-term counselling and treatment programmes after acts of sexual violence, though, require considerable further evaluation.

Formal psychological support for those experiencing sexual violence has been provided largely by the nongovernmental sector, particularly rape crisis centres and various women's organizations. Inevitably, the number of victims of sexual violence with access to these services is small. One solution to extend access is through establishing telephone helplines, ideally ones that are free of charge. A ''Stop Woman Abuse'' helpline in South Africa, for example, answered 150 000 calls in the first 5 months of operation (*180*).

Programmes for perpetrators

The few programmes targeting perpetrators of sexual violence have generally been aimed at men convicted of assault. They are found mainly in industrialized countries and have only recently begun to be evaluated (see Chapter 4 for a discussion of such programmes). A common response of men who commit sexual violence is to deny both that they are responsible and that what they are doing is violent (*146, 181*). To be effective, programmes working with perpetrators need to make them admit responsibility and to be publicly seen as responsible for their actions (*182*). One way of achieving this is for programmes that target male perpetrators of sexual violence to collaborate with support services for victims as well as with campaigns against sexual violence.

Life-skills and other educational programmes

In recent years, several programmes for sexual and reproductive health promotion, particularly those promoting HIV prevention, have begun to introduce gender issues and to address the problem of sexual and physical violence against women. Two notable examples – developed for Africa but used in many parts of the developing world – are ''Stepping Stones'' and ''Men As Partners'' (*183, 184*). These programmes have been designed for use in peer groups of men and women and are delivered over several workshop sessions using participatory learning approaches. Their comprehensive approach helps men, who might otherwise be reluctant to attend programmes solely concerned with violence against women, participate and discuss a range of issues concerning violence. Furthermore, even if the men are perpetrators of sexual violence, the programmes are careful to avoid labelling them as such.

A review of the effect of the Stepping Stones programme in Africa and Asia found that the workshops helped the men participating take greater responsibility for their actions, relate better to others, have greater respect for women and communicate more effectively. As a result of the programme, reductions in violence against women have been reported in communities in Cambodia, the Gambia, South Africa, Uganda and the United Republic of Tanzania. The evaluations to date, though, have generally used qualitative methods and further research is needed to adequately test the effectiveness of this programme (*185*).

Developmental approaches

Research has stressed the importance of encouraging nurturing, with better and more gender-balanced parenting, to prevent sexual violence (*124, 125*). At the same time, Schwartz (*186*) has developed a prevention model that adopts a developmental approach, with interventions before birth, during childhood and in adolescence and young adulthood. In this model, the prenatal element would include discussions of parenting skills, the stereotyping of gender roles, stress, conflict and violence. In the early years of childhood, health providers would pursue these issues and introduce child sexual abuse and exposure to violence in the media to the list of discussion topics, as well as promoting the use of non-sexist educational materials. In later childhood, health promotion would include modelling behaviours and attitudes that avoid stereotyping, encouraging children to distinguish between ''good'' and ''bad'' touching, and enhancing their ability and confidence to take control over their own bodies. This intervention would allow room for talking about sexual aggression. During adolescence and young adulthood, discussions would cover myths about rape, how to set boundaries for sexual activity, and breaking the links between sex, violence and coercion. While Schwartz's model was designed for use in industrialized countries, some of the principles involved could be applicable to developing countries.

Health care responses

Medico-legal services

In many countries, where sexual violence is reported the health sector has the duty to collect medical and legal evidence to corroborate the accounts of the victims or to help in identifying the perpetrator. Research in Canada suggests that medico-legal documentation can increase the chance of a perpetrator being arrested, charged or convicted (*187, 188*). For instance, one study found that documented physical injury, particularly of the moderate to severe type, was associated with charges being filed – irrespective of the patient's income level or whether the patient knew the assailant, either as an acquaintance or an intimate partner (*188*). However, a study of women attending a hospital in Nairobi, Kenya, following a rape, has highlighted the fact that in many countries rape victims are not examined by a gynaecologist or an experienced police examiner and that no standard protocols or guidelines exist on this matter (*189*).

The use of standard protocols and guidelines can significantly improve the quality of treatment and psychological support of victims, as well as the evidence that is collected (*190*). Comprehensive protocols and guidelines for female victims of assault should include:

- recording a full description of the incident, listing all the assembled evidence;
- listing the gynaecological and contraceptive history of the victim;
- documenting in a standard way the results of a full physical examination;
- assessment of the risk of pregnancy;
- testing for and treating sexually transmitted diseases, including, where appropriate, testing for HIV;
- providing emergency contraception and, where legal, counselling on abortion;
- providing psychological support and referral.

In some countries, the protocol forms part of the procedure of a ''sexual assault evidence kit'' that includes instructions and containers for collecting evidence, appropriate legal forms and documents for recording histories (*191*). Examinations of rape victims are by their nature extremely stressful. The use of a video to explain the procedure before an examination has been shown significantly to reduce the stress involved (*192*).

Training for health care professionals

Issues concerning sexual violence need to be addressed in the training of all health service staff, including psychiatrists and counsellors, in basic training as well as in specialized postgraduate courses. Such training should, in the first place, give health care workers greater knowledge and awareness of sexual violence and make them more able to detect and handle cases of abuse in a sensitive but

effective way. It should also help reduce instances of sexual abuse within the health sector, something that can be a significant, though generally unacknowledged, problem.

In the Philippines, the Task Force on Social Science and Reproductive Health, a body that includes doctors, nurses and social scientists and is supported by the Department of Health, has produced training modules for nursing and medical students on gender-based violence. The aims of this programme are (*193*):

- To understand the roots of violence in the context of culture, gender and other social aspects.
- To identify situations, within families or homes that are at a high risk for violence, where it would be appropriate to undertake:
  - — primary interventions, in particular in collaboration with other professionals;
  - — secondary interventions, including identifying victims of violence, understanding basic legal procedures and how to present evidence, referring and following up patients, and helping victims reintegrate into society.

These training modules are built into the curricula for both nursing and medical students. For the nursing curriculum, the eleven modules are spread over the 4 years of formal instruction, and for medical students over their final 3 years of practical training.

Prophylaxis for HIV infection

The possibility of transmission of HIV during rape is a major cause for concern, especially in countries with a high prevalence of HIV infection (*194*). The use of antiretroviral drugs following exposure to HIV is known in certain contexts to be reasonably effective. For instance, the administration of the antiretroviral drug zidovudine (AZT) to health workers following an occupational needle-stick exposure (puncturing the skin with a contaminated needle) has been shown to reduce the subsequent risk of developing HIV infection by 81% (*195*).

The average risk of HIV infection from a single act of unprotected vaginal sex with an infected partner is relatively low (approximately 1–2 per 1000, from male to female, and around 0.5–1 per 1000 from female to male). This risk, in fact, is of a similar order to that from a needle-stick injury (around 3 per 1000), for which postexposure prophylaxis is now routine treatment (*196*). The average risk of HIV infection from unprotected anal sex is considerably higher, though, at around 5–30 per 1000. However, during rape, because of the force used, it is very much more likely that there will be macroscopic or microscopic tears to the vaginal mucosa, something that will greatly increase the probability of HIV transmission (*194*).

There is no information about the feasibility or cost-effectiveness in resource-poor settings of routinely offering rape victims prophylaxis for HIV. Testing for HIV infection after rape is difficult in any case. In the immediate aftermath of an incident, many women are not in a position fully to comprehend complicated information about HIV testing and risks. Ensuring proper follow-up is also difficult as many victims will not attend further scheduled visits for reasons that probably relate to their psychological coping following the assault. The side-effects of antiretroviral treatment may also be significant, causing people to drop out from a course (*195, 197*), though those who perceive themselves as being at high risk are much more likely to be compliant (*197*).

Despite the lack of knowledge about the effectiveness of HIV prophylaxis following rape, many organizations have recommended its use. For instance, medical aid schemes in high-income countries are increasingly including it in their care packages. Research is urgently needed in middle-income and low-income countries on the effectiveness of antiretroviral treatment after rape and how it could be included in patient care.

Centres providing comprehensive care to victims of sexual assault

Because of the shortage of doctors in many countries, specially trained nurses have been used in some places to assist victims of sexual assault (*187*). In Canada, nurses, known as ''sexual assault nurse examiners'', are trained to provide

comprehensive care to victims of sexual violence. These nurses refer clients to a physician when medical intervention is needed. In the province of Ontario, Canada, the first sexual assault care centre opened in 1984 and since then 26 others have been established. These centres provide or coordinate a wide range of services, including emergency medical care and medical follow-up, counselling, collecting forensic evidence of assault, legal support, and community consultation and education (*198*). Centres that provide a range of services for victims of sexual assault, often located in places such as a hospital or police station, are being developed in many countries (see Box 6.3). Specialized centres such as these have the advantage of providing appropriately trained and experienced staff. In some places, on the other hand, integrated centres exist providing services for victims of different forms of violence.

Community-based efforts

Prevention campaigns

Attempts to change public attitudes towards sexual violence using the media have included advertising on hoardings (''billboards'') and in public transport, and on radio and television. Television has been used effectively in South Africa and Zimbabwe. The South African prime-time television series *Soul City* is described in Box 9.1 of Chapter 9. In Zimbabwe, the nongovernmental organization Musasa has produced awareness-raising initiatives using theatre, public meetings and debates, as well as a television series where survivors of violence described their experiences (*199*).

Other initiatives, besides media campaigns, have been used in many countries. The Sisterhood Is Global Institute in Montreal, Canada, for instance, has developed a manual suitable for Muslim communities aimed at raising awareness and

BOX 6.3

Integrated services for rape victims in Malaysian hospitals

In 1993, the first ''One-Stop Crisis Centre'' for battered women was established in the accident and emergency department of Kuala Lumpur Hospital in Malaysia. Its aim was to provide a coordinated interagency response to violence against women, in such a way as to enable victims of assault to address their medical, legal, psychological and social problems at a single location. Initially, the centre dealt exclusively with domestic violence, but has since extended its scope to cover rape, with specific procedures for victims of rape.

At Kuala Lumpur Hospital, a crisis intervention team handles around 30 rape cases and 70 cases of domestic violence each month. This team brings in expertise from the hospital itself and from various women's groups, the police, the department of medical social workers, the legal aid office and the Islamic Religious Bureau.

In 1996, the Malaysian Ministry of Health decided to extend this innovative health care strategy and to establish similar centres in every public hospital of the country. Within 3 years, 34 such centres had been set up. In these centres, psychiatrists, counsellors and medical social workers carry out counselling on rape, and some of the clients become outpatients in the hospital's psychiatric department. Trained social workers need to be on call 24 hours a day.

As the ''One-Stop Crisis Centre'' programme developed, various problems came to light. One was the need for hospital staff to be better trained in handling issues of sexual violence with sensitivity. Some hospital workers were seen to blame victims of rape for the violence they had suffered, while others regarded the victims with voyeuristic curiosity instead of concentrating on providing support. There was also a lack of forensic medical officers and of sufficient sheltered accommodation for rape victims. Identifying these problems was an important first step towards improving the programme and providing a higher quality of service for rape victims.

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stimulating debate on issues related to gender equality and violence against women and girls (*200*). The manual has been pilot-tested in Egypt, Jordan and Lebanon and – in an adaptation for non-Muslim settings – used in Zimbabwe.

A United Nations interagency initiative to combat gender-based violence is being conducted in 16 countries of Latin America and the Caribbean (*201*). The campaign is designed:

— to raise awareness about the human, social and economic costs of violence against women and girls;

— to build capacity at the governmental level to develop and implement legislation against gender violence;

— to strengthen networks of public and private organizations and carry out programmes to prevent violence against women and girls.

Community activism by men

An important element in preventing sexual and physical violence against women is a collective initiative by men. Men's groups against domestic violence and rape can be found in Australia, Africa, Latin America and the Caribbean and Asia, and in many parts of North America and Europe. The underlying starting point for this type of initiative is that men as individuals should take measures to reduce their use of violence (*202*). Typical activities include group discussions, education campaigns and rallies, work with violent men, and workshops in schools, prisons and workplaces. Actions are frequently conducted in collaboration with women's organizations that are involved in preventing violence and providing services to abused women.

In the United States alone, there are over 100 such men's groups, many of which focus specifically on sexual violence. The ''Men Can Stop Rape'' group in Washington, DC, for instance, seeks to promote alternative forms of masculinity that foster non-violence and gender equality. Its recent activities have included conducting presentations in secondary schools, designing posters, producing a handbook for teachers and publishing a youth magazine (*202*).

School-based programmes

Action in schools is vital for reducing sexual and other forms of violence. In many countries a sexual relation between a teacher and a pupil is not a serious disciplinary offence and policies on sexual harassment in schools either do not exist or are not implemented. In recent years, though, some countries have introduced laws prohibiting sexual relations between teachers and pupils. Such measures are important in helping eradicate sexual harassment in schools. At the same time, a wider range of actions is also needed, including changes to teacher training and recruitment and reforms of curricula, so as to transform gender relations in schools.

Legal and policy responses

Reporting and handling cases of sexual violence

Many countries have a system to encourage people to report incidents of sexual violence to the police and to improve the speed and sensitivity of the processing of cases by the courts. The specific mechanisms include dedicated domestic violence units, sexual crime units, gender training for the police and court officials, women-only police stations and courts for rape offences. Some of these mechanisms are discussed in Chapter 4.

Problems are sometimes created by the unwillingness of medical experts to attend court. The reason for this is frequently that the court schedules are unpredictable, with cases often postponed at short notice and long waits for witnesses who are to give short testimonies. In South Africa, to counter this, the Directorate of Public Prosecutions has been training magistrates to interrupt proceedings in sexual violence cases when the medical expert arrives so that testimonies can be taken and witnesses cross-examined without delay.

Legal reform

Legal interventions that have been adopted in many places have included:

— broadening the definition of rape;

— reforming the rules on sentencing and on admissibility of evidence;

— removing the requirements for victims' accounts to be corroborated.

In 1983, the Canadian laws on rape were reformed, in particular removing the requirement that accounts of rape be corroborated. Nonetheless, an evaluation has found that the prosecutors have tended to ignore this easing of the requirement for corroboration and that few cases go to court without forensic evidence (*203*).

Several countries in Asia, including the Philippines, have recently enacted legislation radically redefining rape and mandating state assistance to victims. The result has been a substantial increase in the number of reported cases. Campaigns to inform the general public of their legal rights must also take place if the reformed legislation is to be fully effective.

To ensure that irrelevant information was not admitted in court, the International Criminal Tribunal for the Former Yugoslavia drew up certain rules, which could serve as a useful model for effective laws and procedures elsewhere. Rule 96 of the Tribunal specifies that in cases of sexual assault there is no need for corroboration of the victim's testimony and that the earlier sexual history of the victim is not to be disclosed as evidence. The rule also deals with the possible claim by the accused that there was consent to the act, stating that consent as a defence shall not be allowed if the victim has been subjected to or threatened with physical or psychological violence, or detention, or has had reason to fear such violence or detention. Furthermore, consent shall not be allowed under the rule if the victim had good reason to believe that if he or she did not submit, another person might be so subjected, threatened or put in fear. Even where the claim of consent is allowed to proceed, the accused has to satisfy the court that the evidence for such a claim is relevant and credible, before this evidence can be presented.

In many countries, judges hand out particularly short sentences for sexual violence (*204, 205*). One way of overcoming this has been to introduce minimum sentencing for convictions for rape, unless there are extenuating circumstances.

International treaties

International treaties are important as they set standards for national legislation and provide a lever for local groups to campaign for legal reforms. Among the relevant treaties that impinge on sexual violence and its prevention include:

- the Convention on the Elimination of All Forms of Discrimination Against Women (1979);
- the Convention on the Rights of the Child (1989) and its Optional Protocol on the Sale of Children, Child Prostitution and Child Pornography (2000);
- the Convention Against Transnational Organized Crime (2000) and its supplemental Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children (2000);
- the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (1984).

A number of other international agreements set norms and limits of behaviour, including behaviour in conflicts, that necessitate provisions in national legislation. The Rome Statute of the International Criminal Court (1998), for instance, covers a broad spectrum of gender-specific crimes, including rape, sexual slavery, enforced prostitution, forced pregnancy and forced sterilization. It also includes certain forms of sexual violence that constitute a breach or serious violation of the 1949 Geneva Conventions, as well as other forms of sexual violence that are comparable in gravity to crimes against humanity. The inclusion of gender crimes in the definitions of the statute is an important historical development in international law (*206*).

Actions to prevent other forms of sexual violence

Sexual trafficking

Initiatives to prevent the trafficking of people for sexual purposes have generally aimed to:

- create economic programmes in certain countries for women at risk of being trafficked;
- provide information and raise awareness so that women at potential risk are aware of the danger of trafficking.

In addition, several government programmes and nongovernmental organizations are develop-

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ing services for the victims of trafficking (*207*). In Cyprus, the Aliens and Immigration Department approaches women entering the country to work in the entertainment or domestic service sectors. The Department advises the women on their rights and obligations and on available forms of protection against abuse, exploitation and procurement into prostitution. In the European Union and the United States, victims of trafficking willing to cooperate with the judicial system in prosecuting traffickers can receive temporary residence permits. In Belgium and Italy, shelters have been set up for victims of trafficking. In Mumbai, India, an anti-trafficking centre has been set up to facilitate the arrest and prosecution of offenders, and to provide assistance and information to trafficked women.

Female genital mutilation

Addressing cultural practices that are sexually violent requires an understanding of their social, cultural and economic context. Khafagi has argued (*208*) that such practices – which include female genital mutilation – should be understood from the perspective of those who perform them and that such knowledge can be used to design culturally appropriate interventions to prevent the practices. In the Kapchorwa district of Uganda, the REACH programme has been successful in reducing rates of female genital mutilation. The programme, led by the Sabiny Elders' Association, sought to enlist the support of elders in the community in detaching the practice of female genital mutilation from the cultural values it purported to serve. In its place, alternative activities were substituted, that upheld the original cultural tradition (*209*). Box 6.4 describes another programme, in Egypt, to prevent female genital mutilation.

Child marriage

Child marriage has a cultural basis and is often legal, so the task of achieving change is considerable. Simply outlawing early marriages will not, of itself, usually be sufficient to prevent the practice. In many countries the process of registering births is so irregular that age at first marriage may not be known (*100*). Approaches that address poverty – an important factor underlying many such marriages – and those that stress educational goals, the health consequences of early childbirth and the rights of children are more likely to achieve results.

Rape during armed conflicts

The issue of sexual violence in armed conflicts has recently again been brought to the fore by organizations such as the Association of the Widows of the Genocide (AVEGA) and the Forum for African Women Educationalists. The former has supported war widows and rape victims in Rwanda and the latter has provided medical care and counselling to victims in Sierra Leone (*210*).

In 1995, the Office of the United Nations High Commissioner for Refugees released guidelines on the prevention of and response to sexual violence among refugee populations (*211*). These guidelines include provisions for:

- the design and planning of camps, to reduce susceptibility to violence;
- documenting cases;
- educating and training staff to identify, respond to and prevent sexual violence;
- medical care and other support services, including procedures to avoid further trauma to victims.

The guidelines also cover public awareness campaigns, educational activities and the setting up of women's groups to report and respond to violence.

Based on work in Guinea (*212*) and the United Republic of Tanzania (*96*), the International Rescue Committee has developed a programme to combat sexual violence in refugee communities. It includes the use of participatory methods to assess the prevalence of sexual and gender-based violence in refugee populations, the training and deployment of community workers to identify cases and set up appropriate prevention systems, and measures for community leaders and other officials to prosecute perpetrators. The programme has been used in many places against sexual and gender-based violence, including Bosnia and Herzegovina, the Democratic Republic of the Congo, East Timor, Kenya, Sierra Leone and The former Yugoslav Republic of Macedonia.

BOX 6.4

Putting an end to female genital mutilation: the case of Egypt

Female genital mutilation is extremely common among married women in Egypt. The 1995 Demographic and Health Survey found that the age group in which the practice was most frequently used was 9–13 years. Nearly half of those performing female circumcisions were doctors and 32% were midwives or nurses. Sociological research has found that the main reasons given for practising female circumcision were to uphold tradition, to control the sexual desires of women, to make women ''clean and pure'' and, most importantly, to make them eligible for marriage.

Largely stemming from the public awareness created by the International Conference on Population and Development held in Cairo in 1994, a movement against female genital mutilation, spanning a broad range of sectors, was built up.

In terms of the response from health officials and professionals, a joint statement in 1998 from the Egyptian Society of Gynaecology and Obstetrics and the Egyptian Fertility Care Society declared that female genital mutilation was both useless and harmful, and constituted unethical practice for a doctor. The Egyptian Minister of Health and Population also issued a decree banning anyone from performing female genital mutilation.

Religious leaders in the Muslim world also voiced their opposition to the practice. The Grand Mufti put out a statement pointing out that there was no mention of female circumcision in the Koran and that sayings (*hadith*) attributed to the Prophet Muhammad on the subject were not definitively confirmed by evidence. Furthermore, in 1998, the Conference on Population and Reproductive Health in the Muslim World adopted a recommendation calling on Islamic countries to move to end all forms of violence against women, with a reminder that under Islamic law (*sharia*) no obligation existed to circumcise girls.

Egyptian nongovernmental organizations have mobilized on the issue, disseminating information on female genital mutilation and including it in community development, health awareness and other programmes. A task force of some 60 nongovernmental organizations has been set up to combat the practice.

Several nongovernmental organizations — often working through male community leaders — are now actively involving men, educating them about the dangers of female genital mutilation. In this process, young men are being encouraged to declare that they will marry uncircumcised women.

In Upper Egypt there is a programme aimed at various social groups — including community leaders, religious leaders and professional people — to train them as campaigners against female genital mutilation. Counselling is also offered to families who are considering not circumcising their daughters and discussions are conducted with health workers to dissuade them from performing the practice.

Recommendations

Sexual violence has generally been a neglected area of research in most parts of the world, yet the evidence suggests that it is a public health problem of substantial proportions. Much more needs to be done both to understand the phenomenon and to prevent it.

More research

The lack of an agreed definition of sexual violence and the paucity of data describing the nature and extent of the problem worldwide have contributed to its lack of visibility on the agendas of policy-makers and donors. There is a need for substantial further research on almost every aspect of sexual violence, including:

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— the incidence and prevalence of sexual violence in a range of settings, using a standard research tool for measuring sexual coercion;
— the risk factors for being a victim or a perpetrator of sexual violence;
— the health and social consequences of different forms of sexual violence;
— the factors influencing recovery of health following a sexual assault;
— the social contexts of different forms of sexual violence, including sexual trafficking, and the relationships between sexual violence and other forms of violence.

Determining effective responses

Interventions must also be studied to produce a better understanding of what is effective in different settings for preventing sexual violence and for treating and supporting victims. The following areas should be given priority:

- Documenting and evaluating services and interventions that support survivors or work with perpetrators of sexual violence.
- Determining the most appropriate health sector responses to sexual violence, including the role of prophylactic antiretroviral therapy for HIV prevention after rape – with different basic packages of services being recommended for different settings, depending on the level of resources.
- Determining what constitutes appropriate psychological support for different settings and circumstances.
- Evaluating programmes aimed at preventing sexual violence, including community-based interventions – particularly those focusing on men – and school-based programmes.
- Studying the impact of legal reforms and criminal sanctions.

Greater attention to primary prevention

Primary prevention of sexual violence is often marginalized in favour of providing services for survivors. Policy-makers, researchers, donors and nongovernmental organizations should therefore give much greater attention to this important area. Priority should be given to the following:

— the primary prevention of all forms of sexual violence through programmes in communities, schools and refugee settings;
— support for culturally sensitive and participatory approaches to changing attitudes and behaviour;
— support for programmes addressing the prevention of sexual violence in the broader context of promoting gender equality;
— programmes that address some of the underlying socioeconomic causes of violence, including poverty and lack of education, for example by providing job opportunities for young people;
— programmes to improve child rearing, reduce the vulnerability of women and promote more gender-equitable notions of masculinity.

Addressing sexual abuse within the health sector

Sexual violence against patients in the health sector exists in many places, but is not usually acknowledged as a problem. Various steps need to be taken to overcome this denial and to confront the problem, including the following (*83, 85*):

— incorporating topics pertaining to gender and sexual violence, including ethical considerations relevant to the medical profession, in the curricula for basic and postgraduate training of physicians, nurses and other health workers;
— actively seeking ways to identify and investigate possible cases of abuse of patients within health institutions;
— utilizing international bodies of the medical and nursing professions, and nongovernmental organizations (including women's organizations) to monitor and compile evidence of abuse and campaign for action on the part of governments and health services;
— establishing proper codes of practice and complaints procedures, and strict disciplinary procedures for health workers who abuse patients in health care settings.

Conclusion

Sexual violence is a common and serious public health problem affecting millions of people each year throughout the world. It is driven by many factors operating in a range of social, cultural and economic contexts. At the heart of sexual violence directed against women is gender inequality.

In many countries, data on most aspects of sexual violence are lacking, and there is a great need everywhere for research on all aspects of sexual violence. Of equal importance are interventions. These are of various types, but the essential ones concern the primary prevention of sexual violence, targeting both women and men, interventions supporting the victims of sexual assault, measures to make it more likely that perpetrators of rape will be caught and punished, and strategies for changing social norms and raising the status of women. It is vital to develop interventions for resource-poor settings and rigorously to evaluate programmes in both industrialized and developing countries.

Health professionals have a large role to play in supporting the victims of sexual assault – medically and psychologically – and collecting evidence to assist prosecutions. The health sector is considerably more effective in countries where there are protocols and guidelines for managing cases and collecting evidence, where staff are well-trained and where there is good collaboration with the judicial system. Ultimately, the strong commitment and involvement of governments and civil society, along with a coordinated response across a range of sectors, are required to end sexual violence.

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CHAPTER 7

Self-directed violence

Background

In the year 2000 an estimated 815 000 people died from suicide around the world. This represents an annual global mortality rate of about 14.5 per 100 000 population – or one death about every 40 seconds. Suicide is the thirteenth leading cause of death worldwide (see Statistical annex). Among those aged 15–44 years, self-inflicted injuries are the fourth leading cause of death and the sixth leading cause of ill-health and disability (*1*).

Deaths from suicide are only a part of this very serious problem. In addition to those who die, many more people survive attempts to take their own lives or harm themselves, often seriously enough to require medical attention (*2*). Furthermore, every person who kills himself or herself leaves behind many others – family and friends – whose lives are profoundly affected emotionally, socially and economically. The economic costs associated with self-inflicted death or injuries are estimated to be in the billions of US dollars a year (*3*).

How is suicide defined?

Suicidal behaviour ranges in degree from merely thinking about ending one's life, through developing a plan to commit suicide and obtaining the means to do so, attempting to kill oneself, to finally carrying out the act (''completed suicide'').

The term ''suicide'' in itself evokes direct reference to violence and aggressiveness. Apparently, Sir Thomas Browne was the first to coin the word ''suicide'' in his *Religio medici* (1642). A physician and a philosopher, Browne based the word on the Latin *sui* (of oneself) and *caedere* (to kill). The new term reflected a desire to distinguish between the homicide of oneself and the killing of another (*4*).

A well-known definition of suicide is the one that appears in the 1973 edition of the Encyclopaedia Britannica, quoted by Shneidman: ''the human act of self-inflicting one's own life cessation'' (*5*). Certainly in any definition of suicide, the intention to die is a key element. However, it is often extremely difficult to reconstruct the thoughts of people who commit suicide unless they have made clear statements before their death about their intentions or left a suicide note. Not all those who survive a suicidal act intended to live, nor are all suicidal deaths planned. To make a correlation between intent and outcome can therefore be problematic. In many legal systems, a death is certified as suicide if the circumstances are consistent with suicide and if murder, accidental death and natural causes can all be ruled out.

There has been much disagreement about the most suitable terminology to describe suicidal behaviour. Recently, the outcome-based term ''fatal suicidal behaviour'' has been proposed for suicidal acts that result in death – and similarly ''non-fatal suicidal behaviour'' for suicidal actions that do not result in death (*6*). Such actions are also often called ''attempted suicide'' (a term common in the United States of America), ''parasuicide'' and ''deliberate self-harm'' (terms which are common in Europe).

The term ''suicidal ideation'' is often used in the technical literature, and refers to thoughts of killing oneself, in varying degrees of intensity and elaboration. In the literature, the term also refers to a feeling of being tired of life, a belief that life is not worth living, and a desire not to wake from sleep (*7, 8*). Although these different feelings – or ideations – express different degrees of severity, there is not necessarily a continuum between them. Furthermore, the intention to die is not a necessary criterion for non-fatal suicidal behaviour.

Another common form of self-directed violence is self-mutilation. This is the direct and deliberate destruction or alteration of parts of the body without conscious suicidal intention. Favazza (*9*) has proposed three main categories:

- Major self-mutilation – including self-blinding and the amputation of fingers, hands, arms, limbs, feet or genitalia.
- Stereotypical self-mutilation – such as banging one's head, biting oneself, hitting one's arm, gouging one's eyes or throat, or pulling one's hair.
- Superficial-to-moderate self-mutilation – such as cutting, scratching or burning one's skin, sticking needles into one's skin, or pulling one's hair compulsively.

Self-mutilation involves very different factors from suicidal behaviour and will not be discussed here further. For an extensive review of self-mutilation, see Favazza (*9*).

The extent of the problem

Fatal suicidal behaviour

National suicide rates vary considerably (see Table 7.1). Among countries reporting suicide to the World Health Organization, the highest suicide rates are found in Eastern European countries (for example, Belarus 41.5 per 100 000, Estonia 37.9 per 100 000, Lithuania 51.6 per 100 000 and the Russian Federation 43.1 per 100 000). High rates of suicide have also been reported in Sri Lanka (37 per 100 000 in 1996), based on data from the WHO Regional Office for South-East Asia (*10*). Low rates are found mainly in Latin America (notably Colombia 4.5 per 100 000 and Paraguay 4.2 per 100 000) and some countries in Asia (for example, the Philippines 2.1 per 100 000 and Thailand 5.6 per 100 000). Countries in other parts of Europe, in North America, and parts of Asia and the Pacific tend to fall somewhere in between these extremes (for example, Australia 17.9 per 100 000, Belgium 24.0 per 100 000, Canada 15.0 per 100 000, Finland 28.4 per 100 000, France 20.0 per 100 000, Germany 14.3 per 100 000, Japan 19.5 per 100 000, Switzerland 22.5 per 100 000 and the United States

TABLE 7.1

Age-adjusted suicide rates by country, most recent year available[a]

Country or area	Year	Total number of suicides	Suicide rate per 100 000 population			
			Total	Male	Female	Male: female ratio
Albania	1998	165	7.1	9.5	4.8	2.0
Argentina	1996	2 245	8.7	14.2	3.9	3.6
Armenia	1999	67	2.3	3.6	—[b]	—[b]
Australia	1998	2 633	17.9	28.9	7.0	4.1
Austria	1999	1 555	20.9	32.7	10.2	3.2
Azerbaijan	1999	54	1.1	1.7	—[b]	—[b]
Belarus	1999	3 408	41.5	76.5	11.3	6.7
Belgium	1995	2 155	24.0	36.3	12.7	2.9
Bosnia and Herzegovina	1991	531	14.8	25.3	4.2	6.1
Brazil	1995	6 584	6.3	10.3	2.5	4.1
Bulgaria	1999	1 307	16.4	26.2	7.7	3.4
Canada	1997	3 681	15.0	24.1	6.1	3.9
Chile	1994	801	8.1	15.0	1.9	8.1
China						
Hong Kong SAR	1996	788	14.9	19.5	10.4	1.9
Selected rural and urban areas	1999	16 836	18.3	18.0	18.8	1.0
Colombia	1995	1 172	4.5	7.4	1.8	4.1
Costa Rica	1995	211	8.8	14.4	3.0	4.7
Croatia	1999	989	24.8	40.6	11.6	3.5
Cuba	1997	2 029	23.0	32.1	14.2	2.3
Czech Republic	1999	1 610	17.5	30.1	6.3	4.8
Denmark	1996	892	18.4	27.2	10.1	2.7
Ecuador	1996	593	7.2	10.4	4.1	2.5
El Salvador	1993	429	11.2	16.3	6.8	2.4
Estonia	1999	469	37.9	68.5	12.0	5.7
Finland	1998	1 228	28.4	45.8	11.7	3.9
France	1998	10 534	20.0	31.3	9.9	3.2
Georgia	1992	204	5.3	8.7	2.5	3.4
Germany	1999	11 160	14.3	22.5	6.9	3.3
Greece	1998	403	4.2	6.7	1.8	3.7
Hungary	1999	3 328	36.1	61.5	14.4	4.3
Ireland	1997	466	16.8	27.4	6.3	4.3
Israel	1997	379	8.7	14.6	3.3	4.4
Italy	1997	4 694	8.4	13.4	3.8	3.5
Japan	1997	23 502	19.5	28.0	11.5	2.4
Kazakhstan	1999	4 004	37.4	67.3	11.6	5.8
Kuwait	1999	47	2.0	2.2	—[b]	—[b]
Kyrgyzstan	1999	559	18.7	31.9	6.3	5.1
Latvia	1999	764	36.5	63.7	13.6	4.7
Lithuania	1999	1 552	51.6	93.0	15.0	6.2
Mauritius	1999	174	19.2	26.5	12.1	2.2
Mexico	1997	3 369	5.1	9.1	1.4	6.3
Netherlands	1999	1 517	11.0	15.2	7.1	2.1
New Zealand	1998	574	19.8	31.2	8.9	3.5
Nicaragua	1996	230	7.6	11.2	4.3	2.6
Norway	1997	533	14.6	21.6	8.0	2.7
Panama (excluding Canal Zone)	1997	145	7.8	13.2	2.3	5.7
Paraguay	1994	109	4.2	6.5	1.8	3.6
Philippines	1993	851	2.1	2.5	1.6	1.6
Poland	1995	5 499	17.9	31.0	5.6	5.5
Portugal	1999	545	5.4	9.0	2.4	3.8

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TABLE 7.1 *(continued)*

Country or area	Year	Total number of suicides	Suicide rate per 100 000 population			
			Total	Male	Female	Male: female ratio
Puerto Rico	1998	321	10.8	20.9	2.0	10.4
Republic of Korea	1997	6 024	17.1	25.3	10.1	2.5
Republic of Moldova	1999	579	20.7	37.7	6.3	6.0
Romania	1999	2 736	14.3	24.6	4.8	5.1
Russian Federation	1998	51 770	43.1	77.8	12.6	6.2
Singapore	1998	371	15.7	18.8	12.7	1.5
Slovakia	1999	692	15.4	27.9	4.3	6.5
Slovenia	1999	590	33.0	53.9	14.4	3.7
Spain	1998	3 261	8.7	14.2	3.8	3.8
Sweden	1996	1 253	15.9	22.9	9.2	2.5
Switzerland	1996	1 431	22.5	33.7	12.3	2.7
Tajikistan	1995	199	7.1	10.9	3.4	3.2
Thailand	1994	2 333	5.6	8.0	3.3	2.4
The former Yugoslav Republic of Macedonia	1997	155	10.0	15.2	5.2	2.9
Trinidad and Tobago	1994	148	16.9	26.1	6.8	3.8
Turkmenistan	1998	406	13.7	22.2	5.4	4.1
Ukraine	1999	14 452	33.8	61.8	10.1	6.1
United Kingdom	1999	4 448	9.2	14.6	3.9	3.8
England and Wales	1999	3 690	8.5	13.4	3.6	3.7
Northern Ireland	1999	121	9.9	17.0	—[b]	—[b]
Scotland	1999	637	15.7	25.3	6.3	4.0
United States	1998	30 575	13.9	23.2	5.3	4.4
Uruguay	1990	318	12.8	22.0	4.8	4.6
Uzbekistan	1998	1 620	10.6	17.2	4.4	3.9
Venezuela	1994	1 089	8.1	13.7	2.7	5.0

SAR: Special Administrative Region.

[a] Most recent year available between 1990 and 2000 for countries with ⩾1 million population.

[b] Fewer than 20 deaths reported; rate and rate ratio not calculated.

13.9 per 100 000). Unfortunately, little information is available on suicide from countries in Africa (*11*).

Two countries, Finland and Sweden, have data on suicide rates dating from the 18th century and both show a trend for increasing suicide rates over time (*12*). During the 20th century, Finland, Ireland, the Netherlands, Norway, Scotland, Spain and Sweden experienced a significant increase in suicides, while England and Wales (combined data), Italy, New Zealand and Switzerland experienced a significant decrease. There was no significant change in Australia (*12*). During the period 1960–1990, at least 28 countries or territories had rising suicide rates, including Bulgaria, China (Province of Taiwan), Costa Rica, Mauritius and Singapore, while eight had declining rates, including Australia, and England and Wales (combined data) (*12*).

Rates of suicide are not distributed equally throughout the general population. One important demographic marker of suicide risk is age. Globally, suicide rates tend to increase with age, although some countries such as Canada have also recently seen a secondary peak in young people aged 15–24 years. Figure 7.1 shows the global rates recorded by age and sex in 1995. The rates ranged from 0.9 per 100 000 in the group aged 5–14 years to 66.9 per 100 000 among people aged 75 years and older. In general, suicide rates among those aged 75 years and older are approximately three times higher than those of young people aged 15–24 years. This trend is found for both sexes, but is more marked among men. For women, suicide rates present differing patterns. In some cases, female suicide rates increase steadily with age, in others the rates peak in middle age, and in yet others, particularly in developing countries and among minority groups, female rates peak among young adults (*13*).

Although suicide rates are generally higher among older people, the absolute number of cases recorded is actually higher among those under 45 years of age than among those over 45 years, given demographic distributions (see Table 7.2). This is a remarkable change from just 50 years ago, when the absolute number of cases of suicide roughly increased with age. It is not explained in terms of the overall ageing of the global population; in fact, it runs counter to this demographic trend. At present, suicide rates are already higher among people under 45 years of age than among those over 45 years in approximately one-third of all countries, a phenomenon that appears to exist in all continents and is not correlated to levels of industrialization or wealth. Examples of countries

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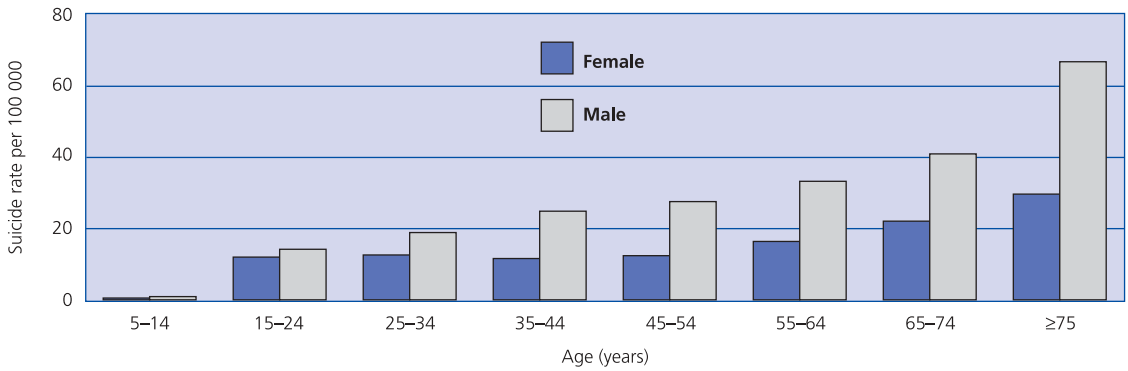
FIGURE 7.1
Global suicide rates by age and sex, 1995



and areas in which current suicide rates (as well as the absolute number of cases) are higher among those below 45 years of age than among those above 45 years include Australia, Bahrain, Canada, Colombia, Ecuador, Guyana, Kuwait, Mauritius, New Zealand, Sri Lanka and the United Kingdom. Youth suicide rates are particularly high in several Pacific Islands, such as Fiji (among ethnic Indians) and Samoa, both among males and females (*14*).

Sex, culture, race and ethnicity are also important factors in the epidemiology of suicide. Suicide rates are higher among men than women. The ratio of the suicide rate among males to that among females ranges from 1.0:1 to 10.4:1 (see Table 7.1). This ratio seems to be influenced, in part, by the cultural context. It is relatively low in parts of Asia (for example 1.0:1 in China, 1.6:1 in the Philippines, 1.5:1 in Singapore), high in several countries of the former Soviet Union (6.7:1 in Belarus, 6.2:1 in Lithuania), and very high in Chile (8.1:1) and Puerto Rico (10.4:1). On average, it appears that there are about three male suicides for every female one, and that this is so more or less consistently for different age groups, with the exception of advanced old age when men tend to have even higher rates. Generally speaking, the difference between the sexes in terms of suicide rates is narrower in Asian countries (*15*) than elsewhere in the world. The often large differences in rates between countries and by sex show how important it is for each country to monitor its epidemiological trends to determine the population groups at greatest risk for suicide.

Within countries, the prevalence of suicide among Caucasians is approximately twice that observed in other races, although an increasing rate among African Americans has recently been reported in the United States (*2*). This pattern of higher prevalence among Caucasians has also been reported in South Africa and Zimbabwe (*16*). Exceptions to the generally higher rate among Caucasians are found in the former Soviet republics of Armenia, Azerbaijan and Georgia (*17*).

Belonging to the same ethnic group seems to be associated with similar suicide rates, as in the interesting example of Estonia, Finland and Hungary, all of which have very high rates, even though Hungary is geographically quite distant from Estonia and Finland. Conversely, different ethnic groups – even if they live in the same place – may have very dissimilar rates of suicide. In

TABLE 7.2
Percentage of all suicides, by age and sex[a]

	Age (years)								
	5–14	15–24	25–34	35–44	45–54	55–64	65–74	⩾75	Total
Males	0.7	12.7	18.3	20.5	17.0	13.9	9.6	7.3	100
Females	0.9	13.3	15.0	15.4	14.7	13.9	13.7	13.1	100
All	0.8	12.8	17.5	19.2	16.4	13.9	10.7	8.7	100

[a] Based on data from countries reporting to the World Health Organization: most recent year available between 1990 and 2000.

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Singapore, for instance, ethnic Chinese and Indians have much higher rates than ethnic Malays (*18*).

Suicide rates are frequently higher in indigenous groups, for example in some indigenous groups in Australia (*19*), China (Province of Taiwan) (*20*) and North America (*21*) (see Box 7.1).

Care in using suicide data

The way in which deaths of all types are recorded varies greatly between countries, making comparison of suicide rates between different countries extremely difficult. Even in those countries that have developed standard criteria, such as Australia, the way in which these criteria are applied can vary considerably (*24*). Erroneous estimates of suicide rates can sometimes result from such simple circumstances as government-imposed cut-off dates for published official statistics or delays because of coroners' inquiries. In Hong Kong SAR, China, for example, suicides are thought to be underestimated by between 5% and 18% solely for reasons of this nature (*25*).

Within a particular country, reported suicide rates can also vary according to the source of the data. For example, in China, estimates range from 18.3 per 100 000 (data reported to the World Health Organization), through 22 per 100 000 (Ministry of Health data), up to 30 per 100 000 (statistics from the Chinese Academy of Preventive Medicine) (*26*).

Data on mortality from suicide usually underestimate the true prevalence of suicide in a population. Such data are the end-product from a chain of informants, including those (often family members) who find the body, doctors, police, coroners and statisticians. Any of these people, for a variety of reasons, may be reluctant to call the death a suicide. This is likely to be particularly true in places where religious and cultural attitudes condemn suicide. Nevertheless, Cooper & Milroy (*27*) have found an underreporting of suicide by 40% in official records in certain regions of England. A suicide may be concealed so as to avoid stigmatization of the person who has taken his or her own life or of the person's family, for social convenience, for political reasons, to benefit from insurance policies, or because it was deliberately masked as an accident by the person committing it – for example, as a road accident. Suicide can also be misclassified as an undetermined cause of death, or as a natural cause, for example when people – particularly the elderly – fail to take life-sustaining medicines.

Suicide can go officially unrecognized when drug users take an overdose, when people deliberately starve themselves (in what are termed "suicidal erosions"(*28*)), or when people die some time after their suicide attempt. In these cases, as well as cases of euthanasia or assisted suicide, the clinical cause of death is usually the one officially reported. Underreporting is also related to age, with the phenomenon generally much more prevalent among elderly people. Despite all these caveats, it has been argued that the relative ranking of national suicide rates is reasonably accurate.

Non-fatal suicidal behaviour and ideation

Relatively few countries have reliable data on non-fatal suicidal behaviour, the main reason lying in the difficulty of collecting information. Only a minority of those attempting suicide go to health facilities for medical attention. In addition, in many developing countries, attempted suicide remains a punishable offence and hospitals therefore do not register cases. Furthermore, in many places, injuries do not need to be reported and information on them is consequently not collected at any level. Other factors can also affect reporting, such as age, method of attempted suicide, culture and accessibility to health care. In short, the scale of attempted suicide is not clearly known for most countries.

There is some evidence to suggest that on average only about 25% of those carrying out suicidal acts make contact with a public hospital (possibly one of the best places for data collection) (*29, 30*) and these cases are not necessarily the most serious ones. The reported cases are thus only the tip of the iceberg, and the large majority of suicidal people remain unnoticed (*31*). Several institutions, including national centres for injury control and prevention, departments of statistics and, in several countries, departments of justice, keep records of non-fatal events registered with the health services. Such

BOX 7.1

Suicide among indigenous peoples: the cases of Australia and Canada

In the past 20 to 30 years, suicide rates have increased strikingly among indigenous peoples in both Australia and Canada. In Australia, suicide among the Aboriginal and Torres Strait Islander populations used to be considered very uncommon. Slightly over a quarter of these people live in the state of Queensland. The overall suicide rate in Queensland for the period 1990–1995 was 14.5 per 100 000, while the rate for Aboriginal and Torres Strait Islander peoples was 23.6 per 100 000.

Suicides among indigenous Australians are heavily concentrated among young men. In Queensland, 84% of all indigenous suicides were among men aged between 15 and 34 years, and the rate for indigenous men aged 15–24 years was 112.5 per 100 000 (*22*). By far the most common method of suicide among young indigenous men is by hanging.

In Canada's Arctic north, suicide rates among the Inuit of between 59.5 and 74.3 per 100 000 have been reported in various studies, compared with around 15.0 per 100 000 in the overall population. Young Inuit men are at the highest risk for suicide, and their suicide rate is rising. Rates as high as 195 per 100 000 have been recorded among those aged 15–25 years (*23*).

Various explanations have been put forward for the high rates of suicide and suicidal behaviour among indigenous peoples. Among the proposed underlying causes are the enormous social and cultural turmoil created by the policies of colonialism and the difficulties faced ever since by indigenous peoples in adjusting and integrating into the modern-day societies.

In Australia, aboriginal groups were the object of stringent racial laws and discrimination as late as the 1960s. When these laws, including the restrictions on alcohol sales, were lifted within a short period in the 1970s, the rapid social changes in the previously oppressed indigenous peoples gave rise to instability in community and family life. This instability has continued ever since, with high rates of crime, delinquency and imprisonment, violence and accidents, alcohol dependence and substance abuse, and a homicide rate that is tenfold that among the general population.

In the Canadian Arctic in the early 19th century, epidemics swept the region as the first outsiders — whalers and fur traders — arrived, taking tens of thousands of lives and leaving a population reduced in size by two-thirds by 1900. By the 1930s the fur trade had collapsed, and Canada introduced a welfare state in the Arctic. In the 1940s and 1950s missionaries came to the Arctic and there was an attempt to assimilate the Inuit. Feverish exploration for oil, starting in 1959, further added to the social disintegration.

Research on suicide among the Canadian Inuit has identified several factors as likely indirect causes of suicide, including:

- poverty;
- childhood separation and loss;
- accessibility to firearms;
- alcohol abuse and dependence;
- a history of personal or familial health problems;
- past sexual or physical abuse.

Efforts are being made in both Australia and Canada to address suicidal behaviour among indigenous populations. In Australia, the national strategy to prevent suicides among young people includes a number of programmes for indigenous youths. These programmes are designed to address the specific needs of indigenous youths and are conducted in partnership with organizations representing the interests of indigenous peoples such as the Aboriginal Coordinating Council.

Constructive measures to prevent suicide in the Canadian Arctic include improved responses to crises, widespread community redevelopment and progress toward self-government in the indigenous areas. The new and vast territory of Nunavut was created on 1 April 1999, giving the Inuit people local self-determination and returning to them some of their rights and heritage.

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records provide useful data for research and prevention purposes, since those who attempt suicide are at high risk for subsequent suicidal behaviour, both fatal and non-fatal. Public health officials also rely on reviews of hospital records, population surveys and special studies, sources that often include data lacking in mortality data systems.

Available figures show – both relative to their population size and in absolute numbers – that non-fatal suicidal behaviour is more prevalent among younger people than among older people. The ratio of fatal to non-fatal suicidal behaviour in those over the age of 65 years is usually estimated to be of the order of 1:2–3, while in young people under 25 years the ratio may reach 1:100–200 (*32, 33*). Although suicidal behaviour is less frequent in the elderly, the probability of a fatal outcome is much higher (*28, 34*). On average, suicide attempts in old age are, in psychological and medical terms, more serious and the ''failure'' of a suicide attempt is often the result of chance. Also, as a general trend, rates of non-fatal suicidal behaviour tend to be 2–3 times higher in women than in men. Finland, though, is a remarkable exception to this pattern (*35*).

Data from an ongoing, cross-national study of non-fatal suicidal behaviour in 13 countries, show that in the period 1989–1992 the highest average age-standardized rate of suicide attempts in men was found in Helsinki, Finland (314 per 100 000), while the lowest rate (45 per 100 000) was in Guipúzcoa, Spain – a sevenfold difference (*35*). The highest average age-standardized rate for women was in Cergy-Pontoise, France (462 per 100 000) and the lowest (69 per 100 000) was again in Guipúzcoa. With only one exception, that of Helsinki, the rates of suicide attempts were higher among women than among men. In the majority of centres, the highest rates were found in the younger age groups, while the rates among people aged 55 years and over were generally the lowest. The most common method used was poisoning, followed by cutting. More than half of those attempting suicide made more than one attempt, with nearly 20% of second attempts being made within 12 months of the first.

Data from a longitudinal, representative sample of nearly 10 000 adolescents aged 12–20 years in Norway found that 8% had at one time attempted suicide and 2.7% had made such an attempt during the 2 years of the study period. Logistic regression analyses of the data showed that there was a greater likelihood of attempted suicide if the person had made an earlier suicide attempt, was female, was around the age of puberty, had suicidal ideation, consumed alcohol, did not live with both parents, or had a low level of self-esteem (*36*).

Suicidal ideation is more common than both attempted and completed suicide (*8*). However, its extent is still unclear. A review of studies published after 1985 on adolescent populations (particularly secondary-school students) suggested that between 3.5% and 52.1% of adolescents report suicidal thoughts (*31*). It is possible that these large percentage differences could be explained by the use of different definitions of suicidal ideation and by the different time periods to which the studies referred. There is evidence that women, including those in old age, are more prone to suicidal thoughts than are men (*37*). Overall, the prevalence of suicidal ideation among older adults of both sexes has been estimated at between 2.3% (for those having had suicidal thoughts in the past 2 weeks) and 17% (for those ever having had suicidal thoughts) (*38*). However, compared with other forms of suicidal behaviours, such as attempted suicide, suicidal ideation may not be a useful indicator of which adolescents or adults are most in need of preventive services.

What are the risk factors for suicidal behaviour?

Suicidal behaviour has a large number of underlying causes. The factors that place individuals at risk for suicide are complex and interact with one another. Identifying these factors and understanding their roles in both fatal and non-fatal suicidal behaviour are central to preventing suicides. Epidemiologists and experts in suicide have described a number of specific characteristics that are closely associated with a heightened risk for suicidal behaviour. Apart from demographic factors – such as age and sex, both already mentioned above – these include psychiatric, biological, social

and environmental factors, as well as factors related to an individual's life history.

Psychiatric factors

Much of what is known about suicide risk comes from studies where researchers have interviewed a surviving parent or other close relative or friend to identify specific life events and psychiatric symptoms that a suicide victim had experienced in the weeks or months before dying. This type of work is known as a ''psychological autopsy''. Using this approach, research has shown that many adults who complete suicide exhibit prior evidence of signs or symptoms suggestive of a psychiatric condition months or even years before their death (*39, 40*).

Some of the principal psychiatric and psychological factors associated with suicide are (*41–48*):

- major depression;
- other mood [affective] disorders, such as bipolar disorder (a condition characterized by periods of depression, alternating with periods of elevated mood, or mania, and in which the changed states can last for days or even months);
- schizophrenia;
- anxiety and disorders of conduct and personality;
- impulsivity;
- a sense of hopelessness.

Depression plays a major role in suicide and is thought to be involved in approximately 65–90% of all suicides with psychiatric pathologies (*42*). Among patients with depression, the risk seems to be higher when they do not follow their treatment,

BOX 7.2

Depression and suicide

Depression is the mental disorder most often associated with suicide. Anxiety, a powerful driving force in the process of suicide, is closely interwoven with depression and the two disorders are sometimes indistinguishable. Studies have revealed that up to 80% of people who committed suicide had several depressive symptoms.

People of all ages can experience depression. However, it is frequently difficult to detect depression in men, who, in any case, seek medical help more seldom than women. Depression in men is sometimes preceded by various types of abuse and violence, both within and outside the family. The treatment of depression in men is of great importance, since in many cultures suicide is to a large extent a male phenomenon.

Among children and adolescents, the nature of depression usually differs from that found in adults. Depressed young people tend to exhibit more ''acting-out'' — such as truancy from school, declining school grades, bad behaviour, violence and abuse of alcohol or drugs — and also to sleep and eat more. At the same time, a refusal to eat and anorexic behaviour are frequently found in combination with depression in young people, particularly among girls, but also in boys. These severe eating disorders are themselves associated with an increased risk for suicide.

Depression often has physical manifestations, particularly among older people, including stomach ailments, dizziness, palpitations of the heart and pain in various parts of the body. Depression in the elderly may accompany other diseases and disorders, such as stroke, myocardial infarction, cancer, rheumatism, and Parkinson or Alzheimer disease.

The tendency to suicide can be reduced if depression and anxiety are treated. Many studies have confirmed the beneficial effects of antidepressants and various forms of psychotherapy, particularly cognitive behavioural therapy. Providing good psychosocial support for elderly people, including the use of a telephone to reach social and health workers and others, has also been shown to produce a significant reduction in depression and the number of deaths from suicide among older people.

consider themselves untreatable, or are considered by specialists to be untreatable (*43*) (see Box 7.2). The lifetime risk of suicide in those affected by major and bipolar depression has been estimated at around 12–15% (*44, 45*), although a recent re-examination of the evidence has suggested a much lower level of risk (*46*).

Schizophrenia is another psychiatric condition with a high association with suicide, and the lifetime risk of suicide among people with schizophrenia is estimated to be about 10–12% (*47*). The risk is particularly strong in: young male patients; patients in the early stages of the disease, especially those who performed well, mentally and socially, before the onset of the illness; patients with chronic relapses; and patients with a fear of ''mental disintegration'' (*48*).

Other factors, such as feelings of hopelessness and helplessness also increase the risk of committing suicide. In a 10-year longitudinal study in the United States, for example, Beck et al. (*49*) brought out the importance of feelings of hopelessness as a major predictor of suicidal behaviour. In this study, lack of future expectations correctly identified 91% of subjects who subsequently committed suicide.

Alcohol and drug abuse also play an important role in suicide. In the United States, at least one-quarter of all suicides are reported to involve alcohol abuse (*50*). The lifetime risk of committing suicide among people who are dependent on alcohol is not much lower than that among people with depressive disorders (*50*). There are, however, many close links between alcohol abuse and depression, and it is often difficult to determine which of the two is the leading condition. For instance:

- Alcohol abuse may lead directly to depression or indirectly through the sense of decline and failure that most people who are dependent on alcohol experience.
- Alcohol abuse may be a form of self-medication to alleviate depression.
- Both depression and alcohol abuse may be the result of specific stresses in the person's life.

However, while suicide among those suffering depressive disorders happens relatively early in the history of the disease, particularly in the 30–40-year-old age group, suicide among those suffering from alcohol dependence usually occurs late in the condition. In addition, when it does then occur, it is often alongside other factors such as a breakdown in relationships, social marginalization, poverty and the onset of physical deterioration resulting from chronic abuse of alcohol. It is thought that alcohol and drug abuse play a lesser role in suicide in parts of Asia than elsewhere. In a study of suicide among teenagers in Hong Kong SAR, China, only about 5% of those who committed suicide had a history of alcohol or drug abuse (*51*). This finding might explain the relatively low rate of teenage suicide in Asia, except for China.

A previous suicide attempt is, however, one of the most powerful predictors of subsequent fatal suicidal behaviour (*2*). The risk is higher in the first year – and especially in the first 6 months – after the attempt. Almost 1% of individuals who attempt suicide die within 1 year (*52*), and approximately 10% eventually complete suicide. Estimates of the increase in risk resulting from a history of previous attempts vary from one study to another. Gunnell & Frankel, for example, report a 20–30-fold increase in risk in comparison with the general population, which is consistent with other reports (*53*). While the presence of a previous suicide attempt increases the risk that a person will commit suicide, the majority of those who commit suicide have not previously attempted it (*24*).

Biological and medical markers

A family history of suicide is a recognized marker for increased risk of suicide. To some researchers, this suggests that there may be a genetic trait that predisposes some people to suicidal behaviour. Indeed, data from studies on twins and adopted children confirm the possibility that biological factors may play a role in some suicidal behaviour. Studies on twins have shown that monozygotic twins, who share 100% of their genes, have a significantly higher concordance for both suicide and attempted suicide than dizygotic twins, who

share 50% of their genes (*54*). However, there have as yet been no studies on monozygotic twins reared apart – a prerequisite for a methodologically sound study – and none of the studies on twins have carefully controlled for psychiatric disorders. It could be that it is a psychiatric disorder that is inherited, rather than a genetic predisposition to suicidal behaviour, and that this disorder makes suicidal behaviour in related individuals more likely.

Findings from a case–control study of adopted children showed that those who committed suicide tended to have biological relatives who committed suicide (*55*). These suicides were largely independent of the presence of a psychiatric disorder, suggesting that there is a genetic predisposition for suicide independent of – or possibly in addition to – the major psychiatric disorders associated with suicide. Other social and environmental factors probably also interact with family history to increase the risk of suicide.

Further evidence suggesting a biological basis for suicide comes from studies of neurobiological processes that underlie many psychiatric conditions, including those that predispose individuals to suicide. Some studies, for example, have found altered levels of serotonin metabolites in the cerebrospinal fluid of adult psychiatric patients who committed suicide (*56, 57*). Serotonin is a very important neurohormone that controls mood and aggression. Low levels of serotonin and blunted responses to those tests that interfere with its metabolism have been shown to persist for some time after episodes of illness (*58, 59*). An impaired functioning of those neurons that contain serotonin in the prefrontal cortex of the brain may be an underlying cause of a person's reduced ability to resist impulses to act on suicidal thoughts (*60, 61*).

Suicide may also be the consequence of a severe and painful illness, especially one that is disabling. The prevalence of physical illness in those who commit suicide is estimated to be at least 25%, though it may be as high as 80% among elderly people who commit suicide (*62*). In more than 40% of cases, physical illness is considered an important contributory factor to suicidal behaviour and ideation, especially if there are also mood disorders or depressive symptoms (*63*). It is understandable that the prospect of unbearable suffering and humiliating dependency might lead people to consider ending their life. However, several investigations have shown that people suffering from a physical illness rarely commit suicide in the absence of any psychiatric symptoms (*42*).

Life events as precipitating factors

Certain life events may serve as precipitating factors for suicide. Particular events that a small number of studies have tried to link to risk of suicide include personal loss, interpersonal conflict, a broken or disturbed relationship, and legal or work-related problems (*64–67*).

The loss of a loved one, whether through divorce, separation or death, may trigger intense depressive feelings, especially if the person lost was a partner or was exceptionally close. Conflicts in interpersonal relationships in the home, or in places of study or work can also unleash feelings of hopelessness and depression. In a study of over 16 000 adolescents in Finland, for example, researchers found an increased prevalence of depression and severe suicidal ideation both among those who were bullied in school and among those who were perpetrators of bullying (*68*). A retrospective study in south-east Scotland that controlled for age, sex and mental disorders found adverse interpersonal conflict to be independently associated with suicides (*69*). In a review of all suicides over a 2-year period in Ballarat, Australia, researchers found that social and personal difficulties were associated with suicide in over one-third of the cases (*70*). Research has also indicated a greater likelihood of depression and suicide attempts among victims of violence between intimate partners (*71–74*).

A history of physical or sexual abuse in childhood can increase the risk of suicide in adolescence and adulthood (*75–77*). Humiliation and shame are commonly felt by victims of sexual abuse (*2*). Those who were abused during childhood and adolescence often feel mistrustful in interpersonal relationships and have difficulty in maintaining such

relationships. They experience persistent sexual difficulties and intense feelings of inadequacy and inferiority. Researchers in the Netherlands examined the relationship between sexual abuse and suicidal behaviour in 1490 adolescent students, and found that those who had experienced abuse displayed significantly more suicidal behaviour, as well as other emotional and behavioural problems, than their non-abused peers (*78*). An ongoing 17-year longitudinal study of 375 subjects in the United States found that 11% had reported physical or sexual abuse before the age of 18 years. Subjects aged between 15 and 21 years who had been abused reported more suicidal behaviour, depression, anxiety, psychiatric disorders, and other emotional and behavioural problems than those who had not been abused (*79*).

Sexual orientation may also be related to an increased risk for suicide in adolescents and young adults (*80, 81*). Estimates of the prevalence of suicide among gay and lesbian youths, for example, range from 2.5% to 30% (*82, 83*). The factors that may contribute to suicides and attempted suicide here include discrimination, stress in interpersonal relations, drugs and alcohol, anxiety about HIV/AIDS and limited sources of support (*84, 85*).

Being in a stable marital relationship, on the other hand, would seem generally to be a ''protective'' factor against suicide. Responsibilities for bringing up children confer an additional protective element (*86*). Studies on the relationship between marital status and suicide reveal high rates of suicide among single or never-married people in Western cultures, even higher rates among widowed people, and some of the highest rates among people who are separated or divorced (*87, 88*). This last phenomenon is particularly evident in males, especially in the first few months after their loss or separation (*89*).

In an exception to the generally protective effect of marriage, those who marry early (before 20 years of age) have higher rates of suicidal behaviour than their unmarried peers, according to some studies (*90, 91*). Furthermore, marriage is not protective in all cultures. Higher rates of both fatal and non-fatal suicidal behaviour have been reported among married women in Pakistan, compared with both married men and single women (*92, 93*). This may be because social, economic and legal discrimination creates psychological stress that predisposes these women to suicidal behaviour (*92*). Higher rates of suicide have also been reported among married women over the age of 60 years in Hong Kong SAR, China, compared with widowed and divorced women in this age group (*90*).

While problems in interpersonal relationships may increase the risk of suicidal behaviour, social isolation can also be a precipitating factor for suicidal behaviour. Social isolation lay behind Durkheim's concepts of ''egoistic'' and ''anomic'' suicide (*94*), both of which were related to the idea of inadequate social connectedness. A large body of literature suggests that individuals who experience isolation in their lives are more vulnerable to suicide than those who have strong social ties with others (*95–98*). Following the death of a loved one, for example, a person may attempt suicide if there is insufficient support provided during the grieving period by those close to the bereaved person.

In a comparative study of social behaviour between groups of people who have attempted suicide, people who have completed suicide and people dying of natural causes, Maris (*99*) found that those who completed suicide had participated less in social organization, were often without friends and had shown a progressive decline in interpersonal relationships leading to a state of total social isolation. Psychological autopsy studies show that social withdrawal frequently precedes the suicidal act (*99*). This was also brought out in a study by Negron et al. (*100*), who found that people who attempted suicide were more likely to isolate themselves during an acute suicidal phase than those with suicidal ideation. Wenz (*101*) identified anomie – the feeling of alienation from society caused by the perceived absence of a supporting social framework – as one factor in the suicidal behaviour of widows, along with actual and expected social isolation. Social isolation has frequently been identified as a contributing factor in suicidal ideation among the elderly (*102, 103*). A study of suicide attempts among

adolescents under 16 years of age who had been referred to a general hospital found that the most frequent problems underlying such behaviour were relationship difficulties with parents, problems with friends, and social isolation (*104*).

Social and environmental factors

Research has identified a number of important social and environmental factors related to suicidal behaviour. These include such diverse factors as: the availability of the means of suicide; a person's place of residence, employment or immigration status; affiliation to a religion; and economic conditions.

Method chosen

A major factor determining whether suicidal behaviour will be fatal or not is the method chosen. In the United States, guns are used in approximately two-thirds of all suicides (*105*). In other parts of the world, hanging is more common, followed by the use of a gun, jumping from a height and drowning. In China, intoxication by pesticides is the most common method (*106, 107*).

In the past two decades, in some countries such as Australia, there has been a remarkable increase in hanging as a means of suicide, especially among younger people, accompanied by a corresponding decrease in the use of firearms (*108*). In general, elderly people tend to adopt methods involving less physical strength, such as drowning or jumping from heights; this has been recorded particularly in Hong Kong SAR, China, and Singapore (*18*). Nearly everywhere, women tend to adopt "softer" methods – for example, overdosing with medicines – both in fatal and in non-fatal suicide attempts (*35*). A notable exception to this is the practice of self-immolation in India.

Apart from age and sex, the choice of method in suicide may be influenced by other factors. In Japan, for example, the traditional practice of self-disembowelment with a sword (also known as *hara-kiri*) continues to occur. Imitation of a means of suicide, especially among young people and in relation to the death of a celebrity, is known to occur (*109–111*). How determined a person is to kill themselves is usually related to the lethalness of the method chosen: elderly people, for instance, normally express a greater determination than others to die and tend to choose more violent methods – such as shooting, jumping from a height or hanging – that afford less possibility of being rescued in the act (*112*).

Differences between urban and rural areas

There are frequently large disparities in suicide rates between urban and rural areas. In 1997 in the United States, for example, the district of Manhattan in New York City recorded 1372 suicides, a number three times that of the largely rural state of Nevada (411), but the rate in Nevada was more than three times that of New York state (24.5 per 100 000 – the highest in the United States – against 7.6 per 100 000) (*113*). Similar differences between urban and rural areas have been reported, for instance, in Australia (*114*), and in European countries, such as England and Wales (combined data) and Scotland, where farmers have high rates of suicide (*115*). Suicide rates among women in rural areas of China are also reported to be higher than in urban areas (*26*).

Reasons for the higher rates in many rural areas may include social isolation and the greater difficulty in detecting warning signs, the limited access to health facilities and doctors, and lower levels of education. Methods of suicide in rural areas are also often different from those used in urban areas. In rural communities in Eastern Europe and parts of south-east Asia, the easy availability of herbicides and pesticides makes them popular choices for the purposes of suicide. The same is true in Samoa, where the control of sales of the herbicide paraquat led to a decrease in the number of suicides (*116*). In rural communities of Australia, where the possession of guns is common, shooting is frequently reported as a method of suicide (*114*).

Immigration

The impact of immigration on suicide rates has been studied in countries such as Australia, Canada and the United States, all of which have a large mix

TABLE 7.3

Age-standardized suicide rates per 100 000 population in Australia, by place of birth, 1982–1992

Year	Place of birth							Total born overseas
	Asia	Australia	Europe			Ireland and United Kingdom	Oceania[b]	
			Eastern	Southern	Western[a]			
1982	8	11	31	7	19	12	14	13
1983	12	11	21	8	16	12	10	12
1984	9	11	17	5	17	11	17	11
1985	7	11	20	6	17	12	14	12
1986	8	12	17	6	19	13	14	12
1987	8	14	28	7	17	14	17	13
1988	9	13	20	8	14	15	17	13
1989	8	12	16	7	16	13	14	12
1990	8	13	14	5	19	12	14	11
1991	8	14	22	9	19	14	13	12
1992	7	13	24	8	17	13	14	12

Source: Reproduced, with minor editorial amendments, from reference *118* with the permission of the publisher.

[a] Excluding Ireland and the United Kingdom.

[b] Excluding Australia.

of ethnic groups. In these countries, the rate of suicidal behaviour in a given immigrant group has been found to be similar to that in their country of origin. In Australia, for example, immigrants from Greece, Italy and Pakistan have suicide rates that are lower than those of immigrants from countries in Eastern Europe or from Ireland or Scotland, all countries with traditionally high suicide rates (*117*) (see also Table 7.3). This suggests a strong role for cultural factors in suicidal behaviour.

Employment and other economic factors

Several studies have found increased rates of suicide during periods of economic recession and high unemployment (*119–123*) and the converse has also been demonstrated. In a study examining the impact of economic factors on suicide in Germany, Weyerer & Wiedenmann (*122*) investigated the effect of four economic variables and their relationship to suicide rates in the period 1881–1989. The strongest correlation was found during times of social disintegration, where there was high unemployment, with low levels of state welfare or protection and increased risks of bankruptcy. A preliminary investigation into the above-average suicide rate in the Kutznetsk Basin, Russian Federation, between 1980 and 1995 cited economic instability, the disintegration of the former Soviet Union and other specific historical factors as possible contributory factors (*123*). In relating his visits to Bosnia and Herzegovina, Berk (*124*) wrote of a higher-than-expected rate of suicide as well as alcohol dependence among children. While they had survived the most immediate threats of the armed conflict during 1992–1995, the children had succumbed to long-term stress. In Sri Lanka, the Tamil community, which has a history of violence and political and economic instability, has traditionally had high rates of suicide. Today the Sinhalese community, which 20 years ago reported very low rates, also have high rates. This clearly highlights the close association between suicide, political violence and social collapse.

At an individual level, suicidal behaviour is more frequent in unemployed than in employed people (*119, 125, 126*). Poverty and a socially diminished role – both consequences of unemployment – often appear to be associated with increased suicidal behaviour, especially where the job has been lost suddenly. Research in this area, however, has some limitations. In particular, it has not always taken account of the duration of unemployment. Those waiting for their first job have sometimes been grouped together with others who have lost their jobs, and psychiatric conditions and personality disorders have been ignored (*127, 128*).

Religion

Religion has long been regarded as an important factor in suicidal behaviour. Research has shown that an approximate ranking of countries, by religious affiliation, in descending order of suicide rates, is as follows:

- Countries where religious practices are prohibited or strongly discouraged (as was the case in the former communist countries of Eastern Europe and in the former Soviet Union).

- Countries where Buddhism, Hinduism or other Asian religions predominate.
- Countries where many people are Protestant.
- Countries that are predominantly Roman Catholic.
- Countries that are largely Muslim.

Lithuania is a notable exception to this rough pattern. The country has always been largely Catholic, with many practising adherents and a strong influence of the church, even when it was part of the former Soviet Union. Nevertheless, suicide rates were and remain extremely high. The approximate ranking given above clearly does not take into account how strongly individuals in a particular country believe in and adhere to their religion (*129*). The ranking also does not include animism – mainly found in Africa – because suicide rates among adherents to animistic beliefs are generally not known.

Durkheim believed that suicide stemmed from a lack of identification with a unitary group and postulated that suicide rates should be lower where there was a high level of religious integration. Accordingly, he argued that shared religious practices and beliefs, such as those associated with Catholicism, are protective factors against suicide (*94*). Some studies testing Durkheim's hypothesis have tended to support him (*130, 131*). Other studies have, however, found no association between the proportion of Roman Catholics in a population and suicide rates (*132, 133*). A study by Simpson & Conlin (*134*) on the impact of religion found that belief in Islam reduced suicide rates more than a belief in Christianity.

Some studies have tried to use church attendance and the extent of religious networks as a measure of religious faith, which they have then sought to link with suicide rates. Their findings suggest that church attendance has a strong preventive influence (*135*), with the degree of commitment to a particular religion being an inhibitor of suicide (*136*). Similarly, a study by Kok (*137*) examined suicide rates among the three ethnic groups of Singapore. The conclusion was that the ethnic Malays, overwhelmingly adherents of Islam, which is strongly opposed to suicide, had by far the lowest suicide rate. At the same time, the ethnic Indians had the highest rate of suicide on the island. Singapore's ethnic Indians are generally followers of Hinduism, a faith that believes in reincarnation and does not strictly forbid suicide. Another study examining differences between African-American and Caucasian populations in the United States found that the lower rate of suicide among African Americans could be attributed to greater personal devotion to a religion (*138*).

Summary

Risk factors for suicidal behaviour are numerous and interact with one another. Knowing which individuals possess a predisposition to suicide, and also possibly face a combination of risk factors, can help pinpoint those most in need of prevention efforts.

Where there are sufficiently strong protective factors, even the presence of several risk factors – such as major depression, schizophrenia, alcohol abuse or loss of a loved one – may not create the conditions for suicidal ideation or behaviour in an individual. The study of protective factors is still in its infancy. If suicide research and prevention is to make real progress, there should be much greater knowledge about protective factors, to match the advances made in recent decades in the understanding of predisposing and precipitant factors in suicide.

Apart from Durkheim's observations on marriage and religion, a number of investigations have provided insights into the protective functions of parenthood (*139*), social support and family connectedness (*36, 140–142*), self-esteem (*143*) and repression of the ego (*144*). Other studies have directly weighed up the balance of risk and protective factors in trying to predict suicidal behaviour. In one such study, a survey of American Indian and Alaskan Native youths, Borowsky et al. (*145*) found that focusing on protective factors such as emotional well-being and connectedness with family and friends was as effective as or more effective than trying to reduce risk factors in the prevention of suicide. The study of protective factors would appear to be a promising field for future research.

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What can be done to prevent suicides?

With the overall increase in suicidal behaviour, particularly among young people, there is a great need for effective interventions. As has been seen, there are a large number of possible risk factors for suicidal behaviour and interventions are usually based on a knowledge of these factors. Although many interventions have existed for a considerable period of time, very few of them have shown a significant effect in reducing suicidal behaviour or have produced long-term sustainable results (*146*).

Treatment approaches

Treatment of mental disorders

Since much published material and clinical experience show that a number of mental disorders are significantly associated with suicide, the early identification and appropriate treatment of these disorders is an important strategy for preventing suicide. Particularly relevant here are mood disorders, alcohol dependence and abuse of other substances, schizophrenia and certain types of personality disorder.

There is evidence that educating primary health care personnel to diagnose and treat people with mood disorders may be effective in reducing suicide rates among those at risk. Also, the new generation of drugs for the treatment of both mood and schizophrenic disorders, which have fewer side-effects and more specific therapeutic profiles than those used previously, would appear to improve patients' adherence to treatment and produce a better outcome, thus reducing the likelihood of suicidal behaviour in patients.

Pharmacotherapy

Pharmacotherapy has been examined for its efficacy in working on neurobiological processes that underlie certain psychiatric conditions, including those that are related to suicidal behaviour. Verkes et al. (*147*), for instance, showed that the substance paroxetine might be effective in reducing suicidal behaviour. The reason for choosing paroxetine was that suicidal behaviour has been associated with reduced serotonin function. Paroxetine is known as a selective serotonin reuptake inhibitor (SSRI), and as such increases the availability of serotonin for the neural transmission of signals. In a 1-year double-blind study, paroxetine and a placebo were compared in patients who had a history of suicide attempts and had recently attempted suicide. These patients had not suffered major depression, but the majority had a ''cluster B personality disorder'' (which includes antisocial, narcissistic, borderline and histrionic personality disorders). The results showed that enhancing serotonin function with an SSRI, in this case paroxetine, may reduce suicidal behaviour in those patients with a history of suicide attempts, but not in those suffering from major depression.

Behavioural approaches

While many treatment approaches focus primarily on the mental disorder and assume that improvement in the disorder will lead to a reduction in suicidal behaviour, other approaches directly target the behaviour (*148*). Following this approach, a number of interventions have been developed, some of which are discussed below.

Behavioural therapy

In behavioural interventions, a mental health worker conducts therapy sessions with the patient, discussing previous and current suicidal behaviour and thoughts of suicide, and through probing tries to establish connections with possibly underlying factors (*148*). Early results on the efficacy of this type of treatment are promising, though there are no conclusive answers yet.

A study in Oxford, England, examined patients at high risk of multiple suicide attempts, aged 16–65 years, who had been admitted to an emergency unit after taking an overdose of antidepressants (*149*). Patients received either the standard treatment for suicide attempts or the standard treatment along with a brief ''problem-oriented'' intervention – a form of short-term psychotherapy that focused on the problem identified as being the most troublesome for the patient. The study found a significant benefit for the experimental group (those receiving

the intervention along with the standard treatment) 6 months after treatment, in terms of a decline in their rates of repeated suicide attempts. Unfortunately, this difference was no longer significant when the subjects were reassessed after 18 months.

A study in the United States (*150*) examined the effectiveness of dialectical behaviour therapy with patients exhibiting borderline personality disorders, multiple behavioural dysfunctions, significant mental disorders and a history of multiple suicide attempts. Dialectical behaviour therapy is a treatment designed for chronically suicidal patients. It uses behaviour analysis and a problem-solving strategy. During the first year after treatment, patients who had received the therapy made fewer suicide attempts than those who had received the standard treatment.

Another research study in the United States (*151*) that adopted a behavioural therapy approach examined patients with a history of attempting suicide. The aim was to see whether they displayed a ''deficit in positive future thinking'' – that is to say, whether they lacked hope and expectation for the future. If so, the study sought to establish whether such a deficit could be changed by a brief psychological intervention known as ''manual-assisted cognitive behaviour therapy'' (MACT). In such an intervention, the problem is worked through with the guidance of a manual, so as to standardize the treatment. Patients were randomly assigned to either MACT or the standard treatment for suicide attempts and reassessed after 6 months. The study found that patients with a history of attempting suicide showed less hope and had fewer positive expectations for the future than the matched group of community controls. After the MACT intervention, their expectations significantly improved, while those who received the standard treatment improved only marginally.

Green cards

The so-called green card is a relatively simple intervention. The client receives a card, giving him or her direct and immediate access to a range of options, such as an on-call psychiatrist or hospitalization. While it has not proved to be a particularly effective intervention, the green card does seem to have some beneficial effects for those considering suicide for the first time (*152, 153*).

A recent study used the green card with patients who had attempted suicide for the first time and those with a history of suicide attempts (*154*). Study participants were randomly assigned to control groups that received only the standard treatment for suicide attempts, and experimental groups that received the standard treatment plus a green card. The green card offered a 24-hour crisis telephone consultation with a psychiatrist. The effect of the green card differed between the two types of experimental groups. It had a protective effect with those who had attempted suicide for the first time (though not a statistically significant one), but had no effect on those who had made previous attempts. It may be that the telephone support alone offered by the green card in the study was not enough, and that the card should have provided easy access to other crisis services.

Another intervention, based on the principle of connectedness and easy access and availability of help, is the Tele-Help/Tele-Check service for the elderly operating in Italy (*155*). Tele-Help is an alarm system that the client can activate to call for help. The Tele-Check service contacts clients twice a week to check on their needs and offer emotional support. In one study, 12 135 individuals aged 65 years and over were given the Tele-Help/Tele-Check service for 4 years (*155*). During this period, there was only one suicide in the group, compared with a statistically expected seven (*156*).

Relationship approaches

It is known that susceptibility to suicide is related to the social relationships that a person has: the greater the number of social relationships, the less in general is the susceptibility to suicide (*156*). Several interventions have sought to enhance social relationships so as to reduce repeated suicidal behaviour. The general approach is to explore problems in different areas of the patient's social life and for the therapist to try to tackle these problems. Although the main goal is to prevent recurrent suicidal behaviour, the improvement of social relationships is in itself also considered important.

Research into the efficacy of relationship approaches has not demonstrated a positive benefit, in terms of reducing suicidal behaviour. However, the approach has been shown to produce improved social relationships.

Psychosocial interventions

Litman & Wold (*156*) investigated a particular outreach method, known as ''continuing relationship maintenance'' (CRM). In this method, the counsellor actively reaches out to the suicidal person and tries to maintain a constant relationship with him or her. A total of 400 people at high risk of suicide underwent this programme for an average of 18 months, being assigned either to the experimental (CRM) group or to a control group. In the control group, subjects received ongoing counselling and took the initiative *themselves* to contact the counsellor. The intervention did not manage to reduce suicidal ideation, attempted suicide or completed suicide. However, a number of intermediate goals were achieved, with the CRM group showing significant improvements compared with the control group. These improvements included reduced loneliness, more satisfactory intimate relationships, less depression and greater confidence in using community services.

Gibbons et al. (*157*) compared the effectiveness of ''task-centred casework'' – a problem-solving method that emphasizes collaboration between a patient and a social worker over matters related to daily living – with standard treatment in patients who had made a previous suicide attempt. There was no difference in the rate of repeated suicide attempts between the two groups, but the group that received task-centred casework showed a greater improvement in handling social problems than the control group.

In a study by Hawton et al. (*158*), 80 patients who had taken an overdose either received outpatient counselling or were referred back to their general practitioners with recommendations for further care. Again, there was no statistical difference in the rates of repeated suicide attempts, but there did seem to be some degree of benefit for the outpatient group when assessed after 4 months. A greater proportion of the outpatient group, as compared with the second group, showed improvements in social adjustment, marital adjustment and relationships with their families. Counselling seemed most beneficial for women and for patients with problems involving a one-to-one relationship, such as husband–wife, parent–child or supervisor–employee relationships.

Community-based efforts

Suicide prevention centres

Besides the interventions described above, specific community mental health services exist for people exhibiting suicidal behaviour. A suicide prevention centre is designed to serve as a crisis centre offering immediate help, usually by telephone link, but there are also programmes with face-to-face counselling and outreach work.

Dew et al. (*159*) conducted a quantitative literature review of the effectiveness of suicide prevention centres and found no overall effect, either positive or negative, on suicide rates. The methodological limitations of their study, however, make it difficult to reach a definite conclusion. The authors did find that the proportion of suicides among clients attending prevention centres was greater than the proportion of suicides in the general population, and that individuals who completed suicide were more likely to have been clients at these centres. These findings suggest that the suicide prevention centres are at least attracting the high-risk population they are supposed to be helping.

Lester (*160*) reviewed 14 studies that examined the effectiveness of suicide prevention centres on suicide rates. Seven of these studies provided some evidence for a preventive effect. A study on suicide prevention centres in 25 cities in Germany actually found an increase in suicide rates in three of the cities (*161*).

School-based interventions

Programmes have been set up to train school staff, community members and health care providers to identify those at risk for suicide and refer them to appropriate mental health services. The extent of training will vary from programme to programme,

but in all cases a strong link to local mental health services is essential.

Lester (*162*), though, struck a note of caution in suggesting that as school staff become more knowledgeable, they may refer students to mental health professionals more rarely, which in itself may result in more suicides. Although education of school staff members, parents and others involved in school programmes is highly important, these people cannot replace mental health professionals. Nevertheless, health care facilities alone cannot meet all the needs of young people, and schools must be able to act as a medium for suicide prevention.

Societal approaches

Restricting access to means

Restricting access to the means of suicide is particularly relevant when such access can readily be controlled. This was first demonstrated in 1972 in Australia by Oliver & Hetzel (*163*), who found a reduction in suicide rates when access to sedatives – mainly barbiturates, which are lethal in high doses – was reduced.

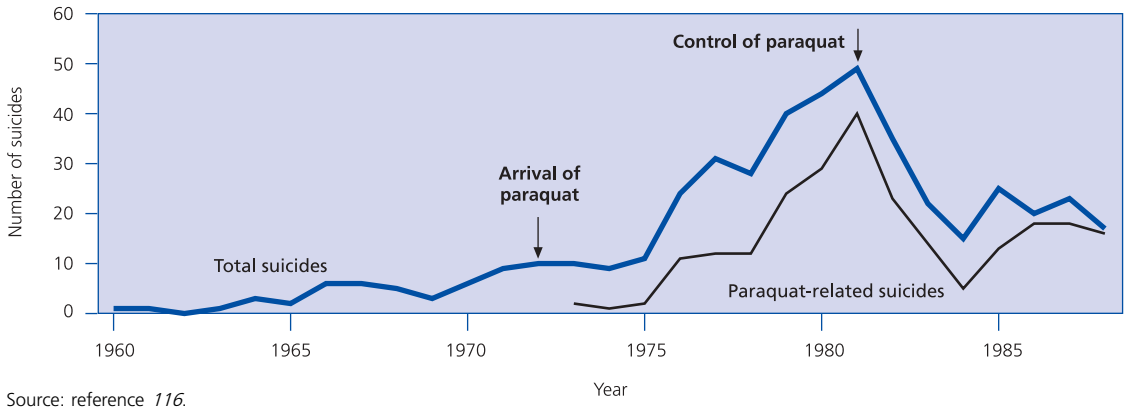
In addition to this study concerning sedatives, there is also evidence of a reduction in suicide rates when other toxic substances are controlled, for example pesticides, which are widely disseminated in the rural areas of many developing countries. Perhaps one of the best-studied examples is that in Samoa (*116*), where until 1972, when paraquat was first introduced into the country, the number of suicides was below 10. The number began to climb sharply in the mid-1970s and reached nearly 50 in 1981, when efforts to control the availability of paraquat began. During this period, suicide rates increased by 367%, from 6.7 per 100 000 in 1972 to 31.3 per 100 000 in 1981. Within 3 years, the suicide rate had dropped back to 9.4 per 100 000. Despite subsequent control of paraquat, more than 90% of all suicides in 1988 were effected by its use (see Figure 7.2).

Gas detoxification – the removal of carbon monoxide from domestic gas and from car exhausts – has proved effective in reducing suicide rates. In England, suicides from poisoning with domestic gas began to decline soon after carbon monoxide was removed from domestic gas (*164*) (see Figure 7.3). Similar declines in the use of domestic gas for suicide have been noted in Japan, the Netherlands, Scotland, Switzerland and the United States (*165*). Other studies have also found a reduction in suicides following the introduction of catalytic converters, which among other things remove carbon monoxide from car exhausts (*165, 166*).

The association between possession of handguns in the home and suicide rates has been noted (*167–169*). There are various approaches to reducing injuries from guns, whether accidental or intentional. They usually centre on legislation on gun sales and ownership, and on gun safety. Gun safety

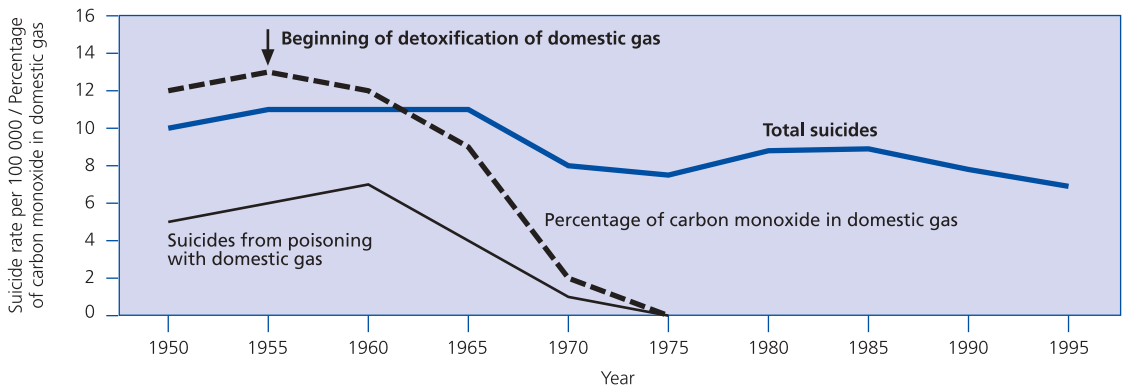
FIGURE 7.2

Number of suicides in Samoa in relation to the arrival of pesticides containing paraquat and the control of sales of paraquat



Source: reference *116*.

FIGURE 7.3
Impact of detoxification of domestic gas (%CO) on suicide rates, England and Wales, 1950–1995



Source: reference *164*.

measures include education and training, various storage practices (such as storing guns and ammunition separately, and keeping guns unloaded and in locked places) and trigger-blocking devices. In some countries – including Australia, Canada and the United States – restrictions on the ownership of firearms have been associated with a decrease in their use for suicide (*165, 169*).

Media reporting

The potential impact of the media on suicide rates has been known for a long time. More than two centuries ago, a widely read novel inspired a spate of imitation suicides. Johann Wolfgang Goethe's *Die Leiden des jungen Werther [The sufferings of young Werther]*, written in 1774 and loosely based on the case of a friend of the author's, described the inner turmoil of Werther as he anguishes over his unrequited love for Lotte. ''The effect on the book's first readers was overwhelming. The novel inspired not just emotion but emulation, in a wave of suicides similarly costumed [as Werther was], blue coat, yellow waistcoat'' (*170*).

Present-day evidence suggests that the effect of media reporting in encouraging imitation suicides depends largely on the manner of reporting – the tone and language used, how the reports are highlighted, and whether accompanying graphic or other inappropriate material is used. The concern is that the extreme vulgarization of reporting of suicides may create a suicide culture, in which suicide is seen as a normal and acceptable way of leaving a difficult world.

Responsible reporting of suicides by the media is seen as absolutely imperative, and any way of achieving it is to be welcomed. Various organizations and governments have proposed guidelines for reporting suicidal behaviour, including Befrienders International in the United Kingdom, the Centers for Disease Control and Prevention in the United States, the World Health Organization, and the Australian and New Zealand governments (*171*).

Intervention after a suicide

The loss of a person by suicide can arouse different feelings of grief in the relatives and close friends of those who have committed suicide than the feelings they experience when death is from natural causes. In general, there is still a taboo attached to the discussion of suicide and those bereaved by suicide may have less opportunity to share their grief with others. Communicating one's feelings is an important part of the healing process. For this reason, support groups serve an important role. In 1970, the first self-help support groups for the relatives and friends of people who have committed suicide started up in North America (*172*). Similar groups were subsequently established in various countries around the world. Self-help support groups are run by their members, but with access to outside help and resources. Such self-help groups appear to be beneficial for those who have lost someone through

suicide. The common experience of loss by suicide bonds people and encourages them to communicate their feelings (*172*).

Policy responses

In 1996, the United Nations Department for Policy Coordination and Sustainable Development brought out a document highlighting the importance of a guiding policy on suicide prevention (*173*). The World Health Organization subsequently issued a series of documents on the prevention of suicide (*171, 172, 174–177)*, and two publications on mental, neurological and psychosocial disorders (*41, 178*). Other reports and guidelines on suicide prevention have also been developed (*179*).

In 1999, the World Health Organization launched a global initiative for the prevention of suicide, with the following objectives:

- To bring about a lasting reduction in the frequency of suicidal behaviours, with emphasis on developing countries and countries in social and economic transition.
- To identify, assess and eliminate at an early stage, as far as possible, factors that may result in young people taking their own lives.
- To raise the general awareness about suicide and provide psychosocial support to people with suicidal thoughts or experiences of attempted suicide, as well as to the friends and relatives of those who have attempted or completed suicide.

The main strategy for the implementation of this global initiative has two strands, along the lines of the World Health Organization's primary health care strategy:

- The organization of global, regional and national multisectoral activities to increase awareness about suicidal behaviours and how to effectively prevent them.
- The strengthening of countries' capabilities to develop and evaluate national policies and plans for suicide prevention, which may include:
  - — support and treatment of populations at risk, such as people with depression, the elderly and young people;
  - — reduction of the availability of and access to means of suicide, for example, toxic substances;
  - — support for and strengthening of networks for survivors of suicide;
  - — training of primary health care workers and workers in other relevant sectors.

The initiative has now been complemented by a study which seeks to identify specific risk factors and specific interventions that are effective in reducing suicidal behaviours.

Recommendations

Several important recommendations for reducing both fatal and non-fatal suicidal behaviour can be drawn from this chapter.

Better data

There is an urgent need for more information on the causes of suicide, nationally and internationally, particularly among minority groups. Cross-cultural studies should be encouraged. They can lead to a better understanding of the causative and protective factors, and consequently can help improve prevention efforts. The following are some specific recommendations for better information on suicide:

- Governments should be encouraged to collect data on both fatal and non-fatal suicidal behaviour and to make such data available to the World Health Organization. Hospitals and other social and medical services should be strongly encouraged to keep records of non-fatal suicidal behaviour.
- Data on suicide and attempted suicide should be valid and up to date. There should be a set of uniform criteria and definitions and – once established – these should be consistently applied and continually reviewed.
- Data collection should be organized so as to avoid duplication of statistical records; at the same time, information should be easily accessible for researchers conducting analytical and epidemiological surveys.
- Efforts should be made to improve data linkage across a variety of agencies, including hospi-

tals, psychiatric and other medical institutions, and coroners' and police departments.

- All health professionals and officials in relevant agencies should be trained to detect and refer people at risk of suicidal behaviour, and to code such cases appropriately in data collection systems.
- There is a need to collect information on social indicators – such as quality-of-life indicators, divorce rates, and social and demographic changes – in tandem with data on suicidal behaviour, in order to improve the current understanding of the problem.

Further research

More research should be conducted to examine the relative contribution of psychosocial and biological factors in suicidal behaviour. A greater coupling of the two types of factor in research programmes would allow for major advances in the current knowledge on suicide. One particularly promising area is the rapidly expanding research in molecular genetics, where among other things there is now greater knowledge relating to the control of serotonin metabolism.

More clinical research should be carried out on the causative role of co-morbid conditions, for example the interaction between depression and alcohol abuse. There should also be a greater focus on subgroups of the population based on age (since suicide among the elderly has different features from that in young people), personality and temperament. Brain imaging is another area that calls for more research effort. Finally, there should be more research on the role of hostility, aggression and impulsivity in suicidal behaviour.

Better psychiatric treatment

The considerable contribution that psychiatric factors make towards suicidal behaviour suggests that improving treatment for those with psychiatric disturbances is important in preventing suicide. In this respect, the following steps should be taken:

- Pharmaceutical companies should be urged to develop more medications that are effective for psychiatric disorders. The advent of selective serotonin reuptake inhibitors, for instance, may have brought about a decline in suicide rates in Scandinavia (*180*).
- Research funding should be directed towards devising more effective techniques of psychotherapy and counselling for suicidal individuals. In particular, there should be more specific techniques for those people whose personality disorders are closely associated with suicidal behaviour.
- Many more people need to be made aware of the signs and symptoms of suicidal behaviour and of where help, if needed, can be obtained – whether from family and friends, doctors, social workers, religious leaders, employers or teachers and other school staff. Doctors and other health care providers, in particular, should be educated and trained to recognize, refer and treat those with psychiatric disorders, especially affective disorders.
- An urgent priority for governments and their health care planning departments is the early identification and treatment of individuals suffering not only from mental disorders but also from drug and alcohol abuse and dependence. The programme set up in Gotland, Sweden, by Rutz (*181*) may provide a useful model for other countries to follow.

Environmental changes

A range of environmental changes are suggested for restricting access to methods of suicide, including:

- Fencing in high bridges.
- Limiting access to the roofs and high exteriors of tall buildings.
- Obliging car manufacturers to change the shape of exhaust pipes of vehicles and to introduce a mechanism by which the engine automatically turns off after running idle for a specified time.
- Restricting access by people other than farmers to pesticides and fertilizers.
- Where potentially lethal medications are concerned:
  - requiring strict monitoring of prescriptions by doctors and pharmacists;

  - — reducing the maximum size of prescriptions;
  - — packaging medications in plastic blisters;
  - — where possible, prescribing medication in the form of suppositories.
- Reducing access to guns among groups at risk for suicide.

Strengthening community-based efforts

Local communities are important settings for existing suicide prevention activities, though much more can be done to strengthen community-based efforts. In particular, attention should be given to:

- Developing and evaluating community-based programmes.
- Improving the quality of services for existing programmes.
- Greater government funding and more professional support by governments for activities such as:
  - — suicide prevention centres;
  - — support groups for people who have experienced the suicide of someone very close to them (such as a child, an intimate partner or a parent) and who may thus themselves be at a heightened risk for suicide;
  - — reducing social isolation, by promoting community-based programmes such as youth centres and centres for older people.
- Establishing partnerships and improving collaboration between the relevant agencies.
- Devising educational programmes to prevent suicidal behaviour, not only for schools, as is mainly the case at present, but also for workplaces and other settings in communities.

Conclusion

Suicide is one of the leading causes of death worldwide and is an important public health problem. Suicide and attempted suicide are complex phenomena that arise, in very individualistic ways, from the interplay of biological, psychological, psychiatric and social factors. The complexity of causes necessarily requires a multifaceted approach to prevention that takes into account cultural context. Cultural factors play a major role in suicidal behaviour (*182*), producing large differences in the characteristics of this problem around the world (*183*). Given these differences, what has a positive effect in preventing suicide in one place may be ineffective or even counterproductive in another cultural setting.

Major investment is needed, both for research and for preventive efforts. While short-term efforts contribute to an understanding of why suicide occurs and what can be done to prevent it, longitudinal research studies are necessary to fully understand the role of biological, psychosocial and environmental factors in suicide. There is also a great need for rigorous and long-term evaluations of interventions. To date, most projects have been of short duration with little, if any, evaluation.

Finally, suicide prevention efforts will be ineffective if they are not set within the framework of large-scale plans developed by multidisciplinary teams, comprising government officials, health care planners and health care workers, and researchers and practitioners from a variety of disciplines and sectors. Major investments in planning, resources and collaboration between these groups will go a long way towards reducing this important public health problem.

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CHAPTER 8

Collective violence

Background

Collective violence, in its multiple forms, receives a high degree of public attention. Violent conflicts between nations and groups, state and group terrorism, rape as a weapon of war, the movements of large numbers of people displaced from their homes, gang warfare and mass hooliganism – all of these occur on a daily basis in many parts of the world. The effects of these different types of event on health in terms of deaths, physical illnesses, disabilities and mental anguish, are vast.

Medicine has long been involved with the effects of collective violence, both as a science and in practice – from military surgery to the efforts of the International Committee of the Red Cross. Public health, though, began dealing with the phenomenon only in the 1970s, following the humanitarian crisis in Biafra, Nigeria. The lessons learnt there, largely by nongovernmental organizations, were the basis for what has become a growing body of knowledge and medical interventions in the field of preventive health care.

The world is still learning how best to respond to the various forms of collective violence, but it is now clear that public health has an important part to play. As the World Health Assembly declared in 1981 (*1*), the role of health workers in promoting and preserving peace is a significant factor for achieving health for all.

This chapter focuses mainly on violent conflicts, with particular emphasis on complex emergencies related to conflicts. While crises of this type are often widely reported, many of their aspects, including the non-fatal impact on victims and the causes of and responses to the crises, frequently remain hidden, sometimes deliberately so. Forms of collective violence that do not have political objectives, such as gang violence, mass hooliganism and criminal violence associated with banditry, are not covered in this chapter.

How is collective violence defined?

Collective violence may be defined as:

> the instrumental use of violence by people who identify themselves as members of a group – whether this group is transitory or has a more permanent identity – against another group or set of individuals, in order to achieve political, economic or social objectives.

Forms of collective violence

Various forms of collective violence have been recognized, including:

- Wars, terrorism and other violent political conflicts that occur within or between states.
- State-perpetrated violence such as genocide, repression, disappearances, torture and other abuses of human rights.
- Organized violent crime such as banditry and gang warfare.

Complex emergencies

As defined by the Inter-Agency Standing Committee (*2*) – the United Nations primary mechanism for coordination of humanitarian assistance in response to complex and major emergencies – a complex emergency is:

> ''a humanitarian crisis in a country, region or society where there is total or considerable breakdown of authority resulting from internal or external conflict and which requires an international response that goes beyond the mandate or capacity of any single agency and/or the ongoing United Nations country programme.''

Although occasionally used to describe other forms of natural or man-made disasters that have a significant impact, the term is used here to describe those emergencies strongly associated with violent conflict, often with major political implications.

Leaning (*3*) identifies four characteristic outcomes of complex emergencies, all of which have profound consequences for public health:

— dislocation of populations;
— the destruction of social networks and ecosystems;
— insecurity affecting civilians and others not engaged in fighting;
— abuses of human rights.

Some analysts (*4*) use the term ''complex political emergencies'' to highlight the political nature of particular crises. Complex political emergencies typically:

— occur across national boundaries;
— have roots relating to competition for power and resources;
— are protracted in duration;
— take place within and reflect existing social, political, economic and cultural structures and divisions;
— are often characterized by ''predatory'' social domination.

Armed conflict

Although ''war'' is a term that is widely used to describe conflict – and commonly understood in its historical sense as violence between states – its legal definition is controversial. Controversy revolves around such questions as quantification (for example, how many deaths the fighting must cause in order to qualify as a war and during what period of time), whether or not hostilities have been openly declared, and its geographical boundaries (for example, whether the war is necessarily between states or internal to one state). To avoid these controversies and, in particular, to prevent loopholes in the applicability of humanitarian law, many international instruments (such as the 1949 Geneva Conventions) use the term ''armed conflict''.

The great variety of armed conflicts and the combatants involved has, however, forced observers to search for new terms to describe them. Examples include ''new wars'' to describe conflicts where the boundaries between traditional concepts of war, organized crime and large-scale violations of human rights have been blurred (*5*), and ''asymmetric warfare''. The latter term, which is closely associated with the phenomenon of modern terrorism (*6*), is used to describe a form of conflict in which an organized group – lacking conventional military strength and economic power – seeks to attack the weak points inherent in relatively affluent and open societies. The attacks take place with unconventional weapons and tactics, and with no regard to military or political codes of conduct.

Genocide

Genocide is a particularly heinous form of collective violence, especially since perpetrators of genocide intentionally target a population group with the aim of destroying it. Genocide thus has, by definition, a collective dimension.

The concept of genocide, however, is a recent one. Although it has been applied by historians and others retrospectively to events that occurred before 1939 (and it is applied in the historical sense in examples cited later in this chapter), the term was only given a legal definition after the Second World War. The horrors of the Nazi holocaust prompted international debate that led to the codification of the term in 1948 in the Convention on the Prevention and Punishment of the Crime of Genocide. This Convention came into force on 12 January 1951. Article 2 of the Convention defines genocide as ''any of the following acts committed with intent to destroy, in whole or in part, a national, ethnical, racial or religious group, as such:

— killing members of the group;
— causing serious bodily or mental harm to members of the group;
— deliberately inflicting on the group conditions of life calculated to bring about its physical destruction in whole or in part;
— imposing measures intended to prevent births within the group;
— forcibly transferring children of the group to another group''.

The crime of genocide is punishable under the Convention along with complicity in genocide, and conspiracy, direct and public incitement, and the attempt to commit genocide.

Following the 1994 conflict in Rwanda, the United Nations Security Council expressed in various resolutions its grave concerns about reports of genocide, and decided to establish an ad hoc International Criminal Tribunal for Rwanda. The Tribunal has already imposed, and confirmed on appeal, several convictions for genocide. The Trial Chamber of the International Criminal Tribunal for the former Yugoslavia, in August 2001, issued its first conviction on genocide in the context of the conflict in Bosnia and Herzegovina, with regard to the massacre of Bosnian Muslims which took place at Srebrenica in July 1995.

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Data on collective violence

Sources of data

A range of research institutes collect and analyse data on the victims of international conflicts and conflicts within a single country. They include the Stockholm International Peace Research Institute (SIPRI), which has developed a detailed, standardized format for its annual reports on the impact of conflicts, and the Correlates of War project at the University of Michigan in the United States, a widely cited source on the magnitude and causes of conflicts from the 19th century to the present day.

Data specifically on torture and human rights abuses are gathered by a wide range of national human rights agencies, as well as a growing number of international nongovernmental organizations, including African Rights, Amnesty International and Human Rights Watch. In the Netherlands, the Interdisciplinary Research Programme on Root Causes of Human Rights Violations monitors deaths and other outcomes of abuses worldwide.

Problems with data collection

Most poor countries lack reliable health registration systems, making it particularly difficult to determine the proportions of deaths, disease and disability that are related to conflicts. In addition, complex emergencies invariably disrupt what surveillance and information systems there are (*7*). Some innovative techniques, though, have been developed to overcome these difficulties. In Guatemala, three separate sets of data along with data from witnesses and victims were combined to arrive at an estimate of the total deaths from the civil war. This method suggested that around 132 000 people had lost their lives. The officially recorded figure was far less, having missed some 100 000 deaths (*8*).

Casualties among armed forces are usually recorded according to prescribed military procedures and are likely to be fairly accurate. Figures relating to genocides are clearly subject to greater manipulation and are thus more difficult to confirm. Estimates for mass killings of civilians may vary by as much as a factor of 10. In the Rwandan genocide of 1994, estimated deaths varied from 500 000 to 1 000 000. In East Timor, tens of thousands of people were reported missing immediately after the conflict in 1999, and several months later it was still unclear whether or not the original estimates had been correct. Little was known for certain about the number of casualties in the conflict in the Democratic Republic of the Congo between 1998 and 2001, though recent estimates have suggested that over 2.5 million people are likely to have lost their lives (*9*).

There are many difficulties in collecting data. These include problems of assessing health and mortality among rapidly changing populations, lack of access to services from which data can be collected, and a range of biases. Parties to a conflict often try to manipulate data on casualties and resources. There are therefore likely to be biases in information and in the way in which casualties are measured. For this reason, civil society organizations have an important role to play in documenting instances of collective violence. Data on human rights abuses are also often difficult to verify as the perpetrators do their best – through abductions, disappearances and political assassinations – to hide evidence of such abuses. Several organizations, including Amnesty International, Human Rights Watch and Physicians for Human Rights, have developed comprehensive techniques to gather, assess and verify data on human rights abuses.

The extent of the problem

The World Health Organization estimates that about 310 000 people died from war-related injuries in 2000 (see Statistical annex). These deaths are categorized according to the International Classification of Disease (ICD) codes for injuries resulting from operations of war (ICD-9[1] E990–E999 or ICD-10[2] Y36). Rates of war-related deaths varied from less than 1 per 100 000 population in high-income countries to 6.2 per 100 000 in low-income and middle-income countries. Worldwide, the highest rates of war-related deaths were found in the WHO African Region (32.0 per 100 000), followed by low-income and

[1] *International classification of diseases*, ninth revision (*10*).
[2] *International statistical classification of diseases and related health problems*, tenth revision (*11*).

middle-income countries in the WHO Eastern Mediterranean Region (8.2 per 100 000) and WHO European Region (7.6 per 100 000), respectively.

Casualties of conflicts

Between the 16th and 20th centuries, the estimated totals of conflict-related deaths per century were, respectively, 1.6 million, 6.1 million, 7.0 million, 19.4 million and 109.7 million (*12, 13*). Such figures naturally conceal the circumstances in which people died. Six million people, for instance, are estimated to have lost their lives in the capture and transport of slaves over four centuries, and 10 million indigenous people in the Americas died at the hands of European colonists.

According to one estimate (*14*), some 191 million people lost their lives directly or indirectly in the 25 largest instances of collective violence in the 20th century, 60% of those deaths occurring among people not engaged in fighting. Besides the First World War and the Second World War, two of the most catastrophic events in terms of lives lost were the period of Stalinist terror and the millions of people who perished in China during the Great Leap Forward (1958–1960). Both events are still surrounded by uncertainty over the scale of human losses. Conflict-related deaths in the 25 largest events included some 39 million soldiers and 33 million civilians. Famine related to conflict or genocide in the 20th century killed a further 40 million people.

A relatively new development in armed conflicts is the increasing number of violent deaths of civilian United Nations employees and workers from nongovernmental organizations in conflict zones. In the period 1985–1998, over 380 deaths occurred among humanitarian workers (*15*), with more United Nations civilian personnel than United Nations peacekeeping troops being killed.

Torture and rape

Torture is a common practice in many conflicts (see Box 8.1). Because victims are inclined to hide the trauma they have suffered and because there are also political pressures to conceal the use of torture, it is difficult to estimate how widespread it is.

Rape as a weapon of war has also been documented in numerous conflicts. Though women form the overwhelming majority of those targeted, male rape also occurs in conflicts. Estimates of the number of women raped in Bosnia and Herzegovina during the conflict between 1992 and 1995 range from 10 000 to 60 000 (*22*). Reports of rape during violent conflicts in recent decades have also been documented from Bangladesh, Liberia, Rwanda and Uganda, amongst others (see Chapter 6). Rape is often used to terrorize and undermine communities, to force people to flee, and to break up community structures. The physical and psychological effects on the victims are far-reaching (*23, 24*).

The nature of conflicts

Since the Second World War, there have been a total of 190 armed conflicts, only a quarter of which were between states. In fact, modern-day conflicts are increasingly within rather than between states. Most of the armed conflicts since the Second World War have been shorter than 6 months in duration. Those that lasted longer often went on for many years. For example, in Viet Nam, violent conflict spanned more than two decades. Other examples include the conflicts in Afghanistan and Angola. The total number of armed conflicts in progress was less than 20 in the 1950s, over 30 in both the 1960s and 1970s, and rose to over 50 during the late 1980s. While there were fewer armed conflicts in progress after 1992, those that took place were, on average, of longer duration.

While conflicts within states are most common, conflicts between states still occur. The war between Iraq and the Islamic Republic of Iran in 1980–1988 is estimated to have left 450 000 soldiers and 50 000 civilians dead (*13*). The conflict between Eritrea and Ethiopia at the end of the 20th century was largely fought between two conventional armies, using heavy weaponry and trench warfare, and claimed tens of thousands of lives. There have also been coalitions of multinational forces engaged in conflict by means of massive air attacks – as in the Gulf War against Iraq in 1991 and in the North Atlantic Treaty Organization (NATO) campaign against the Federal Republic of Yugoslavia in 1999.

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BOX 8.1

Torture

A number of international treaties have defined torture. The United Nations Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment of 1984 refers to an ''act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person'', for a purpose such as obtaining information or a confession, punishment, intimidation or coercion, ''or for any reason based on discrimination of any kind''. The Convention is concerned with torture by public officials or others acting in an official capacity.

In preparing its 2000 report on torture (*16*), the human rights organization Amnesty International found reports of torture or ill-treatment by officials in more than 150 countries. In more than 70 countries, the practice was apparently widespread and in over 80 countries, people reportedly died as a result of torture. Most of the victims appeared to have been people suspected or convicted of criminal offences, and most of the torturers were police officers.

The prevalence of torture against criminal suspects is most likely to be underreported, as the victims are generally less able to file complaints. In some countries, a long-standing practice of torturing common criminals attracts attention only when more overt political repression has declined. In the absence of proper training and investigative mechanisms, police may resort to torture or ill-treatment to extract confessions quickly and obtain convictions.

In some instances of torture, the purpose is to extract information, to obtain a confession (whether true or false), to force collaboration or to ''break'' the victim as an example to others. In other cases, punishment and humiliation are the primary aim. Torture is also sometimes employed as a means of extortion. Once established, a regime of torture can perpetuate itself.

Torture has serious implications for public health, as it damages the mental and physical health of populations. The victims may stay in their own country, adapting as best they can, with or without medical and psychosocial support. If their needs are not properly attended to they risk becoming increasingly alienated or dysfunctional members of society. The same is true if they go into exile. Existing data on asylum-seekers, some of whom have undergone torture in their home country, suggest that they have significant health needs (*17, 18*).

Failure to control the use of torture encourages poor practice by the police and security forces and an increased tolerance of human rights abuses and violence. Various organizations of health professionals have taken a vigorous stand against torture, seeing its prevention as closely linked to their medical calling and to the good of public health (*19*). Nongovernmental organizations have also promoted prevention (*20*).

One particular control mechanism — the inspection system of the Council of Europe — has been recommended for use at the global level. A draft ''Optional Protocol'' to the United Nations Convention on Torture would provide for a similar such inspection system in places of detention. To date, progress in elaborating an Optional Protocol has been slow.

Initiatives to investigate and document torture have grown in recent years. The United Nations guidelines on assessing and recording medical evidence of torture, known as the ''Istanbul Protocol'', were drawn up in 1999 by forensic scientists, doctors, human rights monitors and lawyers from 15 countries and published 2 years later (*21*).

Many of the conflicts since the end of the Second World War have been in developing countries. After the collapse of communist regimes in Eastern Europe and the former Soviet Union in the late 1980s and early 1990s, there was a sharp increase, for a while, in armed conflicts taking place in Europe.

The size of the area of conflict has changed radically in the past two centuries. Until the early

19th century, warfare between states took place on a ''field of battle''. The mobilization of citizen-soldiers during the Napoleonic wars created larger, but essentially similar battlefields. With the development in the 19th century of railways and the mechanization of mass transport, mobile warfare with rapidly moving positions in large geographical areas became possible. Subsequently, the development of tanks, submarines, fighter/bombers and laser-guided missiles laid the foundations for battlefields without geographical limits. Recent conflicts, such as the one waged in 1999 by NATO against the Federal Republic of Yugoslavia, have been referred to as ''virtual wars'' (*25*), given the extent to which these conflicts are fought with missiles controlled from a distance, without the involvement of troops on the ground.

What are the risk factors for collective violence?

Good public health practice requires identifying risk factors and determinants of collective violence, and developing approaches to resolve conflicts without resorting to violence. A range of risk factors for major political conflicts has been identified. In particular, the Carnegie Commission on Preventing Deadly Conflict (*26*) has listed indicators of states at risk of collapse and internal conflict (see Table 8.1). In combination, these factors interact with one another to create conditions for violent conflict. On their own, none of them may be sufficient to lead to violence or disintegration of a state.

The risk factors for violent conflicts include:

- Political factors:
  - — a lack of democratic processes;
  - — unequal access to power.
- Economic factors:
  - — grossly unequal distribution of resources;
  - — unequal access to resources;
  - — control over key natural resources;
  - — control over drug production or trading.
- Societal and community factors:
  - — inequality between groups;
  - — the fuelling of group fanaticism along ethnic, national or religious lines;
  - — the ready availability of small arms and other weapons.
- Demographic factors:
  - — rapid demographic change.

Many of these risk factors can be identified before overt collective violence takes place.

Political and economic factors

The grossly unequal distribution of resources, particularly health and education services, and of access to these resources and to political power –

TABLE 8.1

Indicators of states at risk of collapse and internal conflict

Indicator	Signs
Inequality	• Widening social and economic inequalities – especially those between, rather than within, distinct population groups
Rapidly changing demographic characteristics	• High rates of infant mortality • Rapid changes in population structure, including large-scale movements of refugees • Excessively high population densities • High levels of unemployment, particularly among large numbers of young people • An insufficient supply of food or access to safe water • Disputes over territory or environmental resources that are claimed by distinct ethnic groups
Lack of democratic processes	• Violations of human rights • Criminal behaviour by the state • Corrupt governments
Political instability	• Rapid changes in regimes
Ethnic composition of the ruling group sharply different from that of the population at large	• Political and economic power exercised – and differentially applied – according to ethnic or religious identity • Desecration of ethnic or religious symbols
Deterioration in public services	• A significant decline in the scope and effectiveness of social safety nets designed to ensure minimum universal standards of service
Severe economic decline	• Uneven economic development • Grossly unequal gains or losses between different population groups or geographical areas resulting from large economic changes • Massive economic transfers or losses over short periods of time
Cycles of violent revenge	• A continued cycle of violence between rival groups

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whether by geographical area, social class, religion, race or ethnicity – are important factors that can contribute to conflict between groups. Undemocratic leadership, especially if it is repressive and if power stems from ethnic or religious identity, is a powerful contributor to conflict. A decline in public services, usually affecting the poorest segments of society most severely, may be an early sign of a deteriorating situation.

Conflict is less likely in situations of economic growth than in contracting economies, where competition over resources is intensified.

Globalization

Trends in the global economy have accelerated the pace of global integration and economic growth for some countries, and for some groups within countries, and at the same time have contributed to the fragmentation and economic marginalization of others. Other possible risk factors for conflict that may be linked to globalization are financial (the frequently large and rapid movements of currencies around the world) and cultural (individual and collective aspirations raised by the global media that cannot realistically be met). It is still unknown whether current trends in globalization are likely to lead to more conflict and greater violence within or between states. Figure 8.1 shows potential links between trends in globalization and the occurrence of conflict (*27*).

Natural resources

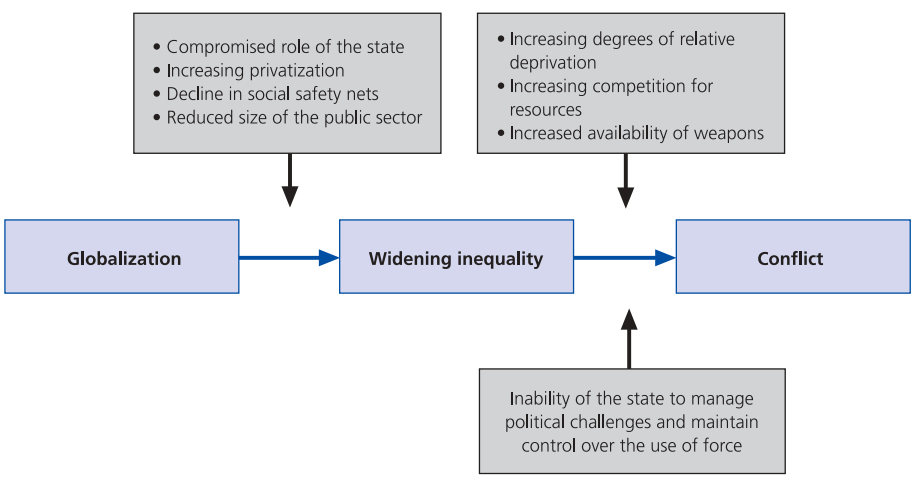
Struggles over access to key natural resources frequently play a role in fuelling and prolonging conflicts. Examples from conflicts in the past two decades are those related to diamonds in Angola, the Democratic Republic of the Congo and Sierra Leone; to oil in Angola and southern Sudan; and to timber and gems in Cambodia. In other places, including Afghanistan, Colombia and Myanmar, the desire to control the production and distribution of drugs has contributed to violent conflicts.

Societal and community factors

A particularly important risk factor associated with the occurrence of conflict is the existence of intergroup inequalities, especially if these are widening (*28*) and are seen to reflect the unequal allocation of resources within a society. Such a factor is often seen in countries where the government is dominated by one community, that wields political, military and economic power over quite distinct communities.

The ready availability of small arms or other weapons in the general population can also heighten the risk of conflict. This is particularly

FIGURE 8.1
Possible linkages between globalization, inequalities and conflict



problematic in places where there have previously been conflicts, and where programmes of demobilization, decommissioning of weapons and job creation for former soldiers are inadequate or where such measures have not been established.

Demographic factors

Rapid demographic change – including an increased population density and a greater proportion of young people – combined with the inability of a country to match the population increase with correspondingly more jobs and schools, may contribute to violent conflict, particularly where other risk factors are also present. In these conditions, large population movements may occur as desperate people seek a more sustainable life elsewhere, and this in turn may increase the risk of violence in the areas into which people move.

Technological factors

The level of weapons technology does not necessarily affect the risk of a conflict, but it does determine the scale of any conflict and the amount of destruction that will take place. Many centuries ago, the progression from the arrow to the crossbow increased the range and destructive force of projectile weapons. Much later, simple firearms were developed, followed by rifles, machine guns and submachine guns. The ability to fire more bullets, more quickly, and with greater range and accuracy, has greatly increased the potential destructive power of such weapons.

Nonetheless, even basic weapons, such as the machete, can contribute to the occurrence of massive human destruction, as was seen in the genocide in Rwanda in 1994 (*29*). In the acts of terrorism in the United States on 11 September 2001, where hijacked passenger aircraft were deliberately crashed into the World Trade Center Towers and the Pentagon, killing several thousand people, conventional weapons were not a major feature of the incidents.

The consequences of collective violence

Impact on health

The impact of conflict on health can be very great in terms of mortality, morbidity and disability (see Table 8.2).

Infant mortality

In times of conflict, infant mortality generally increases. Preventable diseases such as measles, tetanus and diphtheria may become epidemic. In

TABLE 8.2
Examples of the direct impact of conflict on health

Health impact	Causes
Increased mortality	• Deaths due to external causes, mainly related to weapons • Deaths due to infectious diseases (such as measles, poliomyelitis, tetanus and malaria) • Deaths due to noncommunicable diseases, as well as deaths otherwise avoidable through medical care (including asthma, diabetes and emergency surgery)
Increased morbidity	• Injuries from external causes, such as those from weapons, mutilation, anti-personnel landmines, burns and poisoning • Morbidity associated with other external causes, including sexual violence • Infectious diseases: — water-related (such as cholera, typhoid and dysentery due to *Shigella* spp.) — vector-borne (such as malaria and onchocerciasis) — other communicable diseases (such as tuberculosis, acute respiratory infections, HIV infection and other sexually transmitted diseases) • Reproductive health: — a greater number of stillbirths and premature births, more cases of low birth weight and more delivery complications — longer-term genetic impact of exposure to chemicals and radiation • Nutrition: — acute and chronic malnutrition and a variety of deficiency disorders • Mental health: — anxiety — depression — post-traumatic stress disorder — suicidal behaviour
Increased disability	• Physical • Psychological • Social

the mid-1980s, infant mortality in Uganda rose above 600 per 1000 in some conflict-affected areas (*30*). According to the United Nations Children's Fund, reductions in infant mortality were reported for all countries in southern Africa over the period 1960–1986, with the exception of Angola and Mozambique, both of which were subject to ongoing conflicts (*31*). Efforts to eradicate infectious diseases such as poliomyelitis are hampered by residues of the disease in conflict-affected areas.

In Zepa, Bosnia and Herzegovina – a United Nations-controlled ''safe area'' subsequently overrun by Bosnian Serb forces – perinatal and childhood mortality rates doubled after only one year of conflict. In Sarajevo, deliveries of premature babies had doubled and average birth weights fallen by 20% by 1993.

Communicable diseases

The increased risk during conflicts of communicable diseases stems generally from:

- the decline in immunization coverage;
- population movements and overcrowding in refugee camps;
- greater exposure to vectors and environmental hazards, such as polluted water;
- the reduction in public health campaigns and outreach activities;
- the lack of access to health care services.

During the fighting in Bosnia and Herzegovina in 1994, fewer than 35% of children were immunized, compared with 95% before hostilities broke out (*32, 33*). In Iraq, there were sharp declines in immunization coverage after the Gulf War of 1991 and the subsequent imposition of economic and political sanctions. However, recent evidence from El Salvador indicates that it is possible, with selective health care interventions and the provision of adequate resources, to improve certain health problems during ongoing conflicts (*34*).

In Nicaragua in 1985–1986, a measles epidemic was attributed in large part to the declining ability of the health service to immunize those at risk in conflict-affected areas (*35*). A deterioration in malaria-control activities was linked to epidemics of malaria in Ethiopia (*36*) and Mozambique (*37*), highlighting the vulnerability of disease control programmes during periods of conflict. The outbreak of Ebola haemorrhagic fever in Gulu, Uganda, in 2000, was widely believed to be connected with the return of troops from fighting in the Democratic Republic of the Congo.

In Ethiopia in the late 1980s, epidemics of typhus fever and relapsing fever – infectious diseases transmitted by infected ticks, lice or fleas – were believed to come from crowded army camps, prisons and relief camps, as well as from the sale of infected blankets and clothes to local communities by retreating soldiers (*36*). In the exodus from Rwanda in 1994, epidemics of water-related diseases, such as cholera and dysentery due to *Shigella* spp., led to the death within a month of 6–10% of the refugee population arriving in Zaire (now the Democratic Republic of the Congo) (*38*). The crude death rate of 20–35 per 10 000 population per day was 2–3 times higher than that previously reported in refugee populations.

During and in the wake of violent conflicts, there is often a greatly increased risk of transmission of HIV infection and other sexually transmitted diseases (*39*). In many armed forces, the prevalence of HIV infection has already reached high levels (*40*). In times of conflict, military forces (including sometimes also peacekeeping forces) assume the power to command sexual services from local people, either by force or payment (*41*). The transmission of HIV and other sexually transmitted diseases is further fuelled by the fact that troops have a high degree of mobility, and ultimately return to different regions after demobilization (*36, 42, 43*). Overall, refugees from conflicts and internally displaced people have an increased risk of HIV infection (*44*) because:

- They are generally more vulnerable to sexual abuse and violence.
- They are more likely to turn to prostitution – having been deprived of their normal sources of income for surviving.
- Displaced children, with little else to occupy them and possibly no one to supervise them, may become sexually active earlier than they would otherwise.

- Blood used in emergencies for transfusions may not have been screened for HIV.

Disability

Data on conflict-related disability are scant. A nationwide survey conducted in 1982 in Zimbabwe found that 13% of all physical disabilities were a direct result of the previous armed conflict. Over 30 years of armed conflict in Ethiopia led to some 1 million deaths, around half of which were among civilians (*36*). About one-third of the 300 000 soldiers returning from the front line after the end of the conflict had been injured or disabled and at least 40 000 people had lost one or more limbs in the conflict.

Landmines are a major contributor to disability. In Cambodia, 36 000 people have lost at least one limb after accidentally detonating a landmine – one in every 236 of the population (*45*). A total of 6000 people were disabled in this way in 1990 alone. Over 30 million mines were laid in Afghanistan in the 1980s.

In some conflicts, mutilation in the form of cutting off ears or lips, as practised in Mozambique during the civil war (*46*), or limbs, as more recently in Sierra Leone (*47*), has been systematically practised in order to demoralize the opposing forces.

Mental health

The impact of conflicts on mental health is influenced by a range of factors. These include (*48*):

— the psychological health of those affected, prior to the event;
— the nature of the conflict;
— the form of trauma (whether it results from living through and witnessing acts of violence or whether it is directly inflicted, as with torture and other types of repressive violence);
— the response to the trauma, by individuals and communities;
— the cultural context in which the violence occurs.

Psychological stresses related to conflicts are associated with or result from (*49*):

— displacement, whether forced or voluntary;
— loss and grief;
— social isolation;
— loss of status;
— loss of community;
— in some settings, acculturation to new environments.

Manifestations of such stress can include:

— depression and anxiety;
— psychosomatic ailments;
— suicidal behaviour;
— intra-familial conflict;
— alcohol abuse;
— antisocial behaviour.

Single and isolated refugees, as well as women who are heads of households, may be at particular risk of suffering psychological stress.

Some experts (*48, 50*) have cautioned against assuming that people do not have the ability and resilience to respond to the adverse conditions stemming from violent conflict. Others have warned of the danger (*51*) that humanitarian assistance programmes may become a substitute for political dialogue with parties to the conflict – possibly those who are its main driving force. Studies in South Africa (*52*) have found that not all those who were subject to trauma under apartheid became ''victims''. Instead, at least in some cases, individuals were able to respond strongly because they saw themselves as fighting for worthwhile and legitimate causes. The medical model which ascribes to individuals the condition of ''post-traumatic stress syndrome'' may fail to take account of the variety and complexity of human responses to stressful events (*48*). It is now becoming clearer that recovery from psychological trauma resulting from violent conflict is associated with the reconstruction of social and economic networks and cultural institutions (*50*).

Increased rates of depression, substance abuse and suicide frequently result from violent conflicts (*34*). Before its two decades of violent conflict, Sri Lanka had a much lower suicide rate overall than it does now (*53*). Similar findings have been reported from El Salvador (*34*). In both these cases, the sharp increase in suicides was at least in part a consequence of political violence.

From a mental health point of view, populations affected by violent conflict can be divided into three groups (*54*):

— those with disabling psychiatric illnesses;
— those with severe psychological reactions to trauma;
— those, forming the majority, who are able to adapt once peace and order are restored.

The first two groups are likely to benefit considerably from the provision of mental health care that takes into account cultural and socio-economic factors.

Impact on specific populations

The direct effect of conflict on the health of armed forces is usually recorded with some degree of precision; however, the effect of conflict on particular groups is often especially difficult to determine. Population size and density can vary greatly over short periods of time as people move to safe areas and to places where more resources are available. This fact complicates measurements of the impact of conflict on health.

Civilians

According to the 1949 Geneva Conventions, armed forces must apply the principles of proportionality and distinction in their choice of targets. *Proportionality* involves trying to minimize civilian casualties when pursuing military and related targets. *Distinction* means avoiding civilian targets wherever possible (*52*). Despite such attempts to regulate their impact, armed conflicts cause many deaths among civilians.

While civilian deaths may be the direct result of military operations, increased mortality rates among civilians in times of conflict are usually a reflection of the combined effects of:

— decreased access to food, leading to poor nutrition;
— increased risk of communicable diseases;
— reduced access to health services;
— reduced public health programmes;
— poor environmental conditions;
— psychosocial distress.

Refugees and internally displaced people

Refugees and internally displaced people typically experience high mortality, especially in the period immediately after their migration (*55, 56*). Reviews of the health of refugees and displaced populations have revealed massively raised mortality rates – at their worst, up to 60 times the expected rates during the acute phase of displacement (*55, 57, 58*). In Monrovia, Liberia, the death rate among civilians displaced during the conflict in 1990 was seven times greater than the pre-conflict rate (*57*).

Deaths from malnutrition, diarrhoea and infectious diseases occur especially in children, while other infectious diseases such as malaria, tuberculosis and HIV, as well as a range of noncommunicable diseases, injuries and violence typically affect adults. The prior health status of the population, their access to key determinants of health (such as food, shelter, water, sanitation and health services), the extent to which they are exposed to new diseases, and the availability of resources all have an important influence on the health of refugees during and after conflicts.

Demographic impact

One consequence of the shift in the methods of modern warfare, where entire communities are increasingly being targeted, has been the large numbers of displaced people. The total numbers of refugees fleeing across national borders rose from around 2.5 million in 1970 and 11 million in 1983 to 23 million in 1997 (*59, 60*). In the early 1990s, in addition, an estimated 30 million people were internally displaced at any one time (*60*), most of them having fled zones of conflict. Those displaced within countries probably have less access to resources and international support than refugees escaping across borders, and are also more likely to be at continuing risk of violence (*61*).

Table 8.3 shows the movements of refugees and internally displaced populations during the 1990s (*62*). In Africa, the Americas and Europe during this period there were far more internally displaced people than refugees, while in Asia and the Middle East the reverse was true.

TABLE 8.3
Internally displaced people and refugees (in millions), by continent and year

	1990	1991	1992	1993	1994	1995	1996	1997	1998
Internally displaced people (IDP)									
Africa	13.5	14.2	17.4	16.9	15.7	10.2	8.5	7.6	8.8
Americas	1.1	1.2	1.3	1.4	1.4	1.3	1.2	1.6	1.8
East Asia and the Pacific	0.3	0.7	0.7	0.6	0.6	0.6	1.1	0.8	0.5
South Asia	3.1	2.7	1.8	0.9	1.8	1.6	2.4	2.2	2.1
Europe	1.0	1.8	1.6	2.8	5.2	5.1	4.7	3.7	3.3
Middle East	1.3	1.4	0.8	2.0	1.7	1.7	1.5	1.5	1.6
Refugees									
Africa	5.4	5.3	5.7	5.8	5.9	5.2	3.6	2.9	2.7
Americas	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.4
East Asia and the Pacific	0.7	0.8	0.5	0.8	0.7	0.6	0.6	0.7	0.7
South Asia	6.3	6.9	4.7	3.9	3.3	2.8	3.2	3.0	2.9
Europe	0	0.1	2.5	1.9	1.8	1.8	1.9	1.3	1.3
Middle East	3.5	2.8	2.8	3.0	3.8	4.0	4.4	4.3	4.4
IDP:refugee ratio									
Africa	2.5	2.7	3.0	2.9	2.7	2.0	2.4	2.6	3.2
Americas	7.5	10.1	13.5	14.0	11.7	18.3	17.4	27.0	4.9
East Asia and the Pacific	0.5	0.8	1.4	0.8	0.9	0.9	1.6	1.1	0.8
South Asia	0.5	0.4	0.4	0.2	0.5	0.6	0.8	0.8	0.7
Europe		14.7	0.6	1.4	2.9	2.8	2.5	2.8	2.5
Middle East	0.4	0.5	0.3	0.7	0.4	0.4	0.3	0.3	0.4

Source: reference *62*.

The forced resettlement of populations, something practised by several governments for stated reasons of security, ideology or development, can also have a severe impact on health. Between 1985 and 1988, some 5.7 million people, 15% of the total rural population, were moved from the northern and eastern provinces to villages in the south-west under an enforced government programme in Ethiopia (*63*). During the regime of Pol Pot in Cambodia (1975–1979), hundreds of thousands of urban people were forcibly displaced to rural areas.

Socioeconomic impact

The economic impact of conflict can be profound (*64, 65*). Public expenditure on sectors including health and education is likely to be sharply reduced, as the state faces difficulty in collecting taxes and bringing in other sources of income – for instance, from tourism – and as it increases military spending. In Ethiopia, military expenditure increased from 11.2% of the government budget in 1973–1974 to 36.5% in 1990–1991, while at the same time the share of the health budget declined sharply, falling from 6.1% to 3.2% (*36*).

Conflicts also significantly affect human resources and productivity. At the household level, the available sources of income are also likely to be greatly curtailed. Further disruption to people's livelihood may be caused by the manipulation of prices or the supply of essential goods, and by other forms of profiteering.

There has been some attempt to measure the opportunity costs of development foregone as a result of conflict. Countries that are in conflict have made systematically less progress in extending life expectancy and reducing infant mortality and crude death rates, when compared with other countries in the same region and of similar socioeconomic status (*66*). Analyses such as these, though, may be confounded by the simultaneous influence of the AIDS pandemic, which can itself be considerably exacerbated by conflict and instability (*42, 43*).

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Food and agriculture

Food production and distribution are often specifically targeted during periods of conflict (*67*). In the conflict in Ethiopia between government forces and Eritrean and Tigrayan separatist forces in the period 1974–1991, farmers were forcibly prevented from planting and harvesting their crops and soldiers looted seeds and livestock. In Tigray and Eritrea, the combatants conscripted farmers, mined the land, confiscated food and slaughtered cattle (*36*). The loss of livestock deprives farmers of an asset needed to put land into production and therefore has an adverse effect both in the immediate and in the long term.

Infrastructure

Important infrastructure may be damaged during periods of conflict. In the case of water and sanitation infrastructure, the damage caused can have a direct and severe effect on health. In the conflicts in southern Sudan and Uganda in the early and mid-1980s, village hand pumps were deliberately destroyed by government troops operating in areas controlled by rebel forces and by guerrillas in areas under government control (*30*). During the military operations against Iraq in 1991, water supplies, sewage disposal and other sanitation services were drastically affected by intense bombing (*68*).

Health care services

The impact of conflict on health care services is wide ranging (see Table 8.4). Before the Gulf War of 1991, health services in Iraq reached 90% of the population and the vast majority of children under the age of 5 years were routinely immunized. During the conflict, many hospitals and clinics were severely damaged and had to close, while those still operating

TABLE 8.4
The impact of conflict on health care services

Object of impact	Manifestation of impact
Access to services	• Reduced security (through factors such as landmines and curfews) • Reduced geographical access (for example, through poor transport) • Reduced economic access (for example, because of increased charges for health services) • Reduced social access (for example, because service providers fear being identified as participants in the conflict)
Service infrastructure	• Destruction of clinics • Disrupted referral systems • Damage to vehicles and equipment • Poor logistics and communication
Human resources	• Injury, disappearance and death of health care workers • Displacement and exile of people • Low morale • Difficulty in retaining health care workers in the public sector, particularly in insecure areas • Disrupted training and supervision
Equipment and supplies	• Lack of drugs • Lack of maintenance • Poor access to new technologies • Inability to maintain cold chain for vaccines
Health care activity	• Shift from primary to tertiary care • Increased urbanization of health care provision • Reduction in peripheral and community-based activities • Contraction in outreach, preventive and health promotion activities • Disrupted surveillance and health information systems • Compromised vector control and public health programmes (including partner notification and case-finding) • Programmes focusing more on a single disease (such as malaria) or a single intervention (such as immunization) • Reliance on a greater range of organizations to provide project-based services
Formulation of health policy	• Weakened national capacity • Inability to control and coordinate nongovernmental organization and donor activities • Less information upon which to base decisions • Less engagement in policy debates locally and internationally • Weakened community structures and reduced participation
Relief activities	• Limited access to certain areas • Increased cost of delivering services • Increased pressure on host communities, systems and services • A greater focus on single problems and programmes with less integration across services • Greater insecurity for relief personnel • Weakened coordination and communication between agencies

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had to serve much larger catchment areas. Widespread damage to water supplies, electricity and sewage disposal further reduced the ability of what remained of the health services to operate (*68*). In the violent conflict in East Timor in 1999 following the referendum for independence, militia forces destroyed virtually all the health care services. Only the main hospital in the principal town, Dili, was left standing.

During and in the wake of conflicts the supply of medicines is usually disrupted, causing increases in medically preventable conditions, including potentially fatal ones, such as asthma, diabetes and a range of infectious diseases. Apart from medicines, medical personnel, diagnostic equipment, electricity and water may all be lacking, seriously affecting the quality of health care available.

Human resources in the health care services are also usually seriously affected by violent conflicts. In some instances, such as in Mozambique and Nicaragua, medical personnel have been specifically targeted. Qualified personnel often retreat to safer urban areas or may leave their profession altogether. In Uganda between 1972 and 1985, half of the doctors and 80% of the pharmacists left the country for their security. In Mozambique, only 15% of the 550 doctors present during the last years of Portuguese colonial rule were still there at the end of the war of independence in 1975(*69*).

What can be done to prevent collective violence?

Reducing the potential for violent conflicts

Among the policies needed to reduce the potential for violent conflicts in the world, of whatever type, are (*70*):

- Reducing poverty, both in absolute and relative terms, and ensuring that development assistance is targeted so as to make the greatest possible impact on poverty.
- Making decision-making more accountable.
- Reducing inequality between groups in society.
- Reducing access to biological, chemical, nuclear and other weapons.

Promoting compliance with international agreements

An important element in preventing violent conflict and other forms of collective violence is ensuring the promotion and application of internationally agreed treaties, including those relating to human rights.

National governments can help prevent conflicts by upholding the spirit of the United Nations Charter, which calls for the prevention of aggression and the promotion of international peace and security. At a more detailed level, this involves adhering to international legal instruments, including the 1949 Geneva Conventions and their 1977 Protocols.

Laws pertaining to human rights, especially those that stem from the International Covenant on Civil and Political Rights, place limits on the way governments exercise their authority over persons under their jurisdiction, and unconditionally prohibit, among other acts, torture and genocide. The establishment of the International Criminal Court will ensure a permanent mechanism for dealing with war crimes and crimes against humanity. It may also provide disincentives against violence directed at civilian populations.

Efforts to produce treaties and agreements covering collective violence, with disincentives against and sanctions for abuse, tend to be more effective concerning violence between states and generally have far less power within national borders, which is the area where conflicts are increasingly occurring.

The potential benefits of globalization

Globalization is producing new ways for raising public awareness and knowledge about violent conflicts, their causes and their consequences. The new technologies that are appearing provide new means not only to exchange ideas but also pressure decision-makers to increase the accountability and transparency of governance and reduce social inequalities and injustices.

An increasing number of international organizations – including Amnesty International, Human Rights Watch, the International Campaign to Ban

Landmines and Physicians for Human Rights – are monitoring conflicts and urging preventive or corrective actions. Individuals and groups affected by conflict can now – through these organizations and in other ways – make use of the new technologies to relate their experiences and concerns to a wide public.

The role of the health sector

Investing in health development also contributes to the prevention of violent conflict. A strong emphasis on social services can help maintain social cohesion and stability.

Early manifestations of situations that can lead to conflicts can often be detected in the health sector. Health care workers have an important role to play in drawing attention to these signs and in calling for appropriate social and health interventions to reduce the risks of conflict (see Box 8.2).

In terms of reducing inequalities between social groups and unequal access to resources – both important risk factors for violence – the health sector is well placed to detect inequalities in health status and access to health care. Identifying these inequalities early on and promoting corrective measures are important preventive actions against potential conflicts, especially so where the gaps between social groups are growing. Monitoring the distribution and trends in diseases associated with poverty, in medically preventable or treatable conditions, and in inequalities in survival, are all essential for detecting largely unrecognized, but important and possibly widening, disparities in society.

The health sector can also perform a major service by publicizing the social and economic impacts of violent conflicts and their effects on health.

Responses to violent conflicts

Service provision during conflicts

Common problems confronting humanitarian operations during periods of conflict include (*71*):

- how best to upgrade health care services for the host population in parallel with providing services for refugees;
- how to provide good-quality services, humanely and efficiently;
- how to involve communities in determining priorities and the way in which services are provided;
- how to create sustainable mechanisms through which experience from the field is used in formulating policy.

Refugees fleeing their country across borders lose their usual sources of health care. They are then dependent on whatever is available in the host country or can be provided in additional services by international agencies and nongovernmental organizations. The services of the host government may be overwhelmed if large numbers of refugees suddenly move into an area and seek to use local health services. This can be a source of antagonism between the refugees and population of the host country, that may spill over into new violence. Such antagonism may be aggravated if refugees are offered services, including health services, more easily or cheaply than are available to the local population, or if the host country does not receive resources from outside to cope with its greatly increased burden. When ethnic Albanians from Kosovo fled into Albania and The former Yugoslav Republic of Macedonia during the conflict in 1999, the World Health Organization and other agencies tried to help the existing health and welfare systems of these host countries to deal with the added load, rather than simply allowing a parallel system to be imported through the aid agencies.

When planning responses during crises, governments and agencies need to:

- assess at a very early stage who is particularly vulnerable and what their needs are;
- strictly coordinate activities between the various players;
- work towards increasing global, national and local capabilities so as to deliver effective health services during the various stages of the emergency.

The World Health Organization has developed surveillance mechanisms to help identify and respond, earlier rather than later, to conflicts. Its Health Intelligence Network for Advanced Contingency Planning provides rapid access to up-to-date information on particular countries and their

BOX 8.2

Health as a bridge for peace

The concept that health can further regional conciliation and collaboration was enshrined in 1902 in the founding principles of the Pan American Health Organization, the oldest international health organization in the world. For the past two decades, the Pan American Health Organization/WHO Regional Office for the Americas has been instrumental in applying this concept.

In 1984, PAHO/WHO, in partnership with national health ministries and other institutions, launched a strategic initiative in war-torn areas of Central America. The aim was to improve the health of the peoples of Central America, while building cooperation between and within countries of the region. Under the overall theme of ''Health as a bridge for peace, solidarity and understanding'', the plan consisted of a range of programmes.

In the first phase, up to 1990, there were seven priorities for collaboration:

— strengthening health services;
— developing human resources;
— essential drugs;
— food and nutrition;
— major tropical diseases;
— child survival;
— water supply and sanitation.

Within a few years, over 250 projects in these priority areas had been developed, stimulating collaboration among nations and groupings in Central America otherwise in dispute with one another. In El Salvador, for example, despite the difficulty of working in the midst of political violence, ''days of tranquillity'' were negotiated and fighting was suspended so that children could be immunized. This arrangement lasted from 1985 until the end of the conflict in 1992, allowing some 300 000 children to be immunized annually. The incidence of measles, tetanus and poliomyelitis dropped dramatically, that of poliomyelitis falling to zero.

Collaboration also took place in malaria control, cross-border distribution of medicines and vaccines, and training. Regional and subregional health information networks were established and a rapid-response system for natural disasters was set up. These efforts created a precedent for wider dialogue within the region, until the eventual peace accords.

During the second phase of the initiative, from 1990 to 1995, health sectors across Central America supported efforts for development and democracy. Following the peace settlements, PAHO/WHO helped in demobilization, rehabilitation and social reintegration of those most affected by the conflict — including indigenous and border populations. Health continued to be a driving factor for democratic consolidation in the third phase between 1995 and 2000.

Between 1991 and 1997, similar programmes were set up in Angola, Bosnia and Herzegovina, Croatia, Haiti and Mozambique. In each programme, representatives from the WHO regional offices worked in partnership with the government, local nongovernmental organizations and other United Nations agencies. All these programmes were instrumental in reconstructing the health sector following the end of the conflicts. In Angola and Mozambique, the World Health Organization participated in the demobilization process, promoted the reintegration into the national system of health services formerly outside the control of the central government, and retrained health workers from these regions. In Bosnia and Herzegovina and in Croatia, the World Health Organization facilitated exchanges between different ethnic groups and enabled regular contacts and collaboration between health professionals from all communities.

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BOX 8.2 (continued)

All the experiences of this period were consolidated by the World Health Organization in 1997 under a global programme, ''Health as a Bridge for Peace''. Since then, new programmes have been set up in the Caucasus Region, Bosnia and Herzegovina, Indonesia, Sri Lanka and The former Yugoslav Republic of Macedonia. In Indonesia, for instance, the World Health Organization has organized teams of health professionals to operate in areas of actual or potential conflict. One such group, comprising both Muslim and Christian professionals, is working in the islands of Maluku province, an area of acute religious conflict in recent years.

Through the ''Health as a Bridge for Peace'' programme, health workers around the world are being organized to contribute to peace, to bring about stability and reconstruction as conflicts end, and to help conciliation in divided and strife-torn communities.

health indices, as well as guidance on best practices and data on disease surveillance.

In emergencies, humanitarian organizations try in the first instance to prevent loss of life and subsequently to re-establish an environment where health promotion is possible. Many relief organizations see their primary role as saving lives that have been placed at risk as a result of atypical events, without necessarily being concerned whether their activities can be replicated or sustained over the longer term. Those agencies that adopt a specifically development-related perspective, on the other hand, attempt early on to take into account issues such as efficiency, sustainability, equality and local ownership – all of which will produce greater benefits in the longer term. This approach stresses creating local capacity and maintaining low costs. Extending the short-term responses to try to set up longer-term systems is, however, difficult.

Organizations need to work closely together if they are to maximize the use of their resources, keep to a minimum any duplication of activities, and enhance the efficiency of operations. The Code of Conduct for Humanitarian Organizations, as put forward by the International Federation of Red Cross and Red Crescent Societies (*62*), states a number of key principles that many humanitarian organizations see as forming a basis for their work. Such a code is voluntary, though, and there are no effective measures for enforcing its principles or evaluating whether they are being effectively implemented.

Ethical considerations of aid provision

There are ethical problems relating to interventions in emergency situations and particularly how to distribute aid. In some cases, such as the crisis in Somalia in the early 1990s, aid agencies have hired armed guards in order to be able to carry out their operations, an action which is regarded as ethically questionable. As regards the distribution of aid, there is frequently an expectation that a proportion will be diverted to the warring parties. Aid agencies have generally taken the view that some degree of ''leakage'' of resources is acceptable, provided that most still reach their intended destination. In some places, though, the proportion of food and other aid being siphoned off has been so great that the agencies have chosen to withdraw their services.

Other ethical concerns centre around the fact that working with warring factions indirectly confers a degree of legitimacy on them and on their activities. Questions arise concerning whether aid agencies should be silent about observed abuses or speak out, and whether they should carry on providing services in the light of continued abuses. Anderson (*72*), among others, discusses the broader issues of how emergency aid can help promote peace – or alternatively, prolong conflicts.

Community involvement

During periods of conflict, local community structures and activities may be seriously disrupted. People may fear actively debating such issues as social policy or campaigning on behalf of marginalized or vulnerable groups. This is likely to be even

more the case under undemocratic political regimes and where state violence is being threatened against perceived opponents of the regime.

In some cases, though, there may be a positive outcome in terms of the community response, where the development of social structures, including health services, is actually made easier. This type of response would appear to be more common in conflicts based on ideology – such as those in the latter part of the 20th century in Mozambique, Nicaragua and Viet Nam. In the conflict in Ethiopia between 1974 and 1991, community-based political movements in Eritrea and Tigray were heavily involved in creating participatory local structures for decision-making and in developing health promotion strategies (*73*).

Re-establishing services after conflicts

There has been considerable discussion on how best to re-establish services as countries emerge from major periods of conflict (*74–76*). When inaccessible areas open up in the aftermath of complex emergencies, they release a backlog of public health needs that have long previously been unattended to, typically flagged by epidemics of measles. In addition, ceasefire arrangements, even if precarious, need to include special health support for demobilizing soldiers, plans for demining, and arrangements for refugees and internally displaced people to return. All these demands are likely to occur at a time when the infrastructure of the local health system is seriously weakened and when other economic resources are depleted.

More precise information is needed on interventions in various places, the conditions under which they take place, and their effects and limitations. One problem in collecting data on conflicts is defining a notional end-point. Usually, the boundary between the end of a conflict and the beginning of the post-conflict period is far from clear cut, as significant levels of insecurity and instability often persist for a considerable time.

Table 8.5 outlines some of the typical approaches to rebuilding health care systems in the aftermath of conflicts. In the past, there has been considerable emphasis on physical reconstruction and on disease control programmes, but relatively little consideration of coordinating donor responses or setting up effective policy frameworks.

Documentation, research and dissemination of information

Surveillance and documentation are core areas for public health activities relating to conflicts. While it is the case, as mentioned above, that data on collective violence are often unsatisfactory and imprecise, too rigid a concern with precision of data is not usually warranted in this field. It is essential, however, that data are valid.

Providing valid data to policy-makers is an equally important component of public health action. The United Nations, international agencies, nongovernmental organizations and health professionals all have key roles to perform in this area. The International Committee of the Red Cross (ICRC), for instance, through its extensive research and campaigning work, played a significant part in promoting the Ottawa process which led to the adoption of the anti-personnel Mine Ban Treaty that entered into force on 1 March 1999. As one ICRC staff member involved in this effort put it: ''Observing and documenting the effects of weapons does not bring about changes in belief, behaviour or law unless communicated compellingly to both policy-makers and the public'' (*77*).

Some nongovernmental organizations, such as Amnesty International, have explicit mandates to speak out about abuses of human rights. So do some United Nations bodies, such as the Office of the United Nations High Commissioner for Human Rights. Some agencies, however, are reluctant to speak out against those involved in conflicts for fear that their ability to deliver essential services could be compromised. In such cases, agencies may choose to convey information indirectly, through third parties or the media.

If dissemination is to be effective, good data are needed and the experiences from interventions must be properly analysed. Research is crucial for assessing the impact of conflicts on health and on health care systems, and for establishing which interventions are effective.

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TABLE 8.5

Post-conflict health challenges

Component of post-conflict health sector activity	Typical situation at present	Actions for a more appropriate response
Setting policy	• Activities are seen as independent projects • Limited attention is given to setting up policy frameworks	• At an early stage, develop policy frameworks within which projects can be based • Encourage donor support to the Ministry of Health for policy development and for gathering and disseminating information • Facilitate communication between key participants
Donor coordination	• Donors agree in principle that coordination is desirable, but none wishes to be coordinated	• Identify areas of common interest and build on these • Strengthen the capacity of the Ministry of Health to take a leading role and to coordinate donors and nongovernmental organizations
Working with the government	• The government is often bypassed, with support being channelled through nongovernmental organizations and United Nations agencies	• Reform the international aid system so as to allow development activities to take place earlier in the period of post-conflict recovery • Consider sector-wide approaches, where donors agree to work within an agreed policy framework
Developing infrastructure	• The aim is to reconstruct exactly what existed before	• Review the needs for services and their distribution • Rationalize and make more equitable the distribution of available services • In placing new services, recognize changed population patterns
Specific disease problems	• Disease control and service delivery is narrowly focused • Donors have considerable control over programmes and provide most of the funds	• Facilitate linkages between different programmes • Ensure programmes operate through the major health system structures • Ensure that disease-focused interventions and those that are health system-oriented complement each other • Fully involve all relevant participants, including the national and local public sector, nongovernmental organizations and the private sector
Reconciliation work	• Activities are focused around temporary cessation of hostilities, so as to carry out disease control	• Recognize the symbolic value of health care in restoring relationships between communities • Recognize the promotion of justice and reconciliation as long-term goals involving the often slow rebuilding of trust between communities • Promote every reasonable opportunity for collaboration between communities • Consider innovative responses, such as truth and reconciliation commissions
Role of the private sector	• Efforts are made to diversify the range of service providers and to deregulate the private sector	• Promote the role of the state in framing policies, setting standards and monitoring the quality of services • Recognize at the same time the important role of the private sector in providing health care • Develop incentives to promote equitable access to and delivery of important public health services
Promoting an equitable society	• Usually considered important but often postponed to a later period	• Recognize that achieving equitable social structures is a prime objective but that in the short term, in the interests of stability, some reforms may need to be delayed • Build links between competing population groups and different localities as key elements of post-conflict reform
Training	• Training is often overlooked, fragmented and uncoordinated	• Recognize the importance of developing human resources • Work out ways to integrate people who have been trained under different systems • Invest in training for planners and managers
Information systems	• Information is not considered a priority • Even when information exists it is not shared	• Make documentation a priority • Set up a central repository for information • Make use of new technologies to disseminate information • Make funding conditional on sharing information

Recommendations

Various measures need to be taken to prevent the occurrence of conflict and – where it does occur – to lessen its impact. These measures fall into the following broad categories:

— obtaining more extensive information and a better understanding of conflicts;
— taking political action to predict, prevent and respond to conflicts;
— peacekeeping activities;

— health sector responses to conflicts;
— humanitarian responses.

Information and understanding

Data and surveillance

Some important measures that need to be taken, with the aim of producing more valid and precise information on conflicts and how to respond to them, include the following:

- Indicators related to public health and the performance of health services should be identified, together with effective ways in which these indicators can be measured, so that deviations in particular groups from health norms, which may be early signs of inter-group tensions, can be detected.
- Recent data-collecting and surveillance techniques dealing with health status in conflict-affected populations should be further refined so as to improve the understanding of the impact of conflicts on other populations – including internally displaced people, refugees who have become integrated with their host communities, and specific vulnerable groups such as child soldiers (see Box 8.3).
- Methods analysing the impact of conflicts on health systems, and how these systems respond, should be improved.

Further research

There is clearly a great need for further research, documentation and analysis, so as to prevent future conflicts, reduce the vulnerability of specific groups, and deliver the most appropriate services in the most effective ways during and after crises of violence. Two particular aspects of documentation and analysis that need to be focused on are:

- Developing effective ways of recording the experiences of conflict-affected populations.
- Conducting objective post-conflict analyses, describing the build-up to violence, its impact and the responses to it. Some analyses along these lines have been carried out, particularly following the Rwandan genocide of 1994 (*74*).

One specific question that needs addressing is why certain countries that exhibit a number of the signs of risk for violent conflict are in fact able to avoid it, while others progress to conflicts or even near-collapse of the state. Angola, Liberia, Sierra Leone, Somalia and the former Yugoslavia are some examples of the latter category. One useful avenue of research would be to determine a pre-emergency set of indicators that could help predict whether a crisis would degenerate into a major complex emergency.

Preventing violent conflicts

The outright prevention of conflict must be a priority from the point of view of public health.

Key measures for governments here include:

- Respecting human rights, adhering strictly to the spirit of the United Nations Charter and promoting the full adoption of human rights laws and international humanitarian laws.
- Promoting the adoption of treaties and other measures restricting the production, distribution and use of anti-personnel landmines.
- Promoting efforts to decrease the production and availability of biological, chemical, nuclear and other weaponry; specifically, new initiatives on light weapons, including the European code of conduct on the transfer of light weapons, should be strongly encouraged.
- Building on recent measures to integrate the monitoring of the movement of small arms with other early-warning systems for conflict (*79*). Since 1992, for example, the United Nations has maintained a Register of Conventional Arms, which includes data on international arms transfers as well as information provided by Member States on military holdings, procurement through national production, and relevant policies.
- Monitoring the adverse effects of globalization, and promoting more equitable forms of development and more effective development assistance.
- Working for accountable forms of governance throughout the world.

Boutros Boutros-Ghali, the former Secretary-General of the United Nations, has stated that social integration must be seen as a development priority: ''Manifestations of the lack of social integration are

BOX 8.3

Child soldiers: issues for health professionals

The number of child soldiers active around the world at any time has been estimated at some 300 000, though this figure is almost certainly a considerable underestimate. Unless children are routinely recruited into armed forces, they normally become involved only after a conflict has been in progress for some time. However, once children start being recruited, their numbers generally escalate rapidly and their average age decreases.

Health consequences

Clearly, the involvement of children as combatants in armed conflicts exposes them to risks of death and combat-related injury. Other serious health effects are less publicized, such as the mental and public health aspects.

Research (*78*) has shown that the most frequent combat-related injuries of child soldiers are:

- loss of hearing;
- loss of sight;
- loss of limbs.

These injuries partly reflect the greater sensitivity of children's bodies and partly the ways in which they are likely to be involved in conflicts – such as laying and detecting landmines. Child recruits are also prone to health hazards not directly related to combat – including injuries caused by carrying weapons and other heavy loads, malnutrition, skin and respiratory infections, and infectious diseases such as malaria.

Girl recruits, and to a lesser extent young boys, are often required to provide sexual services as well as to fight. This puts them at high risk of sexually transmitted diseases including HIV, as well as exposing them – in the case of girls – to the dangers associated with abortion or childbirth. In addition, child recruits are often given drugs or alcohol to encourage them to fight, creating problems of substance dependency, apart from the other associated health risks.

Teenagers recruited into regular government armies are usually subjected to the same military discipline as adult recruits, including initiation rites, harsh exercises, punishments and denigration designed to break their will. The impact of such discipline on adolescents can be highly damaging – mentally, emotionally and physically.

Health sector aspects

Medical professionals should understand the need for thorough, but sensitive, medical screening of all former child soldiers at the earliest possible opportunity. This may be at the time of formal demobilization, but may also occur when child soldiers are captured, escape or otherwise leave service. Screening may need to be carried out in stages, addressing the most vital problems first and then proceeding to more sensitive issues, such as sexual abuse.

Special attention should be given to the mental and psychosocial health of child soldiers, as well as to their physical health. The problems that may afflict former child soldiers include:

- nightmares, flashbacks and hallucinations;
- poor concentration and memory;
- chronic anxiety;
- regression in behaviour;
- increased substance abuse as a coping mechanism;
- a sense of guilt and refusal to acknowledge the past;
- poor control of aggression;

BOX 8.3 *(continued)*

— obsessive thoughts of revenge;

— feelings of estrangement from others.

In addition, the ''militarized behaviour'' of the children may lead to a low level of acceptance of the norms of civilian society. As the World Health Organization pointed out in its contribution to the United Nations study on child soldiers (*78*):

''Children going through the development stages of socialization and acquisition of moral judgement in [a military] environment are ill-prepared to be reintegrated into a non-violent society. They acquire a premature self-sufficiency, devoid of the knowledge and skills for moral judgement and for discriminating inappropriate risk behaviours – whether reflected in violence, substance abuse or sexual aggression. Their rehabilitation constitutes one of the major social and public health challenges in the aftermath of armed conflict.''

Health professionals may also play a valuable educational role in helping prevent children being recruited into armies (including as volunteers), by raising awareness among children and adolescents who are at risk, as well as among their families and communities, and by stressing the associated dangers, including the severe damage to psychological and mental health.

familiar: discrimination, fanaticism, intolerance, persecution. The consequences are also familiar: social disaffection, separatism, micronationalism and conflict'' (*80*).

Peacekeeping

Despite massive increases in peacekeeping activities by the United Nations, the effectiveness of such operations has often been questionable. The reasons include uncertainty about the mandates for such interventions, poor lines of control between the various forces contributing to a peacekeeping effort and inadequate resources for the task. In response to these problems, the Secretary-General of the United Nations created a Panel on United Nations Peace Operations to assess the shortcomings of the existing system and to make specific recommendations for change. The Panel, composed of individuals experienced in various aspects of conflict prevention, peacekeeping and peace-building, made recommendations covering operational and organizational areas for improvement, as well as politics and strategy. These recommendations were summarized in a report that is more commonly known as the ''Brahimi report'' (*81*).

Health sector responses

The potential – and limitations – of the health care sector in helping prevent and respond to conflicts should be more thoroughly researched and documented. More documentation of good practice is required, particularly with regard to providing effective services after conflicts – an area where new lessons are beginning to emerge.

Governments should support organizations, such as the World Health Organization and other United Nations agencies, in a global effort to devise more effective policies for the prevention of and responses to conflicts.

Humanitarian responses

Both the standards and the level of accountability of organizations responding to violent crises need to be raised. The Sphere Project, which is based in Geneva, Switzerland, is seeking to have minimum standards for humanitarian assistance agreed and acted upon. Similarly, the Humanitarian Accountability Project, a network also based in Geneva and supported by donor agencies and nongovernmental organizations, is working to raise levels of accountability, especially among potential beneficiaries of humanitarian activities. Governments and humanitarian agencies are urged to support both these efforts.

Conclusion

This chapter has focused on the impact of violent conflicts on public health and health care systems, and has attempted to describe the range of possible

responses to such crises. Clearly, there is a need for a greater emphasis on primary prevention, which seeks to prevent conflicts from occurring in the first place.

There is much that needs to be learnt – and acted upon – concerning the prevention of collective violence and dealing with its underlying causes. In the first instance, this applies to the forms of collective violence that have become common in the past hundred years or more – conflicts between states or involving organized groups within a specific geographical area (such as regions in rebellion against the central state), civil wars and the various forms of state-sponsored violence against individuals or groups.

The shape of collective violence is changing, though. At the start of the 21st century, new forms of collective violence are emerging, involving organized but highly dispersed organizations and networks of organizations – groups without a ''fixed address'', whose very aims, strategies and psychology differ radically from earlier ones. These groups make full use of the high technologies and modern financial systems that the globalized world order has created. Their weaponry is also new, as they seek to exploit such forms as biological, chemical and possibly nuclear weapons in addition to more conventional explosives and missiles. Their goals are physical as well as psychological, involving both mass destruction and the creation of widespread fear.

The world will need to learn quickly how to combat the new threat of global terrorism in all of its forms, while at the same time showing a high degree of determination to prevent and lessen the impact of conventional forms of collective violence, which continue to cause the overwhelming proportion of deaths, illness, injuries and destruction. A strong will is needed, together with a generous commitment of resources, not only to reach a much deeper understanding of the problems of violent conflict, but also to find solutions.

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CHAPTER 9

The way forward: recommendations for action

Background

Violence leaves no continent, no country and few communities untouched. Although it appears everywhere, violence is not an inevitable part of the human condition, nor is it an intractable problem of ''modern life'' that cannot be overcome by human determination and ingenuity.

Earlier chapters of this report have supplied considerable detail about specific types of violence and the public health interventions that may be applied in an attempt to reduce both their occurrence and their consequences. This final chapter highlights a number of global patterns and themes that cut across the various types of violence. It reiterates the case for a public health approach and provides a set of recommendations for decision-makers and practitioners at all levels.

Responding to violence: what is known so far?

Major lessons to date

Although important gaps exist in the information base, and much research needs to be done, useful lessons have been learned about preventing and reducing the consequences of violence.

Predictable and preventable

Violence is often predictable and preventable. As this report has shown, certain factors appear to be strongly predictive of violence within given populations, even if direct causality is sometimes difficult to establish. These range from individual and family factors – such as impulsivity, depression, poor monitoring and supervision of children, rigid gender roles and marital conflict – to macro-level factors, such as rapid changes in social structures and sharp economic downturns, bringing high unemployment and deteriorating public services. There are also local factors, specific to a given place and time, such as an increased presence of weapons or changing patterns of drug dealing in a particular neighbourhood. Identifying and measuring these factors can provide timely warning to decision-makers that action is required.

At the same time, the array of tools with which to take action is growing as public health-oriented research advances. In each category of violence examined in this report, examples have been cited of interventions that show promise for reducing violence and its consequences. These range from small-scale individual and community efforts to country-level policy changes that have achieved reductions in violence. While the majority of such interventions that have been documented and formally evaluated are to be found in wealthier parts of the world, many innovative interventions also exist in developing countries.

Upstream investment, downstream results

There is a tendency worldwide for authorities to act only after cases of highly visible violence occur, and then to invest resources for a short time on programmes for small, easily identified groups of people. Periodic police ''crackdowns'' on areas with high levels of violence are classic examples of this, usually following a much-publicized incident. In contrast, public health emphasizes prevention, especially primary prevention efforts operating ''upstream'' of problems – efforts that try to stop violent incidents from occurring in the first place or that prevent violent conditions from resulting in serious injury. Primary prevention approaches operate on the basis that even small investments may have large and long-lasting benefits.

Understanding the context of violence

All societies experience violence, but its context – the circumstances in which it occurs, its nature and its social acceptability – varies greatly from one setting to another. Wherever prevention programmes are planned, the context of violence must be understood in order to tailor the intervention to the targeted population.

Chapters 4 (intimate partner violence) and 6 (sexual violence) provide a wealth of examples in which the cultural context exacerbates the consequences of violence, creating formidable problems for prevention. One example is the belief in many societies that men have the right to discipline their wives – including through the use of physical force – for a variety of reasons, including the refusal to have sex. Behaviour resulting from such a belief puts these

women at risk not only of immediate physical and psychological violence, but also of unwanted pregnancy and sexually transmitted diseases. Another example is the approval of harsh, physical punishment in child-rearing, which is deeply ingrained in some societies. Interventions are unlikely to be successful unless they take into account the strength of these beliefs and attitudes, and the way they relate to other aspects of local culture.

At the same time, cultural traditions can also be protective; researchers and programme designers must be prepared to identify and make use of them in interventions. For example, Chapter 7 (self-directed violence) describes the contribution that religious affiliation appears to make in reducing the risk of suicide, and discusses the reasons – such as identification with a religion and specific prohibitions against suicide – why this may be so.

Exploiting linkages

Different types of violence are linked to each other in many important ways, often sharing similar risk factors. An example can be seen in Chapter 3 (child abuse and neglect by parents and other caregivers), where the list of common risk factors overlaps to a large degree with those for other types of violence. Some of these factors include:

- Poverty – linked with all forms of violence.
- Family or personal histories marked by divorce or separation – a factor also associated with youth violence, intimate partner violence, sexual violence and suicide.
- Alcohol and substance abuse – associated with all interpersonal forms of violence, as well as suicide.
- A history of family violence – linked to youth violence, intimate partner violence, sexual violence and suicide.

The overlap between the set of risk factors for different types of violence suggests a strong potential for partnerships between groups with a major interest in both primary and secondary prevention: local government and community officials, social housing planners, the police, social workers, women's and human rights groups, the medical profession and researchers working in each specific field. Partnerships may be advantageous in a variety of ways, including:

- improving the effectiveness of interventions;
- avoiding a duplication of efforts;
- increasing the resources available through a pooling of funds and personnel in joint actions;
- allowing research and prevention activities to be conducted in a more collective and coordinated way.

Unfortunately, research and prevention efforts for the various types of violence have often been developed in isolation from one another. If this fragmentation can be overcome, there is considerable scope in the future for more comprehensive and effective interventions.

Focusing on the most vulnerable groups

Violence, like many health problems, is not neutral. While all social classes experience violence, research consistently suggests that people with the lowest socioeconomic status are at greatest risk. More often it is the factors related to poverty, rather than poverty itself, that increase the risk for violence. Chapter 2, for instance, discusses the roles of poor housing, lack of education, unemployment, and other poverty-related conditions in youth violence – and how these factors place some young people at heightened risk of being influenced by delinquent peers and participation in criminal activities. The rate at which people enter into poverty – losing resources that were previously available – and the differential way in which they experience poverty (that is, their relative deprivation within a particular setting rather than their absolute level of poverty) are also important.

Chapter 6 (sexual violence) describes how poverty exacerbates the vulnerability of women and girls. In carrying out everyday tasks such as working in the fields, collecting water alone or walking home from work late at night, poor women and girls in rural or economically depressed areas are often at risk of rape. The conditions of poverty make them vulnerable to sexual exploitation in situations as diverse as seeking employment, engaging in trade or obtain-

ing an education. Poverty is also a leading factor that pushes women into prostitution and forces families to sell children to sexual traffickers. Chapter 8 (collective violence) broadens the discussion further, pointing out that poverty and inequality are among the driving forces in violent conflict and that long periods of conflict may increase poverty – in turn creating the conditions that give rise to other forms of violence.

The neglect of poor people is not new: the poorest people in most societies are generally those least served by the state's various protection and care services. However, the fact that violence is linked with poverty may be an additional reason why policy-makers and government authorities have neglected public health approaches to violence – approaches that would mean a greater proportion of services and resources going to poor families and communities – in favour of policing and prisons. This neglect must be corrected if violence is to be prevented.

Combating complacency

Something that greatly encourages violence – and is a formidable obstacle in responding to it – is complacency. This is particularly true of the attitude that regards violence – like the closely related problem of gender inequality – as something that has always been present in human society and will therefore always continue to be so. Often, this complacency is strongly reinforced by self-interest. The social acceptance, for instance, of the right of men to ''correct'' their wives clearly benefits men more than it does women. The drug trade thrives on its illegal status, in which violence is an acceptable way for those involved to settle disputes or increase their market share.

In describing some of the elements that create a culture of violence, several chapters in this report emphasize that such a culture is often supported by both laws and attitudes. Both may be at work in factors such as the glorification of violence by the media, the tolerance of sexual assault or violence against intimate partners, harsh physical disciplining of children by parents in the home, bullying in schools and playgrounds, the use of unacceptable levels of force by police, and the prolonged exposure of children and adolescents to armed conflict. Achieving significant reductions in both interpersonal and collective violence will be difficult unless the complacency surrounding such issues is abolished.

Gaining commitment from decision-makers

While much can be achieved by grassroots organizations, individuals and institutions, much of the success of public health efforts ultimately depends on political commitment. Support from political leaders is not only necessary to ensure proper funding and effective legislation, but also to give prevention efforts increased legitimacy and a higher profile within the public consciousness. Commitment is as important at national level – where policy and legislative decisions are made – as at provincial, district and municipal levels, where the day-to-day functioning of many interventions is controlled.

Gaining the strong commitment necessary for addressing violence is often the result of sustained efforts by many sectors of society. Public health practitioners and researchers have an important contribution to make to this process by providing decision-makers with solid information on the prevalence, consequences and impact of violence, and by carefully documenting the proven and promising practices that can lead to its prevention or management.

Why should the health sector be involved?

Until recently, the responsibility for remedying or containing violence in most modern societies fell on the judicial system, police and correctional services, and in some cases the military. The health sector, both public and private, was relegated to the role of providing care after the event, when the victims of violence came forward for treatment.

Assets and comparative advantages

Today, the health sector is an active and valuable ally in the global response to violence and brings a variety of advantages and assets to this work. One such asset is its closeness to, and therefore

familiarity with the problem. The personnel of hospitals and clinics, and other health care providers dedicate a great amount of time to the victims of violence.

Another important asset is the information that the health sector has at its disposal to facilitate research and prevention work. Possession of data means that the sector is uniquely placed to draw attention to the health burden imposed by violence. When combined sensitively with the human stories the health sector witnesses every day, such information can provide a powerful tool both for advocacy and for action.

A special responsibility

The health sector's role in preventing violence stems from its responsibility to the public – the people who ultimately pay for services and for the governmental structures that organize them. With this responsibility and its various assets and advantages, the health sector has the potential to take a much more proactive role in violence prevention – ideally, in collaboration with other sectors – than it has done in the past. On a day-to-day basis, doctors, nurses and other health care personnel are well placed to identify cases of abuse, and to refer victims to other services for follow-up treatment or protection. At the programme level, hospitals and other health care facilities can serve as useful settings for interventions, using their resources and infrastructure for prevention activities. Equally important, the design and implementation of interventions can be enhanced by the close cooperation of health care professionals and institutions with other institutions or sectors concerned with violence, including nongovernmental organizations and research bodies.

These functions of the health sector are already being carried out in many parts of the world, though sometimes in a tentative or piecemeal fashion. The time has now come for more decisive and coordinated action, and for extending efforts to places where they do not yet exist, despite being sorely needed. Anything less will be a failure of the health sector.

Assigning responsibilities and priorities

Given the multifaceted nature of violence and its complex roots, governments and relevant organizations at all levels of decision-making – local, national and international – must be engaged in its prevention. Complementary and coordinated action across sectors will enhance the effectiveness of violence prevention activities.

In addition to working at their own level of government or authority, decision-makers and practitioners can and must work together across levels for significant progress to be made. The various components of civil society – such as the media, community organizations, professional associations, labour organizations, religious institutions and traditional structures – may contain a great volume of relevant knowledge and experience.

Each country has its own particular governing structure, from a highly centralized unitary state to a federal system that divides powers between local, regional and national governments. Whatever the structure, however, strategic planning processes – usually led by national governments but including other levels and sectors – may be useful for creating consensus, setting objectives and timetables, and assigning responsibilities to all those with something to contribute. Certain United Nations organizations and bilateral development agencies have considerable expertise in strategic planning for public health issues in developing countries, which could profitably contribute to violence prevention.

Recommendations

The following recommendations aim to mobilize action in response to violence. All recommendations need to be addressed by a range of sectors and stakeholders if they are to achieve their objectives.

These recommendations must obviously be applied with flexibility and with proper understanding of local conditions and capacities. Countries currently experiencing collective violence, or with scarce financial and human resources, will find it difficult or impossible to apply some of the national and local recommendations on their own. Under such circumstances, they may be able to work with international organizations or nongov-

ernmental organizations operating within their borders that are able to support or implement some of the recommendations.

Recommendation 1. Create, implement and monitor a national action plan for violence prevention

The development of a multisectoral national action plan is a key element for sustained violence prevention efforts. It may not always be easy to achieve, given understandable public demands for immediate action to deal with the more visible effects of violence. National leaders, though, must understand that the benefits of a sustained public health approach will be more substantial and longer-lasting than short-term, reactive policies. Such an action plan will require visible political commitment and the investment of moral authority.

A national action plan to prevent violence should include objectives, priorities, strategies and assigned responsibilities, as well as a timetable and evaluation mechanism. It should be based on a consensus developed by a wide range of governmental and nongovernmental actors, including appropriate stakeholder organizations. The plan should take into account the human and financial resources that are and will be made available for its implementation. It should include elements such as the review and reform of existing legislation and policy, building data collection and research capacity, strengthening services for victims, and developing and evaluating prevention responses. To ensure that the plan moves beyond words to action, it is essential that a specific organization be mandated to monitor and report periodically on progress made in these and other elements of the plan.

Coordinating mechanisms at the local, national and international level will be required to enable fruitful collaboration between such sectors as criminal justice, education, labour, health, social welfare, and others potentially involved in the development and implementation of the plan. Mechanisms such as national task forces, interministerial committees and United Nations working groups may be able to facilitate such coordination. At the local level, councils, community-based task forces and networks can be created or utilized to help build and implement the plan.

Recommendation 2. Enhance capacity for collecting data on violence

The national action plan for violence prevention must include establishing or enhancing national capacity to collect and analyse data covering the scope, causes and consequences of violence. These data are necessary in order to set priorities, guide programme design, and monitor the progress of the action plan. As described throughout the report, in all countries at least some data collection efforts are under way, but the quality and the sharing of the data could be strengthened.

In some countries, it may be most efficient for the national government to designate an institution, agency or government unit to be responsible for collating and comparing information from health, law enforcement and other authorities that maintain regular contact with the victims and perpetrators of violence. Such an institution could be a ''centre of excellence'', with responsibility for documenting the extent of violence within the country, promoting or carrying out research, and training people for these functions. It should liaise with other comparable institutions and agencies in order to exchange data, research tools and methods. In countries with limited resources, it may also assume the monitoring function described under Recommendation 1.

Data collection is important at all levels, but it is at the local level that the quality and completeness of data will be determined. Systems must be designed that are simple and cost-effective to implement, appropriate to the level of skills of the staff using them, and conforming to both national and international standards. In addition, there should be procedures to share data between the relevant authorities (such as those responsible for health, criminal justice and social policy) and interested parties, and the capability to carry out comparative analysis.

At the international level, the world currently lacks internationally accepted standards for data collection on violence to enhance the comparison of data across

nations and cultures. This is serious, not least because current gaps in information make it difficult to quantify the magnitude of violence worldwide, and therefore to undertake global-level research or develop interventions. While many of these gaps are simply the result of missing data, others result from differences in the way data are classified by different countries (and sometimes by different agencies within individual countries). This can and should be remedied by the development and propagation of internationally accepted standards for data collection. The *International classification for external causes of injuries* (*1*) and the *Injury surveillance guidelines* developed by the World Health Organization and the United States Centers for Disease Control and Prevention (*2*) are steps in that direction.

Recommendation 3. Define priorities for, and support research on, the causes, consequences, costs and prevention of violence

Although the report has shown that progress has been made in understanding violence among different population groups and in various settings, additional research is urgently needed. There are many reasons to undertake such research, but a main priority is to gain a better understanding of the problem in different cultural contexts so that appropriate responses can be developed and evaluated.

At the national level, and as part of the plan of action, a research agenda can be advanced by government policy, by direct involvement of government institutions (many social service or interior ministries, as well as criminal justice agencies, have in-house research programmes), and by funding to academic institutions and independent researchers.

Research can and should also be undertaken at the local level. Local research is first and foremost valuable for its use in local violence prevention activities, but it is also an important component in the larger research effort required to tackle violence on a global scale. For maximum benefit, local authorities should involve all partners possessing relevant expertise, including university faculties (such as medicine, social sciences, criminology and epidemiology), research facilities and nongovernmental organizations.

While the bulk of research required to prevent violence must be carried out at the local level, in response to local conditions and needs, some high-priority issues of global importance call for cross-national research at the international level. These issues include: the relationship between violence and various aspects of globalization, including economic, environmental and cultural impacts; risk and protective factors common to different cultures and societies; and promising prevention approaches applicable in a variety of contexts.

Some aspects of globalization have an important impact on different types of violence in different settings, but little is known about precisely what factors cause the violence or how these might be mitigated. Not enough research has been done about risk factors that are shared across different settings, and even less has been done on the potentially highly rewarding area of protective factors. In addition, although there is considerable information about individual interventions from a variety of countries (some of the most promising are described in this report), few have been evaluated.

Recommendation 4. Promote primary prevention responses

The importance of primary prevention is a theme echoed throughout this report. Research suggests that primary prevention is most effective when carried out early, and among people and groups known to be at higher risk than the general population – though even efforts directed at the general population can have beneficial effects. Yet as the various chapters in this report indicate, not enough emphasis is being given at any level to primary prevention. This situation must be redressed.

Some of the important primary prevention interventions for reducing violence include:

— prenatal and perinatal health care for mothers as well as preschool enrichment and social development programmes for children and adolescents;

— training for good parenting practices and improved family functioning;

— improvements to urban infrastructure (both physical and socioeconomic);
— measures to reduce firearm injuries and improve firearm-related safety;
— media campaigns to change attitudes, behaviour and social norms.

The first two interventions are important for reducing child abuse and neglect as well as violence perpetrated during adolescence and adulthood.

Important contributions can also be made through improvements to infrastructure (both physical and socioeconomic). Specifically, this means addressing environmental factors within communities: identifying locations where violence frequently occurs, analysing the factors that make a given place dangerous (for example, bad lighting, isolation, or being near an establishment where alcohol is consumed), and modifying or removing these factors. It also calls for an improvement to the socioeconomic infrastructure of local communities through greater investment and improved educational and economic opportunities.

Another issue for both national and local interventions is prevention of firearm injuries and improvement of firearm-related safety measures. Firearms are an important risk factor in many types of violence, including youth and collective violence and suicide. Interventions to reduce injuries from guns – whether accidental or intentional – include, for example, legislation on gun sales and ownership, programmes to collect and decommission illegal weapons in areas of frequent gun-related violence, programmes to demobilize militia and soldiers after conflicts, and measures to improve safe storage of weapons. Further research is needed to determine the effectiveness of these and other types of interventions. This is a prime area in which multisectoral collaboration between legislative, policing and public health authorities will be important in achieving overall success.

The media have considerable potential as both negative and positive forces in violence prevention. While no conclusive research results are yet available on how exposure to violence through the media affects many types of violence, there is evidence for a relationship between reporting of suicides and subsequent suicides. The media can be used to change violence-related attitudes and behaviour as well as social norms by printing or broadcasting anti-violence information, or by incorporating anti-violence messages into entertainment formats such as soap operas (see Box 9.1).

Depending on conditions in specific locations, most of these primary interventions can also have important mutual reinforcing effects.

Recommendation 5. Strengthen responses for victims of violence

The health, social and legal services provided to victims of violence should be strengthened in all countries. This requires a review of services currently provided, better training of staff, and improved integration of health, social and legal support.

The health system as a whole should have as a national goal to strengthen the capacity and funding to provide high-quality care to victims of all types of violence, as well as the rehabilitation and support services needed to prevent further complications. Priorities include:

— improvements to emergency response systems and the ability of the health care sector to treat and rehabilitate victims;
— recognition of signs of violent incidents or ongoing violent situations, and referral of victims to appropriate agencies for follow-up and support;
— ensuring that health, judicial, policing and social services avoid a renewed victimization of earlier victims, and that these services effectively deter perpetrators from re-offending;
— social support, prevention programmes, and other services to protect families at risk of violence and reduce stress on caregivers;
— incorporation of modules on violence prevention into curricula for medical and nursing students.

Each of these responses can help minimize the impact of violence on individuals and the cost to health and social systems. Emergency response systems and pre-hospital care can significantly

BOX 9.1

Health promotion, violence prevention and the media: the *Soul City* campaign

In South Africa, the Institute for Health and Development Communication (IHDC) has won acclaim for the innovative way in which it uses the power of the mass media to promote health and development. The nongovernmental organization's project intertwines social and health issues into prime-time television and radio dramas, reaching audiences of millions throughout the country. By closely involving its viewers and listeners on an emotional level, the format of the programmes aims to change basic attitudes and social norms, and ultimately to change behaviour. One broadcast series, called *Soul City*, targets the general public, while a second, *Soul Buddyz*, is for children aged 8–12 years. *Soul City* is one of the most popular programmes on South African television, reaching almost 80% of its target audience of some 16 million people, and *Soul Buddyz* is viewed by two-thirds of all children in South Africa.

To accompany the broadcast programmes, IHDC has produced booklets providing further information on the topics covered, with illustrations of popular characters from the television dramas. The project has also produced audio and video tapes for use in a variety of formal and informal educational settings.

Violence is a major public health priority in South Africa, and the broadcast series have dealt with this issue in most of their programmes. Particular topics covered have included general interpersonal violence, bullying, gang violence, domestic violence, rape and sexual harassment. The project aims to prevent violence by:

- making audiences fully aware of the extent of violence in their society and its consequences;
- persuading people that they are in a position to do something about violence, both as individuals and as members of the community;
- encouraging better parenting, through the use of role models, and better communications and relationships between parents and children.

The IHDC project also runs a toll-free telephone helpline for audiences of the programmes, providing crisis counselling and referring people where necessary to community-based support services. It has also developed training materials on violence against women for counsellors and health workers, the police and legal officials.

An evaluation of the first series of *Soul Buddyz* is currently being conducted. Evaluations of the adult *Soul City* series have found increased knowledge and awareness, and shifts in attitudes and social norms concerning domestic violence and gender relations. Furthermore, there has been a significant increase in the willingness to change behaviour and take action against violence, both in urban and rural areas and among both men and women.

reduce the risk of death or disability resulting from physical trauma. Less tangible but equally important are measures such as changing the attitudes of the police and other public officials, educating them about intimate partner and sexual violence, and training them to recognize and respond to cases of violence.

Where health ministries provide guidelines for curricula within medical and nursing schools, national policy should see that all health personnel – while they are students – receive training on violence, its consequences and its prevention. Having graduated, health personnel should be able to recognize signs of violence and should be intent on doing so. Such measures can be particularly helpful to people who are unable to communicate what has happened to them, such as small children or incapacitated elderly people, or else are afraid to do so – for instance, victims of domestic violence, sex workers or undocumented migrants.

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The practical application of these policies must be carefully implemented and evaluated in order to avoid creating renewed victimization of victims of violence. For example, if staff ascertain that a patient has suffered violence, procedures to pursue that evidence should not place the patient at risk of further violence from the perpetrator, censure from his or her family or community, or other negative consequences.

Recommendation 6. Integrate violence prevention into social and educational policies, and thereby promote gender and social equality

Much violence has links with gender and social inequalities that place large sections of the population at increased risk. The experience of countries that have improved the status of women and reduced social discrimination suggests that an array of interventions will be required. At the national level, these will include legislative and legal reforms, communications campaigns aimed at public awareness of the problem, training and monitoring of the police and public officials, and educational or economic incentives for disadvantaged groups. Cultural and social research will be necessary in developing these interventions, so that they will be feasible and effective.

At the same time, social protection policies and programmes, both for the general population and for disadvantaged groups, need to be strengthened. These measures are under considerable strain in many parts of the world as a result of a range of factors, including the impacts of globalization, debt and structural adjustment policies, the transformation from planned to market economies, and armed conflicts. Many countries have seen real wages fall, basic infrastructure deteriorate – particularly in urban areas – and steady reductions in the quality and quantity of health, education and social services. Because of the established links between such conditions and violence, governments should do their utmost to keep social protection services operational, if necessary reordering the priorities in their national budgets.

Recommendation 7. Increase collaboration and exchange of information on violence prevention

Working relations and communications between international agencies, governmental agencies, researchers, networks and nongovernmental organizations engaged in the prevention of violence should be assessed in order to achieve better sharing of knowledge, agreement on prevention goals, and coordination of action. All have important roles to play in violence prevention (see Box 9.2).

A number of international agencies, regional institutions and United Nations bodies are either currently working in violence prevention or have mandates or activities highly relevant to reducing violence, including those dealing with economic matters, human rights, international law and sustainable development. To date, coordination across all these agencies is still insufficient. This should be remedied in order to avoid much needless duplication and to benefit from the economies of pooling expertise, networks, funding and in-country facilities. Mechanisms to improve cooperation should be explored, possibly starting on a small scale and involving a small number of organizations with both a mandate and practical experience in violence prevention (see Box 9.3).

The vastly improved communications technology of recent years is a positive aspect of globalization, which has permitted thousands of networks in a whole variety of fields. In violence prevention and related fields, networks of researchers and practitioners have greatly enhanced the world's knowledge base by proposing a range of prevention models, discussing methodologies and critically examining research results. Their exchange of information and ideas is crucial to future progress, alongside the work of government authorities, service providers and advocacy groups.

Advocacy groups are also important partners in public health. Advocacy groups concerned with violence against women and abuses of human rights (notably torture and war crimes) are prime examples. These groups have proved their ability to mobilize resources, gather and convey information

BOX 9.2

Responding to the threat of violence: the Inter-American Coalition for the Prevention of Violence

In countries on the American continent, as throughout the world, public safety is an issue of urgent concern for governments. From a national economic standpoint, violence affects foreign and domestic investment, impeding long-term growth and development. Violence also causes citizens to feel insecure and to lose faith in their criminal justice and political systems.

As a response to this concern, five international and regional bodies and one national organization joined forces in June 2000 to set up an initiative called the Inter-American Coalition for the Prevention of Violence. The participating organizations were:

— the Inter-American Development Bank;
— the Organization of American States;
— the Pan American Health Organization;
— the United Nations Educational, Scientific and Cultural Organization;
— the United States Centers for Disease Control and Prevention;
— the World Bank.

The Coalition believes that it can give effective support to national initiatives — whether by governments, civil society or the private sector — in preventing violence, particularly by mobilizing new partners and resources. While its activities are based on the principle of cooperation, it respects the freedom of individual countries to make their own decisions regarding the prevention of violence.

The main actions planned by the Coalition include:

— sponsoring campaigns to raise public awareness of the importance of violence prevention;
— supporting efforts to gather and publish reliable data on violence and crime, at local and national levels;
— setting up a web site on violence prevention, with a database of best practices;
— providing information on violence prevention to policy-makers and decision-makers throughout the region;
— organizing regional seminars and workshops on violence prevention, as well as study tours and initiatives between twinned cities;
— working with the media;
— working with government ministers and city mayors, and other national and local officials;
— working with the private sector, nongovernmental organizations, and ethnic and religious communities;
— providing technical support in the design, implementation and evaluation of national programmes to prevent violence.

This is the first violence prevention effort of its kind on the American continent, and it may provide a model for similar regional initiatives in other parts of the world.

about important problems, and mount campaigns that have had an impact on decision-makers. Groups focusing on other issues, notably abuse of the elderly and suicide, have also become prominent in recent years. The value of advocacy groups should be recognized. This can be achieved by practical measures such as offering them official status at key international conferences and including them in official working groups.

Another important area where progress could be made is in the sharing of information between experts working on the different types of violence. Experts working on issues such as child abuse, youth violence, violence against intimate partners,

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BOX 9.3

United Nations efforts to prevent interpersonal violence

Much work is currently being done by United Nations agencies to prevent interpersonal violence, particularly through initiatives addressing specific types of violence in particular settings. However, until recently, a large proportion of this work was being carried out in isolation.

In November 2001, representatives from ten United Nations agencies met in Geneva, Switzerland, to discuss their work on interpersonal violence and to find ways to coordinate future efforts in this field. Although United Nations agencies had previously collaborated successfully on conflict-related violence, little interagency work had been done to prevent everyday acts of violence and crime — incidents that affect individuals, families, communities and institutions such as schools and workplaces. Considerable benefits were envisaged if greater collaboration could take place on this complex problem, within and particularly between United Nations agencies. The meeting was the first step in that direction.

In a message to the representatives, United Nations Secretary-General Kofi Annan stated: ''Men and women everywhere have the right to live their lives and raise their children free from the fear of violence. We must help them enjoy that right by making it clearly understood that violence is preventable, and by working together to identify and address its underlying causes.''

Participants outlined a range of collaborative activities they would undertake. For the short term, these include the preparation of a guide to United Nations resources and activities for the prevention of interpersonal violence, highlighting the core competencies of each agency in preventing interpersonal violence and identifying areas not currently addressed by United Nations organizations. Based on this guide, a web site will be developed to help participating agencies exchange information and to serve as a resource for other United Nations agencies, governments, nongovernmental organizations, researchers and donors. For the medium and longer term, collaborative efforts will include advocacy work, data collection and analysis, research and prevention initiatives.

abuse of the elderly or suicide prevention often collaborate closely with experts working on the same type of violence, but much less successfully with those working on other types of violence. As this report has shown, the different types of violence share common risk factors and prevention strategies. Therefore, much could be gained by developing platforms that will facilitate the exchange of information, as well as joint research and advocacy work.

Recommendation 8. Promote and monitor adherence to international treaties, laws and other mechanisms to protect human rights

Over the past half-century, national governments have signed a variety of international legal agreements that have direct relevance to violence and its prevention. Such agreements set standards for national legislation and establish norms and limits of behaviour. Some of the most important in the context of this report are:

- The Convention on the Prevention and Punishment of the Crime of Genocide (1948).
- The Convention for the Suppression of the Traffic in Persons and of the Exploitation of the Prostitution of Others (1949).
- The Convention on the Elimination of All Forms of Racial Discrimination (1965).
- The International Covenant on Economic, Social and Cultural Rights (1966).
- The International Covenant on Civil and Political Rights (1966).
- The Convention on the Elimination of All Forms of Discrimination against Women (1979).

- The Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (1984).
- The Convention on the Rights of the Child (1989) and its two Optional Protocols on the Involvement of Children in Armed Conflict (2000) and on the Sale of Children, Child Prostitution and Child Pornography (2000).
- The Rome Statute of the International Criminal Court (1998).

There are also other important agreements that are highly pertinent to various aspects of violence, such as the African Charter on Human and Peoples' Rights (1981) and the Inter-American Convention on the Prevention, Punishment and Eradication of Violence Against Women (1994).

While many national governments have made progress in harmonizing legislation with their obligations and commitments, others have not. Some do not have the resources or expertise to put the provisions of such international instruments into practice. Where the obstacle is the scarcity of resources or information, the international community should do more to assist. In other cases, strong campaigning will be necessary to bring about changes in legislation and practice.

Recommendation 9. Seek practical, internationally agreed responses to the global drugs trade and the global arms trade

The global drugs trade and the global arms trade are integral to violence in both developing and industrialized countries, and come within the purview of both the national and the international levels. From the evidence provided in various parts of this report, even modest progress on either front will contribute to reducing the amount and degree of violence suffered by millions of people. To date, however – and despite their high profile in the world arena – no solutions seem to be in sight for these problems. Public health strategies could help reduce the health impacts of both in a variety of settings at the local and national levels, and should therefore be allotted a much higher profile in global-level responses.

Conclusion

Violence is not inevitable. We can do much to address and prevent it. The individuals, families and communities whose lives each year are shattered by it can be safeguarded, and the root causes of violence tackled to produce a healthier society for all.

The world has not yet fully measured the size of this task and does not yet have all the tools to carry it out. But the global knowledge base is growing and much useful experience has already been gained.

This report attempts to contribute to the knowledge base. It is hoped that the report will inspire and facilitate increased cooperation, innovation and commitment to preventing violence around the world.

References

1. WHO Collaborating Centre on Injury Surveillance. *International classification for external causes of injuries*. Amsterdam, Consumer Safety Institute, 2001.
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Statistical annex

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Background

Each year, over 100 countries send detailed information on the number of deaths from various diseases, illnesses or injuries to the World Health Organization (WHO). Data from these WHO Member States are compiled from vital registration systems using the International Classification of Diseases (ICD) codes (*1, 2*). National vital registration systems capture about 17 million deaths that occur annually throughout the world. Data from these registration systems, as well as from surveys, censuses and epidemiological studies, are analysed by the World Health Organization to determine patterns of causes of death for countries, regions and the world.

WHO has also used these data, along with other information, to assess the global burden of disease. First published in 1996, these estimates represent the most comprehensive examination of global mortality and morbidity ever produced (*3*). A new assessment of the global burden of disease for the year 2000 is in progress (*4*). Estimates of the global burden of injury for the year 2000 are presented here. A description of the tables included in the annex and the data used to produce the 2000 estimates of violence-related deaths is provided below.

Types of tables

The statistical annex includes three types of tables:

— global and regional estimates of mortality;
— the ten leading causes of death and disability-adjusted life years (DALYs) for all WHO Member States combined and for each of the WHO regions;
— country-level rates of mortality.

Global and regional estimates of mortality

Table A.1 provides an overview of the population counts used to estimate global and regional rates of mortality. Tables A.2–A.5 contain estimates of violence-related mortality for the year 2000. Table A.2 presents mortality estimates for all intentional injuries, by sex, age group, WHO region and income level. Estimates for homicide, suicide and war, by sex, age group, WHO region and income level, are given separately in Tables A.3–A.5.

Cause of death and DALY rankings

Table A.6 presents the ten leading causes of death and DALYs for the year 2000, as well as the rankings for violence-related deaths and DALYs. These rankings are given for all WHO Member States combined and for each of the WHO regions.

Country-level rates of mortality

Tables A.7–A.9, respectively, present the numbers and rates of deaths due to intentional injury, homicide and suicide, while Table A.10 provides the corresponding figures for firearm-related mortality, categorized by manner of death. In these tables, the absolute numbers and rates per 100 000 population are presented by sex and age group for countries reporting data to WHO.

Methods

Categories

Deaths and non-fatal injuries are categorically attributed to one underlying cause using the rules and conventions of the International Classification of Diseases (*1, 2*). The cause list for the Global Burden of Disease project for 2000 (GBD 2000 project) has four levels of disaggregation and includes 135 specific diseases and injuries (*5*). Unintentional and intentional injury categories are defined in terms of external cause codes. For instance, the codes for intentional injuries are as follows:[1]

- Homicide – ICD-9 E960–E969 or ICD-10 X85–Y09.
- Suicide – ICD-9 E950–E959 or ICD-10 X60–X84.
- War-related injuries – ICD-9 E990–E999 or ICD-10 Y36.
- Legal intervention – ICD-9 E970–E978 or ICD-10 Y35.
- All intentional injury – ICD-9 E950–E978, E990–E999 or ICD-10 X60–Y09, Y35, Y36.

Absolute numbers and rates per 100 000 in the population are presented by sex and WHO region for

[1] Based on the *International classification of diseases*, ninth revision (ICD-9) (*1*) and the *International statistical classification of diseases and related health problems*, tenth revision (ICD-10) (*2*).

six age groups: 0–4 years, 5–14 years, 15–29 years, 30–44 years, 45–59 years and 60 years or older.

WHO regions

WHO Member States are grouped in six regions: the African Region, the Region of the Americas, the South-East Asia Region, the European Region, the Eastern Mediterranean Region and the Western Pacific Region. The countries included in each region are indicated in Table A.1.

Countries within the six WHO regions in Tables A.1–A.5 are further divided by income level based on 1996 estimates of gross national product (GNP) per capita (now referred to as gross national income) compiled by the World Bank and used in the *World health report 1999* (*6*). On the basis of the GNP per capita, economies are classified as low income (US$ 785 or less), middle income (US$ 786–9635) or high income (US$ 9636 or more).

Global estimates of mortality

The GBD 2000 project uses the latest population estimates for WHO Member States prepared by the United Nations Population Division (*7*). New life tables for the year 2000 have been constructed for all 191 WHO Member States (*8, 9*). The results for injuries reported here from Version 1 of the GBD 2000 project are based on an extensive analysis of mortality data for all regions of the world, together with systematic reviews of epidemiological studies and health service data (*4*). Complete or incomplete vital registration data together with sample registration systems cover 72% of global mortality. Survey data and indirect demographic techniques provide information on levels of child and adult mortality for the remaining 28% of estimated global mortality.

Data on causes of death have been analysed to take into account incomplete coverage of vital registration in countries and the likely differences in cause-of-death patterns that would be expected in the uncovered and often poorer subpopulations (*4*). For example, the patterns of causes of death in China and India were based on existing mortality registration systems. In China, the disease surveillance points system and the vital registration system of the Ministry of Health were used. In India, mortality data from the medical certificate of cause of death were used for urban areas and the annual survey of cause of death was employed for rural areas.

For all other countries lacking vital registration data, cause-of-death models were used for an initial estimate of the maximum likelihood distribution of deaths across the broad categories of communicable and noncommunicable diseases and injuries, based on estimated total mortality rates and income. A regional model pattern of specific causes of death was then constructed based on local vital registration and verbal autopsy data and this proportionate distribution was then applied within each broad group of causes. Finally, the resulting estimates were adjusted based on other epidemiological evidence from studies on specific diseases and injuries.

Special attention has been paid to problems of misattribution or miscoding of causes of death. The category ''Injury undetermined whether accidentally or purposely inflicted'' (E980–E989 in the 3-digit ICD-9 codes or Y10–Y34 in ICD-10) can often include a significant share of deaths due to injury. Except where more detailed local information is available, these deaths have been proportionately allocated to the other injury causes of death.

Global and regional rankings of DALYs

The DALY measure is used to quantify the burden of disease (*3, 10*). The DALY is a health-gap measure that combines information on the number of years of life lost from premature death with the loss of health from disability.

Years lived with disability (YLDs) are the disability component of DALYs. YLDs measure the equivalent healthy years of life lost as a result of disabling sequelae of diseases and injuries. They require estimation of incidence, average duration of disability and disability weights (in the range 0–1).

Many sources of information were used to estimate YLDs for diseases and injuries in the GBD 2000 project. These included national and international surveillance data and disease registries, health survey data, data on use of hospital and medical

services, and international and country-specific epidemiological studies (*4*).

The analysis of the burden of injury in the GBD 2000 project is based on methods developed for the 1990 project. These methods define a case of injury as one severe enough to warrant medical attention or one that leads to death. Estimation of YLDs resulting from injuries was based on analysis of databases of health facility data that recorded both type and nature of injury codes. National databases in Australia, Chile, Mauritius, Sweden and the United States of America were used to develop ratios of death to incidence. These ratios were then applied to extrapolate YLDs from injury deaths for all regions of the world. The death:incidence ratios were quite consistent for developed and developing countries. The proportion of incident cases resulting in long-term disabling sequelae was estimated for each nature of injury category from a review of long-term epidemiological studies of injury outcomes.

To produce the rankings in Table A.6, deaths and disabilities were first divided into three broad groups:

— communicable diseases, maternal causes and conditions arising in the perinatal period, and nutritional deficiencies;
— noncommunicable diseases;
— injuries.

Next, deaths and disabilities were grouped into categories. For example, injuries were divided between unintentional and intentional injuries. Following this level of disaggregation, deaths and disabilities were further divided into subcategories. Unintentional injuries, for example, were subdivided into road traffic injuries, poisonings, falls, fires, drowning and other unintentional injuries, while intentional injuries were subdivided into self-inflicted injuries, interpersonal violence and war-related injuries. The rankings were produced by ordering the subcategories.

The ten leading causes of death and DALYs are reported in Table A.6 for all WHO Member States combined and for each of the six WHO regions. In regions where violence-related deaths and DALYs rank below the ten leading causes, the actual rank order is reported. The DALYs reported in Table A.6 use the standard rates of time discounting (3%) and standard age weights (*3*).

Country-level rates of mortality

The numbers and rates of violence-related mortality reported in Tables A.7–A.10 are for the most recent year between 1990 and 2000 reported to WHO by countries with a population greater than 1 million. For countries with populations under 1 million, an average rate based on the last 3 years of data reported to WHO between 1990 and 2000 is given.

Rates were not calculated where the number of deaths in a particular category was less than 20, though the number of deaths is reported. Age-specific and age-standardized rates are reported. Age-standardized rates are calculated by applying the age-specific rates to the World Standard Population (*11*) and they allow comparison of rates in populations with different age structures.

The population counts used to estimate the rates of mortality for each country in Tables A.7–A.10 are available from the World Health Organization at http://www3.who.int/whosis/whsa/ftp/download.htm.

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TABLE A.1

Population (in thousands) by sex and age group, for all WHO Member States, 2000[a]

Member States by WHO region and income level	Total[b]	Males						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	**6 045 172**	**3 045 375**	**314 256**	**615 986**	**797 048**	**643 148**	**404 000**	**270 937**
High-income	**915 866**	**451 069**	**27 970**	**59 366**	**94 800**	**106 787**	**86 747**	**75 398**
Low-income and middle-income	**5 129 306**	**2 594 306**	**286 286**	**556 619**	**702 249**	**536 361**	**317 253**	**195 539**
African Region (low-income and middle-income)[c]	**639 631**	**318 751**	**54 547**	**87 461**	**88 948**	**48 416**	**25 515**	**13 865**
Algeria	30 291	15 346	1 798	3 601	4 724	2 959	1 425	839
Angola	13 134	6 499	1 300	1 867	1 683	888	493	269
Benin	6 272	3 092	557	900	839	441	227	127
Botswana	1 541	755	113	214	234	118	50	26
Burkina Faso	11 535	5 576	1 114	1 713	1 531	658	332	227
Burundi	6 356	3 088	559	955	837	423	211	104
Cameroon	14 876	7 405	1 182	2 046	2 099	1 089	609	381
Cape Verde	427	199	31	54	62	38	5	9
Central African Republic	3 717	1 811	304	494	489	268	158	98
Chad	7 885	3 900	749	1 087	1 031	557	302	174
Comoros	706	354	59	95	104	55	27	13
Congo	3 018	1 478	282	413	391	212	113	68
Côte d'Ivoire	16 013	8 206	1 219	2 166	2 317	1 301	785	417
Democratic Republic of the Congo	50 948	25 245	5 043	7 427	6 522	3 414	1 834	1 005
Equatorial Guinea	457	225	40	60	58	35	20	12
Eritrea	3 659	1 817	311	496	488	287	156	78
Ethiopia	62 908	31 259	5 628	8 629	8 284	4 730	2 617	1 372
Gabon	1 230	609	98	150	147	95	69	49
Gambia	1 303	644	103	159	165	118	66	32
Ghana	19 306	9 613	1 421	2 555	2 836	1 526	823	452
Guinea	8 154	4 102	733	1 087	1 129	646	338	169
Guinea-Bissau	1 199	591	105	156	154	93	53	31
Kenya	30 669	15 273	2 367	4 333	4 697	2 251	1 023	602
Lesotho	2 035	1 009	148	256	281	167	99	59
Liberia	2 913	1 465	277	347	499	183	99	61
Madagascar	15 970	7 943	1 436	2 140	2 122	1 248	646	350
Malawi	11 308	5 617	1 038	1 609	1 534	783	420	233
Mali	11 351	5 624	1 081	1 552	1 531	778	394	287
Mauritania	2 665	1 321	236	354	361	203	110	56
Mauritius	1 161	579	48	103	154	145	84	45
Mozambique	18 292	9 042	1 589	2 426	2 475	1 377	753	421
Namibia	1 757	868	142	245	242	132	64	44
Niger	10 832	5 459	1 157	1 584	1 457	746	352	162
Nigeria	113 862	57 383	9 996	16 068	15 825	8 410	4 546	2 538
Rwanda	7 609	3 765	642	1 040	1 137	540	267	140
Sao Tome and Principe	138	64	10	17	20	12	2	3
Senegal	9 421	4 697	805	1 303	1 296	731	385	178
Seychelles	80	40	3	7	11	10	6	3
Sierra Leone	4 405	2 165	403	568	580	336	185	94
South Africa	43 309	21 323	2 608	4 784	6 334	4 340	2 270	986
Swaziland	925	456	70	123	130	72	39	22
Togo	4 527	2 248	386	620	628	335	178	100
Uganda	23 300	11 625	2 358	3 393	3 181	1 515	774	403
United Republic of Tanzania	35 119	17 422	3 015	4 937	4 960	2 552	1 319	639
Zambia	10 421	5 236	954	1 497	1 501	701	369	214
Zimbabwe	12 627	6 315	1 030	1 831	1 864	898	418	273
Region of the Americas (high-income)	**314 291**	**155 035**	**11 201**	**23 350**	**32 303**	**37 526**	**28 679**	**21 977**
Bahamas	304	150	15	30	42	35	17	11
Canada	30 757	15 229	920	2 095	3 166	3 817	2 953	2 277
United States of America	283 230	139 655	10 265	21 225	29 095	33 674	25 709	19 689

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Member States by WHO region and income level	Females						
	All ages	**0–4 years**	**5–14 years**	**15–29 years**	**30–44 years**	**45–59 years**	**⩾60 years**
All	**2 999 797**	**297 863**	**582 630**	**761 707**	**621 685**	**402 225**	**333 687**
High-income	**464 797**	**26 478**	**56 255**	**90 803**	**103 963**	**87 204**	**100 094**
Low-income and middle-income	**2 535 000**	**271 385**	**526 375**	**670 904**	**517 722**	**315 021**	**233 593**
African Region (low-income and middle-income)[c]	**320 880**	**53 609**	**86 331**	**88 370**	**48 701**	**27 079**	**16 790**
Algeria	14 945	1 721	3 435	4 515	2891	1 392	992
Angola	6 635	1 292	1 867	1 700	919	534	324
Benin	3 180	551	899	849	503	242	137
Botswana	787	111	211	232	121	68	44
Burkina Faso	5 959	1 096	1 694	1 642	779	417	331
Burundi	3 268	555	955	857	459	272	170
Cameroon	7 471	1 163	2 021	2 088	1 097	652	451
Cape Verde	228	30	53	65	48	14	18
Central African Republic	1 907	304	497	511	286	181	128
Chad	3 985	743	1 085	1 043	574	328	212
Comoros	352	57	92	103	55	29	16
Congo	1 540	281	420	405	223	126	86
Côte d'Ivoire	7 807	1 202	2 157	2 279	1 141	648	380
Democratic Republic of the Congo	25 703	4 984	7 392	6 532	3 479	2 012	1 304
Equatorial Guinea	231	40	60	58	36	22	15
Eritrea	1 842	306	494	490	293	165	94
Ethiopia	31 649	5 568	8 589	8 287	4 815	2 787	1 602
Gabon	621	97	149	148	96	73	58
Gambia	658	103	159	169	123	69	36
Ghana	9 692	1 397	2 527	2 827	1 545	871	525
Guinea	4 052	715	1 057	1 101	637	348	194
Guinea-Bissau	608	105	156	156	96	57	37
Kenya	15 396	2 330	4 301	4 697	2 284	1 103	681
Lesotho	1 026	145	250	276	170	109	75
Liberia	1 448	274	346	491	168	97	72
Madagascar	8 028	1 430	2 137	2 122	1 258	675	406
Malawi	5 692	1 016	1 576	1 513	811	485	291
Mali	5 727	1 061	1 540	1 527	788	445	365
Mauritania	1 344	234	352	360	210	117	70
Mauritius	583	47	100	149	140	88	59
Mozambique	9 251	1 589	2 434	2 482	1 407	825	515
Namibia	889	140	242	238	136	77	56
Niger	5 373	1 128	1 532	1 410	737	372	193
Nigeria	56 479	9 688	15 549	15 357	8 304	4 700	2 881
Rwanda	3 844	642	1 047	1 150	537	289	179
Sao Tome and Principe	73	10	17	21	15	4	6
Senegal	4 723	787	1 281	1 292	741	405	218
Seychelles	40	3	7	10	10	6	4
Sierra Leone	2 239	403	575	591	350	203	116
South Africa	21 986	2 569	4 773	6 369	4 356	2 443	1 476
Swaziland	469	69	123	132	75	42	27
Togo	2 279	381	617	629	340	192	120
Uganda	11 676	2 333	3 382	3 171	1 480	827	482
United Republic of Tanzania	17 697	2 960	4 889	5 020	2 637	1 425	767
Zambia	5 185	933	1 465	1 466	669	393	259
Zimbabwe	6 313	1 021	1 826	1 841	858	446	320
Region of the Americas (high-income)	**159 256**	**10 666**	**22 263**	**31 189**	**36 916**	**29 301**	**28 922**
Bahamas	154	15	29	41	36	20	14
Canada	15 527	874	1 993	3 040	3 773	2 987	2 860
United States of America	143 575	9 777	20 240	28 108	33 108	26 294	26 048

TABLE A.1 *(continued)*

Member States by WHO region and income level	Total[b]	Males						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Region of the Americas (low-income and middle-income)	**513 081**	**254 252**	**27 942**	**54 610**	**72 444**	**51 530**	**29 507**	**18 219**
Antigua and Barbuda	65	32	3	7	9	7	4	3
Argentina	37 032	18 163	1 779	3 436	4 785	3 454	2 612	2 098
Barbados	267	130	9	19	33	35	19	14
Belize	226	115	15	29	34	20	10	7
Bolivia	8 329	4 144	617	1 063	1 155	683	393	233
Brazil	170 406	84 169	8 145	16 804	24 344	18 495	10 440	5 941
Chile	15 211	7 531	734	1 469	1 865	1 737	1 057	669
Colombia	42 105	20 786	2 429	4 608	5 758	4 375	2 318	1 297
Costa Rica	4 024	2 040	226	441	557	438	236	142
Cuba	11 199	5 611	368	850	1 310	1 432	918	733
Dominica	71	35	3	7	9	7	4	3
Dominican Republic	8 373	4 254	479	950	1 215	876	466	268
Ecuador	12 646	6 350	747	1 429	1 857	1 239	668	410
El Salvador	6 278	3 082	407	731	954	495	293	201
Grenada	94	46	5	9	13	10	6	4
Guatemala	11 385	5 741	942	1 593	1 637	828	448	292
Guyana	761	369	41	76	118	74	36	23
Haiti	8 142	3 989	578	1 099	1 179	601	326	206
Honduras	6 417	3 230	491	874	935	524	252	153
Jamaica	2 576	1 270	134	278	370	242	132	113
Mexico	98 872	48 926	5 705	11 012	14 605	9 374	5 094	3 136
Nicaragua	5 071	2 523	408	691	741	389	189	105
Panama	2 856	1 441	154	303	393	302	176	113
Paraguay	5 496	2 772	394	711	761	509	267	129
Peru	25 662	12 726	1 475	2 877	3 743	2 399	1 368	865
Saint Kitts and Nevis	38	19	2	4	5	4	2	2
Saint Lucia	148	72	9	16	22	14	7	5
Saint Vincent and the Grenadines	113	56	6	11	15	12	7	5
Suriname	417	207	20	44	65	45	17	15
Trinidad and Tobago	1 294	644	45	119	188	143	91	57
Uruguay	3 337	1 619	145	278	396	318	244	239
Venezuela	24 170	12 161	1 429	2 771	3 371	2 449	1 404	737
South-East Asia Region (low-income and middle-income)[c]	**1 535 634**	**786 265**	**90 144**	**172 450**	**218 856**	**160 218**	**90 548**	**54 049**
Bangladesh	137 439	70 858	9 562	17 773	20 431	13 252	6 434	3 405
Bhutan	2 085	1 054	167	287	281	157	98	64
Democratic People's Republic of Korea	22 268	11 179	987	2 030	2 789	2 728	1 644	1 001
India	1 008 937	520 312	60 014	114 668	142 803	105 142	60 892	36 792
Indonesia	212 092	106 379	11 094	22 082	31 038	22 647	12 123	7 394
Maldives	291	149	24	41	41	23	12	8
Myanmar	47 749	23 729	2 740	5 246	6 885	4 655	2 696	1 507
Nepal	23 043	11 811	1 833	3 052	3 184	1 923	1 150	669
Sri Lanka	18 924	9 718	794	1 734	2 629	2 214	1 449	898
Thailand	62 806	31 078	2 928	5 536	8 776	7 476	4 049	2 312
European Region (high-income)	**394 607**	**193 120**	**10 797**	**23 462**	**39 208**	**46 232**	**37 098**	**36 323**
Andorra	86	45	2	5	10	13	8	7
Austria	8 080	3 942	209	481	768	1 046	759	680
Belgium	10 249	5 020	282	624	978	1 198	971	966
Denmark	5 320	2 633	169	330	499	607	564	464
Finland	5 172	2 523	148	329	492	569	566	420
France	59 238	28 856	1 862	3 817	6 081	6 431	5 526	5 138
Germany	82 017	40 148	1 965	4 583	7 254	10 564	7 897	7 885
Greece	10 610	5 230	259	565	1 161	1 158	965	1 122

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Member States by WHO region and income level	Females						
	All ages	**0–4 years**	**5–14 years**	**15–29 years**	**30–44 years**	**45–59 years**	**⩾60 years**
Region of the Americas (low-income and middle-income)	**258 829**	**26 872**	**52 717**	**71 810**	**53 591**	**31 566**	**22 273**
Antigua and Barbuda	33	3	6	8	7	4	3
Argentina	18 868	1 720	3 330	4 691	3 509	2 780	2 839
Barbados	138	8	19	33	35	21	22
Belize	112	14	28	34	20	9	7
Bolivia	4 185	593	1 026	1 149	711	426	280
Brazil	86 238	7 860	16 268	24 223	19 206	11 301	7 380
Chile	7 680	707	1 418	1 821	1 742	1 110	882
Colombia	21 319	2 331	4 438	5 727	4 669	2 555	1 599
Costa Rica	1 983	216	420	528	426	235	158
Cuba	5 588	350	809	1 258	1 423	953	796
Dominica	36	3	7	9	8	5	4
Dominican Republic	4 119	461	915	1 150	841	468	284
Ecuador	6 296	719	1 383	1 812	1 231	684	466
El Salvador	3 196	390	707	949	573	327	250
Grenada	47	4	9	12	10	6	5
Guatemala	5 645	903	1 527	1 593	852	460	310
Guyana	392	40	75	119	86	43	30
Haiti	4 153	557	1 072	1 187	683	402	253
Honduras	3 187	472	844	910	526	261	173
Jamaica	1 307	129	270	367	268	139	134
Mexico	49 946	5 463	10 590	14 694	10 008	5 483	3 707
Nicaragua	2 548	393	669	742	414	203	127
Panama	1 415	147	290	384	302	174	118
Paraguay	2 725	379	688	740	495	259	164
Peru	12 935	1421	2794	3727	2560	1442	992
Saint Kitts and Nevis	19	2	4	5	4	3	2
Saint Lucia	75	8	15	22	15	8	7
Saint Vincent and the Grenadines	57	5	11	15	12	8	6
Suriname	210	20	43	63	46	20	19
Trinidad and Tobago	651	43	116	185	147	93	67
Uruguay	1 718	139	266	383	331	265	334
Venezuela	12 009	1 368	2 659	3 271	2 433	1 421	857
South-East Asia Region (low-income and middle-income)[c]	**749 369**	**85 306**	**162 342**	**204 600**	**149 046**	**88 487**	**59 589**
Bangladesh	66 582	9 090	16 765	19 111	12 132	6 093	3 391
Bhutan	1 032	160	276	271	153	99	71
Democratic People's Republic of Korea	11 090	945	1 940	2 675	2 629	1 665	1 236
India	488 626	56 384	106 854	131 070	95 662	58 596	40 060
Indonesia	105 713	10 688	21 367	30 239	22 054	12 615	8 750
Maldives	142	23	39	39	22	11	7
Myanmar	24 020	2 667	5 154	6 866	4 752	2 848	1 734
Nepal	11 232	1 730	2 839	2 968	1 878	1 125	692
Sri Lanka	9 206	767	1 681	2 546	2 113	1 238	861
Thailand	31 728	2 851	5 426	8 815	7 650	4 197	2 788
European Region (high-income)	**201 490**	**10 224**	**22 287**	**37 512**	**45 016**	**37 338**	**49 109**
Andorra	41	2	4	9	12	7	7
Austria	4 138	198	456	739	992	758	996
Belgium	5 229	269	596	944	1 159	959	1 302
Denmark	2 687	159	314	481	581	553	600
Finland	2 649	141	315	472	549	560	612
France	30 382	1 771	3 648	5 875	6 483	5 584	7 021
Germany	41 869	1 861	4 330	6 838	9 876	7 778	11 184
Greece	5 380	242	532	1 104	1 158	982	1 361

TABLE A.1 *(continued)*

Member States by WHO region and income level	Total[b]	Males						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
European Region (high-income) ***(continued)***								
Iceland	279	140	11	23	32	31	24	19
Ireland	3803	1890	136	286	502	384	324	258
Israel	6 040	2 980	316	560	773	561	429	341
Italy	57 530	27 902	1 350	2 870	5 665	6 676	5 434	5 908
Luxembourg	437	215	14	28	42	53	42	36
Monaco	33	16	1	2	3	4	3	3
Netherlands	15 864	7 862	480	1 005	1 520	1 992	1 616	1 249
Norway	4 469	2 213	149	305	437	509	437	376
Portugal	10 016	4 819	288	569	1 159	1 065	860	879
San Marino	27	13	1	1	3	3	3	3
Spain	39 910	19 511	939	2 088	4 657	4 634	3 454	3 738
Sweden	8 842	4 375	226	599	817	941	921	870
Switzerland	7 170	3 546	187	424	619	896	764	655
United Kingdom	59 415	29 242	1 804	3 972	5 733	6 896	5 529	5 307
European Region (low-income and middle-income)	**478 968**	**230 651**	**15 396**	**38 477**	**59 421**	**51 974**	**36 583**	**28 800**
Albania	3 134	1 603	159	326	418	365	203	131
Armenia	3 787	1 834	106	356	496	433	231	212
Azerbaijan	8 041	3 959	314	886	1 083	935	392	350
Belarus	10 187	4 746	241	732	1 153	1 150	793	677
Bosnia and Herzegovina	3 977	1 968	106	283	462	521	342	254
Bulgaria	7 949	3 864	162	479	890	813	773	747
Croatia	4 654	2 253	138	292	486	527	434	377
Czech Republic	10 272	4 995	231	633	1 229	1 045	1 096	761
Estonia	1 393	649	31	95	155	150	118	99
Georgia	5 262	2 512	153	399	611	575	379	395
Hungary	9 968	4 756	251	613	1 149	1 001	983	758
Kazakhstan	16 172	7 844	648	1 570	2 131	1 807	1 011	676
Kyrgyzstan	4 921	2 413	265	579	676	486	230	177
Latvia	2 421	1 116	48	168	261	265	203	171
Lithuania	3 696	1 743	95	272	412	423	289	252
Malta	390	193	12	28	44	40	40	28
Poland	38 605	18 761	1 024	2 767	4 772	4 143	3 498	2 557
Republic of Moldova	4 295	2 054	133	375	539	453	325	229
Romania	22 438	10 977	584	1 511	2 760	2 376	1 930	1 816
Russian Federation	145 491	68 130	3 254	10 103	16 713	16 737	11 983	9 339
Slovakia	5 399	2 625	148	391	686	590	479	331
Slovenia	1 988	966	46	116	222	230	201	151
Tajikistan	6 087	3 032	393	822	852	551	232	182
The former Yugoslav Republic of Macedonia	2 034	1 017	75	162	249	226	172	133
Turkey	66 668	33 676	3 614	6 581	10 002	6 843	4 024	2 612
Turkmenistan	4 737	2 345	305	598	653	463	197	128
Ukraine	49 568	23 019	1 122	3 397	5 549	5 281	4 011	3 659
Uzbekistan	24 881	12 357	1 407	3 182	3 538	2 436	1 045	749
Yugoslavia	10 552	5 248	332	762	1 226	1 109	970	848
Eastern Mediterranean Region (high-income)	**5 870**	**3 594**	**230**	**597**	**783**	**1 000**	**763**	**221**
Cyprus	784	391	28	66	89	85	69	55
Kuwait	1 914	1 115	73	231	287	261	205	57
Qatar	565	366	27	50	62	141	74	13
United Arab Emirates	2 606	1 722	102	250	345	513	414	97
Eastern Mediterranean Region (low-income and middle-income)	**475 785**	**242 847**	**34 697**	**62 275**	**67 412**	**41 988**	**23 809**	**12 666**
Afghanistan	21 765	11 227	1 954	2 923	3 018	1 814	1 008	510

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Member States by WHO region and income level	Females						
	All ages	**0–4 years**	**5–14 years**	**15–29 years**	**30–44 years**	**45–59 years**	**⩾60 years**
European Region (high-income) ***(continued)***							
Iceland	139	10	21	31	31	23	23
Ireland	1 913	128	270	481	393	321	321
Israel	3 060	298	533	737	581	458	453
Italy	29 628	1 271	2 726	5 460	6 631	5 603	7 937
Luxembourg	222	13	26	41	52	40	49
Monaco	17	1	2	3	4	3	4
Netherlands	8 002	457	960	1 464	1 904	1 567	1 649
Norway	2 256	141	289	420	487	422	498
Portugal	5 197	272	542	1 132	1 098	943	1 210
San Marino	14	1	1	3	3	3	4
Spain	20 400	877	1 970	4 462	4 584	3 555	4 952
Sweden	4 467	214	569	781	898	896	1 109
Switzerland	3 624	178	405	589	837	743	871
United Kingdom	30 173	1 719	3 778	5 447	6 704	5 578	6 947
European Region (low-income and middle-income)	**248 317**	**14 736**	**36 869**	**57 486**	**52 418**	**40 312**	**46 495**
Albania	1 531	150	305	391	346	189	150
Armenia	1 953	101	336	479	477	274	286
Azerbaijan	4 082	296	836	1 024	996	437	493
Belarus	5 441	227	704	1 147	1 205	911	1 248
Bosnia and Herzegovina	2 009	99	266	437	511	357	339
Bulgaria	4 086	155	457	852	815	831	976
Croatia	2 401	131	279	469	518	442	562
Czech Republic	5 276	220	602	1 178	1 015	1 136	1 125
Estonia	745	30	91	151	151	140	182
Georgia	2 750	146	379	587	611	437	591
Hungary	5 212	239	586	1 099	995	1 084	1 209
Kazakhstan	8 329	625	1 520	2 094	1 818	1 141	1 131
Kyrgyzstan	2 508	259	567	670	497	249	266
Latvia	1 305	46	160	254	269	242	334
Lithuania	1 953	91	261	400	427	341	434
Malta	197	12	26	41	39	40	38
Poland	19 844	970	2 634	4 594	4 080	3 724	3 843
Republic of Moldova	2 242	126	360	533	485	379	358
Romania	11 461	553	1 447	2 659	2 351	2 044	2 406
Russian Federation	77 361	3 108	9 657	16 269	16 974	13 768	17 584
Slovakia	2 773	141	374	662	580	515	501
Slovenia	1 022	44	110	212	228	198	230
Tajikistan	3 055	381	801	836	573	232	233
The former Yugoslav Republic of Macedonia	1 017	70	153	238	220	176	160
Turkey	32 992	3 494	6 332	9 528	6 659	3 960	3 019
Turkmenistan	2 393	296	583	646	477	212	179
Ukraine	26 549	1 068	3 254	5 399	5 527	4 775	6 526
Uzbekistan	12 524	1 354	3 079	3 487	2 506	1 089	1 009
Yugoslavia	5 305	308	710	1 148	1 068	988	1 083
Eastern Mediterranean Region (high-income)	**2 276**	**219**	**563**	**627**	**440**	**289**	**137**
Cyprus	393	26	62	85	83	70	68
Kuwait	800	71	224	262	126	88	28
Qatar	199	26	48	46	51	23	5
United Arab Emirates	884	96	229	234	180	108	37
Eastern Mediterranean Region (low-income and middle-income)	**232 939**	**33 023**	**59 158**	**64 526**	**39 940**	**22 641**	**13 650**
Afghanistan	10 538	1 852	2 736	2 796	1 679	955	519

TABLE A.1 *(continued)*

Member States by WHO region and income level	Total[b]	Males						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Eastern Mediterranean Region (low-income and middle-income) *(continued)*								
Bahrain	640	368	29	63	75	120	64	16
Djibouti	632	297	52	86	80	38	28	14
Egypt	67 884	34 364	4 096	8 182	9 788	6 652	3 721	1 925
Iraq	22 946	11 666	1 817	3 063	3 329	1 939	1 018	501
Islamic Republic of Iran	70 330	35 998	3 882	9 640	10 578	6 420	3 702	1 776
Jordan	4 913	2 554	390	618	780	459	194	113
Lebanon	3 496	1 711	171	384	498	357	163	137
Libyan Arab Jamahiriya	5 290	2 741	329	589	877	473	316	157
Morocco	29 878	14 964	1 832	3 441	4 457	2 948	1 429	856
Oman	2 538	1 347	206	363	334	223	166	55
Pakistan	141 256	72 622	11 427	18 985	19 041	11 856	7 234	4 080
Saudi Arabia	20 346	10 872	1 630	2 835	2 682	1 731	1 471	523
Somalia	8 778	4 358	897	1 216	1 154	619	314	158
Sudan	31 095	15 639	2 412	3 943	4 390	2 645	1 456	792
Syrian Arab Republic	16 189	8 200	1 146	2 228	2 488	1 400	575	363
Tunisia	9 459	4 776	430	1 013	1 441	986	511	396
Yemen	18 349	9 142	1 996	2 703	2 402	1 308	439	294
Western Pacific Region (high-income)	**201 099**	**99 320**	**5 743**	**11 957**	**22 505**	**22 029**	**20 208**	**16 878**
Australia	19 138	9 529	648	1 368	2 127	2 176	1 788	1 421
Brunei Darussalam	328	173	18	36	41	44	25	9
Japan	127 096	62 212	3 159	6 424	13 293	12 493	14 004	12 839
New Zealand	3 778	1 861	142	302	393	424	335	265
Republic of Korea	46 740	23 522	1 631	3 517	6 239	6 309	3 679	2 147
Singapore	4 018	2 023	145	310	412	583	376	197
Western Pacific Region (low-income and middle-income)	**1 486 206**	**761 540**	**63 560**	**141 345**	**195 168**	**182 236**	**111 291**	**67 940**
Cambodia	13 104	6 389	1 070	1 846	1 700	1 050	518	205
China	1 282 437	659 410	51 092	116 265	165 941	162 699	101 353	62 059
Cook Islands	20	10	1	2	3	2	1	1
Federated States of Micronesia	123	64	9	15	16	12	7	4
Fiji	814	414	50	90	118	85	49	22
Kiribati	83	43	6	10	11	8	5	3
Lao People's Democratic Republic	5 279	2 636	426	722	719	420	210	139
Malaysia	22 218	11 255	1 350	2 541	3 029	2 286	1 357	692
Marshall Islands	51	26	4	6	7	5	3	2
Mongolia	2 533	1 268	139	315	387	259	105	63
Nauru	12	6	1	2	2	1	1	<1
Niue	2	1	<1	<1	<1	<1	<1	<1
Palau	19	10	1	2	2	2	1	1
Papua New Guinea	4 809	2 507	366	635	746	436	223	101
Philippines	75 653	38 092	5 031	9 474	10 973	6 925	3 785	1 903
Samoa	159	83	11	23	27	12	6	5
Solomon Islands	447	230	41	63	66	33	18	10
Tonga	99	52	6	12	15	10	6	3
Tuvalu	10	5	1	1	2	1	1	<1
Vanuatu	197	101	16	27	27	17	9	5
Viet Nam	78 137	38 938	3 939	9 293	11 379	7 973	3 633	2 722

Source: United Nations, 2001.

[a] Numbers are rounded to the nearest 1000. Any apparent discrepancies in total sums are a result of rounding.

[b] Combined total for males and females.

[c] No high-income countries in the region.

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Member States by WHO region and income level	Females						
	All ages	**0–4 years**	**5–14 years**	**15–29 years**	**30–44 years**	**45–59 years**	**⩾60 years**
Eastern Mediterranean Region (low-income and middle-income) ***(continued)***							
Bahrain	272	28	60	68	72	30	14
Djibouti	335	51	85	83	53	43	21
Egypt	33 521	3 915	7 811	9 197	6 367	3 871	2 359
Iraq	11 280	1 739	2 935	3 178	1 875	1 001	553
Islamic Republic of Iran	34 332	3 672	9 107	10 154	6 007	3 496	1 895
Jordan	2 359	372	588	713	392	184	110
Lebanon	1 786	164	370	489	404	197	162
Libyan Arab Jamahiriya	2 549	314	563	848	444	248	133
Morocco	14 914	1 764	3 318	4 307	2 966	1 511	1 049
Oman	1 191	198	352	325	170	94	52
Pakistan	68 634	10 783	17 826	18 240	11 178	6 542	4 065
Saudi Arabia	9 474	1 556	2 713	2 590	1 330	831	453
Somalia	4 420	890	1 206	1 164	639	336	184
Sudan	15 457	2 316	3 803	4 284	2 641	1 507	905
Syrian Arab Republic	7 988	1 093	2 144	2 417	1 340	593	401
Tunisia	4 682	403	964	1 387	1 005	522	402
Yemen	9 207	1 914	2 575	2 285	1 378	680	375
Western Pacific Region (high-income)	**101 778**	**5 368**	**11 142**	**21 475**	**21 591**	**20 276**	**21 926**
Australia	9 608	615	1 296	2 052	2 179	1 762	1 705
Brunei Darussalam	156	17	34	38	39	19	8
Japan	64 884	2 993	6 118	12 730	12 229	14 135	16 679
New Zealand	1 917	135	288	383	452	337	323
Republic of Korea	23 218	1 474	3 118	5 883	6 107	3 653	2 984
Singapore	1 995	135	289	388	585	370	227
Western Pacific Region (low-income and middle-income)	**724 667**	**57 838**	**128 958**	**184 113**	**174 027**	**104 936**	**74 795**
Cambodia	6 715	1 037	1 797	1 681	1 170	665	366
China	623 027	45 892	104 807	155 577	154 205	94 679	67 867
Cook Islands	9	1	2	3	2	1	1
Federated States of Micronesia	59	8	15	15	11	6	4
Fiji	400	47	85	112	82	50	25
Kiribati	40	6	10	10	7	4	3
Lao People's Democratic Republic	2 643	410	698	705	441	231	157
Malaysia	10 964	1 280	2 405	2 925	2 269	1 314	771
Marshall Islands	25	4	6	6	4	3	2
Mongolia	1 265	133	305	380	262	108	78
Nauru	6	1	1	1	1	1	<1
Niue	1	<1	<1	<1	<1	<1	<1
Palau	9	1	2	2	2	1	1
Papua New Guinea	2 303	344	583	637	422	217	98
Philippines	37 561	4 800	9 090	10 641	6 901	3 837	2 293
Samoa	75	11	21	22	9	6	6
Solomon Islands	217	38	59	61	34	17	9
Tonga	47	6	11	13	9	5	4
Tuvalu	5	1	1	1	1	1	<1
Vanuatu	96	14	25	26	17	8	5
Viet Nam	39 199	3 804	9 034	11 295	8 179	3 782	3 106

TABLE A.2

Estimated mortality caused by intentional injury,[a] by sex, age group, WHO region and income level, 2000

Absolute numbers (in thousands)[b]

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	1 659	1 153	41	54	351	320	205	182
	high	149	111	1	1	24	31	27	27
	low and middle	1 510	1 042	40	54	326	288	178	156
African Region[d]	low and middle	311	225	17	23	72	57	31	25
Region of the Americas	all	228	196	2	3	87	60	28	17
	high	56	44	<1	1	13	14	9	7
	low and middle	171	152	1	2	74	46	19	10
South-East Asia Region[d]	low and middle	317	216	5	15	69	59	38	29
European Region	all	303	239	2	5	53	78	58	44
	high	55	41	<1	<1	7	11	10	12
	low and middle	248	198	2	5	46	67	48	31
Eastern Mediterranean Region	all	95	62	14	5	20	11	7	5
	high	1	<1	<1	<1	<1	<1	<1	<1
	low and middle	95	61	14	5	20	11	7	5
Western Pacific Region	all	405	216	1	4	50	55	44	62
	high	37	26	<1	<1	4	6	8	7
	low and middle	368	190	1	4	45	48	36	55

Rate per 100 000 population

WHO region	Income level	Total[c, e]	Males						
			All ages[e]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	28.8	40.5	13.0	8.8	44.0	49.7	50.7	67.4
	high	14.4	22.1	2.2	1.5	25.7	29.4	31.3	35.8
	low and middle	32.1	44.8	14.1	9.6	46.5	53.8	56.0	79.6
African Region[d]	low and middle	60.9	94.6	31.2	25.9	80.9	118.0	119.7	182.5
Region of the Americas	all	27.7	48.6	3.8	3.4	83.2	67.2	48.0	43.1
	high	17.2	27.6	4.0	2.4	41.8	36.3	30.7	33.7
	low and middle	34.3	62.1	3.8	3.8	101.7	89.7	64.9	54.5
South-East Asia Region[d]	low and middle	22.8	31.3	6.0	8.9	31.7	36.6	41.8	54.1
European Region	all	32.0	52.5	6.5	7.9	53.7	79.6	78.1	67.0
	high	11.5	17.8	0.9	0.7	16.6	24.7	26.7	34.3
	low and middle	49.6	83.7	10.4	12.4	78.1	128.4	130.2	108.3
Eastern Mediterranean Region	all	21.6	27.4	39.9	7.3	29.1	26.6	27.2	40.8
	high	10.3	13.9	3.9	3.3	19.0	17.6	12.3	20.2
	low and middle	21.8	27.7	40.2	7.3	29.2	26.9	27.7	41.2
Western Pacific Region	all	24.3	26.5	1.9	2.8	22.7	26.7	33.6	72.9
	high	15.4	22.3	1.1	1.2	18.7	27.9	41.3	41.8
	low and middle	26.2	27.7	2.0	3.0	23.2	26.6	32.2	80.6

Proportion of all deaths due to injury (%)

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	32.8	33.8	15.0	20.0	39.8	38.7	34.7	31.9
	high	31.6	35.7	12.8	14.9	37.2	42.7	41.9	26.1
	low and middle	32.9	33.6	15.1	20.1	40.0	38.3	33.8	33.2
African Region[d]	low and middle	41.3	43.9	23.7	29.7	56.3	53.4	43.8	43.0
Region of the Americas	all	40.6	44.9	8.7	17.6	57.7	50.2	41.2	26.0
	high	33.1	37.9	19.6	19.6	46.2	42.8	39.9	25.7
	low and middle	43.9	47.5	7.1	17.1	60.4	52.9	41.8	26.3
South-East Asia Region[d]	low and middle	23.1	24.3	7.9	18.7	28.1	28.4	26.1	21.1
European Region	all	37.1	39.3	16.0	29.7	41.7	43.2	39.2	34.6
	high	29.4	33.7	8.1	10.0	28.9	44.0	42.8	27.1
	low and middle	39.4	40.7	17.0	31.9	44.5	43.1	38.5	38.9

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Absolute numbers (in thousands)[b]

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	506	23	37	153	119	77	97
	high	38	<1	1	6	10	9	12
	low and middle	468	23	37	147	109	68	85
African Region[d]	low and middle	86	12	13	32	15	9	6
Region of the Americas	all	31	1	1	11	9	5	4
	high	12	<1	<1	3	4	3	2
	low and middle	19	1	1	8	5	2	2
South-East Asia Region[d]	low and middle	101	4	13	37	23	13	12
European Region	all	64	1	1	11	17	14	21
	high	15	<1	<1	2	3	4	6
	low and middle	50	1	1	9	13	11	15
Eastern Mediterranean Region	all	34	4	5	12	5	3	4
	high	<1	<1	<1	<1	<1	<1	<1
	low and middle	34	4	5	12	5	3	4
Western Pacific Region	all	189	1	3	50	50	33	52
	high	11	<1	<1	2	2	3	5
	low and middle	178	1	3	48	47	31	47

Rate per 100 000 population

WHO region	Income level	Females						
		All ages[e]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	17.3	7.7	6.4	20.1	19.1	19.1	29.2
	high	6.9	1.8	0.9	6.7	9.2	10.3	12.2
	low and middle	19.7	8.3	7.0	21.9	21.1	21.5	36.5
African Region[d]	low and middle	29.6	21.9	14.6	36.1	31.5	32.2	36.4
Region of the Americas	all	7.5	2.7	1.8	10.5	10.1	8.4	7.2
	high	7.1	3.2	1.4	8.2	10.8	9.3	6.6
	low and middle	7.6	2.6	2.0	11.5	9.6	7.5	7.9
South-East Asia Region[d]	low and middle	14.3	4.3	8.3	18.2	15.2	14.2	19.7
European Region	all	12.5	3.3	2.1	11.3	17.2	18.4	21.6
	high	5.7	0.7	0.5	4.4	7.5	9.7	11.7
	low and middle	18.3	5.2	3.1	15.7	25.5	26.5	31.9
Eastern Mediterranean Region	all	15.5	13.1	8.7	19.1	12.9	11.6	27.2
	high	4.4	2.1	0.7	5.7	6.0	4.0	6.1
	low and middle	15.7	13.2	8.8	19.2	13.0	11.7	27.4
Western Pacific Region	all	22.5	2.2	2.4	24.5	25.3	26.6	53.3
	high	8.8	1.3	0.9	8.4	9.9	12.8	21.0
	low and middle	25.0	2.3	2.5	26.3	27.2	29.2	62.8

Proportion of all deaths due to injury (%)

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	30.7	10.3	18.1	42.9	42.3	37.3	26.0
	high	24.4	14.8	17.1	35.2	45.3	43.1	13.7
	low and middle	31.4	10.2	18.1	43.3	42.0	36.6	29.9
African Region[d]	low and middle	35.8	19.0	27.2	60.8	44.3	36.8	27.4
Region of the Americas	all	25.3	9.2	18.1	42.1	41.0	32.3	9.0
	high	22.6	22.4	19.6	32.6	39.1	35.0	8.1
	low and middle	27.3	7.1	17.7	46.3	42.6	29.6	10.3
South-East Asia Region[d]	low and middle	20.9	7.9	14.6	29.1	26.5	23.8	14.5
European Region	all	30.8	11.7	18.7	39.1	47.6	38.2	21.6
	high	21.8	8.9	12.9	31.0	50.8	48.1	12.5
	low and middle	35.1	12.1	19.5	41.0	46.8	35.7	30.1

TABLE A.2 *(continued)*

Proportion of all deaths due to injury (%) *(continued)*

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Eastern Mediterranean Region	all	28.2	28.9	41.0	17.9	33.1	28.4	23.2	21.0
	high	19.9	19.5	15.8	17.2	21.4	23.0	15.1	16.6
	low and middle	28.3	29.0	41.1	17.9	33.3	28.5	23.4	21.1
Western Pacific Region	all	33.1	28.5	1.9	7.6	29.3	31.6	33.5	39.3
	high	33.0	33.5	5.0	10.5	32.4	41.5	43.8	25.1
	low and middle	33.2	27.9	1.8	7.5	29.1	30.7	31.8	42.3

Proportion of all deaths (%)

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	3.0	3.9	0.7	7.4	18.6	10.6	4.7	1.3
	high	1.9	2.7	1.4	7.3	26.4	15.7	5.2	0.8
	low and middle	3.2	4.1	0.7	7.4	18.2	10.2	4.6	1.4
African Region[d]	low and middle	2.9	4.1	0.8	10.5	13.8	6.4	5.0	2.7
Region of the Americas	all	3.9	6.2	0.6	7.4	40.3	20.3	6.0	0.9
	high	2.1	3.3	2.2	11.0	35.3	16.7	4.7	0.7
	low and middle	5.4	8.4	0.4	6.8	41.3	21.7	6.8	1.1
South-East Asia Region[d]	low and middle	2.2	2.8	0.3	5.9	12.7	7.4	3.1	0.9
European Region	all	3.1	4.8	1.2	16.2	29.5	19.7	7.0	1.3
	high	1.4	2.1	0.7	4.0	18.8	14.6	4.6	0.8
	low and middle	4.3	6.6	1.3	18.1	32.0	20.9	7.9	1.7
Eastern Mediterranean Region	all	2.4	2.9	1.8	5.9	15.3	6.9	2.6	0.7
	high	2.4	3.0	1.3	9.7	16.2	9.7	2.1	0.5
	low and middle	2.4	2.9	1.8	5.9	15.3	6.9	2.6	0.7
Western Pacific Region	all	3.6	3.4	0.2	3.8	17.3	11.4	4.5	1.6
	high	2.6	3.3	0.8	5.2	22.8	16.4	7.2	1.2
	low and middle	3.7	3.4	0.2	3.7	16.9	11.0	4.2	1.6

Source: WHO Global Burden of Disease project for 2000, Version 1.

[a] Intentional injury = ICD-10 X60–Y09, Y35, Y36 (ICD-9 E950–E978, E990–E999).

[b] Absolute numbers are rounded to the nearest 1000. Any apparent discrepancies in total sums are a result of rounding.

[c] Combined total for males and females.

[d] No high-income countries in the region.

[e] Age-standardized.

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Proportion of all deaths due to injury (%) *(continued)*

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Eastern Mediterranean Region	all	27.1	12.2	25.3	44.7	34.5	27.5	24.7
	high	22.3	13.4	9.3	34.2	26.1	18.0	13.8
	low and middle	27.1	12.2	25.3	44.7	34.6	27.5	24.8
Western Pacific Region	all	40.8	2.3	10.1	52.3	56.3	50.4	43.0
	high	32.2	7.4	17.0	46.2	52.1	48.1	22.7
	low and middle	41.5	2.2	10.0	52.6	56.5	50.6	47.1

Proportion of all deaths (%)

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	1.9	0.4	5.2	8.8	5.8	2.9	0.7
	high	1.0	1.5	4.8	18.1	10.0	3.3	0.3
	low and middle	2.1	0.4	5.2	8.6	5.6	2.8	0.8
African Region[d]	low and middle	1.7	0.6	5.7	4.1	1.9	2.0	0.6
Region of the Americas	all	1.1	0.5	5.1	13.7	6.3	1.8	0.2
	high	0.9	2.2	9.1	17.9	9.3	2.4	0.2
	low and middle	1.4	0.4	4.5	12.7	5.0	1.3	0.2
South-East Asia Region[d]	low and middle	1.6	0.2	4.8	7.5	4.2	1.5	0.4
European Region	all	1.4	0.7	6.9	17.4	11.6	4.0	0.5
	high	0.7	0.6	4.1	14.2	9.3	3.4	0.3
	low and middle	1.8	0.8	7.4	18.2	12.4	4.2	0.7
Eastern Mediterranean Region	all	1.8	0.6	6.7	9.7	4.0	1.4	0.6
	high	1.1	0.8	2.8	14.2	5.3	1.1	0.2
	low and middle	1.8	0.6	6.7	9.7	4.0	1.4	0.6
Western Pacific Region	all	3.7	0.3	3.8	24.7	16.5	5.9	1.5
	high	1.8	1.1	6.6	25.0	13.3	5.4	0.8
	low and middle	4.0	0.3	3.7	24.7	16.7	5.9	1.7

TABLE A.3

Estimated mortality caused by homicide,[a] by sex, age group, WHO region and income level, 2000

Absolute numbers (in thousands)[b]

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	520	401	18	13	155	120	60	35
	high	26	19	1	<1	8	6	3	1
	low and middle	494	382	18	13	147	114	57	34
African Region[d]	low and middle	116	82	10	4	30	19	10	9
Region of the Americas	all	159	142	1	2	72	44	17	7
	high	19	15	<1	<1	7	4	2	1
	low and middle	140	128	1	2	65	39	15	6
South-East Asia Region[d]	low and middle	78	54	3	4	13	14	11	9
European Region	all	78	58	<1	1	15	23	13	6
	high	4	3	<1	<1	1	1	1	<1
	low and middle	74	56	<1	<1	14	22	13	6
Eastern Mediterranean Region	all	31	20	2	1	8	5	2	2
	high	<1	<1	<1	<1	<1	<1	<1	<1
	low and middle	30	19	2	1	8	5	2	2
Western Pacific Region	all	59	45	1	2	17	15	6	3
	high	2	1	<1	<1	<1	<1	<1	<1
	low and middle	57	44	1	2	17	15	6	3

Rate per 100 000 population

WHO region	Income level	Total[c, e]	Males						
			All ages[e]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	8.8	13.6	5.8	2.1	19.4	18.7	14.8	13.0
	high	2.9	4.3	2.2	0.7	8.4	5.5	3.3	1.9
	low and middle	10.1	15.6	6.1	2.3	20.9	21.3	17.9	17.3
African Region[d]	low and middle	22.2	33.4	17.9	4.0	34.1	39.6	39.6	63.3
Region of the Americas	all	19.3	34.7	3.5	2.4	68.6	49.1	28.9	16.4
	high	6.5	9.9	4.0	1.2	21.4	11.6	6.7	3.7
	low and middle	27.5	51.0	3.3	2.9	89.7	76.4	50.4	31.9
South-East Asia Region[d]	low and middle	5.8	8.1	3.9	2.2	6.0	8.8	11.6	16.9
European Region	all	8.4	13.0	1.7	0.8	15.1	23.5	18.1	9.3
	high	1.0	1.4	0.9	0.3	1.7	2.1	1.6	1.1
	low and middle	14.8	23.2	2.2	1.2	23.9	42.6	34.8	19.7
Eastern Mediterranean Region	all	7.1	9.4	5.0	2.0	11.3	11.1	9.8	13.6
	high	4.2	6.0	1.4	0.6	10.1	9.1	4.1	5.7
	low and middle	7.2	9.4	5.1	2.0	11.3	11.1	10.0	13.7
Western Pacific Region	all	3.4	5.1	1.9	1.5	7.9	7.4	4.9	3.4
	high	1.1	1.3	1.1	0.5	1.5	2.0	1.6	1.1
	low and middle	3.8	5.6	2.0	1.5	8.6	8.0	5.5	3.9

Proportion of all deaths due to injury (%)

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	10.3	11.7	6.7	4.8	17.6	14.5	10.1	6.2
	high	5.5	6.0	12.7	6.9	12.2	8.0	4.4	1.4
	low and middle	10.8	12.3	6.6	4.8	18.0	15.1	10.8	7.2
African Region[d]	low and middle	15.4	16.0	13.6	4.6	23.7	17.9	14.5	14.9
Region of the Americas	all	28.4	32.6	8.0	12.5	47.5	36.7	24.7	9.9
	high	11.4	12.6	19.6	9.9	23.7	13.7	8.7	2.8
	low and middle	35.8	39.9	6.2	13.1	53.2	45.1	32.5	15.4
South-East Asia Region[d]	low and middle	5.7	6.1	5.1	4.6	5.3	6.8	7.3	6.6
European Region	all	9.5	9.6	4.2	3.1	11.7	12.8	9.1	4.8
	high	2.2	2.3	8.1	3.9	3.0	3.8	2.6	0.9
	low and middle	11.7	11.4	3.7	3.0	13.6	14.3	10.3	7.1

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Absolute numbers (in thousands)[b]

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	119	14	12	33	27	18	15
	high	7	<1	<1	2	2	1	1
	low and middle	112	14	11	32	25	17	14
African Region[d]	low and middle	34	7	2	12	7	4	2
Region of the Americas	all	17	1	1	7	5	2	1
	high	5	<1	<1	1	2	1	<1
	low and middle	12	1	1	5	4	1	1
South-East Asia Region[d]	low and middle	24	3	4	3	4	5	4
European Region	all	20	<1	<1	4	6	4	5
	high	1	<1	<1	<1	<1	<1	<1
	low and middle	18	<1	<1	4	5	4	5
Eastern Mediterranean Region	all	11	2	2	4	2	1	1
	high	<1	<1	<1	<1	<1	<1	<1
	low and middle	11	2	2	3	2	1	1
Western Pacific Region	all	14	1	1	4	4	2	2
	high	1	<1	<1	<1	<1	<1	<1
	low and middle	13	1	1	4	4	2	1

Rate per 100 000 population

WHO region	Income level	Females						
		All ages[e]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	4.0	4.8	2.0	4.4	4.3	4.5	4.5
	high	1.5	1.8	0.5	2.0	2.1	1.2	1.0
	low and middle	4.6	5.1	2.1	4.7	4.7	5.4	6.1
African Region[d]	low and middle	11.8	12.7	2.9	14.1	13.8	14.6	11.8
Region of the Americas	all	4.0	2.6	1.2	6.4	5.7	3.3	2.6
	high	3.0	3.2	1.0	4.4	4.2	2.2	1.7
	low and middle	4.8	2.3	1.3	7.3	6.6	4.3	3.8
South-East Asia Region[d]	low and middle	3.5	3.5	2.6	1.6	2.5	5.7	7.3
European Region	all	3.9	1.2	0.7	4.0	5.7	5.6	5.3
	high	0.6	0.7	0.2	0.7	0.8	0.7	0.7
	low and middle	6.8	1.6	1.0	6.1	9.9	10.1	10.3
Eastern Mediterranean Region	all	4.8	5.5	3.6	5.4	4.3	3.8	5.9
	high	1.2	0.4	0.0	1.5	1.3	1.4	2.6
	low and middle	4.8	5.5	3.6	5.4	4.4	3.8	5.9
Western Pacific Region	all	1.7	2.2	1.0	1.9	2.0	1.4	1.6
	high	0.8	1.3	0.4	0.8	1.1	0.8	0.8
	low and middle	1.8	2.3	1.0	2.0	2.1	1.6	1.9

Proportion of all deaths due to injury (%)

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	7.2	6.4	5.6	9.4	9.5	8.8	4.1
	high	4.4	14.7	10.2	10.4	10.4	5.2	1.1
	low and middle	7.5	6.3	5.5	9.3	9.5	9.2	5.0
African Region[d]	low and middle	14.3	11.0	5.4	23.7	19.4	16.7	8.9
Region of the Americas	all	13.7	8.7	11.8	25.6	23.0	12.7	3.3
	high	8.8	22.4	13.5	17.2	15.3	8.3	2.1
	low and middle	17.4	6.5	11.4	29.3	29.6	17.0	5.0
South-East Asia Region[d]	low and middle	4.9	6.4	4.6	2.6	4.3	9.5	5.4
European Region	all	9.3	4.4	6.2	13.8	15.9	11.6	5.3
	high	2.0	8.9	6.0	4.6	5.7	3.5	0.7
	low and middle	12.8	3.8	6.2	16.0	18.2	13.7	9.7

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TABLE A.3 *(continued)*

Proportion of all deaths due to injury (%) *(continued)*

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Eastern Mediterranean Region	all	9.0	9.2	5.2	4.9	12.9	11.8	8.4	7.0
	high	8.3	8.7	5.6	3.0	11.4	11.8	5.0	4.7
	low and middle	9.1	9.2	5.2	4.9	12.9	11.8	8.5	7.0
Western Pacific Region	all	4.8	5.9	1.9	3.9	10.1	8.7	4.9	1.8
	high	2.0	1.8	5.0	4.5	2.5	2.9	1.7	0.7
	low and middle	5.1	6.4	1.8	3.9	10.8	9.3	5.5	2.1

Proportion of all deaths (%)

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	0.9	1.4	0.3	1.8	8.2	4.0	1.4	0.3
	high	0.3	0.5	1.4	3.4	8.7	2.9	0.6	0.0
	low and middle	1.0	1.5	0.3	1.8	8.2	4.0	1.5	0.3
African Region[d]	low and middle	1.1	1.5	0.4	1.6	5.8	2.2	1.7	0.9
Region of the Americas	all	2.7	4.5	0.5	5.3	33.2	14.8	3.6	0.4
	high	0.7	1.1	2.2	5.5	18.1	5.3	1.0	0.1
	low and middle	4.4	7.0	0.4	5.2	36.4	18.5	5.3	0.7
South-East Asia Region[d]	low and middle	0.5	0.7	0.2	1.4	2.4	1.8	0.9	0.3
European Region	all	0.8	1.2	0.3	1.7	8.3	5.8	1.6	0.2
	high	0.1	0.1	0.7	1.6	2.0	1.2	0.3	0.0
	low and middle	1.3	1.8	0.3	1.7	9.8	6.9	2.1	0.3
Eastern Mediterranean Region	all	0.8	0.9	0.2	1.6	5.9	2.9	0.9	0.2
	high	1.0	1.4	0.5	1.7	8.6	5.0	0.7	0.2
	low and middle	0.8	0.9	0.2	1.6	5.9	2.9	0.9	0.2
Western Pacific Region	all	0.5	0.7	0.2	1.9	6.0	3.1	0.7	0.1
	high	0.2	0.2	0.8	2.2	1.8	1.2	0.3	0.0
	low and middle	0.6	0.8	0.2	1.9	6.3	3.3	0.7	0.1

Source: WHO Global Burden of Disease project for 2000, Version 1.

[a] Homicide = ICD-10 X85–Y09 (ICD-9 E960–E969).

[b] Absolute numbers are rounded to the nearest 1000. Any apparent discrepancies in total sums are a result of rounding.

[c] Combined total for males and females.

[d] No high-income countries in the region.

[e] Age-standardized.

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Proportion of all deaths due to injury (%) *(continued)*

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Eastern Mediterranean Region	all	8.8	5.1	10.5	12.6	11.6	9.0	5.4
	high	5.9	2.9	0.2	9.3	5.5	6.3	6.0
	low and middle	8.8	5.1	10.5	12.6	11.7	9.0	5.4
Western Pacific Region	all	3.0	2.3	4.1	4.0	4.4	2.7	1.3
	high	2.4	7.4	7.6	4.6	5.6	3.0	0.8
	low and middle	3.0	2.2	4.0	4.0	4.4	2.7	1.4

Proportion of all deaths (%)

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	0.5	0.3	1.6	1.9	1.3	0.7	0.1
	high	0.2	1.4	4.0	5.4	2.3	0.4	0.0
	low and middle	0.5	0.3	1.6	1.8	1.3	0.7	0.1
African Region[d]	low and middle	0.7	0.3	1.1	1.6	0.8	0.9	0.2
Region of the Americas	all	0.6	0.5	3.3	8.3	3.5	0.7	0.1
	high	0.3	2.2	6.3	9.5	3.7	0.6	0.0
	low and middle	0.9	0.3	2.9	8.0	3.5	0.8	0.1
South-East Asia Region[d]	low and middle	0.4	0.2	1.5	0.7	0.7	0.6	0.2
European Region	all	0.4	0.3	2.3	6.1	3.9	1.2	0.1
	high	0.1	0.6	1.9	2.1	1.1	0.2	0.0
	low and middle	0.7	0.2	2.4	7.1	4.8	1.6	0.2
Eastern Mediterranean Region	all	0.6	0.2	2.8	2.7	1.3	0.5	0.1
	high	0.3	0.2	0.1	3.9	1.1	0.4	0.1
	low and middle	0.6	0.2	2.8	2.7	1.4	0.5	0.1
Western Pacific Region	all	0.3	0.3	1.5	1.9	1.3	0.3	0.0
	high	0.1	1.1	2.9	2.5	1.4	0.3	0.0
	low and middle	0.3	0.3	1.5	1.9	1.3	0.3	0.1

TABLE A.4

Estimated mortality caused by suicide,[a] by sex, age group, WHO region and income level, 2000

Absolute numbers (in thousands)[b]

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	815	509	0	10	124	138	115	122
	high	122	91	0	<1	16	25	24	25
	low and middle	692	418	0	10	108	113	91	96
African Region[d]	low and middle	27	21	0	1	6	5	5	4
Region of the Americas	all	65	52	0	1	14	15	11	10
	high	36	29	0	<1	6	9	7	6
	low and middle	29	22	0	<1	8	6	4	4
South-East Asia Region[d]	low and middle	168	107	0	5	37	30	21	14
European Region	all	186	149	0	1	30	46	39	33
	high	51	38	0	<1	6	10	9	12
	low and middle	135	111	0	1	24	35	29	21
Eastern Mediterranean Region	all	24	12	0	1	5	3	2	1
	high	<1	<1	0	<1	<1	<1	<1	<1
	low and middle	23	12	0	1	5	3	2	1
Western Pacific Region	all	344	169	0	2	32	39	38	59
	high	35	24	0	<1	4	6	8	7
	low and middle	309	144	0	2	28	33	30	52

Rate per 100 000 population

WHO region	Income level	Total[c, e]	Males						
			All ages[e]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	14.5	18.9	0.0	1.7	15.6	21.5	28.4	44.9
	high	11.4	17.7	0.0	0.8	17.0	23.6	27.9	33.8
	low and middle	15.5	19.5	0.0	1.8	15.4	21.1	28.6	49.2
African Region[d]	low and middle	6.7	10.6	0.0	1.4	6.4	11.2	18.1	26.6
Region of the Americas	all	8.1	13.2	0.0	0.7	13.7	17.1	18.7	26.0
	high	10.6	17.4	0.0	1.2	19.9	24.1	23.8	29.9
	low and middle	6.3	10.2	0.0	0.5	11.0	12.1	13.9	21.2
South-East Asia Region[d]	low and middle	12.0	15.7	0.0	3.1	16.9	18.5	23.3	26.1
European Region	all	19.1	32.2	0.0	1.8	30.2	46.7	52.3	51.3
	high	10.5	16.4	0.0	0.4	14.8	22.6	25.1	33.2
	low and middle	26.6	46.8	0.0	2.6	40.3	68.2	79.9	74.1
Eastern Mediterranean Region	all	5.9	6.3	0.0	0.8	7.6	7.6	8.5	10.8
	high	3.4	4.1	0.0	0.4	5.2	5.6	4.1	7.3
	low and middle	5.9	6.4	0.0	0.8	7.6	7.7	8.6	10.8
Western Pacific Region	all	20.8	21.2	0.0	1.1	14.7	19.0	28.7	69.2
	high	14.3	20.9	0.0	0.7	17.1	25.8	39.7	40.7
	low and middle	22.3	21.8	0.0	1.2	14.4	18.2	26.7	76.2

Proportion of all deaths due to injury (%)

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	16.1	14.9	0.0	3.8	14.1	16.7	19.5	21.3
	high	25.9	28.8	0.0	7.7	24.7	34.4	37.2	24.7
	low and middle	15.1	13.5	0.0	3.7	13.2	15.0	17.3	20.5
African Region[d]	low and middle	3.6	4.0	0.0	1.6	4.5	5.1	6.6	6.3
Region of the Americas	all	11.7	11.8	0.0	3.5	9.5	12.8	16.1	15.7
	high	21.5	24.9	0.0	9.6	22.1	28.5	30.9	22.8
	low and middle	7.4	7.0	0.0	2.1	6.5	7.1	8.9	10.2
South-East Asia Region[d]	low and middle	12.3	12.1	0.0	6.6	15.0	14.3	14.6	10.2
European Region	all	22.8	24.5	0.0	6.6	23.5	25.4	26.2	26.5
	high	27.2	31.3	0.0	6.1	25.8	40.1	40.2	26.2
	low and middle	21.5	22.8	0.0	6.7	23.0	22.9	23.6	26.6

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Absolute numbers (in thousands)[b]

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	305	0	12	93	77	50	74
	high	31	0	<1	4	7	8	11
	low and middle	274	0	11	88	70	43	63
African Region[d]	low and middle	7	0	1	2	2	1	1
Region of the Americas	all	14	0	<1	4	4	3	2
	high	7	0	<1	1	3	2	1
	low and middle	7	0	<1	3	1	1	1
South-East Asia Region[d]	low and middle	61	0	8	30	15	5	4
European Region	all	37	0	<1	5	8	9	15
	high	13	0	<1	1	3	3	5
	low and middle	24	0	<1	4	5	5	10
Eastern Mediterranean Region	all	11	0	1	6	2	1	1
	high	<1	0	<1	<1	<1	<1	<1
	low and middle	11	0	1	6	2	1	1
Western Pacific Region	all	175	0	2	46	46	31	50
	high	10	0	<1	2	2	2	4
	low and middle	164	0	1	45	44	29	46

Rate per 100 000 population

WHO region	Income level	Females						
		All ages[e]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	10.6	0.0	2.0	12.2	12.4	12.6	22.1
	high	5.4	0.0	0.4	4.7	7.1	9.0	11.3
	low and middle	11.9	0.0	2.1	13.2	13.4	13.5	26.8
African Region[d]	low and middle	3.1	0.0	0.7	1.7	4.8	4.1	7.5
Region of the Americas	all	3.3	0.0	0.6	4.0	4.3	5.0	4.4
	high	4.1	0.0	0.4	3.9	6.6	7.1	4.9
	low and middle	2.7	0.0	0.6	4.1	2.8	3.1	3.9
South-East Asia Region[d]	low and middle	8.3	0.0	4.7	14.5	9.9	5.7	7.2
European Region	all	6.8	0.0	0.4	5.8	8.1	11.4	15.7
	high	5.0	0.0	0.2	3.8	6.6	9.0	11.0
	low and middle	8.4	0.0	0.5	7.0	9.4	13.6	20.6
Eastern Mediterranean Region	all	5.4	0.0	2.0	8.6	6.2	4.4	7.0
	high	2.1	0.0	0.1	3.2	3.5	1.7	2.0
	low and middle	5.4	0.0	2.0	8.6	6.2	4.4	7.0
Western Pacific Region	all	20.7	0.0	1.1	22.6	23.3	25.1	51.7
	high	8.0	0.0	0.5	7.6	8.9	12.0	20.2
	low and middle	23.2	0.0	1.1	24.3	25.0	27.7	60.9

Proportion of all deaths due to injury (%)

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	18.5	0.0	5.6	26.0	27.4	24.6	19.7
	high	20.0	0.0	6.6	24.7	34.9	37.9	12.6
	low and middle	18.4	0.0	5.6	26.0	26.8	23.1	22.0
African Region[d]	low and middle	2.8	0.0	1.2	2.9	6.7	4.6	5.6
Region of the Americas	all	11.2	0.0	5.6	16.1	17.6	19.3	5.6
	high	13.8	0.0	5.9	15.3	23.8	26.7	6.0
	low and middle	9.3	0.0	5.5	16.5	12.4	12.2	5.0
South-East Asia Region[d]	low and middle	12.6	0.0	8.2	23.2	17.2	9.5	5.3
European Region	all	17.9	0.0	3.7	19.9	22.5	23.6	15.8
	high	19.7	0.0	6.2	26.4	45.0	44.4	11.8
	low and middle	17.1	0.0	3.4	18.4	17.2	18.3	19.4

TABLE A.4 *(continued)*

Proportion of all deaths due to injury (%) *(continued)*

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Eastern Mediterranean Region	all	7.0	5.8	0.0	2.0	8.6	8.1	7.2	5.6
	high	6.5	5.8	0.0	2.3	5.9	7.3	5.0	6.0
	low and middle	7.0	5.8	0.0	2.0	8.6	8.1	7.3	5.5
Western Pacific Region	all	28.1	22.3	0.0	3.0	18.9	22.5	28.6	37.2
	high	31.0	31.6	0.0	6.0	29.7	38.3	42.0	24.4
	low and middle	27.8	21.2	0.0	2.9	18.1	21.0	26.3	40.0

Proportion of all deaths (%)

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	1.5	1.7	0.0	1.4	6.6	4.6	2.6	0.9
	high	1.5	2.2	0.0	3.8	17.5	12.7	4.6	0.8
	low and middle	1.5	1.6	0.0	1.4	6.0	4.0	2.4	0.9
African Region[d]	low and middle	0.3	0.4	0.0	0.6	1.1	0.6	0.8	0.4
Region of the Americas	all	1.1	1.6	0.0	1.5	6.6	5.2	2.3	0.6
	high	1.3	2.2	0.0	5.4	16.8	11.1	3.7	0.7
	low and middle	0.9	1.2	0.0	0.8	4.5	2.9	1.5	0.4
South-East Asia Region[d]	low and middle	1.2	1.4	0.0	2.1	6.8	3.7	1.7	0.4
European Region	all	1.9	3.0	0.0	3.6	16.6	11.6	4.7	1.0
	high	1.3	1.9	0.0	2.4	16.8	13.3	4.3	0.8
	low and middle	2.3	3.7	0.0	3.8	16.5	11.1	4.9	1.2
Eastern Mediterranean Region	all	0.6	0.6	0.0	0.7	4.0	2.0	0.8	0.2
	high	0.8	0.9	0.0	1.3	4.5	3.1	0.7	0.2
	low and middle	0.6	0.6	0.0	0.7	4.0	2.0	0.8	0.2
Western Pacific Region	all	3.0	2.7	0.0	1.5	11.1	8.1	3.9	1.5
	high	2.4	3.1	0.0	3.0	20.9	15.2	7.0	1.1
	low and middle	3.1	2.6	0.0	1.5	10.5	7.5	3.4	1.5

Source: WHO Global Burden of Disease project for 2000, Version 1.

[a] Suicide = ICD-10 X60–X84 (ICD-9 E950–E959).

[b] Absolute numbers are rounded to the nearest 1000. Any apparent discrepancies in total sums are a result of rounding.

[c] Combined total for males and females.

[d] No high-income countries in the region.

[e] Age-standardized.

Proportion of all deaths due to injury (%) *(continued)*

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Eastern Mediterranean Region	all	9.0	0.0	5.8	20.0	16.5	10.4	6.3
	high	10.8	0.0	0.9	19.3	15.1	7.7	4.5
	low and middle	9.0	0.0	5.8	20.0	16.5	10.4	6.3
Western Pacific Region	all	37.7	0.0	4.6	48.3	51.7	47.7	41.7
	high	29.7	0.0	9.4	41.7	46.5	45.1	21.9
	low and middle	38.3	0.0	4.5	48.5	52.0	47.9	45.7

Proportion of all deaths (%)

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	1.2	0.0	1.6	5.3	3.7	1.9	0.5
	high	0.8	0.0	2.6	12.7	7.7	2.9	0.3
	low and middle	1.2	0.0	1.6	5.1	3.5	1.8	0.6
African Region[d]	low and middle	0.1	0.0	0.3	0.2	0.3	0.3	0.1
Region of the Americas	all	0.5	0.0	1.6	5.2	2.7	1.0	0.1
	high	0.5	0.0	2.8	8.4	5.7	1.9	0.1
	low and middle	0.5	0.0	1.4	4.5	1.5	0.5	0.1
South-East Asia Region[d]	low and middle	0.9	0.0	2.7	6.0	2.7	0.6	0.2
European Region	all	0.8	0.0	1.4	8.9	5.5	2.4	0.4
	high	0.7	0.0	2.0	12.1	8.3	3.1	0.3
	low and middle	0.9	0.0	1.3	8.1	4.6	2.2	0.4
Eastern Mediterranean Region	all	0.6	0.0	1.5	4.4	1.9	0.5	0.2
	high	0.5	0.0	0.3	8.0	3.1	0.5	0.0
	low and middle	0.6	0.0	1.6	4.3	1.9	0.5	0.2
Western Pacific Region	all	3.5	0.0	1.7	22.7	15.1	5.5	1.5
	high	1.6	0.0	3.7	22.5	11.9	5.0	0.8
	low and middle	3.7	0.0	1.7	22.8	15.3	5.6	1.6

TABLE A.5

Estimated mortality caused by war-related injuries,[a] by sex, age group, WHO region and income level, 2000

Absolute numbers (in thousands)[b]

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	310	233	22	30	69	58	29	25
	high	<1	<1	<1	<1	<1	<1	<1	<1
	low and middle	310	233	22	30	69	58	29	25
African Region[d]	low and middle	167	122	7	18	36	33	16	13
Region of the Americas	all	2	2	<1	<1	<1	<1	<1	<1
	high	<1	<1	0	0	0	0	<1	<1
	low and middle	2	2	<1	<1	<1	<1	<1	<1
South-East Asia Region[d]	low and middle	63	49	2	6	18	13	5	5
European Region	all	37	30	1	3	8	9	5	4
	high	<1	<1	0	0	<1	<1	<1	<1
	low and middle	37	30	1	3	8	9	5	4
Eastern Mediterranean Region	all	39	29	12	3	7	3	2	2
	high	<1	<1	<1	<1	<1	<1	<1	<1
	low and middle	39	28	12	3	7	3	2	2
Western Pacific Region	all	2	1	0	<1	<1	<1	0	<1
	high	0	0	0	0	0	0	0	0
	low and middle	2	1	0	<1	<1	<1	0	<1

Rate per 100 000 population

WHO region	Income level	Total[c, e]	Males						
			All ages[e]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	5.2	7.8	7.1	4.9	8.6	9.1	7.1	9.2
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	6.2	9.4	7.8	5.4	9.8	10.9	9.0	12.7
African Region[d]	low and middle	32.0	50.6	13.3	20.4	40.4	67.2	62.1	92.6
Region of the Americas	all	0.2	0.4	0.3	0.3	0.4	0.5	0.3	0.6
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
	low and middle	0.4	0.7	0.4	0.4	0.6	0.9	0.5	1.3
South-East Asia Region[d]	low and middle	4.4	6.6	1.9	3.3	8.0	8.2	5.9	10.0
European Region	all	4.2	7.0	4.2	5.3	8.0	8.7	7.2	6.3
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	7.6	13.0	7.1	8.5	13.3	16.5	14.5	14.3
Eastern Mediterranean Region	all	8.1	11.2	34.6	4.1	9.8	7.5	8.2	15.4
	high	2.7	3.7	2.5	2.3	3.6	2.9	4.1	7.2
	low and middle	8.2	11.3	34.8	4.2	9.9	7.6	8.3	15.6
Western Pacific Region	all	0.1	0.2	0.0	0.3	0.1	0.2	0.0	0.3
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	0.1	0.2	0.0	0.3	0.1	0.2	0.0	0.4

Proportion of all deaths due to injury (%)

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	6.1	6.8	8.2	11.0	7.8	7.1	4.9	4.3
	high	0.0	0.1	0.1	0.2	0.0	0.0	0.1	0.0
	low and middle	6.8	7.5	8.3	11.3	8.4	7.7	5.4	5.3
African Region[d]	low and middle	22.3	23.9	10.1	23.4	28.1	30.4	22.7	21.8
Region of the Americas	all	0.4	0.4	0.7	1.5	0.3	0.4	0.2	0.4
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	0.5	0.5	0.8	1.8	0.4	0.5	0.3	0.6
South-East Asia Region[d]	low and middle	4.6	5.5	2.6	7.0	7.1	6.3	3.7	3.9
European Region	all	4.5	5.0	10.2	19.7	6.2	4.8	3.6	3.3
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	5.8	6.2	11.5	21.8	7.6	5.5	4.3	5.1

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Absolute numbers (in thousands)[b]

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	77	8	14	26	14	8	8
	high	<1	<1	<1	<1	<1	<1	<1
	low and middle	77	8	14	26	14	8	8
African Region[d]	low and middle	45	5	10	18	6	4	3
Region of the Americas	all	<1	<1	<1	<1	<1	<1	<1
	high	0	0	0	0	0	0	0
	low and middle	<1	<1	<1	<1	<1	<1	<1
South-East Asia Region[d]	low and middle	14	<1	1	4	4	2	3
European Region	all	6	<1	1	1	3	1	<1
	high	<1	0	<1	0	<1	0	<1
	low and middle	6	<1	1	1	3	1	<1
Eastern Mediterranean Region	all	10	2	2	3	1	1	2
	high	<1	<1	<1	<1	<1	<1	<1
	low and middle	10	2	2	3	1	1	2
Western Pacific Region	all	1	0	<1	0	<1	0	0
	high	0	0	0	0	0	0	0
	low and middle	1	0	<1	0	<1	0	0

Rate per 100 000 population

WHO region	Income level	Females						
		All ages[e]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	2.6	2.6	2.3	3.4	2.2	1.9	2.4
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	3.0	2.9	2.6	3.9	2.7	2.4	3.4
African Region[d]	low and middle	14.7	9.2	11.0	20.3	12.9	13.5	17.1
Region of the Americas	all	0.1	0.2	0.1	0.1	0.1	0.1	0.1
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	0.1	0.2	0.1	0.1	0.1	0.1	0.2
South-East Asia Region[d]	low and middle	2.2	0.6	0.9	1.8	2.5	2.6	4.8
European Region	all	1.5	0.7	1.0	1.5	3.0	1.2	0.4
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	2.6	1.3	1.5	2.4	5.6	2.4	0.8
Eastern Mediterranean Region	all	4.9	6.6	2.8	4.8	2.0	3.0	13.7
	high	1.0	1.6	0.6	0.9	1.3	0.9	1.5
	low and middle	4.9	6.7	2.8	4.8	2.1	3.0	13.8
Western Pacific Region	all	0.1	0.0	0.3	0.0	0.1	0.0	0.0
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	0.1	0.0	0.4	0.0	0.1	0.0	0.0

Proportion of all deaths due to injury (%)

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	4.7	3.5	6.6	7.3	5.0	3.7	2.1
	high	0.0	0.1	0.3	0.0	0.0	0.0	0.0
	low and middle	5.2	3.6	6.7	7.7	5.4	4.1	2.8
African Region[d]	low and middle	18.8	8.0	20.6	34.2	18.1	15.5	12.9
Region of the Americas	all	0.3	0.5	0.7	0.4	0.3	0.2	0.1
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	0.5	0.6	0.9	0.5	0.6	0.5	0.3
South-East Asia Region[d]	low and middle	3.0	1.1	1.5	2.9	4.3	4.4	3.5
European Region	all	3.1	2.6	8.5	5.1	8.3	2.6	0.4
	high	0.0	0.0	0.6	0.0	0.0	0.0	0.0
	low and middle	4.5	2.9	9.5	6.4	10.2	3.2	0.8

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TABLE A.5 *(continued)*

Proportion of all deaths due to injury (%) *(continued)*

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Eastern Mediterranean Region	all	11.5	13.4	35.6	10.1	11.2	8.0	7.0	7.9
	high	5.0	4.9	10.2	11.9	4.1	3.8	5.1	5.9
	low and middle	11.6	13.5	35.6	10.1	11.3	8.0	7.0	8.0
Western Pacific Region	all	0.2	0.2	0.0	0.7	0.2	0.2	0.0	0.2
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	0.2	0.2	0.0	0.7	0.2	0.3	0.0	0.2

Proportion of all deaths (%)

WHO region	Income level	Total[c]	Males						
			All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	0.6	0.8	0.4	4.1	3.7	1.9	0.7	0.2
	high	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0
	low and middle	0.7	0.9	0.4	4.2	3.8	2.1	0.7	0.2
African Region[d]	low and middle	1.6	2.3	0.3	8.3	6.9	3.7	2.6	1.4
Region of the Americas	all	0.0	0.1	0.0	0.6	0.2	0.2	0.0	0.0
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	0.1	0.1	0.1	0.7	0.3	0.2	0.1	0.0
South-East Asia Region[d]	low and middle	0.4	0.6	0.1	2.2	3.2	1.6	0.4	0.2
European Region	all	0.4	0.6	0.8	10.8	4.4	2.2	0.6	0.1
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	0.6	1.0	0.9	12.4	5.4	2.7	0.9	0.2
Eastern Mediterranean Region	all	1.0	1.3	1.5	3.4	5.2	1.9	0.8	0.3
	high	0.6	0.8	0.8	6.7	3.1	1.6	0.7	0.2
	low and middle	1.0	1.3	1.5	3.4	5.2	1.9	0.8	0.3
Western Pacific Region	all	0.0	0.0	0.0	0.3	0.1	0.1	0.0	0.0
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	0.0	0.0	0.0	0.3	0.1	0.1	0.0	0.0

Source: WHO Global Burden of Disease project for 2000, Version 1.

[a] War-related injuries = ICD-10 Y36 (ICD-9 E990–E999).

[b] Absolute numbers are rounded to the nearest 1000. Any apparent discrepancies in total sums are a result of rounding.

[c] Combined total for males and females.

[d] No high-income countries in the region.

[e] Age-standardized.

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Proportion of all deaths due to injury (%) *(continued)*

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Eastern Mediterranean Region	all	8.4	6.2	8.0	11.3	5.5	7.1	12.5
	high	5.6	10.6	8.2	5.6	5.4	4.0	3.4
	low and middle	8.4	6.2	8.0	11.3	5.5	7.1	12.5
Western Pacific Region	all	0.1	0.0	1.4	0.0	0.1	0.0	0.0
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	0.1	0.0	1.4	0.0	0.2	0.0	0.0

Proportion of all deaths (%)

WHO region	Income level	Females						
		All ages	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
All	all	0.3	0.1	1.9	1.5	0.7	0.3	0.1
	high	0.0	0.0	0.1	0.0	0.0	0.0	0.0
	low and middle	0.4	0.2	1.9	1.5	0.7	0.3	0.1
African Region[d]	low and middle	0.9	0.2	4.3	2.3	0.8	0.9	0.3
Region of the Americas	all	0.0	0.0	0.2	0.1	0.1	0.0	0.0
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	0.0	0.0	0.2	0.1	0.1	0.0	0.0
South-East Asia Region[d]	low and middle	0.2	0.0	0.5	0.7	0.7	0.3	0.1
European Region	all	0.1	0.2	3.1	2.3	2.0	0.3	0.0
	high	0.0	0.0	0.2	0.0	0.0	0.0	0.0
	low and middle	0.2	0.2	3.6	2.8	2.7	0.4	0.0
Eastern Mediterranean Region	all	0.5	0.3	2.1	2.4	0.6	0.4	0.3
	high	0.3	0.6	2.5	2.3	1.1	0.2	0.0
	low and middle	0.5	0.3	2.1	2.4	0.6	0.4	0.3
Western Pacific Region	all	0.0	0.0	0.5	0.0	0.0	0.0	0.0
	high	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	low and middle	0.0	0.0	0.5	0.0	0.0	0.0	0.0

TABLE A.6

The ten leading causes of death and DALYs, and rankings for violence-related deaths and DALYs, by WHO region, 2000

ALL MEMBER STATES

Total

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	12.4
2	Cerebrovascular disease	9.2
3	Lower respiratory infections	6.9
4	HIV/AIDS	5.3
5	Chronic obstructive pulmonary disease	4.5
6	Perinatal conditions	4.4
7	Diarrhoeal diseases	3.8
8	Tuberculosis	3.0
9	Road traffic injuries	2.3
10	Trachea, bronchus, lung cancers	2.2
13	Suicide	1.5
22	Homicide	0.9
30	War	0.6

Rank	Cause	Proportion of total (%)
DALYs		
1	Lower respiratory infections	6.4
2	Perinatal conditions	6.2
3	HIV/AIDS	6.1
4	Unipolar depressive disorders	4.4
5	Diarrhoeal diseases	4.2
6	Ischaemic heart disease	3.8
7	Cerebrovascular disease	3.1
8	Road traffic injuries	2.8
9	Malaria	2.7
10	Tuberculosis	2.4
17	Self-inflicted injuries	1.3
21	Interpersonal violence	1.1
32	War	0.7

Males

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	12.2
2	Cerebrovascular disease	8.1
3	Lower respiratory infections	7.0
4	HIV/AIDS	5.0
5	Chronic obstructive pulmonary disease	4.6
6	Perinatal conditions	4.4
7	Diarrhoeal diseases	4.0
8	Tuberculosis	3.5
9	Road traffic injuries	3.1
10	Trachea, bronchus, lung cancers	3.0
13	Suicide	1.7
17	Homicide	1.4
27	War	0.8

Rank	Cause	Proportion of total (%)
DALYs		
1	Perinatal conditions	6.4
2	Lower respiratory infections	6.4
3	HIV/AIDS	5.8
4	Diarrhoeal diseases	4.2
5	Ischaemic heart disease	4.2
6	Road traffic injuries	4.0
7	Unipolar depressive disorders	3.4
8	Cerebrovascular disease	3.0
9	Tuberculosis	2.9
10	Malaria	2.5
16	Interpersonal violence	1.6
19	Self-inflicted injuries	1.5
26	War	1.0

Females

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	12.6
2	Cerebrovascular disease	10.4
3	Lower respiratory infections	6.9
4	HIV/AIDS	5.6
5	Chronic obstructive pulmonary disease	4.4
6	Perinatal conditions	4.4
7	Diarrhoeal diseases	3.6
8	Tuberculosis	2.4
9	Malaria	2.1
10	Hypertensive heart disease	1.9
17	Suicide	1.2
37	Homicide	0.5
46	War	0.3

Rank	Cause	Proportion of total (%)
DALYs		
1	HIV/AIDS	6.5
2	Lower respiratory infections	6.4
3	Perinatal conditions	6.0
4	Unipolar depressive disorders	5.5
5	Diarrhoeal diseases	4.2
6	Ischaemic heart disease	3.4
7	Cerebrovascular disease	3.2
8	Malaria	3.0
9	Congenital anomalies	2.2
10	Chronic obstructive pulmonary disease	2.1
18	Self-inflicted injuries	1.1
43	Interpersonal violence	0.5
49	War	0.4

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TABLE A.6 *(continued)*

ALL MEMBER STATES *(continued)*

High-income countries

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	17.9
2	Cerebrovascular disease	10.7
3	Trachea, bronchus, lung cancers	5.6
4	Lower respiratory infections	4.7
5	Chronic obstructive pulmonary disease	3.5
6	Colon and rectum cancers	3.2
7	Diabetes mellitus	2.3
8	Stomach cancer	2.0
9	Breast cancer	2.0
10	Alzheimer and other dementias	1.8
13	Suicide	1.5
35	Homicide	0.3
61	War	0.0

Rank	Cause	Proportion of total (%)
DALYs		
1	Unipolar depressive disorders	8.8
2	Ischaemic heart disease	6.7
3	Alcohol use disorders	5.4
4	Cerebrovascular disease	4.9
5	Alzheimer and other dementias	4.3
6	Road traffic injuries	3.1
7	Trachea, bronchus, lung cancers	3.0
8	Osteoarthritis	2.7
9	Chronic obstructive pulmonary disease	2.5
10	Hearing loss, adult onset	2.5
12	Self-inflicted injuries	2.0
31	Interpersonal violence	0.7
88	War	0.0

Low-income and middle-income countries

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	11.5
2	Cerebrovascular disease	8.9
3	Lower respiratory infections	7.3
4	HIV/AIDS	6.1
5	Perinatal conditions	5.1
6	Chronic obstructive pulmonary disease	4.7
7	Diarrhoeal diseases	4.4
8	Tuberculosis	3.4
9	Road traffic injuries	2.4
10	Malaria	2.3
14	Suicide	1.5
21	Homicide	1.0
27	War	0.7

Rank	Cause	Proportion of total (%)
DALYs		
1	Lower respiratory infections	6.8
2	Perinatal conditions	6.7
3	HIV/AIDS	6.6
4	Meningitis	4.6
5	Diarrhoeal diseases	4.6
6	Unipolar depressive disorders	4.0
7	Ischaemic heart disease	3.5
8	Malaria	3.0
9	Cerebrovascular disease	2.9
10	Road traffic injuries	2.8
19	Self-inflicted injuries	1.2
21	Interpersonal violence	1.1
31	War	0.8

Source: WHO Global Burden of Disease project for 2000, Version 1.

TABLE A.6 *(continued)*

AFRICAN REGION

Total

Rank	Cause	Proportion of total (%)	Rank	Cause	Proportion of total (%)
Deaths			DALYs		
1	HIV/AIDS	22.6	1	HIV/AIDS	20.6
2	Lower respiratory infections	10.1	2	Malaria	10.1
3	Malaria	9.1	3	Lower respiratory infections	8.6
4	Diarrhoeal diseases	6.7	4	Perinatal conditions	6.3
5	Perinatal conditions	5.5	5	Diarrhoeal diseases	6.1
6	Measles	4.3	6	Measles	4.5
7	Tuberculosis	3.6	7	Tuberculosis	2.8
8	Ischaemic heart disease	3.1	8	Whooping cough	1.8
9	Cerebrovascular disease	2.9	9	Road traffic injuries	1.6
10	Road traffic injuries	1.6	10	Protein–energy malnutrition	1.6
11	War	1.6	11	War	1.6
14	Homicide	1.1	15	Interpersonal violence	1.0
42	Suicide	0.3	58	Self-inflicted injuries	0.2

Males

Rank	Cause	Proportion of total (%)	Rank	Cause	Proportion of total (%)
Deaths			DALYs		
1	HIV/AIDS	20.9	1	HIV/AIDS	18.7
2	Lower respiratory infections	11.2	2	Lower respiratory infections	9.6
3	Malaria	8.4	3	Malaria	9.5
4	Diarrhoeal diseases	7.2	4	Perinatal conditions	7.2
5	Perinatal conditions	6.1	5	Diarrhoeal diseases	6.7
6	Tuberculosis	4.8	6	Measles	4.5
7	Measles	4.2	7	Tuberculosis	3.6
8	Ischaemic heart disease	2.9	8	Road traffic injuries	2.1
9	War	2.3	9	War	2.1
10	Cerebrovascular disease	2.1	10	Whooping cough	1.8
13	Homicide	1.5	12	Interpersonal violence	1.4
28	Suicide	0.4	44	Self-inflicted injuries	0.3

Females

Rank	Cause	Proportion of total (%)	Rank	Cause	Proportion of total (%)
Deaths			DALYs		
1	HIV/AIDS	24.4	1	HIV/AIDS	22.4
2	Malaria	9.9	2	Malaria	10.7
3	Lower respiratory infections	8.9	3	Lower respiratory infections	7.6
4	Diarrhoeal diseases	6.1	4	Diarrhoeal diseases	5.5
5	Perinatal conditions	4.8	5	Perinatal conditions	5.4
6	Measles	4.4	6	Measles	4.5
7	Cerebrovascular disease	3.7	7	Tuberculosis	1.9
8	Ischaemic heart disease	3.3	8	Whooping cough	1.9
9	Tuberculosis	2.4	9	Protein–energy malnutrition	1.5
10	Whooping cough	1.6	10	Unipolar depressive disorders	1.4
17	War	0.9	18	War	1.0
22	Homicide	0.7	25	Interpersonal violence	0.7
53	Suicide	0.1	69	Self-inflicted injuries	0.1

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TABLE A.6 *(continued)*

AFRICAN REGION[a] *(continued)*

Low-income and middle-income countries

Rank	Cause	Proportion of total (%)
Deaths		
1	HIV/AIDS	22.6
2	Lower respiratory infections	10.1
3	Malaria	9.1
4	Diarrhoeal diseases	6.7
5	Perinatal conditions	5.5
6	Measles	4.3
7	Tuberculosis	3.6
8	Ischaemic heart disease	3.1
9	Cerebrovascular disease	2.9
10	Road traffic injuries	1.6
11	War	1.6
14	Homicide	1.1
42	Suicide	0.3

Rank	Cause	Proportion of total (%)
DALYs		
1	HIV/AIDS	20.6
2	Malaria	10.1
3	Lower respiratory infections	8.6
4	Perinatal conditions	6.3
5	Diarrhoeal diseases	6.1
6	Measles	4.5
7	Tuberculosis	2.8
8	Whooping cough	1.8
9	Road traffic injuries	1.6
10	Protein–energy malnutrition	1.6
11	War	1.6
15	Interpersonal violence	1.0
58	Self-inflicted injuries	0.2

Source: WHO Global Burden of Disease project for 2000, Version 1.

[a] No high-income countries in the region.

TABLE A.6 *(continued)*

REGION OF THE AMERICAS

Total

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	15.6
2	Cerebrovascular disease	7.7
3	Lower respiratory infections	4.4
4	Trachea, bronchus and lung cancers	3.9
5	Diabetes mellitus	3.7
6	Chronic obstructive pulmonary disease	3.5
7	Homicide	2.7
8	Perinatal conditions	2.6
9	Road traffic injuries	2.4
10	Hypertensive heart disease	2.3
21	Suicide	1.1
62	War	0.0

Rank	Cause	Proportion of total (%)
DALYs		
1	Unipolar depressive disorders	8.1
2	Alcohol use disorders	4.4
3	Ischaemic heart disease	4.4
4	Perinatal conditions	3.9
5	Interpersonal violence	3.8
6	Cerebrovascular disease	3.3
7	Road traffic injuries	3.2
8	Lower respiratory infections	2.7
9	Congenital anomalies	2.6
10	Hearing loss, adult onset	2.6
26	Self-inflicted injuries	1.1
86	War	0.0

Males

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	15.5
2	Cerebrovascular disease	6.5
3	Trachea, bronchus and lung cancers	4.6
4	Homicide	4.5
5	Lower respiratory infections	4.1
6	Chronic obstructive pulmonary disease	3.6
7	Road traffic injuries	3.3
8	Diabetes mellitus	3.1
9	Perinatal conditions	2.8
10	Cirrhosis of the liver	2.4
15	Suicide	1.6
51	War	0.1

Rank	Cause	Proportion of total (%)
DALYs		
1	Alcohol use disorders	6.6
2	Interpersonal violence	6.2
3	Unipolar depressive disorders	5.5
4	Ischaemic heart disease	4.9
5	Road traffic injuries	4.5
6	Perinatal conditions	4.1
7	Cerebrovascular disease	2.8
8	Lower respiratory infections	2.7
9	Hearing loss, adult onset	2.6
10	Congenital anomalies	2.5
19	Self-inflicted injuries	1.5
73	War	0.1

Females

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	15.7
2	Cerebrovascular disease	9.1
3	Lower respiratory infections	4.7
4	Diabetes mellitus	4.5
5	Chronic obstructive pulmonary disease	3.4
6	Trachea, bronchus and lung cancers	3.2
7	Breast cancer	3.2
8	Hypertensive heart disease	2.7
9	Perinatal conditions	2.3
10	Colon and rectum cancers	2.0
30	Homicide	0.6
32	Suicide	0.5
66	War	0.3

Rank	Cause	Proportion of total (%)
DALYs		
1	Unipolar depressive disorders	11.2
2	Ischaemic heart disease	3.8
3	Cerebrovascular disease	3.8
4	Perinatal conditions	3.7
5	Diabetes mellitus	2.8
6	Congenital anomalies	2.8
7	Lower respiratory infections	2.7
8	Hearing loss, adult onset	2.6
9	Diarrhoeal diseases	2.0
10	Anaemia	2.0
27	Interpersonal violence	0.9
42	Self-inflicted injuries	0.6
87	War	0.0

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TABLE A.6 *(continued)*

REGION OF THE AMERICAS *(continued)*

High-income countries

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	20.8
2	Cerebrovascular disease	7.0
3	Trachea, bronchus and lung cancers	6.6
4	Chronic obstructive pulmonary disease	4.5
5	Lower respiratory infections	4.0
6	Colon and rectum cancers	2.8
7	Diabetes mellitus	2.8
8	Alzheimer and other dementias	2.2
9	Breast cancer	2.0
10	Hypertensive heart disease	1.8
14	Suicide	1.3
22	Homicide	0.7
66	War	0.0

Rank	Cause	Proportion of total (%)
DALYs		
1	Unipolar depressive disorders	11.0
2	Ischaemic heart disease	7.1
3	Alcohol use disorders	6.7
4	Cerebrovascular disease	3.4
5	Road traffic injuries	3.3
6	Trachea, bronchus and lung cancers	3.2
7	Alzheimer and other dementias	3.1
8	Diabetes mellitus	2.8
9	Chronic obstructive pulmonary disease	2.8
10	Hearing loss, adult onset	2.6
12	Self-inflicted injuries	1.7
18	Interpersonal violence	1.4
87	War	0.0

Low-income and middle-income countries

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	11.2
2	Cerebrovascular disease	8.2
3	Lower respiratory infections	4.7
4	Diabetes mellitus	4.5
5	Homicide	4.4
6	Perinatal conditions	4.2
7	Road traffic injuries	2.9
8	Chronic obstructive pulmonary disease	2.7
9	Hypertensive heart disease	2.6
10	Diarrhoeal diseases	2.4
24	Suicide	0.9
60	War	0.1

Rank	Cause	Proportion of total (%)
DALYs		
1	Unipolar depressive disorders	6.7
2	Perinatal conditions	5.1
3	Interpersonal violence	4.8
4	Alcohol use disorders	3.4
5	Lower respiratory infections	3.4
6	Road traffic injuries	3.2
7	Cerebrovascular disease	3.2
8	Congenital anomalies	3.1
9	Ischaemic heart disease	3.1
10	Diarrhoeal diseases	2.8
30	Self-inflicted injuries	0.8
82	War	0.1

Source: WHO Global Burden of Disease project for 2000, Version 1.

TABLE A.6 *(continued)*

SOUTH-EAST ASIA REGION

Total

Rank	Cause	Proportion of total (%)	Rank	Cause	Proportion of total (%)
Deaths			DALYs		
1	Ischaemic heart disease	13.7	1	Perinatal conditions	8.9
2	Lower respiratory infections	9.5	2	Lower respiratory infections	7.4
3	Perinatal conditions	7.1	3	Diarrhoeal diseases	5.5
4	Diarrhoeal diseases	6.7	4	Unipolar depressive disorders	4.7
5	Cerebrovascular disease	5.7	5	Ischaemic heart disease	4.4
6	Tuberculosis	4.8	6	Tuberculosis	3.5
7	Road traffic injuries	3.1	7	Road traffic injuries	3.3
8	HIV/AIDS	2.6	8	Congenital anomalies	3.0
9	Chronic obstructive pulmonary disease	2.2	9	HIV/AIDS	2.7
10	Congenital anomalies	1.9	10	Anaemia	2.3
16	Suicide	1.2	19	Self-inflicted injuries	1.2
28	Homicide	0.5	38	Interpersonal violence	0.5
34	War	0.4	41	War	0.5

Males

Rank	Cause	Proportion of total (%)	Rank	Cause	Proportion of total (%)
Deaths			DALYs		
1	Ischaemic heart disease	13.6	1	Perinatal conditions	9.0
2	Lower respiratory infections	9.8	2	Lower respiratory infections	7.2
3	Diarrhoeal diseases	7.1	3	Diarrhoeal diseases	5.4
4	Perinatal conditions	6.8	4	Road traffic injuries	5.0
5	Cerebrovascular disease	5.3	5	Ischaemic heart disease	4.8
6	Tuberculosis	5.1	6	Tuberculosis	4.0
7	Road traffic injuries	4.3	7	Unipolar depressive disorders	3.7
8	HIV/AIDS	3.1	8	HIV/AIDS	3.3
9	Chronic obstructive pulmonary disease	2.1	9	Congenital anomalies	3.1
10	Cirrhosis of the liver	1.9	10	Hearing loss, adult onset	2.1
14	Suicide	1.4	17	Self-inflicted injuries	1.3
22	Homicide	0.7	27	War	0.8
25	War	0.6	32	Interpersonal violence	0.7

Females

Rank	Cause	Proportion of total (%)	Rank	Cause	Proportion of total (%)
Deaths			DALYs		
1	Ischaemic heart disease	13.9	1	Perinatal conditions	8.7
2	Lower respiratory infections	9.0	2	Lower respiratory infections	7.6
3	Perinatal conditions	7.5	3	Unipolar depressive disorders	5.7
4	Diarrhoeal diseases	6.3	4	Diarrhoeal diseases	5.6
5	Cerebrovascular disease	6.2	5	Ischaemic heart disease	4.1
6	Tuberculosis	4.3	6	Tuberculosis	3.1
7	Chronic obstructive pulmonary disease	2.3	7	Congenital anomalies	2.9
8	Congenital anomalies	2.0	8	Anaemia	2.7
9	HIV/AIDS	2.0	9	Cerebrovascular disease	2.1
10	Cervix uteri cancer	1.8	10	HIV/AIDS	2.1
20	Suicide	0.9	25	Self-inflicted injuries	1.0
37	Homicide	0.4	51	Interpersonal violence	0.3
48	War	0.2	63	War	0.2

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TABLE A.6 *(continued)*

SOUTH-EAST ASIA REGION[a] *(continued)*

Low-income and middle-income countries

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	13.7
2	Lower respiratory infections	9.5
3	Perinatal conditions	7.1
4	Diarrhoeal diseases	6.7
5	Cerebrovascular disease	5.7
6	Tuberculosis	4.8
7	Road traffic injuries	3.1
8	HIV/AIDS	2.6
9	Chronic obstructive pulmonary disease	2.2
10	Congenital anomalies	1.9
16	Suicide	1.2
28	Homicide	0.5
34	War	0.4

Rank	Cause	Proportion of total (%)
DALYs		
1	Perinatal conditions	8.9
2	Lower respiratory infections	7.4
3	Diarrhoeal diseases	5.5
4	Unipolar depressive disorders	4.7
5	Ischaemic heart disease	4.4
6	Tuberculosis	3.5
7	Road traffic injuries	3.3
8	Congenital anomalies	3.0
9	HIV/AIDS	2.7
10	Anaemia	2.3
19	Self-inflicted injuries	1.2
38	Interpersonal violence	0.5
41	War	0.5

Source: WHO Global Burden of Disease project for 2000, Version 1.

[a] No high-income countries in the region.

TABLE A.6 *(continued)*

EUROPEAN REGION

Total

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	24.3
2	Cerebrovascular disease	15.4
3	Trachea, bronchus and lung cancers	3.9
4	Lower respiratory infections	3.0
5	Chronic obstructive pulmonary disease	2.8
6	Colon and rectum cancers	2.5
7	Suicide	1.9
8	Stomach cancer	1.9
9	Cirrhosis of the liver	1.8
10	Hypertensive heart disease	1.6
18	Homicide	0.8
34	War	0.4

Rank	Cause	Proportion of total (%)
DALYs		
1	Ischaemic heart disease	10.1
2	Cerebrovascular disease	6.8
3	Unipolar depressive disorders	6.0
4	Alcohol use disorders	3.4
5	Alzheimer and other dementias	3.0
6	Self-inflicted injuries	2.6
7	Road traffic injuries	2.5
8	Lower respiratory infections	2.4
9	Hearing loss, adult onset	2.3
10	Trachea, bronchus and lung cancers	2.2
18	Interpersonal violence	1.4
33	War	0.7

Males

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	23.4
2	Cerebrovascular disease	11.6
3	Trachea, bronchus and lung cancers	6.0
4	Chronic obstructive pulmonary disease	3.6
5	Suicide	3.0
6	Lower respiratory infections	3.0
7	Colon and rectum cancers	2.4
8	Stomach cancer	2.2
9	Cirrhosis of the liver	2.2
10	Prostate cancer	1.9
14	Homicide	1.2
29	War	0.6

Rank	Cause	Proportion of total (%)
DALYs		
1	Ischaemic heart disease	11.0
2	Cerebrovascular disease	5.6
3	Alcohol use disorders	5.1
4	Unipolar depressive disorders	4.0
5	Self-inflicted injuries	3.7
6	Road traffic injuries	3.4
7	Trachea, bronchus and lung cancers	3.2
8	Chronic obstructive pulmonary disease	2.6
9	Lower respiratory infections	2.5
10	Poisonings	2.1
15	Interpersonal violence	1.9
26	War	1.0

Females

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	25.2
2	Cerebrovascular disease	19.3
3	Breast cancer	3.3
4	Lower respiratory infections	3.1
5	Colon and rectum cancers	2.5
6	Chronic obstructive pulmonary disease	2.0
7	Hypertensive heart disease	2.0
8	Diabetes mellitus	1.8
9	Stomach cancer	1.6
10	Trachea, bronchus and lung cancers	1.6
16	Suicide	0.8
28	Homicide	0.4
44	War	0.1

Rank	Cause	Proportion of total (%)
DALYs		
1	Ischaemic heart disease	9.0
2	Unipolar depressive disorders	8.6
3	Cerebrovascular disease	8.3
4	Alzheimer and other dementias	4.2
5	Osteoarthritis	2.9
6	Breast cancer	2.8
7	Hearing loss, adult onset	2.5
8	Lower respiratory infections	2.3
9	Diabetes mellitus	2.0
10	Perinatal conditions	1.8
21	Self-inflicted injuries	1.1
34	Interpersonal violence	0.7
58	War	0.3

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TABLE A.6 *(continued)*

EUROPEAN REGION *(continued)*

High-income countries

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	18.4
2	Cerebrovascular disease	11.3
3	Trachea, bronchus and lung cancers	5.1
4	Lower respiratory infections	4.1
5	Colon and rectum cancers	3.4
6	Chronic obstructive pulmonary disease	3.4
7	Breast cancer	2.3
8	Diabetes mellitus	2.1
9	Alzheimer and other dementias	1.9
10	Prostate cancer	1.8
15	Suicide	1.3
44	Homicide	0.1
68	War	0.0

Rank	Cause	Proportion of total (%)
DALYs		
1	Unipolar depressive disorders	7.9
2	Ischaemic heart disease	7.5
3	Alzheimer and other dementias	6.1
4	Alcohol use disorders	5.3
5	Cerebrovascular disease	5.1
6	Trachea, bronchus and lung cancers	3.1
7	Osteoarthritis	2.9
8	Road traffic injuries	2.7
9	Hearing loss, adult onset	2.5
10	Chronic obstructive pulmonary disease	2.4
14	Self-inflicted injuries	1.9
53	Interpersonal violence	0.2
86	War	0.0

Low-income and middle-income countries

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	28.3
2	Cerebrovascular disease	18.1
3	Trachea, bronchus and lung cancers	3.1
4	Chronic obstructive pulmonary disease	2.4
5	Suicide	2.3
6	Lower respiratory infections	2.3
7	Stomach cancer	2.1
8	Cirrhosis of the liver	1.8
9	Poisonings	1.8
10	Colon and rectum cancers	1.8
13	Homicide	1.3
21	War	0.6

Rank	Cause	Proportion of total (%)
DALYs		
1	Ischaemic heart disease	11.4
2	Cerebrovascular disease	7.7
3	Unipolar depressive disorders	5.1
4	Lower respiratory infections	3.0
5	Self-inflicted injuries	2.9
6	Alcohol use disorders	2.5
7	Perinatal conditions	2.4
8	Road traffic injuries	2.3
9	Hearing loss, adult onset	2.2
10	Poisonings	2.1
12	Interpersonal violence	1.9
24	War	1.0

Source: WHO Global Burden of Disease project for 2000, Version 1.

TABLE A.6 *(continued)*

EASTERN MEDITERRANEAN REGION

Total

Rank	Cause	Proportion of total (%)	Rank	Cause	Proportion of total (%)
Deaths			DALYs		
1	Ischaemic heart disease	10.5	1	Perinatal conditions	8.4
2	Lower respiratory infections	9.1	2	Lower respiratory infections	8.4
3	Perinatal conditions	7.5	3	Diarrhoeal diseases	6.9
4	Diarrhoeal diseases	7.1	4	Unipolar depressive disorders	3.5
5	Cerebrovascular disease	5.3	5	Congenital anomalies	3.3
6	Tuberculosis	3.4	6	Ischaemic heart disease	3.1
7	Road traffic injuries	2.3	7	Road traffic injuries	2.5
8	Congenital anomalies	2.2	8	Tuberculosis	2.2
9	Measles	2.0	9	Measles	2.2
10	Hypertensive heart disease	1.8	10	Cerebrovascular disease	2.0
18	War	1.0	20	War	1.0
21	Homicide	0.8	29	Interpersonal violence	0.7
25	Suicide	0.6	34	Self-inflicted injuries	0.5

Males

Rank	Cause	Proportion of total (%)	Rank	Cause	Proportion of total (%)
Deaths			DALYs		
1	Ischaemic heart disease	11.7	1	Perinatal conditions	8.9
2	Lower respiratory infections	8.6	2	Lower respiratory infections	8.3
3	Perinatal conditions	7.6	3	Diarrhoeal diseases	6.7
4	Diarrhoeal diseases	6.7	4	Road traffic injuries	3.7
5	Cerebrovascular disease	5.0	5	Ischaemic heart disease	3.6
6	Tuberculosis	4.3	6	Congenital anomalies	3.3
7	Road traffic injuries	3.2	7	Tuberculosis	2.8
8	Congenital anomalies	2.1	8	Unipolar depressive disorders	2.8
9	Measles	1.9	9	Measles	2.1
10	Nephritis and nephrosis	1.8	10	Cerebrovascular disease	2.0
15	War	1.3	15	War	1.5
21	Homicide	0.9	25	Interpersonal violence	0.9
26	Suicide	0.6	37	Self-inflicted injuries	0.5

Females

Rank	Cause	Proportion of total (%)	Rank	Cause	Proportion of total (%)
Deaths			DALYs		
1	Lower respiratory infections	9.6	1	Lower respiratory infections	8.4
2	Ischaemic heart disease	9.2	2	Perinatal conditions	7.9
3	Diarrhoeal diseases	7.5	3	Diarrhoeal diseases	7.1
4	Perinatal conditions	7.4	4	Unipolar depressive disorders	4.2
5	Cerebrovascular disease	5.7	5	Congenital anomalies	3.2
6	Tuberculosis	2.3	6	Ischaemic heart disease	2.6
7	Congenital anomalies	2.2	7	Anaemia	2.3
8	Measles	2.1	8	Measles	2.2
9	Hypertensive heart disease	2.0	9	Cerebrovascular disease	2.0
10	Diabetes mellitus	1.7	10	Whooping cough	1.7
26	Suicide	0.6	36	Self-inflicted injuries	0.6
27	Homicide	0.6	39	War	0.6
29	War	0.5	40	Interpersonal violence	0.5

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TABLE A.6 *(continued)*

EASTERN MEDITERRANEAN REGION *(continued)*

High-income countries

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	20.7
2	Cerebrovascular disease	11.3
3	Road traffic injuries	6.3
4	Hypertensive heart disease	4.2
5	Trachea, bronchus and lung cancers	3.1
6	Nephritis and nephrosis	2.3
7	Diabetes mellitus	2.3
8	Lower respiratory infections	2.2
9	Congenital anomalies	1.8
10	Chronic obstructive pulmonary disease	1.6
16	Homicide	1.0
22	Suicide	0.8
27	War	0.6

Rank	Cause	Proportion of total (%)
DALYs		
1	Ischaemic heart disease	7.5
2	Road traffic injuries	7.2
3	Unipolar depressive disorders	6.9
4	Hearing loss, adult onset	5.5
5	Cerebrovascular disease	3.4
6	Congenital anomalies	3.1
7	Anaemia	2.7
8	Diabetes mellitus	2.5
9	Drug use disorders	2.3
10	Falls	2.3
22	Interpersonal violence	1.0
31	Self-inflicted injuries	0.7
35	War	0.6

Low-income and middle-income countries

Rank	Cause	Proportion of total (%)
Deaths		
1	Ischaemic heart disease	10.4
2	Lower respiratory infections	9.1
3	Perinatal conditions	7.6
4	Diarrhoeal diseases	7.1
5	Cerebrovascular disease	5.3
6	Tuberculosis	3.4
7	Road traffic injuries	2.2
8	Congenital anomalies	2.2
9	Measles	2.0
10	Hypertensive heart disease	1.8
18	War	1.0
20	Homicide	0.8
26	Suicide	0.6

Rank	Cause	Proportion of total (%)
DALYs		
1	Perinatal conditions	8.5
2	Lower respiratory infections	8.4
3	Diarrhoeal diseases	6.9
4	Unipolar depressive disorders	3.5
5	Congenital anomalies	3.3
6	Ischaemic heart disease	3.1
7	Road traffic injuries	2.5
8	Tuberculosis	2.2
9	Measles	2.2
10	Cerebrovascular disease	2.0
20	War	1.0
29	Interpersonal violence	0.7
34	Self-inflicted injuries	0.5

Source: WHO Global Burden of Disease project for 2000, Version 1.

TABLE A.6 *(continued)*

WESTERN PACIFIC REGION

Total

Rank	Cause	Proportion of total (%)
Deaths		
1	Cerebrovascular disease	16.2
2	Chronic obstructive pulmonary disease	13.8
3	Ischaemic heart disease	8.2
4	Lower respiratory infections	4.7
5	Trachea, bronchus and lung cancers	3.5
6	Liver cancer	3.5
7	Stomach cancer	3.2
8	Suicide	3.0
9	Tuberculosis	3.0
10	Perinatal conditions	2.8
27	Homicide	0.5
66	War	0.0

Rank	Cause	Proportion of total (%)
DALYs		
1	Chronic obstructive pulmonary disease	7.3
2	Cerebrovascular disease	5.8
3	Unipolar depressive disorders	5.8
4	Lower respiratory infections	5.2
5	Perinatal conditions	4.6
6	Road traffic injuries	3.7
7	Anaemia	3.2
8	Ischaemic heart disease	3.0
9	Self-inflicted injuries	2.8
10	Falls	2.6
33	Interpersonal violence	0.7
85	War	0.1

Males

Rank	Cause	Proportion of total (%)
Deaths		
1	Cerebrovascular disease	15.8
2	Chronic obstructive pulmonary disease	13.1
3	Ischaemic heart disease	8.3
4	Liver cancer	4.5
5	Trachea, bronchus and lung cancers	4.5
6	Lower respiratory infections	4.0
7	Stomach cancer	3.8
8	Road traffic injuries	3.4
9	Tuberculosis	3.3
10	Suicide	2.7
23	Homicide	0.7
56	War	0.0

Rank	Cause	Proportion of total (%)
DALYs		
1	Chronic obstructive pulmonary disease	7.3
2	Cerebrovascular disease	6.1
3	Road traffic injuries	4.9
4	Unipolar depressive disorders	4.8
5	Lower respiratory infections	4.6
6	Perinatal conditions	4.3
7	Ischaemic heart disease	3.2
8	Anaemia	3.1
9	Falls	2.8
10	Liver cancer	2.7
13	Self-inflicted injuries	2.3
27	Interpersonal violence	0.9
75	War	0.1

Females

Rank	Cause	Proportion of total (%)
Deaths		
1	Cerebrovascular disease	16.6
2	Chronic obstructive pulmonary disease	14.6
3	Ischaemic heart disease	8.1
4	Lower respiratory infections	5.6
5	Suicide	3.5
6	Perinatal conditions	3.2
7	Hypertensive heart disease	2.8
8	Tuberculosis	2.7
9	Stomach cancer	2.5
10	Trachea, bronchus and lung cancers	2.3
39	Homicide	0.3
67	War	0.0

Rank	Cause	Proportion of total (%)
DALYs		
1	Chronic obstructive pulmonary disease	7.2
2	Unipolar depressive disorders	7.1
3	Lower respiratory infections	5.9
4	Cerebrovascular disease	5.5
5	Perinatal conditions	4.9
6	Self-inflicted injuries	3.5
7	Anaemia	3.3
8	Ischaemic heart disease	2.6
9	Osteoarthritis	2.5
10	Congenital anomalies	2.4
51	Interpersonal violence	0.4
86	War	0.0

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TABLE A.6 *(continued)*

WESTERN PACIFIC REGION *(continued)*

High-income countries

Rank	Cause	Proportion of total (%)
Deaths		
1	Cerebrovascular disease	15.7
2	Ischaemic heart disease	10.8
3	Lower respiratory infections	7.4
4	Trachea, bronchus and lung cancers	5.3
5	Stomach cancer	5.1
6	Colon and rectum cancers	3.4
7	Liver cancer	3.3
8	Suicide	2.4
9	Road traffic injuries	2.2
10	Diabetes mellitus	2.1
43	Homicide	0.2
—[a]	War	—[a]

Rank	Cause	Proportion of total (%)
DALYs		
1	Cerebrovascular disease	7.6
2	Unipolar depressive disorders	6.4
3	Ischaemic heart disease	4.2
4	Osteoarthritis	3.4
5	Road traffic injuries	3.4
6	Alcohol use disorders	3.1
7	Self-inflicted injuries	2.9
8	Stomach cancer	2.7
9	Diabetes mellitus	2.7
10	Trachea, bronchus, lung cancers	2.6
52	Interpersonal violence	0.3
—[a]	War	—[a]

Low-income and middle-income countries

Rank	Cause	Proportion of total (%)
Deaths		
1	Cerebrovascular disease	16.2
2	Chronic obstructive pulmonary disease	15.5
3	Ischaemic heart disease	7.8
4	Lower respiratory infections	4.4
5	Liver cancer	3.5
6	Tuberculosis	3.3
7	Trachea, bronchus and lung cancers	3.3
8	Perinatal conditions	3.2
9	Suicide	3.1
10	Stomach cancer	3.0
26	Homicide	6.0
64	War	0.0

Rank	Cause	Proportion of total (%)
DALYs		
1	Chronic obstructive pulmonary disease	7.7
2	Unipolar depressive disorders	5.8
3	Cerebrovascular disease	5.7
4	Lower respiratory infections	5.5
5	Perinatal conditions	5.0
6	Road traffic injuries	3.7
7	Anaemia	3.3
8	Ischaemic heart disease	2.8
9	Self-inflicted injuries	2.8
10	Falls	2.6
32	Interpersonal violence	0.7
83	War	0.1

Source: WHO Global Burden of Disease project for 2000, Version 1.

[a] No war-related deaths or injuries reported.

TABLE A.7

Mortality caused by intentional injury,[a] by sex, age group and country, most recent year available between 1990 and 2000[b]

Country or area	Year	Measure[c]	Total[d, e]	Males						
				All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Albania	1998	No.	846	689	4	16	333	193	103	39
		Rate	26.7	46.4	—	—	93.1	53.2	45.9	27.8
Argentina	1996	No.	3 980	3 145	37	85	936	720	689	678
		Rate	11.4	19.0	2.1	1.7	21.0	21.9	28.5	34.1
Armenia	1999	No.	167	128	2	3	29	45	27	22
		Rate	4.3	6.9	—	—	5.9	10.4	12.0	10.3
Australia	1998	No.	2 954	2 325	9	23	727	803	435	328
		Rate	14.9	23.6	—	1.1	34.6	37.4	25.7	24.0
Austria	1999	No.	1 629	1 161	3	7	174	304	279	394
		Rate	16.3	25.0	—	—	22.1	29.6	36.7	60.4
Azerbaijan	1999	No.	430	367	0	10	185	107	41	24
		Rate	5.8	10.0	—	—	17.5	12.6	10.9	8.3
Bahamas	1995–1997	No.	47	40	1	2	21	11	3	2
		Rate	16.0	28.4	—	—	50.4	—	—	—
Barbados	1993–1995	No.	36	28	0	0	11	9	4	3
		Rate	14.0	22.1	—	—	—	—	—	—
Belarus	1999	No.	4 537	3 664	3	27	755	1 226	968	685
		Rate	41.4	72.5	—	2.7	67.6	105.9	125.6	101.5
Belgium	1995	No.	2 330	1 653	3	14	276	505	395	460
		Rate	19.5	28.9	—	—	26.6	42.7	44.4	50.4
Brazil	1995	No.	43 866	39 046	99	573	20 183	12 011	4 344	1 835
		Rate	27.7	50.2	1.2	2.2	89.1	71.9	49.5	35.8
Bulgaria	1999	No.	1 550	1 143	4	12	156	227	293	451
		Rate	14.9	23.5	—	—	17.0	27.2	37.0	57.9
Canada	1997	No.	4 145	3 222	14	65	784	1 091	758	510
		Rate	12.8	20.1	—	2.1	24.8	28.4	28.7	23.8
Chile	1994	No.	1 226	1 070	10	16	365	329	191	159
		Rate	9.0	16.5	—	—	19.7	21.5	22.2	28.1
China (Hong Kong SAR)	1996	No.	863	548	5	14	105	181	103	141
		Rate	12.3	15.9	—	—	15.0	19.8	20.0	33.6
Selected urban and rural areas	1999	No.	19 276	9 719	16	143	1 766	2 702	1 944	3 148
		Rate	15.5	15.9	—	1.1	10.1	17.2	20.7	47.7
Colombia	1995	No.	24 728	22 685	56	310	12 169	7 272	2 141	737
		Rate	65.1	122.4	2.3	4.6	220.5	191.3	116.5	65.1
Costa Rica	1995	No.	394	330	3	9	124	124	50	21
		Rate	12.0	20.1	—	—	24.9	32.9	27.0	18.3
Croatia	1999	No.	1 134	825	1	8	131	207	197	281
		Rate	21.4	34.8	—	—	27.1	39.6	49.8	86.2
Cuba	1997	No.	2 819	2 024	7	17	511	581	375	533
		Rate	23.5	33.9	—	—	35.7	44.4	42.7	78.0
Czech Republic	1999	No.	1 769	1 386	3	7	245	335	426	370
		Rate	14.4	24.1	—	—	19.9	31.8	39.6	49.1
Denmark	1996	No.	955	670	2	4	92	178	184	210
		Rate	14.8	21.6	—	—	16.7	29.9	34.6	47.1
Ecuador	1996	No.	2 242	1 905	5	34	872	643	234	117
		Rate	20.8	36.0	—	1.6	50.7	58.5	41.5	32.6
El Salvador	1991	No.	2 776	2 491	2	31	1 464	552	250	192
		Rate	61.9	119.2	—	2.9	204.9	143.2	106.3	125.2
Estonia	1999	No.	701	546	2	4	102	156	167	115
		Rate	42.9	74.0	—	—	63.6	101.8	138.7	112.8
Finland	1998	No.	1 355	1 053	1	5	188	334	312	213
		Rate	23.3	37.3	—	—	38.1	57.3	57.2	52.8

Country or area	Year	Measure[c]	Females						
			All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Albania	1998	No.	156	5	10	76	39	16	11
		Rate	9.1	—	—	17.4	10.8	—	—
Argentina	1996	No.	835	35	60	214	176	160	190
		Rate	4.4	2.1	1.2	4.9	5.2	6.2	7.1
Armenia	1999	No.	39	0	2	3	10	8	16
		Rate	1.9	—	—	—	—	—	—
Australia	1998	No.	629	10	13	161	209	118	117
		Rate	6.2	—	—	7.9	9.7	7.2	7.1
Austria	1999	No.	468	3	4	50	101	109	201
		Rate	8.4	—	—	6.5	10.3	14.3	20.6
Azerbaijan	1999	No.	63	1	3	14	22	12	11
		Rate	1.8	—	—	—	2.4	—	—
Bahamas	1995–1997	No.	7	0	1	2	3	1	0
		Rate	—	—	—	—	—	—	—
Barbados	1993–1995	No.	9	0	0	3	2	2	1
		Rate	—	—	—	—	—	—	—
Belarus	1999	No.	873	3	13	143	215	219	279
		Rate	14.2	—	—	13.2	18.1	24.9	22.8
Belgium	1995	No.	677	3	9	73	195	156	241
		Rate	10.7	—	—	—	17.0	17.5	19.2
Brazil	1995	No.	4 820	84	302	1 977	1 518	569	370
		Rate	6.0	1.0	1.2	8.7	8.8	6.0	6.0
Bulgaria	1999	No.	407	1	5	44	64	86	207
		Rate	7.1	—	—	5.0	7.7	10.1	20.7
Canada	1997	No.	923	10	32	189	303	233	156
		Rate	5.6	—	1.1	6.2	8.0	8.7	5.7
Chile	1994	No.	156	5	12	50	42	25	22
		Rate	2.2	—	—	2.7	2.7	2.7	2.9
China									
Hong Kong SAR	1996	No.	315	4	13	65	83	39	110
		Rate	8.6	—	—	9.0	8.8	8.9	23.4
Selected urban and rural areas	1999	No.	9 557	19	120	2 117	2 587	1 757	2 957
		Rate	15.2	—	1.0	13.1	17.5	19.6	40.5
Colombia	1995	No.	2 043	34	151	982	575	218	83
		Rate	10.4	1.5	2.3	17.8	14.2	10.9	6.0
Costa Rica	1995	No.	64	1	4	31	20	7	1
		Rate	3.7	—	—	6.5	5.3	—	—
Croatia	1999	No.	309	1	3	21	50	74	160
		Rate	9.9	—	—	4.5	9.9	17.1	31.1
Cuba	1997	No.	795	4	14	208	212	164	193
		Rate	13.4	—	—	15.1	16.1	18.1	26.3
Czech Republic	1999	No.	383	4	6	54	64	99	156
		Rate	5.7	—	—	4.6	6.3	8.9	14.0
Denmark	1996	No.	285	1	1	21	73	90	99
		Rate	8.3	—	—	4.0	12.8	17.2	16.8
Ecuador	1996	No.	337	6	28	185	70	24	24
		Rate	5.8	—	1.4	11.0	6.4	4.2	5.9
El Salvador	1991	No.	285	1	23	164	50	29	18
		Rate	11.5	—	2.2	21.6	11.6	11.4	—
Estonia	1999	No.	155	3	4	14	35	43	56
		Rate	16.3	—	—	9.2	22.7	29.7	29.7
Finland	1998	No.	302	1	3	43	77	99	79
		Rate	9.9	—	—	9.1	13.7	18.4	13.2

TABLE A.7 *(continued)*

Country or area	Year	Measure[c]	Total[d, e]	Males						
				All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
France	1998	No.	10 997	8 058	14	36	1 092	2 358	1 938	2 620
		Rate	15.6	24.1	—	0.6	17.8	36.6	36.7	51.7
Georgia	1992	No.	214	160	0	0	38	42	30	50
		Rate	4.1	6.8	—	—	7.0	8.4	8.6	16.9
Germany	1999	No.	11 928	8 532	27	65	1 185	2 348	2 133	2 774
		Rate	11.5	17.7	1.3	1.0	15.9	22.6	26.9	36.4
Greece	1998	No.	548	425	1	1	82	107	100	134
		Rate	4.3	6.9	—	—	6.9	9.5	10.6	12.4
Guyana	1994–1996	No.	126	99	0	0	43	32	16	8
		Rate	19.1	32.3	—	—	37.1	47.8	—	—
Hungary	1999	No.	3 628	2 724	4	19	302	747	873	780
		Rate	29.5	49.0	—	—	25.9	72.8	90.5	102.3
Iceland	1994–1996	No.	29	24	0	0	8	6	5	4
		Rate	10.6	17.8	—	—	—	—	—	—
Ireland	1997	No.	498	398	1	5	156	118	76	42
		Rate	13.4	21.6	—	—	33.8	31.2	25.8	16.9
Israel	1997	No.	430	335	0	2	108	82	48	95
		Rate	7.3	12.1	—	—	14.6	15.1	12.4	28.4
Italy	1997	No.	5 416	4 108	0	11	748	933	873	1 543
		Rate	7.3	11.8	—	—	12.1	14.6	16.2	27.4
Japan	1997	No.	24 300	16 376	32	86	2 036	3 145	5 963	5 114
		Rate	15.1	21.4	1.1	0.9	14.9	26.1	43.2	43.1
Kazakhstan	1992	No.	5 844	4 569	14	99	1 470	1 706	845	434
		Rate	36.7	60.3	—	3.7	68.8	91.6	86.3	74.3
Kuwait	1999	No.	97	71	1	3	24	38	3	2
		Rate	4.2	5.1	—	—	7.5	7.9	—	—
Kyrgyzstan	1999	No.	906	727	1	16	201	272	153	84
		Rate	22.6	38.1	—	—	30.1	56.2	74.3	52.7
Latvia	1999	No.	1 075	806	0	1	132	256	246	171
		Rate	38.6	64.4	—	—	50.5	96.4	122.4	99.1
Lithuania	1999	No.	1 856	1 498	2	13	282	482	468	251
		Rate	45.8	80.5	—	—	68.7	115.1	163.3	100.9
Luxembourg	1995–1997	No.	75	55	0	0	8	17	14	16
		Rate	15.4	23.4	—	—	—	—	—	—
Malta	1997–1999	No.	25	19	0	0	4	8	2	4
		Rate	6.1	—	—	—	—	—	—	—
Mauritius	1999	No.	214	144	2	3	40	66	22	11
		Rate	17.5	23.6	—	—	26.2	45.6	27.5	—
Mexico	1997	No.	17 153	15 131	129	434	6 636	4 540	2 116	1 276
		Rate	19.8	36.5	2.2	2.6	46.6	53.5	46.3	45.0
Netherlands	1999	No.	1 729	1 166	4	15	202	380	308	257
		Rate	9.5	13.1	—	—	12.9	19.5	19.5	20.9
New Zealand	1998	No.	638	479	5	16	180	132	77	69
		Rate	16.6	25.3	—	—	44.0	30.8	24.0	26.5
Nicaragua	1996	No.	522	398	2	13	193	108	51	30
		Rate	14.4	23.8	—	—	30.1	31.7	32.2	32.9
Norway	1997	No.	575	416	1	6	94	114	91	110
		Rate	11.8	17.4	—	—	20.4	23.0	22.6	29.6
Panama (excluding Canal Zone)	1997	No.	453	401	5	8	186	125	44	32
		Rate	17.0	30.1	—	—	48.5	45.3	28.0	31.1
Paraguay	1994	No.	577	508	3	11	203	162	76	53
		Rate	15.9	28.6	—	—	31.8	37.2	39.8	50.4

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Country or area	Year	Measure[c]	Females						
			All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
France	1998	No.	2 939	8	23	308	721	781	1 098
		Rate	7.9	—	0.4	5.1	11.1	14.7	15.8
Georgia	1992	No.	54	0	0	12	13	9	20
		Rate	1.9	—	—	—	—	—	4.4
Germany	1999	No.	3 396	16	42	303	685	783	1 567
		Rate	5.9	—	0.7	4.3	7.0	10.0	14.3
Greece	1998	No.	123	0	1	15	26	37	44
		Rate	1.9	—	—	—	2.3	3.8	3.4
Guyana	1994–1996	No.	27	0	1	13	8	4	2
		Rate	7.5	—	—	—	—	—	—
Hungary	1999	No.	904	5	9	73	173	222	422
		Rate	12.7	—	—	6.6	16.9	20.8	34.8
Iceland	1994–1996	No.	5	0	0	1	0	1	2
		Rate	—	—	—	—	—	—	—
Ireland	1997	No.	100	1	1	26	24	24	24
		Rate	5.1	—	—	5.8	6.2	8.3	7.8
Israel	1997	No.	95	0	3	14	25	8	45
		Rate	3.0	—	—	—	4.4	—	10.4
Italy	1997	No.	1 308	2	14	173	252	279	588
		Rate	3.3	—	—	2.9	4.0	5.0	7.8
Japan	1997	No.	7 923	42	82	903	1 139	2 078	3 679
		Rate	9.0	1.5	0.9	6.9	9.6	14.9	23.7
Kazakhstan	1992	No.	1 275	18	40	299	354	239	325
		Rate	15.1	—	1.5	14.6	18.6	21.8	30.1
Kuwait	1999	No.	26	0	0	6	18	1	1
		Rate	3.2	—	—	—	—	—	—
Kyrgyzstan	1999	No.	179	5	10	56	39	21	48
		Rate	8.2	—	—	8.5	7.9	9.4	20.9
Latvia	1999	No.	269	3	6	27	63	66	103
		Rate	16.7	—	—	10.7	23.5	27.3	31.8
Lithuania	1999	No.	358	5	9	44	78	87	135
		Rate	15.1	—	—	11.0	18.4	25.6	31.4
Luxembourg	1995–1997	No.	20	0	0	3	7	5	5
		Rate	8.3	—	—	—	—	—	—
Malta	1997–1999	No.	6	0	0	2	1	1	2
		Rate	—	—	—	—	—	—	—
Mauritius	1999	No.	70	2	3	29	26	7	3
		Rate	11.4	—	—	19.7	18.8	—	—
Mexico	1997	No.	2 022	109	236	825	467	195	190
		Rate	4.2	2.0	1.5	5.7	5.2	4.0	5.7
Netherlands	1999	No.	563	1	10	96	156	147	153
		Rate	6.1	—	—	6.3	8.3	9.6	9.4
New Zealand	1998	No.	159	2	7	58	51	22	19
		Rate	8.1	—	—	14.2	11.3	6.8	—
Nicaragua	1996	No.	124	2	18	71	17	10	6
		Rate	5.7	—	—	10.9	—	—	—
Norway	1997	No.	159	0	1	28	46	47	37
		Rate	6.4	—	—	6.3	9.7	12.1	7.5
Panama (excluding Canal Zone)	1997	No.	52	3	6	22	10	5	6
		Rate	3.7	—	—	5.9	—	—	—
Paraguay	1994	No.	69	2	4	25	19	9	10
		Rate	3.7	—	—	4.0	—	—	—

TABLE A.7 *(continued)*

Country or area	Year	Measure[c]	Total[d, e]	Males						
				All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Philippines	1993	No.	8 677	7 770	20	80	3 296	3 039	1 041	294
		Rate	15.9	28.5	0.4	0.6	34.9	53.4	35.4	20.0
Poland	1995	No.	6 619	5 364	12	82	944	1 919	1 485	922
		Rate	16.0	27.3	—	1.8	21.8	42.1	50.2	37.9
Portugal	1999	No.	671	494	3	4	70	98	85	234
		Rate	5.2	8.3	—	—	6.0	9.3	10.0	27.0
Puerto Rico	1998	No.	1 129	1 022	1	11	557	238	125	89
		Rate	28.6	53.7	—	—	112.6	65.2	45.1	38.1
Republic of Korea	1997	No.	7 061	4 794	17	71	1 141	1 646	1 125	794
		Rate	14.9	21.3	—	1.3	17.2	26.3	33.9	45.3
Republic of Moldova	1999	No.	999	794	4	15	150	255	221	149
		Rate	26.7	46.2	—	—	33.6	66.0	82.9	76.3
Romania	1999	No.	3 560	2 817	10	57	479	763	843	665
		Rate	14.1	23.3	—	2.6	17.2	32.3	44.5	37.2
Russian Federation	1998	No.	85 511	68 013	98	581	15 476	25 190	16 695	9 973
		Rate	53.7	91.9	2.9	4.0	95.7	146.3	143.5	111.7
Singapore	1998	No.	446	280	0	3	67	97	57	56
		Rate	13.9	17.4	—	—	19.3	21.4	21.3	37.2
Slovakia	1999	No.	825	680	0	5	111	208	215	141
		Rate	13.8	24.1	—	—	16.3	34.9	46.4	42.9
Slovenia	1999	No.	623	476	1	5	65	125	135	145
		Rate	26.0	42.4	—	—	29.5	55.0	68.8	97.7
Spain	1998	No.	3 620	2 757	2	9	561	636	489	1 060
		Rate	7.3	11.7	—	—	11.8	14.3	14.9	29.2
Saint Lucia	1993–1995	No.	21	17	0	0	9	5	2	1
		Rate	16.0	—	—	—	—	—	—	—
Sweden	1996	No.	1 367	947	0	1	147	239	274	286
		Rate	13.0	18.4	—	—	17.0	25.8	31.3	33.7
Switzerland	1996	No.	1 513	1 060	2	10	197	265	262	324
		Rate	17.8	26.5	—	—	28.5	30.8	38.6	55.7
Tajikistan	1995	No.	557	451	4	6	149	175	74	43
		Rate	13.7	22.4	—	—	19.6	37.2	36.3	28.7
Thailand	1994	No.	6 530	5 133	21	106	1 881	1 866	885	375
		Rate	11.6	18.5	0.8	1.3	20.6	29.9	27.7	19.5
The former Yugoslav Republic of Macedonia	1997	No.	202	153	0	1	18	53	31	50
		Rate	9.7	15.0	—	—	—	23.5	19.7	39.1
Trinidad and Tobago	1994	No.	313	243	0	4	82	78	52	27
		Rate	26.1	39.0	—	—	45.3	53.1	64.5	48.1
Turkmenistan	1998	No.	742	603	2	19	249	215	94	23
		Rate	18.9	31.4	—	—	38.1	47.9	53.0	20.1
Ukraine	1999	No.	20 762	16 255	28	148	2 862	5 133	4 710	3 373
		Rate	36.9	63.8	2.5	3.2	51.8	96.7	117.4	93.5
United Kingdom	1999	No.	4 920	3 803	20	34	886	1 329	868	666
		Rate	7.6	12.0	1.1	0.6	15.1	19.3	15.9	12.7
England and Wales	1999	No.	4 015	3 077	19	29	667	1 050	736	576
		Rate	6.9	10.8	—	0.6	12.9	17.2	15.2	12.3
Northern Ireland	1999	No.	145	123	0	1	49	50	15	8
		Rate	8.8	14.9	—	—	25.9	27.6	—	—

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Country or area	Year	Measure[c]	Females						
			All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Philippines	1993	No.	907	11	46	403	226	136	86
		Rate	3.3	—	0.4	4.4	4.0	4.6	4.7
Poland	1995	No.	1 255	14	25	168	379	301	368
		Rate	5.6	—	0.6	4.0	8.4	9.4	10.1
Portugal	1999	No.	177	3	8	18	33	25	90
		Rate	2.5	—	—	—	3.0	2.7	7.6
Puerto Rico	1998	No.	107	3	4	43	30	13	14
		Rate	5.1	—	—	8.9	7.2	—	—
Republic of Korea	1997	No.	2 267	19	72	663	690	363	460
		Rate	9.2	—	1.5	10.5	11.6	10.8	17.2
Republic of Moldova	1999	No.	205	5	11	28	49	48	64
		Rate	9.9	—	—	6.3	11.8	15.4	21.3
Romania	1999	No.	743	11	20	114	157	177	264
		Rate	5.5	—	1.0	4.2	6.7	8.8	11.1
Russian Federation	1998	No.	17 498	90	303	3 000	4 342	3 862	5 902
		Rate	19.2	2.8	2.2	19.3	24.8	28.6	34.5
Singapore	1998	No.	166	0	0	50	30	29	56
		Rate	10.4	—	—	14.5	6.7	11.1	32.4
Slovakia	1999	No.	145	0	1	18	42	40	44
		Rate	4.5	—	—	—	7.2	8.0	8.8
Slovenia	1999	No.	147	0	0	15	28	48	56
		Rate	11.4	—	—	—	12.3	24.6	24.6
Spain	1998	No.	863	1	5	122	174	162	399
		Rate	3.2	—	—	2.7	4.0	4.8	8.3
Saint Lucia	1993–1995	No.	3	0	0	2	0	0	0
		Rate	—	—	—	—	—	—	—
Sweden	1996	No.	420	3	8	48	90	132	139
		Rate	7.7	—	—	5.8	10.2	15.5	12.7
Switzerland	1996	No.	453	3	5	53	102	114	176
		Rate	9.9	—	—	7.7	12.2	16.9	21.8
Tajikistan	1995	No.	106	0	0	38	31	15	21
		Rate	5.3	—	—	5.0	6.4	—	11.0
Thailand	1994	No.	1 397	15	78	550	418	210	126
		Rate	4.9	—	1.0	6.2	6.7	6.3	5.3
The former Yugoslav Republic of Macedonia	1997	No.	49	0	1	6	18	5	19
		Rate	4.7	—	—	—	—	—	—
Trinidad and Tobago	1994	No.	70	2	2	33	19	6	8
		Rate	11.6	—	—	21.2	—	—	—
Turkmenistan	1998	No.	139	1	4	59	35	18	21
		Rate	7.1	—	—	9.1	7.6	—	13.5
Ukraine	1999	No.	4 507	22	72	559	983	1 100	1 771
		Rate	13.6	2.0	1.6	10.5	17.7	22.9	27.4
United Kingdom	1999	No.	1 117	7	14	195	330	261	310
		Rate	3.2	—	—	3.5	4.9	4.7	4.5
England and Wales	1999	No.	938	7	13	152	272	219	275
		Rate	3.0	—	—	3.1	4.6	4.5	4.5
Northern Ireland	1999	No.	22	0	0	11	8	1	2
		Rate	2.7	—	—	—	—	—	—

TABLE A.7 *(continued)*

Country or area	Year	Measure[c]	Total[d, e]	Males						
				All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Scotland	1999	No.	760	603	1	4	170	229	117	82
		Rate	14.1	22.9	—	—	33.4	38.7	25.3	18.7
United States of America	1998	No.	49 586	38 974	396	894	12 511	11 688	6 885	6 600
		Rate	17.4	28.3	4.1	3.0	44.2	36.4	30.1	34.6
Uruguay	1990	No.	457	357	1	5	64	90	86	111
		Rate	14.0	23.5	—	—	17.8	31.5	36.7	50.3
Uzbekistan	1998	No.	2 414	1 821	2	73	585	690	315	156
		Rate	12.1	19.0	—	1.6	17.6	29.7	33.0	22.2
Venezuela	1994	No.	4 704	4 254	16	104	2 435	1 109	357	232
		Rate	23.2	42.0	—	2.6	80.8	53.1	33.4	38.6

Source: WHO mortality database as of September 2001.

[a] Intentional injury = ICD-10 X60–Y09, Y35, Y36 (ICD-9 E950–E978, E990–E999).

[b] Or average of the three most recent years available between 1990 and 2000 for countries with populations under 1 million.

[c] No. = number of deaths; rate = number of deaths per 100 000 population. Deaths where the age of the deceased person was not known were proportionally distributed across age groups based on the distribution of intentional injury deaths in the population. The numbers of deaths have therefore been rounded to the nearest whole number. Any apparent discrepancy in the total sums is due to rounding. The rate was not calculated if fewer than 20 deaths were reported. The population counts on which the rates are based are available from the World Health Organization at http://www3.who.int/whosis/whsa/ftp/download.htm.

[d] Age-standardized.

[e] Combined total for males and females.

Country or area	Year	Measure[c]	Females						
			All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Scotland	1999	No.	157	0	1	32	50	41	33
		Rate	5.4	—	—	6.5	8.4	8.5	5.4
United States of America	1998	No.	10 612	326	613	2 297	3 524	2 170	1 682
		Rate	7.1	3.5	2.2	8.3	10.8	9.0	6.6
Uruguay	1990	No.	100	2	6	25	14	13	39
		Rate	5.6	—	—	7.1	—	—	13.6
Uzbekistan	1998	No.	593	2	17	266	147	77	84
		Rate	5.7	—	—	8.1	6.2	7.8	8.7
Venezuela	1994	No.	450	16	43	202	116	38	35
		Rate	4.4	—	1.1	6.9	5.6	3.5	5.1

TABLE A.8

Mortality caused by homicide,[a] by sex, age group and country, most recent year available between 1990 and 2000[b]

Country or area	Year	Measure[c]	Total[d,e]	Males						
				All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Albania	1998	No.	660	573	2	9	286	165	84	27
		Rate	21.0	38.7	—	—	79.9	45.5	37.2	19.4
Argentina	1996	No.	1 611	1 347	37	35	514	371	239	152
		Rate	4.7	8.1	2.1	1.0	11.5	11.3	9.9	7.6
Armenia	1999	No.	98	77	2	1	20	29	16	9
		Rate	2.6	4.2	—	—	4.1	6.7	—	—
Australia	1998	No.	295	201	9	8	59	66	42	17
		Rate	1.6	2.1	—	—	2.8	3.1	2.5	—
Austria	1999	No.	68	32	3	2	3	15	4	5
		Rate	0.8	0.8	—	—	—	—	—	—
Azerbaijan	1999	No.	375	323	0	10	176	86	32	19
		Rate	5.0	8.7	—	—	16.6	10.1	8.5	—
Bahamas	1995–1997	No.	43	37	1	1	20	10	3	2
		Rate	14.9	26.1	—	—	48.4	—	—	—
Belarus	1999	No.	1 123	784	3	2	203	303	171	102
		Rate	10.5	15.6	—	—	18.2	26.2	22.1	15.1
Belgium	1995	No.	169	100	3	1	24	34	22	16
		Rate	1.6	1.9	—	—	2.3	2.9	2.5	—
Brazil	1995	No.	37 076	33 751	99	436	18 400	10 352	3 393	1 071
		Rate	23.0	42.5	1.2	2.5	81.2	61.9	38.7	20.9
Bulgaria	1999	No.	238	174	4	1	38	47	48	36
		Rate	2.6	4.0	—	—	4.1	5.6	6.1	4.6
Canada	1997	No.	431	285	14	12	100	76	48	35
		Rate	1.4	1.9	—	—	3.2	2.0	1.8	1.6
Chile	1994	No.	410	356	10	4	125	118	58	41
		Rate	3.0	5.4	—	—	6.7	7.7	6.7	7.2
China										
Hong Kong SAR	1996	No.	63	39	5	3	8	10	3	9
		Rate	1.0	1.3	—	—	—	—	—	—
Selected urban and rural areas	1999	No.	2 405	1 655	16	44	514	684	264	133
		Rate	1.8	2.5	—	0.5	3.0	4.4	2.8	2.0
Colombia	1995	No.	23 443	21 705	56	239	11 730	7 039	2 016	625
		Rate	61.6	116.8	2.3	5.5	212.5	185.1	109.7	55.2
Costa Rica	1995	No.	179	153	3	1	57	62	22	7
		Rate	5.4	9.3	—	—	11.5	16.6	12.2	—
Croatia	1999	No.	128	95	1	1	17	33	22	21
		Rate	2.6	4.0	—	—	—	6.3	5.6	6.4
Cuba	1997	No.	747	584	7	5	263	210	63	36
		Rate	6.2	9.6	—	—	18.4	16.0	7.2	5.3
Czech Republic	1999	No.	151	97	3	1	22	36	27	8
		Rate	1.4	1.8	—	—	1.8	3.4	2.5	—
Denmark	1996	No.	59	36	2	1	12	14	4	3
		Rate	1.1	1.4	—	—	—	—	—	—
Ecuador	1996	No.	1 632	1 501	5	21	684	535	178	78
		Rate	15.3	28.2	—	1.5	39.8	48.7	31.5	21.8
El Salvador	1993	No.	2 480	2 290	8	35	1 043	659	344	201
		Rate	55.6	108.4	—	5.1	133.1	165.4	139.5	122.7
Estonia	1999	No.	227	168	2	0	29	59	56	23
		Rate	14.8	23.1	—	—	18.0	38.4	46.3	22.2
Finland	1998	No.	125	90	1	1	15	38	22	13
		Rate	2.2	3.3	—	—	—	6.5	4.0	—
France	1998	No.	436	269	14	12	56	80	75	32
		Rate	0.7	0.9	—	—	0.9	1.2	1.4	0.6

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Country or area	Year	Measure[c]	Females						
			All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Albania	1998	No.	87	4	3	31	30	12	6
		Rate	5.3	—	—	7.2	8.3	—	—
Argentina	1996	No.	264	36	15	86	63	30	35
		Rate	1.5	2.1	—	2.0	1.9	1.2	1.3
Armenia	1999	No.	21	0	2	3	6	5	5
		Rate	1.0	—	—	—	—	—	—
Australia	1998	No.	94	10	1	26	26	15	16
		Rate	1.0	—	—	1.3	1.2	—	—
Austria	1999	No.	36	3	0	4	16	8	5
		Rate	0.8	—	—	—	—	—	—
Azerbaijan	1999	No.	52	1	2	12	19	9	9
		Rate	1.4	—	—	—	—	—	—
Bahamas	1995–1997	No.	7	0	1	2	3	1	0
		Rate	—	—	—	—	—	—	—
Belarus	1999	No.	339	3	6	60	102	78	90
		Rate	5.8	—	—	5.5	8.6	8.8	7.3
Belgium	1995	No.	69	3	3	12	24	9	18
		Rate	1.2	—	—	—	2.1	—	—
Brazil	1995	No.	3 325	85	183	1 484	1 089	308	177
		Rate	4.1	1.1	1.1	6.5	6.3	3.3	2.8
Bulgaria	1999	No.	64	1	1	12	13	15	22
		Rate	1.3	—	—	—	—	—	2.2
Canada	1997	No.	146	10	10	33	48	25	20
		Rate	1.0	—	—	1.1	1.3	0.9	0.7
Chile	1994	No.	54	5	3	17	17	5	7
		Rate	0.8	—	—	—	—	—	—
China									
Hong Kong SAR	1996	No.	24	4	4	4	9	3	0
		Rate	0.8	—	—	—	—	—	—
Selected urban and rural areas	1999	No.	750	19	37	218	283	117	76
		Rate	1.2	—	0.4	1.4	1.9	1.3	1.0
Colombia	1995	No.	1 738	33	106	827	511	189	72
		Rate	9.0	1.4	2.5	15.0	12.6	9.4	5.2
Costa Rica	1995	No.	26	1	2	15	7	1	0
		Rate	1.4	—	—	—	—	—	—
Croatia	1999	No.	33	1	1	3	7	9	12
		Rate	1.2	—	—	—	—	—	—
Cuba	1997	No.	163	4	4	78	55	13	9
		Rate	2.7	—	—	5.7	4.2	—	—
Czech Republic	1999	No.	54	4	2	14	9	13	12
		Rate	1.0	—	—	—	—	—	—
Denmark	1996	No.	23	1	0	7	7	5	3
		Rate	0.8	—	—	—	—	—	—
Ecuador	1996	No.	131	5	5	54	40	9	18
		Rate	2.5	—	—	3.2	3.7	—	—
El Salvador	1993	No.	190	3	4	72	56	34	20
		Rate	8.4	—	—	8.8	12.4	12.9	9.8
Estonia	1999	No.	59	3	1	4	19	21	11
		Rate	7.4	—	—	—	—	14.4	—
Finland	1998	No.	35	1	0	3	12	14	5
		Rate	1.2	—	—	—	—	—	—
France	1998	No.	167	8	6	31	42	41	39
		Rate	0.5	—	—	0.5	0.6	0.8	0.6

TABLE A.8 *(continued)*

Country or area	Year	Measure[c]	Total[d, e]	Males						
				All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Germany	1999	No.	720	418	27	12	95	127	101	56
		Rate	0.9	1.0	1.3	—	1.3	1.2	1.3	0.7
Greece	1998	No.	144	109	1	0	21	38	31	18
		Rate	1.2	1.9	—	—	1.8	3.4	3.3	—
Guyana	1994–1996	No.	42	35	0	0	14	12	6	3
		Rate	6.6	11.8	—	—	—	—	—	—
Hungary	1999	No.	291	170	4	4	19	54	58	31
		Rate	2.6	3.2	—	—	—	5.3	6.0	4.1
Ireland	1997	No.	30	21	1	0	8	6	5	1
		Rate	0.8	1.2	—	—	—	—	—	—
Israel	1997	No.	30	24	0	0	11	8	3	2
		Rate	0.5	0.9	—	—	—	—	—	—
Italy	1997	No.	720	561	0	6	170	207	101	77
		Rate	1.1	1.8	—	—	2.7	3.2	1.9	1.4
Japan	1997	No.	719	435	32	19	72	80	132	99
		Rate	0.6	0.7	1.1	—	0.5	0.7	1.0	0.8
Kazakhstan	1999	No.	2 448	1 841	14	17	483	738	380	209
		Rate	17.1	27.4	—	—	24.8	45.5	42.4	36.1
Kuwait	1999	No.	39	26	1	1	9	12	2	1
		Rate	2.2	2.4	—	—	—	—	—	—
Kyrgyzstan	1999	No.	341	266	1	3	63	110	59	30
		Rate	8.6	14.2	—	—	9.4	22.7	28.7	18.8
Latvia	1999	No.	308	213	0	0	47	69	61	36
		Rate	11.6	17.3	—	—	18.0	26.0	30.4	20.9
Lithuania	1999	No.	297	209	2	3	45	72	55	32
		Rate	7.5	11.3	—	—	11.0	17.2	19.2	12.9
Mauritius	1999	No.	33	19	2	0	3	9	2	3
		Rate	2.9	—	—	—	—	—	—	—
Mexico	1997	No.	13 542	12 170	129	224	5 281	3 810	1 751	975
		Rate	15.9	29.6	2.3	2.1	37.1	44.9	38.3	34.4
Netherlands	1999	No.	203	144	4	4	36	58	31	11
		Rate	1.3	1.7	—	—	2.3	3.0	2.0	—
New Zealand	1998	No.	57	32	5	2	10	6	6	3
		Rate	1.5	1.7	—	—	—	—	—	—
Nicaragua	1996	No.	285	246	2	5	117	66	37	19
		Rate	8.4	15.1	—	—	18.2	19.3	23.3	—
Norway	1997	No.	41	28	1	2	7	11	6	1
		Rate	0.9	1.3	—	—	—	—	—	—
Panama (excluding	1997	No.	293	265	5	2	136	75	29	18
Canal Zone)		Rate	10.9	19.8	—	—	35.3	27.1	18.5	—
Paraguay	1994	No.	459	420	3	4	171	144	61	37
		Rate	12.6	23.4	—	—	26.8	33.0	31.9	35.9
Philippines	1993	No.	7 726	7 181	20	59	3 020	2 845	977	260
		Rate	14.2	26.4	0.4	0.7	31.9	49.9	33.2	17.7
Poland	1995	No.	1 088	785	12	10	132	292	211	128
		Rate	2.7	4.0	—	—	3.0	6.4	7.1	5.3
Portugal	1999	No.	118	82	3	0	30	19	14	16
		Rate	1.1	1.6	—	—	2.6	—	—	—
Puerto Rico	1998	No.	804	731	1	7	500	149	59	15
		Rate	20.6	38.1	—	—	101.0	40.8	21.3	—
Republic of Korea	1997	No.	987	602	17	23	168	243	112	39
		Rate	2.0	2.4	—	0.7	2.5	3.9	3.4	2.2
Republic of Moldova	1999	No.	410	307	4	5	78	106	65	49
		Rate	11.2	18.0	—	—	17.5	27.4	24.4	25.1

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Country or area	Year	Measure[c]	Females						
			All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Germany	1999	No.	302	16	17	53	98	58	60
		Rate	0.7	—	—	0.7	1.0	0.7	0.5
Greece	1998	No.	35	0	0	4	6	9	16
		Rate	0.5	—	—	—	—	—	—
Guyana	1994–1996	No.	7	0	0	3	3	1	0
		Rate	—	—	—	—	—	—	—
Hungary	1999	No.	121	5	3	19	35	23	36
		Rate	2.0	—	—	—	3.4	2.2	3.0
Ireland	1997	No.	9	1	0	2	1	3	2
		Rate	—	—	—	—	—	—	—
Israel	1997	No.	6	0	0	2	3	0	1
		Rate	—	—	—	—	—	—	—
Italy	1997	No.	159	2	6	36	28	27	60
		Rate	0.5	—	—	0.6	0.4	0.5	0.8
Japan	1997	No.	284	42	21	37	29	64	91
		Rate	0.4	1.5	0.3	0.3	0.2	0.5	0.6
Kazakhstan	1999	No.	607	2	19	130	184	117	156
		Rate	7.9	—	—	6.8	11.0	11.2	15.4
Kuwait	1999	No.	13	0	0	4	7	1	1
		Rate	—	—	—	—	—	—	—
Kyrgyzstan	1999	No.	75	5	3	22	17	12	16
		Rate	3.5	—	—	3.4	—	—	—
Latvia	1999	No.	95	3	3	8	31	23	27
		Rate	6.6	—	—	—	11.5	9.5	8.3
Lithuania	1999	No.	88	5	3	10	21	16	33
		Rate	4.0	—	—	—	5.0	—	7.7
Mauritius	1999	No.	14	2	1	1	6	2	2
		Rate	—	—	—	—	—	—	—
Mexico	1997	No.	1 372	110	97	496	360	148	161
		Rate	3.1	2.0	0.9	3.4	4.0	3.0	4.8
Netherlands	1999	No.	59	1	4	21	16	7	10
		Rate	0.8	—	—	1.4	—	—	—
New Zealand	1998	No.	25	2	1	9	11	2	0
		Rate	1.3	—	—	—	—	—	—
Nicaragua	1996	No.	39	2	4	16	7	6	4
		Rate	2.2	—	—	—	—	—	—
Norway	1997	No.	13	0	1	3	3	4	2
		Rate	—	—	—	—	—	—	—
Panama (excluding	1997	No.	28	3	3	13	5	1	3
Canal Zone)		Rate	2.0	—	—	—	—	—	—
Paraguay	1994	No.	39	2	0	16	10	6	5
		Rate	2.2	—	—	—	—	—	—
Philippines	1993	No.	545	11	33	173	160	108	59
		Rate	2.1	—	0.4	1.9	2.8	3.6	3.3
Poland	1995	No.	303	14	5	46	93	56	89
		Rate	1.4	—	—	1.1	2.1	1.8	2.4
Portugal	1999	No.	36	3	2	6	10	9	6
		Rate	0.7	—	—	—	—	—	—
Puerto Rico	1998	No.	73	3	1	33	23	7	6
		Rate	3.7	—	—	6.8	5.6	—	—
Republic of Korea	1997	No.	385	19	19	100	141	59	47
		Rate	1.6	—	—	1.6	2.4	1.8	1.8
Republic of Moldova	1999	No.	103	4	6	13	31	19	30
		Rate	5.2	—	—	—	7.5	—	10.0

TABLE A.8 *(continued)*

Country or area	Year	Measure[c]	Total[d, e]	Males						
				All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Romania	1999	No.	803	572	10	12	122	164	140	124
		Rate	3.3	4.8	—	—	4.4	6.9	7.4	6.9
Russian Federation	1998	No.	33 553	25 130	99	147	6 067	10 595	5 792	2 429
		Rate	21.6	34.0	2.9	1.3	37.5	61.5	49.8	27.2
Singapore	1998	No.	45	29	0	0	9	13	5	2
		Rate	1.3	1.7	—	—	—	—	—	—
Slovakia	1999	No.	132	89	0	0	21	38	18	12
		Rate	2.3	3.2	—	—	3.1	6.4	—	—
Slovenia	1999	No.	30	20	1	0	3	6	7	3
		Rate	1.3	1.8	—	—	—	—	—	—
Spain	1998	No.	355	255	2	3	70	91	50	39
		Rate	0.8	1.2	—	—	1.5	2.1	1.5	1.1
Sweden	1996	No.	110	74	0	0	11	28	21	14
		Rate	1.2	1.5	—	—	—	3.0	2.4	—
Switzerland	1996	No.	77	48	2	4	10	17	11	4
		Rate	1.1	1.4	—	—	—	—	—	—
Tajikistan	1995	No.	354	301	4	2	107	129	38	21
		Rate	8.5	14.3	—	—	14.0	27.4	18.6	14.0
Thailand	1994	No.	4 161	3 481	21	83	1 138	1 394	628	217
		Rate	7.5	12.6	0.8	1.4	12.5	22.3	19.7	11.3
The former Yugoslav Republic of Macedonia	1997	No.	47	38	0	0	5	19	7	7
		Rate	2.2	3.7	—	—	—	—	—	—
Trinidad and Tobago	1994	No.	146	108	0	2	39	35	23	9
		Rate	12.1	17.1	—	—	21.6	23.8	28.5	—
Turkmenistan	1998	No.	333	279	2	2	116	114	32	12
		Rate	8.6	14.6	—	—	17.8	25.5	18.2	—
Ukraine	1999	No.	6 260	4 421	28	41	941	1 674	1 196	541
		Rate	11.7	17.8	2.5	1.2	17.0	31.6	29.8	15.0
United Kingdom	1999	No.	440	335	20	10	108	109	60	28
		Rate	0.8	1.2	1.1	—	1.8	1.6	1.1	0.5
England and Wales	1999	No.	295	214	19	8	68	61	34	24
		Rate	0.6	0.9	—	—	1.3	1.0	0.7	0.5
Northern Ireland	1999	No.	24	20	0	1	4	11	3	1
		Rate	1.4	2.4	—	—	—	—	—	—
Scotland	1999	No.	121	101	1	1	36	37	23	3
		Rate	2.4	4.1	—	—	7.1	6.3	5.0	—
United States of America	1998	No.	17 893	13 652	396	257	6 670	3 984	1 609	736
		Rate	6.9	10.7	4.1	1.3	23.6	12.4	7.0	3.9
Uruguay	1990	No.	136	105	1	1	22	36	22	24
		Rate	4.4	7.1	—	—	6.0	12.6	9.2	10.8
Uzbekistan	1998	No.	790	567	2	18	178	222	100	47
		Rate	4.1	6.0	—	—	5.3	9.6	10.5	6.7
Venezuela	1994	No.	3 353	3 120	15	60	1 926	787	232	100
		Rate	16.0	29.7	—	2.3	63.9	37.7	21.7	16.7

Source: WHO mortality database as of September 2001.

[a] Homicide = ICD-10 X85–Y09 (ICD-9 E960–E969).

[b] Or average of the three most recent years available between 1990 and 2000 for countries with populations under 1 million.

[c] No. = number of deaths; rate = number of deaths per 100 000 population. Deaths where the age of the deceased person was not known were proportionally distributed across age groups based on the distribution of homicides in the population. The numbers of deaths have therefore been rounded to the nearest whole number. Any apparent discrepancy in the total sums is due to rounding. The rate was not calculated if fewer than 20 deaths were reported. The population counts on which the rates are based are available from the World Health Organization at http://www3.who.int/whosis/whsa/ftp/download.htm.

[d] Age-standardized.

[e] Combined total for males and females.

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Country or area	Year	Measure[c]	Females						
			All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Romania	1999	No.	231	11	5	37	56	48	74
		Rate	1.8	—	—	1.4	2.4	2.4	3.1
Russian Federation	1998	No.	8 423	90	135	1 632	2 452	1 907	2 207
		Rate	9.8	2.8	1.3	10.5	14.0	14.1	12.9
Singapore	1998	No.	16	0	0	5	4	3	3
		Rate	—	—	—	—	—	—	—
Slovakia	1999	No.	43	0	1	4	14	11	13
		Rate	1.4	—	—	—	—	—	—
Slovenia	1999	No.	10	0	0	1	4	0	5
		Rate	—	—	—	—	—	—	—
Spain	1998	No.	100	1	0	24	22	15	38
		Rate	0.4	—	—	0.5	0.5	—	0.8
Sweden	1996	No.	36	3	3	5	14	6	5
		Rate	0.8	—	—	—	—	—	—
Switzerland	1996	No.	29	3	2	6	5	4	9
		Rate	0.8	—	—	—	—	—	—
Tajikistan	1995	No.	53	0	0	16	18	7	11
		Rate	2.8	—	—	—	—	—	—
Thailand	1994	No.	680	15	62	208	216	109	71
		Rate	2.5	—	1.1	2.4	3.4	3.3	3.0
The former Yugoslav Republic of Macedonia	1997	No.	9	0	1	0	5	1	2
		Rate	—	—	—	—	—	—	—
Trinidad and Tobago	1994	No.	38	2	0	15	11	5	5
		Rate	6.6	—	—	—	—	—	—
Turkmenistan	1998	No.	54	1	0	13	21	8	11
		Rate	3.0	—	—	—	4.5	—	—
Ukraine	1999	No.	1 839	22	36	285	500	454	541
		Rate	6.1	2.0	1.1	5.3	9.0	9.5	8.4
United Kingdom	1999	No.	105	7	6	26	38	15	13
		Rate	0.4	—	—	0.5	0.6	—	—
England and Wales	1999	No.	81	7	6	19	28	11	10
		Rate	0.3	—	—	—	0.5	—	—
Northern Ireland	1999	No.	4	0	0	2	2	0	0
		Rate	—	—	—	—	—	—	—
Scotland	1999	No.	20	0	0	5	8	4	3
		Rate	0.7	—	—	—	—	—	—
United States of America	1998	No.	4 241	327	202	1 268	1 446	542	457
		Rate	3.1	3.5	1.1	4.6	4.4	2.2	1.8
Uruguay	1990	No.	31	2	1	12	5	2	9
		Rate	1.9	—	—	—	—	—	—
Uzbekistan	1998	No.	223	2	8	58	67	49	39
		Rate	2.4	—	—	1.8	2.8	4.9	4.0
Venezuela	1994	No.	233	16	18	103	67	14	15
		Rate	2.3	—	—	3.5	3.2	—	—

TABLE A.9

Mortality caused by suicide,[a] by sex, age group and country, most recent year available between 1990 and 2000[b]

Country or area	Year	Measure[c]	Total[d,e]	Males						
				All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Albania	1998	No.	165	104	0	2	46	28	18	10
		Rate	5.3	7.1	—	—	12.7	7.8	—	—
Argentina	1996	No.	2 245	1 709	0	14	402	328	442	523
		Rate	6.5	10.6	—	—	9.0	10.0	18.3	26.3
Armenia	1999	No.	67	49	0	0	9	16	11	13
		Rate	1.7	2.6	—	—	—	—	—	—
Australia	1998	No.	2 633	2 108	0	6	666	732	393	311
		Rate	13.3	21.4	—	—	31.7	34.1	23.2	22.7
Austria	1999	No.	1 555	1 126	0	2	171	289	275	389
		Rate	15.5	24.2	—	—	21.7	28.2	36.1	59.7
Azerbaijan	1999	No.	54	44	0	0	9	21	9	5
		Rate	0.8	1.3	—	—	—	2.5	—	—
Belarus	1999	No.	3 408	2 877	0	22	552	923	797	583
		Rate	30.9	56.9	—	2.9	49.4	79.7	103.4	86.3
Belgium	1995	No.	2 155	1 550	0	10	252	471	373	444
		Rate	17.9	27.1	—	—	24.3	39.9	41.9	48.7
Bosnia and Herzegovina	1991	No.	531	457	0	15	167	151	83	41
		Rate	11.3	19.4	—	—	27.0	29.4	22.9	20.4
Brazil	1995	No.	6 584	5 174	0	38	1 812	1 649	935	740
		Rate	4.7	7.6	—	0.2	8.0	9.9	10.7	14.4
Bulgaria	1999	No.	1 307	965	0	7	118	180	245	415
		Rate	12.3	19.6	—	—	12.8	21.5	30.9	53.3
Canada	1997	No.	3 681	2 914	0	39	682	1 010	708	475
		Rate	11.3	18.1	—	1.9	21.6	26.3	26.8	22.1
Chile	1994	No.	801	704	0	2	240	211	133	118
		Rate	6.1	11.1	—	—	12.9	13.8	15.5	20.9
China										
Hong Kong SAR	1996	No.	788	501	0	6	96	168	99	131
		Rate	11.2	14.6	—	—	13.8	18.5	19.4	31.2
Selected urban and rural areas	1999	No.	16 836	8 048	0	83	1 252	2 018	1 680	3 015
		Rate	13.7	13.5	—	0.9	7.2	12.9	17.9	45.7
Colombia	1995	No.	1 172	905	0	15	427	230	123	110
		Rate	3.4	5.5	—	—	7.7	6.1	6.7	9.7
Costa Rica	1995	No.	211	174	0	5	66	61	27	14
		Rate	6.6	10.9	—	—	13.4	16.4	14.8	—
Croatia	1999	No.	989	716	0	5	112	170	171	258
		Rate	18.5	30.2	—	—	23.2	32.5	43.2	79.1
Cuba	1997	No.	2 029	1 401	0	5	235	355	310	496
		Rate	17.1	23.8	—	—	16.4	27.1	35.3	72.6
Czech Republic	1999	No.	1 610	1 285	0	3	223	298	399	362
		Rate	13.0	22.3	—	—	18.1	28.2	37.1	48.1
Denmark	1996	No.	892	631	0	1	80	163	180	207
		Rate	13.6	20.2	—	—	14.5	27.4	33.8	46.5
Ecuador	1996	No.	593	396	0	7	188	107	56	38
		Rate	5.5	7.8	—	—	10.9	9.7	9.9	10.5
El Salvador	1993	No.	429	276	0	4	168	56	26	21
		Rate	8.5	12.1	—	—	21.5	14.0	10.7	13.0
Estonia	1999	No.	469	376	0	2	73	97	111	92
		Rate	28.1	50.9	—	—	45.5	63.6	92.5	90.3
Finland	1998	No.	1 228	962	0	3	173	296	290	200
		Rate	21.1	34.0	—	—	35.1	50.8	53.2	49.6

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Country or area	Year	Measure[c]	Females						
			All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Albania	1998	No.	61	0	1	42	9	4	4
		Rate	3.6	—	—	9.7	—	—	—
Argentina	1996	No.	536	0	9	129	113	130	155
		Rate	3.0	—	—	2.9	3.3	5.1	5.8
Armenia	1999	No.	18	0	0	0	4	3	11
		Rate	—	—	—	—	—	—	—
Australia	1998	No.	525	0	2	135	183	103	101
		Rate	5.2	—	—	6.6	8.5	6.3	6.1
Austria	1999	No.	429	0	1	46	85	101	196
		Rate	7.6	—	—	6.0	8.6	13.2	20.1
Azerbaijan	1999	No.	10	0	0	2	3	3	2
		Rate	—	—	—	—	—	—	—
Belarus	1999	No.	531	0	4	83	113	142	189
		Rate	8.5	—	—	7.7	9.5	16.1	15.4
Belgium	1995	No.	605	0	3	61	171	147	223
		Rate	9.4	—	—	6.1	14.9	16.5	17.8
Bosnia and Herzegovina	1991	No.	74	0	4	19	17	16	18
		Rate	3.3	—	—	—	—	—	—
Brazil	1995	No.	1 410	0	36	496	430	258	190
		Rate	1.9	—	0.2	2.2	2.5	2.7	3.1
Bulgaria	1999	No.	342	0	3	32	51	71	185
		Rate	5.8	—	—	3.6	6.1	8.4	18.5
Canada	1997	No.	767	0	12	156	255	208	136
		Rate	4.6	—	—	5.1	6.7	7.8	5.0
Chile	1994	No.	97	0	4	33	25	20	15
		Rate	1.4	—	—	1.8	1.6	2.2	—
China									
Hong Kong SAR	1996	No.	287	0	5	61	74	36	110
		Rate	7.9	—	—	8.5	7.9	8.2	23.4
Selected urban and rural areas	1999	No.	8 788	0	64	1 899	2 304	1 640	2 881
		Rate	14.0	—	0.8	11.8	15.6	18.3	39.5
Colombia	1995	No.	267	0	10	153	63	29	11
		Rate	1.4	—	—	2.8	1.6	1.4	—
Costa Rica	1995	No.	37	0	1	16	12	6	1
		Rate	2.3	—	—	—	—	—	—
Croatia	1999	No.	273	0	1	18	41	65	148
		Rate	8.6	—	—	—	8.1	15.0	28.8
Cuba	1997	No.	628	0	6	130	157	151	184
		Rate	10.6	—	—	9.5	11.9	16.6	25.1
Czech Republic	1999	No.	325	0	0	40	55	86	144
		Rate	4.7	—	—	3.4	5.4	7.7	12.9
Denmark	1996	No.	261	0	0	14	66	85	96
		Rate	7.5	—	—	—	11.6	16.2	16.3
Ecuador	1996	No.	197	0	17	130	30	14	6
		Rate	3.2	—	—	7.7	2.7	—	—
El Salvador	1993	No.	153	0	13	103	18	11	8
		Rate	5.3	—	—	12.5	—	—	—
Estonia	1999	No.	93	0	0	10	17	22	44
		Rate	8.9	—	—	—	—	15.3	23.4
Finland	1998	No.	266	0	2	40	65	85	74
		Rate	8.8	—	—	8.5	11.6	15.8	12.3

TABLE A.9 *(continued)*

Country or area	Year	Measure[c]	Total[d, e]	Males						
				All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
France	1998	No.	10 534	7 771	0	10	1 036	2 278	1 863	2 584
		Rate	14.8	23.2	—	—	16.9	35.3	35.3	51.0
Georgia	1992	No.	204	151	0	0	35	37	29	50
		Rate	3.9	6.4	—	—	6.4	7.4	8.3	16.9
Germany	1999	No.	11 160	8 082	0	26	1 087	2 221	2 032	2 716
		Rate	10.6	16.7	—	0.6	14.6	21.3	25.6	35.6
Greece	1998	No.	403	315	0	0	61	69	69	116
		Rate	3.1	4.9	—	—	5.2	6.1	7.3	10.7
Guyana	1994–1996	No.	84	64	0	0	28	20	10	5
		Rate	12.5	20.5	—	—	24.6	30.2	—	—
Hungary	1999	No.	3 328	2 550	0	11	283	693	815	749
		Rate	26.9	45.7	—	—	24.3	67.5	84.5	98.2
Iceland	1994–1996	No.	28	24	0	0	8	6	5	4
		Rate	10.4	17.5	—	—	—	—	—	—
Ireland	1997	No.	466	376	0	4	148	112	71	41
		Rate	12.5	20.4	—	—	32.0	29.6	24.1	16.5
Israel	1997	No.	379	301	0	2	95	70	44	90
		Rate	6.5	10.8	—	—	12.8	12.9	11.4	26.9
Italy	1997	No.	4 694	3 547	0	5	578	726	772	1 466
		Rate	6.2	9.9	—	—	9.3	11.4	14.3	26.0
Japan	1997	No.	23 502	15 906	0	34	1 964	3 064	5 829	5 015
		Rate	14.5	20.7	—	0.5	14.4	25.4	42.2	42.3
Kazakhstan	1999	No.	4 004	3 340	0	49	963	1 172	711	445
		Rate	27.9	50.3	—	3.2	49.4	72.2	79.3	76.9
Kuwait	1999	No.	47	34	0	1	11	21	1	0
		Rate	1.5	1.8	—	—	—	4.3	—	—
Kyrgyzstan	1999	No.	559	460	0	12	138	162	94	54
		Rate	14.0	23.9	—	—	20.6	33.5	45.6	34.0
Latvia	1999	No.	764	593	0	1	85	187	185	135
		Rate	27.0	47.1	—	—	32.5	70.4	92.1	78.3
Lithuania	1999	No.	1 552	1 287	0	8	237	410	413	219
		Rate	38.4	69.2	—	—	57.8	97.9	144.1	88.1
Luxembourg	1995–1997	No.	72	53	0	0	8	16	14	15
		Rate	14.7	22.5	—	—	—	—	—	—
Mauritius	1999	No.	174	120	0	1	35	56	20	8
		Rate	14.3	19.7	—	—	23.0	38.7	25.0	—
Mexico	1997	No.	3 369	2 828	0	81	1 350	731	365	300
		Rate	3.9	6.9	—	0.8	9.5	8.6	8.0	10.6
Netherlands	1999	No.	1 517	1 015	0	7	165	321	276	246
		Rate	8.3	11.3	—	—	10.5	16.5	17.5	20.0
New Zealand	1998	No.	574	442	0	9	170	126	71	66
		Rate	15.0	23.6	—	—	41.5	29.4	22.1	25.3
Nicaragua	1996	No.	230	147	0	6	76	41	13	11
		Rate	5.9	8.4	—	—	11.8	12.0	—	—
Norway	1997	No.	533	387	0	3	87	103	85	109
		Rate	10.9	16.1	—	—	18.8	20.8	21.1	29.3
Panama (excluding Canal Zone)	1997	No.	145	124	0	1	48	46	15	14
		Rate	5.8	9.8	—	—	12.5	16.7	—	—
Paraguay	1994	No.	109	82	0	4	30	18	14	15
		Rate	3.2	5.1	—	—	4.8	—	—	—
Philippines	1993	No.	851	509	0	0	256	163	59	31
		Rate	1.5	1.9	—	—	2.7	2.9	2.0	2.1

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Country or area	Year	Measure[c]	Females						
			All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
France	1998	No.	2 763	0	9	277	679	740	1 058
		Rate	7.4	—	—	4.6	10.4	14.0	15.3
Georgia	1992	No.	53	0	0	11	13	9	20
		Rate	1.9	—	—	—	—	—	4.4
Germany	1999	No.	3 078	0	9	250	587	725	1 507
		Rate	5.1	—	—	3.5	6.0	9.2	13.7
Greece	1998	No.	88	0	1	11	20	28	28
		Rate	1.4	—	—	—	1.8	2.9	2.1
Guyana	1994–1996	No.	20	0	1	10	5	3	1
		Rate	5.6	—	—	—	—	—	—
Hungary	1999	No.	778	0	1	54	138	199	386
		Rate	10.7	—	—	4.8	13.5	18.6	31.8
Iceland	1994–1996	No.	5	0	0	1	0	1	2
		Rate	—	—	—	—	—	—	—
Ireland	1997	No.	90	0	0	24	23	21	22
		Rate	4.7	—	—	5.4	5.9	7.3	7.1
Israel	1997	No.	78	0	0	12	20	7	39
		Rate	2.4	—	—	—	3.5	—	9.0
Italy	1997	No.	1 147	0	6	137	224	252	528
		Rate	2.9	—	—	2.3	3.5	4.5	7.0
Japan	1997	No.	7 596	0	19	866	1 110	2 013	3 588
		Rate	8.5	—	—	6.6	9.4	14.4	23.2
Kazakhstan	1999	No.	664	0	10	187	163	136	167
		Rate	8.7	—	—	9.8	9.7	13.1	16.6
Kuwait	1999	No.	13	0	0	2	11	0	0
		Rate	—	—	—	—	—	—	—
Kyrgyzstan	1999	No.	99	0	2	34	22	9	32
		Rate	4.7	—	—	5.2	4.5	—	13.9
Latvia	1999	No.	171	0	0	19	32	43	76
		Rate	10.0	—	—	—	11.9	17.9	23.5
Lithuania	1999	No.	265	0	1	34	57	71	102
		Rate	11.2	—	—	8.5	13.4	20.9	23.7
Luxembourg	1995–1997	No.	19	0	0	3	7	5	5
		Rate	—	—	—	—	—	—	—
Mauritius	1999	No.	54	0	0	28	20	5	1
		Rate	8.9	—	—	19.0	14.5	—	—
Mexico	1997	No.	541	0	30	327	107	47	29
		Rate	1.1	—	0.3	2.3	1.2	1.0	0.9
Netherlands	1999	No.	502	0	5	75	140	139	143
		Rate	5.4	—	—	4.9	7.5	9.1	8.8
New Zealand	1998	No.	132	0	4	49	40	20	19
		Rate	6.8	—	—	12.0	8.9	6.2	—
Nicaragua	1996	No.	83	0	12	55	10	4	2
		Rate	3.5	—	—	8.5	—	—	—
Norway	1997	No.	146	0	0	25	43	43	35
		Rate	5.9	—	—	5.6	9.1	11.0	7.1
Panama (excluding Canal Zone)	1997	No.	21	0	0	9	5	4	3
		Rate	1.7	—	—	—	—	—	—
Paraguay	1994	No.	27	0	2	9	8	3	5
		Rate	1.5	—	—	—	—	—	—
Philippines	1993	No.	342	0	0	226	64	27	24
		Rate	1.2	—	—	2.5	1.1	0.9	1.3

TABLE A.9 *(continued)*

Country or area	Year	Measure[c]	Total[d, e]	Males						
				All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Poland	1995	No.	5 499	4 562	0	60	809	1 625	1 274	794
		Rate	13.4	23.2	—	1.9	18.7	35.7	43.0	32.7
Portugal	1999	No.	545	407	0	1	39	78	71	218
		Rate	4.0	6.7	—	—	3.3	7.4	8.3	25.1
Puerto Rico	1998	No.	321	290	0	3	58	89	66	74
		Rate	8.1	15.6	—	—	11.7	24.4	23.7	31.6
Republic of Korea	1997	No.	6 024	4 162	0	31	966	1 398	1 012	755
		Rate	12.8	18.8	—	0.9	14.6	22.3	30.5	43.1
Republic of Moldova	1999	No.	579	482	0	6	72	149	155	100
		Rate	15.5	28.1	—	—	16.1	38.6	58.2	51.2
Romania	1999	No.	2 736	2 235	0	35	357	599	703	541
		Rate	10.8	18.5	—	2.2	12.8	25.4	37.1	30.3
Russian Federation	1998	No.	51 770	42 785	0	335	9 414	14 614	10 898	7 524
		Rate	32.1	57.9	—	3.0	58.2	84.9	93.7	84.3
Singapore	1998	No.	371	221	0	3	50	66	50	52
		Rate	11.7	14.1	—	—	14.4	14.5	18.8	34.7
Slovakia	1999	No.	692	590	0	5	90	170	197	128
		Rate	11.5	20.8	—	—	13.2	28.5	42.5	38.9
Slovenia	1999	No.	590	453	0	4	61	119	128	141
		Rate	24.6	40.3	—	—	27.7	52.3	65.3	95.0
Spain	1998	No.	3 261	2 499	0	4	490	545	439	1 021
		Rate	6.5	10.5	—	—	10.3	12.3	13.3	28.1
Sweden	1996	No.	1 253	872	0	1	135	211	253	272
		Rate	11.8	16.9	—	—	15.6	22.8	28.9	32.0
Switzerland	1996	No.	1 431	1 010	0	4	187	248	251	320
		Rate	16.7	25.1	—	—	27.0	28.9	37.0	55.0
Tajikistan	1995	No.	199	146	0	0	42	46	36	22
		Rate	5.2	8.1	—	—	5.5	9.8	17.7	14.7
Thailand	1994	No.	2 333	1 631	0	1	743	473	257	158
		Rate	4.1	5.9	—	—	8.1	7.6	8.1	8.2
The former Yugoslav Republic of Macedonia	1997	No.	155	115	0	1	13	34	24	43
		Rate	7.4	11.3	—	—	—	15.1	15.3	33.6
Trinidad and Tobago	1994	No.	148	118	0	2	35	35	28	18
		Rate	12.6	19.5	—	—	19.3	23.8	34.7	—
Turkmenistan	1998	No.	406	322	0	15	133	101	62	11
		Rate	10.4	16.9	—	—	20.3	22.5	34.8	—
Ukraine	1999	No.	14 452	11 806	0	80	1 922	3 460	3 514	2 830
		Rate	25.2	46.0	—	2.3	34.8	65.2	87.6	78.4
United Kingdom	1999	No.	4 448	3 443	0	4	777	1 220	806	636
		Rate	6.8	10.8	—	—	13.2	17.7	14.8	12.1
England and Wales	1999	No.	3 690	2 840	0	2	598	989	700	551
		Rate	6.3	9.9	—	—	11.5	16.2	14.4	11.8
Northern Ireland	1999	No.	121	103	0	0	45	39	12	7
		Rate	7.3	12.5	—	—	23.8	21.5	—	—
Scotland	1999	No.	637	500	0	2	134	192	94	78
		Rate	11.7	18.8	—	—	26.3	32.5	20.3	17.8
United States of America	1998	No.	30 575	24 538	0	241	5 718	7 523	5 218	5 838
		Rate	10.4	17.3	—	1.2	20.2	23.4	22.8	30.6

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Country or area	Year	Measure[c]	Females						
			All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Poland	1995	No.	937	0	6	121	286	245	279
		Rate	4.2	—	—	2.9	6.3	7.7	7.6
Portugal	1999	No.	138	0	3	12	23	16	84
		Rate	1.9	—	—	—	2.1	—	7.1
Puerto Rico	1998	No.	31	0	0	10	7	6	8
		Rate	1.5	—	—	—	—	—	—
Republic of Korea	1997	No.	1 862	0	34	563	549	303	413
		Rate	7.6	—	1.1	8.9	9.3	9.0	15.5
Republic of Moldova	1999	No.	97	1	0	15	18	29	34
		Rate	4.7	—	—	—	—	9.3	11.3
Romania	1999	No.	501	0	4	77	101	129	190
		Rate	3.6	—	—	2.9	4.3	6.4	8.0
Russian Federation	1998	No.	8 985	0	79	1 369	1 893	1 955	3 689
		Rate	9.4	—	0.8	8.8	10.8	14.5	21.6
Singapore	1998	No.	150	0	0	45	26	26	53
		Rate	9.4	—	—	12.9	5.8	9.9	30.5
Slovakia	1999	No.	102	0	0	14	28	29	31
		Rate	3.2	—	—	—	4.8	5.8	6.2
Slovenia	1999	No.	137	0	0	14	24	48	51
		Rate	10.6	—	—	—	10.5	24.6	22.4
Spain	1998	No.	762	0	4	98	152	147	361
		Rate	2.8	—	—	2.1	3.5	4.3	7.5
Sweden	1996	No.	381	0	2	43	76	126	134
		Rate	6.9	—	—	5.2	8.6	14.8	12.2
Switzerland	1996	No.	421	0	0	47	97	110	167
		Rate	9.1	—	—	6.8	11.6	16.3	20.7
Tajikistan	1995	No.	53	0	0	22	13	8	10
		Rate	2.5	—	—	2.8	—	—	—
Thailand	1994	No.	702	0	1	342	202	101	56
		Rate	2.4	—	—	3.9	3.2	3.0	2.4
The former Yugoslav Republic of Macedonia	1997	No.	40	0	0	6	13	4	17
		Rate	3.8	—	—	—	—	—	—
Trinidad and Tobago	1994	No.	30	0	0	18	8	1	3
		Rate	5.0	—	—	—	—	—	—
Turkmenistan	1998	No.	84	0	3	47	14	10	10
		Rate	4.1	—	—	7.1	—	—	—
Ukraine	1999	No.	2 646	0	14	275	484	645	1 228
		Rate	7.6	—	—	5.1	8.7	13.4	19.0
United Kingdom	1999	No.	1 005	0	1	169	292	246	297
		Rate	2.9	—	—	3.0	4.4	4.5	4.3
England and Wales	1999	No.	850	0	0	133	244	208	265
		Rate	2.7	—	—	2.7	4.1	4.3	4.3
Northern Ireland	1999	No.	18	0	0	9	6	1	2
		Rate	—	—	—	—	—	—	—
Scotland	1999	No.	137	0	1	27	42	37	30
		Rate	4.7	—	—	5.5	7.1	7.7	5.0
United States of America	1998	No.	6 037	0	83	1 029	2 076	1 624	1 225
		Rate	4.0	—	0.4	3.7	6.4	6.7	4.8

TABLE A.9 *(continued)*

Country or area	Year	Measure[c]	Total[d, e]	Males						
				All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Uruguay	1990	No.	318	251	0	3	42	54	65	87
		Rate	9.6	16.4	—	—	11.8	19.0	27.5	39.4
Uzbekistan	1998	No.	1 620	1 252	0	53	407	468	215	109
		Rate	8.0	13.0	—	1.7	12.2	20.1	22.5	15.5
Venezuela	1994	No.	1 089	890	0	26	349	262	121	131
		Rate	6.1	10.3	—	1.0	11.6	12.6	11.3	21.8

Source: WHO mortality database as of September 2001.

[a] Suicide = ICD-10 X60–X84 (ICD-9 E950–E959).

[b] Or average of the three most recent years available between 1990 and 2000 for countries with populations under 1 million.

[c] No. = number of deaths; rate = number of deaths per 100 000 population. Deaths where the age of the deceased person was not known were proportionally distributed across age groups based on the distribution of suicides in the population. The numbers of deaths have therefore been rounded to the nearest whole number. Any apparent discrepancy in the total sums is due to rounding. The rate was not calculated if fewer than 20 deaths were reported. The population counts on which the rates are based are available from the World Health Organization at http://www3.who.int/whosis/whsa/ftp/download.htm.

[d] Age-standardized.

[e] Combined total for males and females.

Country or area	Year	Measure[c]	Females						
			All ages[d]	0–4 years	5–14 years	15–29 years	30–44 years	45–59 years	⩾60 years
Uruguay	1990	No.	67	0	3	13	9	11	30
		Rate	3.7	—	—	—	—	—	10.5
Uzbekistan	1998	No.	368	0	7	208	80	28	45
		Rate	3.3	—	—	6.3	3.3	2.8	4.7
Venezuela	1994	No.	199	0	9	98	49	23	20
		Rate	2.1	—	—	3.3	2.4	2.1	2.9

TABLE A.10

Firearm-related mortality, by manner of death[a] and country, most recent year available between 1990 and 2000[b]

Country or area	Year	Measure[c]	Total	Firearm-related deaths			
				Homicide	Suicide	Unintentional	Undetermined
Albania	1998	No.	741	591	98	50	2
		Rate	22.1	17.6	2.9	1.5	—
Australia	1998	No.	334	56	248	23	7
		Rate	1.8	0.3	1.3	0.1	—
Austria	1999	No.	293	17	272	3	1
		Rate	3.6	—	3.4	—	—
Belgium	1995	No.	379	59	289	2	29
		Rate	3.7	0.6	2.9	—	0.3
Bulgaria	1999	No.	133	51	55	20	7
		Rate	1.6	0.6	0.7	0.2	—
Canada	1997	No.	1 034	159	818	45	12
		Rate	3.4	0.5	2.7	0.1	—
China (Hong Kong SAR)	1996	No.	6	3	3	0	0
		Rate	—	—	—	—	—
Croatia	1999	No.	226	69	145	11	1
		Rate	5.0	1.5	3.2	—	—
Czech Republic	1999	No.	259	46	185	17	11
		Rate	2.5	0.4	1.8	—	—
Denmark	1996	No.	101	15	80	4	2
		Rate	1.9	—	1.5	—	—
Estonia	1999	No.	71	31	32	1	7
		Rate	4.9	2.1	2.2	—	—
Finland	1998	No.	295	22	267	3	3
		Rate	5.7	0.4	5.2	—	—
France	1998	No.	2 964	170	2 386	68	340
		Rate	5.0	0.3	4.1	0.1	0.6
Germany	1999	No.	1 201	155	906	16	124
		Rate	1.5	0.2	1.1	—	0.2
Greece	1998	No.	194	74	86	34	0
		Rate	1.8	0.7	0.8	0.3	—
Hungary	1999	No.	129	31	96	1	1
		Rate	1.3	0.3	1.0	—	—
Iceland	1994–1996	No.	7	1	5	0	1
		Rate	—	—	—	—	—
Ireland	1997	No.	54	7	44	3	0
		Rate	1.5	—	1.2	—	—
Israel	1997	No.	161	15	73	0	73
		Rate	2.8	—	1.3	—	1.3
Italy	1997	No.	1 171	463	626	38	44
		Rate	2.0	0.8	1.1	0.1	0.1
Japan	1997	No.	83	22	45	10	6
		Rate	0.1	0.0	0.0	—	—
Kuwait	1999	No.	16	16	0	0	0
		Rate	—	—	—	—	—
Latvia	1999	No.	92	34	47	5	6
		Rate	3.8	1.4	1.9	—	—
Lithuania	1999	No.	67	18	35	4	10
		Rate	1.8	—	0.9	—	—
Luxembourg	1995–1997	No.	12	1	9	0	2
		Rate	—	—	—	—	—
Malta	1997–1999	No.	7	4	2	1	0
		Rate	—	—	—	—	—
Netherlands	1999	No.	131	75	51	5	0
		Rate	0.8	0.5	0.3	—	—

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TABLE A.10 *(continued)*

Country or area	Year	Measure[c]	Total	Firearm-related deaths			
				Homicide	Suicide	Unintentional	Undetermined
New Zealand	1998	No.	84	4	72	6	2
		Rate	2.2	—	1.9	—	—
Norway	1997	No.	139	10	127	2	0
		Rate	3.2	—	2.9	—	—
Portugal	1999	No.	202	61	62	2	77
		Rate	2.0	0.6	0.6	—	0.8
Republic of Korea	1997	No.	59	19	22	9	9
		Rate	0.1	—	0.0	—	—
Republic of Moldova	1999	No.	68	45	7	9	7
		Rate	1.9	1.2	—	—	—
Romania	1999	No.	73	19	24	26	4
		Rate	0.3	—	0.1	0.1	—
Singapore	1998	No.	6	0	5	1	0
		Rate	—	—	—	—	—
Slovakia	1999	No.	171	43	88	20	20
		Rate	3.2	0.8	1.6	0.4	0.4
Slovenia	1999	No.	61	9	49	2	1
		Rate	3.1	—	2.5	—	—
Spain	1998	No.	352	85	224	43	0
		Rate	0.9	0.2	0.6	0.1	—
Sweden	1996	No.	183	11	163	3	6
		Rate	2.1	—	1.8	—	—
Thailand	1994	No.	2 434	2 184	158	84	8
		Rate	4.2	3.8	0.3	0.1	—
The former Yugoslav Republic of Macedonia	1997	No.	41	20	16	5	0
		Rate	2.1	1.0	—	—	—
United Kingdom	1999	No.	197	45	140	6	6
		Rate	0.3	0.1	0.2	—	—
England and Wales	1999	No.	159	23	115	6	15
		Rate	0.3	0.0	0.2	—	—
Northern Ireland	1999	No.	28	15	11	0	2
		Rate	1.7	—	—	—	—
Scotland	1999	No.	25	7	14	0	4
		Rate	0.5	—	—	—	—
United States of America	1998	No.	30 419	11 802	17 432	866	319
		Rate	11.3	4.4	6.4	0.3	0.1

Source: WHO mortality database as of September 2001.

[a] Homicide by firearm discharge = ICD-10 X93–X95 (ICD-9 E965); suicide by firearm discharge = ICD-10 X72–X74 (ICD-9 E955); firearm discharge, unintentional = ICD-10 W32–W34 (ICD-9 E922); firearm discharge, intent undetermined = ICD-10 Y22–Y24 (ICD-9 E985).

[b] Or average of the three most recent years available between 1990 and 2000 for countries with populations under 1 million.

[c] No. = number of deaths; rate = number of deaths per 100 000 population. The rate was not calculated if fewer than 20 deaths were reported. The population counts on which the rates are based are available from the World Health Organization at http://www3.who.int/whosis/whsa/ftp/download.htm.

Resources

The following is a listing of resources on violence-related topics, primarily Internet addresses of organizations involved in violence research, prevention and advocacy. In preparing this listing, the intention was to offer an illustrative sampling rather than a comprehensive listing of resources. Every effort was made to ensure that the web sites listed are reliable, current and content-rich. Section I contains a list of metasites, section II a list of web sites categorized according to type of violence, and section III a list of general web sites which may be of interest to those involved in violence research, prevention and advocacy.

Section I. Violence-related metasites

Included below are five metasites. Collectively, they offer access to hundreds of web sites of violence-related organizations from all over the world. A brief description is provided of each.

WHO Department of Injuries and Violence Prevention: external links

http://www.who.int/violence_injury_prevention/externalinks.htm

The WHO Department of Injuries and Violence Prevention offers an extensive listing of external links to organizations around the world involved in violence research, prevention and advocacy. The web sites of these agencies are listed by geographical region and country and by type of violence and other topics.

Economics of Civil Wars, Crime and Violence: related links

http://www.worldbank.org/research/conflict

Hosted on the web site of the World Bank, this link provides access to web sites dedicated to the study of conflict. The list includes data on political and economic variables for countries that have experienced internal violent conflicts; information on organizations and institutes that are working in the area of conflict resolution; and sites that provide historical background and analyses of specific cases of internal conflict.

Injury Control Resource Information Network

http://www.injurycontrol.com/icrin

The Injury Control Resource Information Network offers a dynamic list of key resources related to the field of injury and violence research and control that are accessible via the Internet. The sites are listed by categories, including data and statistics, recent research, and education and training. While the majority of sites are those of federal and state agencies in the United States, there are a handful of sites from other countries.

Injury Prevention Web

http://www.injuryprevention.org

The Injury Prevention Web contains more than 1400 links to injury and violence prevention web sites worldwide. The sites are listed alphabetically and by categories such as violence prevention, suicide prevention, and war and conflict. The site also offers a weekly literature update of recent journal articles and

agency reports, book reviews, and listings of employment opportunities in the injury and violence research and prevention field.

Minnesota Center Against Violence and Abuse: electronic clearing house

http://www.mincava.umn.edu

The electronic clearing house of the Minnesota Center Against Violence and Abuse provides articles, fact sheets and other information resources, as well as links to web sites on a wide variety of violence-related topics, including child abuse, gang violence and abuse of the elderly. The site also provides searchable databases with over 700 training manuals, videos and other educational resources.

Section II. Violence-related web sites

Table 1 includes a list of web sites, primarily the home pages of organizations concerned with violence, categorized according to the type of violence. The web sites listed provide information not only about the organizations themselves, but also about violence-related topics in general.

TABLE 1
Violence-related web sites

Type of violence	Web site
Child abuse and neglect	
Casa Alianza: Covenant House Latin America	http://www.casa-alianza.org/EN/index-en.shtml
Child Abuse Prevention Network	http://child-abuse.com
Great Lakes Area Regional Resource Center: Early Prevention of Violence Database	http://www.glarrc.org/Resources/EPVD.cfm
International Society for Prevention of Child Abuse and Neglect	http://www.ispcan.org
Minnesota Center Against Violence and Abuse	http://www.mincava.umn.edu
Office of the United Nations High Commissioner for Human Rights: Convention on the Rights of the Child	http://www.unhchr.ch/html/menu2/6/crc.htm
United Nations Children's Fund Innocenti Research Centre	http://www.unicef.org http://www.unicef-icdc.org
Collective violence	
Centre for the Study of Violence and Reconciliation	http://www.wits.ac.za/csvr
Correlates of War Project	http://www.umich.edu/~cowproj
Global Internally Displaced Persons Project	http://www.idpproject.org
International Relations and Security Network: Security Watch	http://www.isn.ethz.ch/infoservice
Office for the Coordination of Humanitarian Affairs	http://www.reliefweb.int/ocha_ol
Office of the United Nations High Commissioner for Refugees	http://www.unhcr.ch
Stockholm International Peace Research Institute	http://www.sipri.se
Elder abuse	
Action on Elder Abuse	http://www.elderabuse.org.uk
Canadian Network for the Prevention of Elder Abuse	http://www.mun.ca/elderabuse
HelpAge International	http://www.helpage.org
International Network for the Prevention of Elder Abuse	http://www.inpea.net
National Center on Elder Abuse	http://www.elderabusecenter.org
National Committee for the Prevention of Elder Abuse	http://www.preventelderabuse.org/index.html

TABLE 1 *(continued)*

Type of violence	Web site
Suicide	
American Association of Suicidology	http://www.suicidology.org
Australian Institute for Suicide Research and Prevention	http://www.gu.edu.au/school/psy/aisrap
National Strategy for Suicide Prevention	http://www.mentalhealth.org/suicideprevention
Suicide Information and Education Centre/Suicide Prevention Training Programmes	http://www.suicideinfo.ca
The Suicidology Web: Suicide and Parasuicide	http://www.suicide-parasuicide.rumos.com
Violence against women	
Global Alliance Against Traffic in Women	http://www.inet.co.en/org/gaatw
International Center for Research on Women	http://www.icrw.org
Latin American and Caribbean Women's Health Network	http://www.reddesalud.web.cl
National Sexual Violence Resource Center	http://www.nsvrc.org
Network of East-West Women	http://www.neww.org/index.htm
Office of the United Nations High Commissioner for Human Rights: Women's Rights are Human Rights	http://www.unhchr.ch/women/index.html
Research, Action and Information Network for the Bodily Integrity of Women	http://www.rainbo.org
United Nations Development Fund for Women	http://www.undp.org/unifem
United Nations Development Programme: Gender in Development	http://www.undp.org/gender
Women Against Violence Europe	http://www.wave-network.org
Youth violence	
Center for the Prevention of School Violence	http://www.ncsu.edu/cpsv
Center for the Study and Prevention of Violence	http://www.colorado.edu/cspv
Inter-American Development Bank: Violence Prevention	http://www.iadb.org/sds/SOC/site_471_e.htm
National Center for Injury Prevention and Control	http://www.cdc.gov/ncipc
National Criminal Justice Reference Service	http://www.ncjrs.org/intlwww.html
Partnerships Against Violence Network	http://pavnet.org
TMR Network Project: Nature and Prevention of Bullying	http://www.goldsmiths.ac.uk/tmr
United Nations Crime and Justice Information Network	http://www.uncjin.org/Statistics/statistics.html

Section III. Other web sites

Table 2 lists other web sites that may be of interest to those involved in violence research, prevention and advocacy. They relate primarily to broad contextual issues such as economic and social development, human rights and crime, but also include some relevant tools for improving the understanding of violence-related injuries.

TABLE 2

Other web sites

Organization	Web site
Amnesty International	http://www.amnesty.org/
Campbell Collaboration's Crime and Justice Coordinating Group	http://www.aic.gov.au/campbellcj/
Centers for Disease Control and Prevention: National Center for Injury Prevention and Control	http://www.cdc.gov/ncipc http://www.cdc.gov/ncipc/pub_res/intimate.htm (*Intimate partner surveillance: uniform elements and recommended data elements*)
Centro Latino-Americano de Estudos sobre Violência e Saúde	http://www.ensp.fiocruz.br/claves.html
Economic and Social Research Council: Violence Research Programme	http://www1.rhbnc.ac.uk/sociopolitical-science/vrp/realhome.htm
Human Rights Watch	http://www.hrw.org/
Institute for Security Studies	http://www.iss.co.za
Inter-American Coalition for the Prevention of Violence	http://www.iacpv.org
International Action Network on Small Arms	http://www.iansa.org
International Campaign to Ban Landmines	http://www.icbl.org/
International Center for the Prevention of Crime	http://www.crime-prevention-intl.org
International Labour Organization	http://www.ilo.org
Medical Research Council of South Africa: Crime, Violence and Injury Lead Programme	http://www.mrc.ac.za/crime/crime.htm
National Library of Medicine: Entrez PubMed	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi
Pan American Health Organization: Prevention of Violence and Injuries	http://www.paho.org/English/hcp/hcn/violence-unit-page.htm http://www.paho.org/English/HCP/HCN/guidelines-eng.htm (*Guidelines for the epidemiological surveillance of violence and injuries in the Americas*)
Red Andina de Prevención de Violencia	http://www.redandina.org
Trauma.org	http://www.trauma.org/trauma.html
United Nations Educational, Scientific and Cultural Organization	http://www.unesco.org
United Nations Human Settlements Programme	http://www.unhabitat.org/default.asp
United Nations Institute for Disarmament Research	http://www.unog.ch/unidir
United Nations Interregional Crime and Justice Research Institute	http://www.unicri.it
United Nations Office of Drug Control and Crime Prevention	http://www.odccp.org/crime_prevention.html
United Nations Population Fund	http://www.unfpa.org
United Nations Research Institute for Social Development	http://www.unrisd.org
University for Peace	http://www.upeace.org
World Health Organization	http://www.who.int/ http://www.who.int/violence_injury_prevention/pdf/injuryguidelines.pdf (*Injury surveillance guidelines*)

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For readers without access to the Internet, the WHO Department of Injuries and Violence Prevention would be pleased to provide the full mailing address of the organizations listed. Kindly contact the Department at the following address:

Department of Injuries and Violence Prevention
World Health Organization
20 Avenue Appia
1211 Geneva 27
Switzerland
Tel.: +41 22 791 3480
Fax: +41 22 791 4332
Email: vip@who.int

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Original Investigation | Psychiatry

Health Care Experiences of Patients Discontinuing or Reversing Prior Gender-Affirming Treatments

Kinnon R. MacKinnon, PhD; Hannah Kia, PhD; Travis Salway, PhD; Florence Ashley, LLM (bioeth); Ashley Lacombe-Duncan, PhD; Alex Abramovich, PhD; Gabriel Enxuga, BSW; Lori E. Ross, PhD

Abstract

IMPORTANCE Medical education, research, and clinical guidelines are available to support the initiation of gender-affirming care for transgender and nonbinary people. By contrast, little is known about the clinical experiences of those who discontinue or seek to reverse gender-affirming medical or surgical interventions due to a change in gender identity, often referred to as *detransition*.

OBJECTIVE To examine the physical and mental health experiences of people who initiated medical or surgical detransition to inform clinical practice.

DESIGN, SETTING, AND PARTICIPANTS Using constructivist grounded theory as a qualitative approach, data were collected in the form of in-depth interviews. Data were analyzed using an inductive 2-stage coding process to categorize and interpret detransition-related health care experiences to inform clinical practice. Between October 2021 and January 2022, individuals living in Canada who were aged 18 years and older with experience of stopping, shifting, or reversing a gender transition were invited to partake in semistructured virtual interviews. Study advertisements were circulated over social media, to clinicians, and within participants' social networks. A purposive sample of 28 participants who discontinued, shifted, or reversed a gender transition were interviewed.

MAIN OUTCOMES AND MEASURES In-depth, narrative descriptions of the physical and mental health experiences of people who discontinued or sought to reverse prior gender-affirming medical and/or surgical interventions.

RESULTS Among the 28 participants, 18 (64%) were assigned female at birth and 10 (36%) were assigned male at birth; 2 (7%) identified as Jewish and White, 5 (18%) identified as having mixed race and ethnicity (which included Arab, Black, Indigenous, Latinx, and South Asian), and 21 (75%) identified as White. Participants initially sought gender-affirmation at a wide range of ages (15 [56%] were between ages 18 and 24 years). Detransition occurred for various reasons, such as an evolving understanding of gender identity or health concerns. Participants reported divergent perspectives about their past gender-affirming medical or surgical treatments. Some participants felt regrets, but a majority were pleased with the results of gender-affirming medical or surgical treatments. Medical detransition was often experienced as physically and psychologically challenging, yet health care avoidance was common. Participants described experiencing stigma and interacting with clinicians who were unprepared to meet their detransition-related medical needs.

CONCLUSIONS AND RELEVANCE This study's results suggest that further research and clinical guidance is required to address the unmet needs of this population who discontinue or seek to reverse prior gender-affirming interventions.

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Key Points

Question What are the health care experiences of adults undergoing medical and/or surgical detransition?

Findings In this qualitative study, 28 adults with heterogenous gender identities were interviewed about their experiences of detransition, including their health care encounters when discontinuing or reversing gender-affirming medical and/or surgical care. A majority of respondents reported no decisional regrets regarding prior gender-affirming interventions; however, participants frequently discussed health care avoidance, clinician stigma, and experiencing clinicians who lacked detransition-related clinical knowledge.

Meaning These findings suggest that clinicians may be insufficiently knowledgeable to meet the needs of this population, and further research and clinical guidance are required to better support people who detransition after pursuing gender-affirming health care.

+ Invited Commentary

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

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Introduction

Transgender and nonbinary people experience to varying degrees gender dysphoria—distress related to an incongruence between one's assigned sex at birth and their experience of gender.[1] To alleviate gender dysphoria, some individuals pursue medical transition, which may include gender-affirming hormonal therapies and surgical procedures. For adults assigned male at birth (AMAB), medical or surgical interventions could include antiandrogens and estrogen therapy, facial feminization surgery, breast augmentation, orchiectomy, and vaginoplasty. For adults assigned female at birth (AFAB), available treatments include testosterone therapy, double mastectomy with male chest contouring, oophorectomy/hysterectomy, and a range of genital surgery options.[2] In the past 10 years, adolescent and adult referrals to gender identity clinics in Canada, Europe, the US, and the United Kingdom (UK) have risen substantially,[3-5] indicating that the number of individuals who medically transition is increasing.

Medical education, research, and clinical guidelines are available to support the initiation of gender-affirming care.[2,6-13] By contrast, there is little clinical guidance when patients stop, or seek to reverse, gender-affirming medical interventions, referred to as detransition.[14] Medical detransition involves ceasing or switching gender-affirming hormone therapy and/or surgical reconstruction or reversal.[15] After medical detransition, individuals may continue identifying as transgender or nonbinary, or they may reidentify with their birth sex (eg, female or male).[16-18] Clinicians who work in gender-affirming health care report fears of detransition as a patient outcome because of limited experience and concerns of harm and liability.[19]

Detransition appears to be an infrequent and occasionally temporary outcome, with estimates ranging from less than 1% to 13%, much of this variability owing to differences in methods, sampling, and conceptual definitions.[14,17,20-23] At the high end of this range, Turban et al[18] found that 13% of 17 151 transgender and nonbinary survey respondents reported a history of temporarily returning to their sex assigned at birth. Hall et al's[22] retrospective case-note analysis shows that out of 175 patients discharged from a gender identity clinic in the UK, 5 (2.8%) stopped transition; 6 (3.4%) paused their transition goals for social or health issues, and 12 (6.9%) reverted back to their assigned sex at birth. Of these 12, 4 patients were rereferred to the clinic, suggesting interest in resuming medical transition following detransition (eg, retransition). Individuals report detransitioning for reasons such as mental and/or physical health concerns,[15,17,21,22] fertility preservation,[17] change in political beliefs,[15] shifting gender identity[14-17,21,24] or understanding of one's sexuality,[15,21] social challenges living as a transgender person,[17,21] pressure from a romantic partner or family member,[17] employment discrimination,[17] postoperative surgical pain,[25] and career-related or financial concerns,[17,25] among others. Some report regretting their initial gender transition, whereas others experienced it as an opportunity to explore and clarify their gender identity.[16,24,26]

There are scant studies that center patient experiences of detransition. One international survey of 237 self-identified detransitioners found 49% wanted information on stopping or changing hormones, and 15% required information on surgical reversals.[14] However, 31% of the sample had not medically transitioned. Authors have called for qualitative research into detransition to understand this population's everyday lives and their clinical needs.[16,22,27] In response, we explored the physical and mental health experiences, gender identities, and other characteristics of a sample of detransitioners and retransitioners living in Canada. To our knowledge, this is the first qualitative study of detransition and retransition in the adult population.

Methods

We selected constructivist grounded theory (CGT) methodology for its analytic utility in constructing new concepts grounded in research participants' descriptive statements about their life events.[28] The study protocol was reviewed and approved by the York University Research Ethics Board.

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Prospective participants were emailed a copy of the informed consent form to review in advance of the scheduled interview, and prior to initiating the interview participants provided verbal consent.

Quality and Reflexivity Statement

We followed the Consolidated Criteria for Reporting Qualitative Research (COREQ) reporting guideline. CGT stresses that credibility is enhanced when researchers engage in reflexivity, acknowledging how their experiences can shape the research and interpretation process. Our team is composed of cisgender, trans, and nonbinary researchers. The interview guide was developed by the research team and each question was reviewed for concept accuracy by 2 project consultants with detransition/retransition experiences (eAppendix 1 in the Supplement). To elicit high quality data, all interviews were conducted by transgender or nonbinary interviewers with experience of accessing gender-affirming medical treatments, one of whom has medically detransitioned. Interviewers brought clinical social work training and/or qualitative interviewing skills, using rapport-building strategies with interviewees. These strategies included a preinterview eligibility screener conversation to confirm eligibility and answer all questions about the study posed by prospective participants. Within the interview itself, interviewers applied verbal agreements (eg, "Yes that makes sense."), as well as clarifying participant responses by summarizing (eg, "To be clear, what you are telling me is..."). Following the recruitment and data analysis phases, participants were communicated an update regarding how their interview data were being mobilized, such as upcoming presentations and the sharing of anonymized quotes on social media. Participants were invited to opt out of having their personal quotes shared on social media. During data analysis and interpretation, we consulted with 2 additional detransitioners—both living in the US—and 2 Canadian psychiatrists working clinically with this population.

Participant Selection and Interview Procedures

Participants were sampled using purposive and snowball sampling. To be eligible, participants had to be aged 18 years and older, living in Canada, able to participate in an interview conducted in 1 of the 2 official national languages—English or French—and self-identify as detransitioning, retransitioning, detrans, retrans, reidentifying, experiencing a shift in gender identity after initiating transition, or having stopped transition. Transition included social, legal, or medical gender transition. A broad definition of detransition consistent with existing literature was used to maximize heterogeneity in the sample. We used language neutral in tone to invite a diverse range of individuals (see eAppendix 2 and 3 in the Supplement for study advertisements). Recruitment flyers were promoted using Twitter, Facebook, Instagram, TikTok, and private internet-based detransition support groups. Flyers were sent to clinicians known to serve trans people and those pursuing detransition in 6 urban centers across Canada. Following purposive and snowball sampling, participants who discussed gender transition reversal and/or reidentifying with their birth sex—in particular—were encouraged to share the research flyer among their networks.

Data were collected between October 2021 and January 2022; 42 individuals expressed interest in the study and were invited for eligibility screening via telephone or Zoom. Of those who initially contacted the study, 14 did not partake because they: (1) were unresponsive to follow-up emails; (2) did not live in Canada; or (3) had never discontinued or reversed a gender transition and were therefore ineligible. Semistructured, in-depth one-on-one virtual interviews (n = 28) were conducted with participants who met eligibility criteria and all participants completed the full interview and demographic questions. Two interviews were conducted in French. The Zoom platform enabled geographic sampling of participants living in urban, suburban, and rural regions of Canada. Zoom interviews are a useful alternative to in-person interviews in qualitative research and offer a level of perceived anonymity that can be beneficial for data collection on sensitive topics.[29,30] Interviews were between 50 to 90 minutes, audio-recorded, and transcribed verbatim. Participants received a $30 CAD (US $23) electronic gift card. To understand the demographic characteristics and heterogeneity of the sample, participants were asked how they self-described their race and/or

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ethnicity, assigned sex at birth, and sexual orientation. These categories were constructed by directly following participants' own language. See the eTable in the Supplement for sample characteristics.

Data Analysis

In-depth narrative interview data were analyzed inductively and involved 2 phases of coding. Following 20 interviews, K.M. and G.E. pursued initial coding in which data were classified into preliminary themes and a coding framework. We leveraged this initial process to assess saturation, a measure of analytical rigor in qualitative research which confirm no new themes emerge from the data. In the second stage of coding, the final 8 interviews served to confirm theoretical saturation across the data set, and to finalize the coding framework (eAppendix 4 in the Supplement). All transcripts were read and reread by a minimum of 2 authors (K.M., G.E., L.R.) and coded in Dedoose.

Because each participant experienced a shift in how they understood or expressed their gender after initiating gender transition, alongside the illustrative quotes we present participants' assigned sex at birth together with a description of their current gender. See the eFigure in the Supplement for current gender identities.

Results

Among the 28 participants, 18 (64%) were assigned female at birth and 10 (36%) were assigned male at birth. Twenty participants (71%) were between the ages of 20 to 29 years, 6 (22%) were between 30 to 39 years, and 2 (7%) were aged 40 years or older. When asked demographic questions about race and ethnicity, participants were provided the option to use preferred language; 2 (7%) identified as Jewish and White, 5 (18%) identified as having mixed race and ethnicity (which included Arab, Black, Indigenous, Latinx, and South Asian), and 21 (75%) identified as White. One participant's transition and detransition was exclusively social and was therefore removed from the analysis of medical detransition. Medical transition was initiated by 27 participants at a wide range of ages (15 [56%] were between the ages of 18 and 24 years and 6 (22%) were between ages 25 and 29 years).

Participants discussed multiple reasons for discontinuing or reversing their gender transition and these intersected with experiences of detransition-related care and health care encounters. Factors included physical and/or mental health concerns, surgical complications and/or postoperative pain, unsupportive parents or romantic partners, employment discrimination, difficulty accessing clinical appointments or gender-affirming surgery due to COVID-19 lockdowns or because they lived in low-resourced regions of Canada, among other reasons consistent with existing literature. Participants experienced the medical detransition process as physically and psychologically challenging and health care was perceived as suboptimal because of detransition-related stigma, or clinicians lacked information. Illustrative quotes supporting these findings are shared here and in the **Table**.

Gender-Affirming Hormonal Therapy Cessation or Switching and Clinical Care Needs

Discontinuing gender-affirming hormone therapy was characterized by participants as a medical detransition event and disengagement from health care was frequently reported. Many stopped hormone treatments "cold turkey" without psychological supports or medical supervision. Participants did not have a clear understanding of what health implications to expect when stopping gender-affirming hormones. Rather than rely on clinicians who were often experienced as a source of distrust, they turned instead to online detransition networks and social media.

"I actually just stopped talking to them [clinicians]… I felt like they were going to be mad at me [for detransitioning]… I didn't refill my next prescription. I didn't get the bloodwork tests. I just stopped seeing my endocrinologist when I decided to detransition… So unfortunately that involved quitting testosterone cold turkey… I was in a bit of a low [mood] just kind of weaning off and getting my hormones back to normal. I kept looking after myself and it passed. I, around that time, too, stopped seeing my therapist. I had like almost no supports when that was happening [detransition].

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Table. Demonstrative Quotes

Theme	Illustrative quotations
Gender-affirming hormonal therapy cessation or switching and clinical care needs	"I'm sort of in the detrans Twitter circle... I was really helped by other detransitioners, because there wasn't [detransition-related medical] information..." (Participant #10, AFAB, female)
	"Once I transitioned in the system from youth to adult care, at 18, my family doctor was just prescribing my testosterone... So, I stopped taking it, didn't tell him. I stopped taking it cold turkey... I started going to a youth group for queer youth, and that's where I met a bunch of other trans people my age, including trans-masculine people who did not present in extremely binary ways, who did not speak about gender the way I was taught to speak about gender, did not dislike themselves as much as I did, and I am still friends with most of those people... And I think now, what was going on in my head was that I didn't think that I could be part of something—something being the trans community—I didn't think I really could be part of something that would require me to love myself that much. So I detransitioned... I returned to presenting as a butch lesbian." (Participant #13, AFAB, nonbinary trans)
	"[T]he woman I was talking to—the one with the series of YouTube videos—I met her a few days after the last dose of testosterone. She was like 'Oh, well have you talked to a doctor about this?' I was like, 'No, I have no idea what's going to happen. I'm just not going to do it anymore.' And she was like, 'OK, so you're going to want to look out for, as it leaves your system.... you're going to have a week or two where you're super tired all the time. It's going to be really intense. You're going to be exhausted.' ...I didn't know what to expect, except for what the other detransitioned women on the internet had told me." (Participant #05, AFAB, trans)
	"[When I began my transition, my] doc sent me to Dr [name of doctor], and that was inconvenient for me. I mean, it's a 2 ½ to 3-hour drive there, and the parking and everything, taking time off of work. And so, yeah, it was just, it was a nightmare in a sense. But I was really keen and eager, and I was so happy to have my prescription and begin hormones finally. And I went from euphoria, yay me, to like, it's the end of the world kind of feeling now [detransitioned]... everything went into [COVID-19] lockdown... But at this point I just thought it was safer to, you know, not mess around with my dosages myself... and reanalyze once this all COVID thing clears up and goes away, or whatever. And hopefully start again, yeah." (Participant #02, AMAB, gender-fluid nonbinary)
	"I think I still felt like a little bit of guilt and shame about the whole [detransition]. I don't really entirely know. I think it's just always revolved around not wanting other [trans] people to look bad." (Participant #20, AFAB, female)
	Participant: "I'm really lucky... (Doctor's name) and she's been my family doctor, since I started my transition basically. So, she's very knowledgeable. She works with lots of trans folk. And yeah, so I'm really lucky in that in that regard." Interviewer: "And so, how did you feel at the time when you started taking estrogen [during detransition-related hormonal switching]?" Participant: "Definitely some weird changes over time. The mental part of it was actually the hardest. So, there's definitely, dealing with a wider breadth of emotional experiences. Being on testosterone for so long, I think... You get kind of, like flat, you know... Because I don't have ovaries. So, there's no other hormones in my body." (Participant #09, AFAB, undefined gender identity)
	"I wish [detransition] was something I could have done on my own, but I had to go see a doctor because I would have had to switch from testosterone to estrogen. I did go see a doctor and I had a pretty bad experience... So, I ended up having to see another one... The first doctor I went to... She was not very tactful, I guess you could say... We only have 2 gender specialist doctors here in my city. We don't have a lot. She wasn't very tactful. She made comments about how I should have thought about [my initial transition] harder." (Participant #14, AFAB, female)
	"The first doctor I went to—and the second doctor—both didn't have a clue what was going on... What's going to happen when you go off testosterone and back on estrogen? ...I was struggling with a lot of dizziness and sick feelings... So, I feel like more information [is needed] around specifically people who need to get off testosterone to go back onto another [hormone]. Because I've had [oophorectomy and] hysterectomy." (Participant #14, AFAB, female)
	"I've been going to the same doctor since I started hormonal care...They were very supportive of my gender transition. They wrote letters for gender confirmation surgery [orchiectomy]. When I went in, I don't think I framed [detransition] clearly because I was a bit nervous how they would react. I was like 'I think I need to go on testosterone for these medical issues.' And they were like, 'This is outside of my practice. You should see an endocrinologist.' So, when I saw the endocrinologist he was very helpful and I was much more clear. I was like 'I want to start taking testosterone anyway. I want to change the gender trajectory I'm on.' ...He's like "OK we'll do a blood test. Come back in a few weeks. We'll talk about doing testosterone." ...Neither he nor the other endocrinologist at that clinic had treated a transgender patient who needed to go on testosterone to detransition... But I've gotten good support and the same doctor's been helping me taper off the feminine hormone and get ready to switch to the testosterone." (Participant #17, AMAB, gender-fluid male)
	"I'm like, 'Is it the estrogen that's throwing me off and I'm all over the place and, you know, my brain is just, you know, going crazy?' So nobody was giving me any answers so I said 'Oh, well that's it. I can't do this anymore. I can't live like this for the rest of my life.' So I went off estrogen and then things started improving. When I went to the endocrinologist at that point, I said, 'Hey can I just be nothing? Like why do I need testosterone or estrogen?' And sometimes I think I'd prefer that feeling of that in-between. I still feel like that now that I'm back on testosterone for the last couple years, I have this low-level anxiety that I'm just tense all the time on testosterone. I think that's what drove me to transition in the first place, right. Like I have that back now, from prior to [year] when I transitioned." (Participant #28, AMAB, nonbinary male)
	"That is what my transition looked like. It was a hot mess. I was a hot mess. But I know people that it has benefited. I know people that [transition] has helped, with their mental health and they've done better. But they started to do better earlier in their transition. So, like as they were on hormones and they started to pass, their mental health was improving... And that pattern wasn't seen in me. The farther I got into transition, the worse my [borderline personality disorder] symptoms and my presentation was." (Participant #10, AFAB, female)

(continued)

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Table. Demonstrative Quotes (continued)

Theme	Illustrative quotations
Current perspectives on past gender-affirming hormones and surgeries	Interviewer: "Do you feel regretful of having had the double mastectomy?" Participant: "Some days I do, some days I don't. Some days it doesn't bother me, other days it bothers me. It just depends." Interviewer: "Are you thinking of getting breast augmentation surgery in the future?" Participant: "No. No. I'm just going to leave myself alone. It's part of my story. It's part of my journey. That's the way I try to look at it." (Participant #22, AFAB, female)
	"My body's changed, right. I have small breasts that estrogen created, and I still have a vagina and I have no plans to change that. I may have the breasts reduced because there is a bit of self-consciousness there with people seeing me as male… I'm not a hundred percent sure on that. I don't want to put myself through any more surgery. As far as my body goes, I'm OK with it." (Participant #28, AMAB, nonbinary male)
	"As I've said, I've got my beard still… the facial hair doesn't go away once it starts growing. And I wouldn't have that if I had just stayed in my estrogen-based body the whole time. I had some physical changes from testosterone. Like my voice did drop, I had like genital changes. And I'm very happy with all of that stuff. The reason that I'm comfortable not being on testosterone is because I had those changes and those are things that aren't going to reverse themselves. So, I have a really gender-ambiguous body. And that's not something that I would have been able to have if I hadn't taken the steps that I did." (Participant #16, AFAB, nonbinary)
	Participant: "Well, I identify as a cisgender woman. But like, I feel like my experience having detransitioned is different than a lot of cis women's. Like in public, I don't pass as a cis woman. So that's kind of like…. It's kind of a unique experience to, like, be a cis woman who doesn't pass [as a cis woman]. And so, I'm usually read as a trans person even though I don't identify as a trans person anymore…" Interviewer: "Yeah. And so now looking back, now that you have detransitioned, do you feel like starting hormones was the right or the wrong decision at the time?" Participant: "I actually I feel like it was really the right decision. Everyone assumed that I would regret it because I don't pass for a cis woman anymore. But, at the time, that was absolutely what I knew I had to do. I'm actually not upset about any of the permanent changes it had on my body." (Participant #07, AFAB, cis woman)
	"I think it [transition] was definitely the right decision… The only thing I wish that I would have known is what going off of hormones looked like. Because it took about a year for the full changes, and my voice got higher again, which I did not expect. And I lost most of my body hair. I was extremely hairy. But I can still grow a full beard, so it's strange and I definitely don't regret it, but I wish I would have had more information [on stopping hormones]." (Participant #03, AFAB. nonbinary trans)
	"Like after I got over a lot of these initial feelings of like, 'I don't know what to do, I made a mistake, I didn't make the right choice, where do I go from here? What if my next decision is the wrong one?' I started to feel none of the choices that I've ever made in my transitions have ever been the wrong ones, because they were the right choices to make at the time that I made them. (Participant #01, AMAB, gender-fluid nonbinary)
	"There's always someone waiting to pounce on [detransition] and say 'Oh, see, trans people are fake, they're just faking it,' and it's like, 'No, if I had've had better access to trans health care I wouldn't have made decisions that I would have regretted.' Because I've basically had to prove that I was 'trans enough' [by taking testosterone] in order to access [surgery] that I needed in order to feel OK. And like I don't regret top surgery [chest masculinization] for a minute. Like it's just the testosterone and how that presentation worked." (Participant #12, AFAB, gender-fluid)
	"I've had at various points feelings of regret about transition, both in terms of regretting going on hormones or regretting how soon I decided to go on hormones… I'm like, 'Maybe I want to undo that, maybe I want to just fully detransition and just be a guy again or change my name to a less feminine name or something'… And it happens most often when I'm having bad social encounters, like if I meet a bunch of people and constantly get gendered as male, it hits me real bad that day. Or if I'm thinking about future jobs or future careers that I'm trying to get into and I'm thinking how hard is this going to be to navigate if I am trans or if I am nonbinary, that's when I start thinking maybe I'll just detransition, maybe that'll be easier." (Participant #25, AMAB, nonbinary)

Abbreviations: AFAB, assigned female at birth; AMAB, assigned male at birth.

So I just really kind of looked online like see what kind of groups there were for people who had detransitioned." (Participant #20, AFAB, female)

During her initial medical transition, participant #20 noted having overall positive relationships with her health care clinicians and therapist. Yet she felt "guilt and shame" about detransitioning and was concerned that her initial transition would be misinterpreted by clinicians as a "mistake" or through a lens of "regret" which was inauthentic to her feelings.

Overall, the medical detransition process was experienced as physically and psychologically challenging and participants described clinicians who lacked sufficient information. Even those reporting good access to clinical supports noted challenges with hormone therapy cessation, such as resumed gender dysphoria. For some, gender-affirming hormonal therapy had substantially reduced symptoms of gender dysphoria but they discontinued this treatment for other health considerations.

"I have a family history of breast cancer. Both my grandmother and mother and also on my father's side… [To reduce risk for breast cancer] Went off [the anti-androgen] and then tapered off

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the estrogen. But it was over a period of less than a month. And I saw a lot of changes in my body that were difficult, [gave] me a lot of dysphoria. Facial hair in particular started growing back in full force. So that was the most difficult part. It was difficult giving up some of the good parts about estrogen. There was a bit of a mourning period there and there still is." (Participant #15, AMAB, nonbinary)

Other participants disclosed that their parents or family circumstances explicitly forced, or implicitly encouraged, detransition—typically without medical supports. Each of these participants sought care again later.

"It was a couple weeks after I turned 18 that [the clinic] put me on the hormones. I was then able to be on hormones for a while without my parents' knowledge. But since I had come out [as trans] before, [my parents] knew what to look out for and started going through my stuff [at home]. So one day [my parents] found my HRT [hormone replacement therapy] and made me stop taking it and quit contact with the doctor I was seeing in the clinic… I was [on hormones] for about four months and then I was caught and I stopped for a year." (Participant #24, AMAB, transgender woman)

This participant returned to the same clinic 1 year later and noted that during this period of care disengagement there was no follow-up from the clinic. A lack of follow-up from clinicians after disconnecting from care was a consistent theme described by many participants.

Given the need to switch hormone therapy (rather than discontinue), most participants who had past gender-affirming gonadectomies reported medical supervision. The care they received was described as "bad" because clinicians were inadequately knowledgeable or judgmental. This amplified some participants' internal emotional struggles with feeling shame, and it confirmed their fears of clinician judgment. Most participants described access to gender-affirming care as scarce in the first place, which in turn restricted their detransition-related care options.

Current Perspectives on Past Gender-Affirming Hormones and Surgical Procedures

Participants discussed a range of divergent perspectives about their history of gender-affirming hormones and/or surgical procedures and how these intersected with shifts in their gender identities over time. Of the 27 participants who pursued gender-affirming hormones and/or surgical procedures, 18 (67%) expressed no regrets and/or positive feelings associated with past gender-affirming interventions. Six (22%) experienced regret and felt that medical transition was the wrong pathway for them. Three (11%) expressed ambivalent feelings such that they do not regret their decision to medically transition but would have slowed the process, or feeling dissatisfied with their bodies some days and content other days. Of those who were regretful or ambivalent, many discussed a need for psychological and social supports.

One participant sought surgical reversal to address both feelings of regret and surgical complications and pain sustained over several years. "I had complications with [genital] surgery which were bad… I was dealing with a complication that was painful for 6 years, 7 years… I went back to the clinic. And this same doctor who had done the original surgery.… They fixed the complication. Then I had another complication that I lived with for a long time. And just this [past] summer I went and had that fixed. And while I was there, I told the surgeon that I was detransitioning and had been detransitioned for about a year and I asked if he could… Well, basically undo some of the surgery. And he did… He did more than he had to. That was a good interaction for me… And he didn't ask many questions about it. I don't know why. But anyway, it went really well and I'm pleased with how it how it turned out." (Participant #9, AFAB, undefined gender identity)

Others felt neutral or satisfied with their bodies and physical changes caused by gender-affirming medical interventions. Some noted preference for their current physical bodies which had been hormonally or surgically altered, including individuals who no longer identified as transgender or nonbinary and who had returned to living socially in their assigned sex at birth.

"The few changes I did have, when I was on hormones and stuff, I do not really regret… And I do actually like the changes [from hormones]… I wasn't too fond of how my voice sounded when growing up. So hormones did help with that." (Participant #20, AFAB, female)

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Discussion

At the population level, hormonal and surgical interventions are effective in improving transgender people's gender dysphoria, mental health outcomes, and social well-being.[3,11,31,32] Yet, at the individual level it is not always possible for patients—or their clinicians—to predict with absolute certainty how treatments will be experienced.[19] Our study highlights clinical practice gaps when medical detransition occurs.

Our analysis points to a concerning trend of disengagement from psychosocial and medical supports when initiating hormonal cessation—a period marked by increased need for care owing to participants' reports of changes in energy and mood, worsened gender dysphoria, and overall uncertainty about detransition. We note that robust clinical outcomes research is needed to understand further the physiological and psychological effects of discontinuing or switching gender-affirming hormones, as data to triangulate these participants' accounts are presently unavailable. Still, our data offer qualitative interpretation to Hall et al's[22] retrospective case-note analysis, which raised questions about gender identity clinic disengagement and detransition or retransition. Our data clarify disengagement may occur for several complex reasons, such as having poor access in the first place, or feeling shame and anticipating stigma. Participants avoided clinicians and detransition-related mental health care despite reporting psychological distress. Health care avoidance behaviors associated with clinician judgment and stigma are broadly reported by lesbian, gay, bisexual, and transgender populations.[33-36] Clinicians providing gender-affirming care must be careful to avoid shaming patients who are pursuing hormonal cessation or switching or surgical reversals and instead strive to address current mental and physical health needs. Failure to do so will likely only exacerbate such disengagement behaviors. We recommend that when discussing treatment options for gender dysphoria, clinicians state explicitly that if the patient chooses to discontinue any gender-affirming interventions they will continue to support the patient.

Our study also included participants who experienced family pressure to detransition, which in turn contributed to medically unsupervised hormonal cessation and later re-initiation—a finding consistent with Turban et al's[17] study indicating some transgender and nonbinary people report a history of externally-influenced detransition. In our sample this occurred among younger transgender people who were living with unsupportive families. Clinicians ought to be attuned to patients' family environments and disconnection from care.

Our findings confirm previous research indicating a clinical need for information on stopping or changing hormones.[14] Yet, our analysis shows clinicians may be insufficiently prepared. Given the absence of clinical guidance on detransition/retransition, this is an unsurprising finding. Our data also uncover widely divergent perspectives on past gender-affirming medical interventions and how those relate to current gender identities, with a majority of participants expressing no decisional regret. As such, clinicians should investigate patients' feelings and care needs without assuming people experience their initial transition as a "mistake". Those with ambivalence or regrets may require formal psychosocial supports offered from an affirming and nonjudgemental approach. Relatedly, participants sourced peer-based medical advice and support from online detransition networks to address unmet clinical care. This is consistent with existing research showing transgender people seek and provide peer-based mental health support[37] and engage in peer-to-peer health information sharing.[38]

Limitations

Several weaknesses and strengths of our study warrant consideration. Study limitations include recall bias, as most participants described life events that spanned over ten years. Moreover, we did not interview clinicians to triangulate participants' accounts of their health care experiences. One strength of our study is its heterogenous sample in terms of age range, past and current gender identities, and age of initiating transition. Another strength is its national scope. As health care delivery is affected by geopolitical context, studies[15,16] that sample detransitioners internationally

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may be insensitive to local medical education curricula, the impact of regional health care funding on service delivery, and gender-affirming care legislation.

Conclusions

We responded to calls for qualitative research on detransition,[22,27] analyzing in-depth narratives spanning decades of life experiences and dynamic gender transitions. We found accounts of people ceasing or reversing gender-affirming treatments with sub-optimal care, warranting more robust clinical practice knowledge. Future research studies should examine clinicians' knowledge of detransition and determine sources of stigma. This study's results show that further research and clinical guidance is required to address the unmet needs of this population who discontinue or seek to reverse prior gender-affirming medical interventions.

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SUPPLEMENT.

eFigure. Current Reported Gender Identity
eTable. Demographics
eAppendix 1. Sample Interview Questions
eAppendix 2. Study Advert (English)
eAppendix 3. Study Advert (French)
eAppendix 4. Coding Framework – Detransition/Retransition and Healthcare Needs

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California Department of Corrections and Rehabilitation

SB 132 The Transgender Respect, Agency, and Dignity Act Implementation Review Report

November 2022

THE MOSS GROUP, INC.
Experienced Practitioners Committed to Excellence in Correctional Practice

In partnership with the California Department of Corrections and Rehabilitation

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Executive Summary

The California Department of Corrections and Rehabilitation (CDCR) contracted with The Moss Group (TMG) to review and assess its implementation efforts in response to the adoption of State Senate Bill 132 *Transgender Respect, Agency, and Dignity Act* (SB 132). This act requires CDCR to ask each individual entering into its custody to specify gender identity, pronoun, honorific, and search preference. It also requires that individuals be housed according to gender identity and individual preference. To gain understanding of how this act has been translated into practice, TMG reviewed relevant data, documentation, and classification processes; conducted interviews with key personnel, stakeholders, and incarcerated individuals who transferred to women's institutions under SB 132; and conducted an onsite assessment at the Central California Women's Facility (CCWF) in Chowchilla, California. The onsite assessment was conducted April 5 – 8, 2022, and included observations, operational tours, interviews with key personnel, staff focus groups, and discussion groups with incarcerated individuals.

In recent years, there have been several significant influencing factors for the department including the shift in institution dynamics that occurred as a result of AB109 which changed the risk and offense profile of the facility, the detrimental consequences of COVID-19, and the transitions that have accompanied enhancements in practice specific to the housing and management of transgender, non-binary, and intersex (TGNBI) individuals in custody. The latter included the development of the transgender housing and searches policy workgroup in January 2019, state legislation, reviews by the California Office of the Inspector General, and both support and concern from various stakeholders. Further, an internal working group was charged with drafting policy and procedure as well as integrating necessary resources to support the implementation of SB 132.

Overall Themes, Strengths, and Opportunities for Enhancement

Agency and institution leadership have demonstrated a high level of commitment to safe placements consistent with gender identity. CDCR developed a thoughtful approach to preparing both staff and incarcerated individuals for a successful transition in housing assignment processes as well as changes in practice to increase safety and respect in the management of TGNBI individuals. Since 2016, the agency has been developing a variety of processes and procedures to support respectful management of transgender and gender diverse individuals. Examples include but are not limited to, the development of a new questionnaire to allow individuals to specify gender identity, honorific, pronoun, and search preference; a card that allows access to authorized property, canteen, and clothing; and educational materials for the population—informational brochure, handbook updates, video, and a four-week pre-transfer course— as well as training for staff.

The evolution of the Institution Classification Committee (ICC) review process for gender-identity based housing transfer requests is a notable strength. The ICCs at hub institutions are chaired by one of the three wardens of the female designated institutions who rotate these duties. During assessment observations, incarcerated individuals requesting transfer were present at committee reviews and the individual's own perception of safety was seriously considered in determination of institution placement. Another strength is the observed, and reported, commitment by most staff to use the pronoun and honorific identified by the incarcerated individual, ,and to honor search preference.

It will be imperative for the department to maintain the fidelity of the promising practices mentioned above to build upon those foundational strengths. Figure 1 below summarizes key recommendations designed to incorporate the agency's lessons learned and practices that have been effective in other jurisdictions in a way that promotes long term, sustainable change.

Classification Criteria

- Establish written criteria for consideration to support consistency in decision making specific to institution placement. Focus of the placement process is not to determine gender identity, but rather safe placement, and as such, management and security issues must be considered.
- Develop an interactive, practice based training for staff involved in the process of case review and placement decision making to strengthen and enhance consistency in the process. Both the policy and training should emphasize the need for individualized decision making on every case before the ICC.

Housing—Unit and Bed Assignments

- Seek to admend statute to discontinue the practice pursuant to Sec 4, Section 2606 (a)(4) in which SB132 individuals are permitted to single cells, the choice of cellmates, and ability to remove other individuals from any location, solely based on the status as an SB 132 individual.
- Define a structured process for institution-based unit and bed placement that includes clear guidelines for placement based on, at a minimum, PREA screening and safety considerations for transgender, non-binary, intersex and cisgender women.
- Construct or establish additional celled living capacity to support safe and effective management of individuals who are not appropriate for dorm-style living and where single cells are limited.
- Create a structured, program and timeline driven, transition housing unit that houses transgender, non-binary, intersex and cisgender woman who apply, and are selected, to serve as peer mentors.

Staffing

- Conduct an analysis to identify adequate staffing levels to supervise and meet the safety, security, program, and clinical needs, of a TGNBI population as well as the workload impact created by recent operational, policy, and process changes, such as the revised grievance process.
- Communicate intentionally and routinely with staff, incarcerated indivduals, and stakeholders to reduce anxiety and misunderstandings. Ensure there is a feedback loop for leadership to maintain awareness of concerns and garner input on solutions. Reinforce that leadership will support staff if they are operating within agency policy and the code of conduct to minimize anxiety about fairly and equitably holding incarcerated individuals accountable.

Training and Education

- Consider revising the *Right Person Right Prison* course to include input from those who have previously attended the course, a structure that ensures it is consistently delivered, includes medical or mental health staff as facilitators to address a wider range of transition concerns, and updates on the transfer request process, housing layouts, and preparation for transfer.
- Provide additional training and resources to the cisgender population, including opportunities to ask questions, learn about the experiences of TGNBI individuals, and to work with leadership and staff on strategies for safety to assist with and further support the implementation of SB 132.

Figure 1: Sampling of Key Recommendations

Next Steps

TMG will host a report debrief session for CDCR leadership to provide an opportunity for additional clarification on findings and recommendations, as well as to ensure the report is factually accurate, such as housing units properly identified, accurate acronym usage, and timelines. Recommendations require varying degrees of time, effort, and resources to implement. Therefore, the plan for further enhancement of practice based on this report will need to be sequenced appropriately considering strengths, barriers, and resources. As such, TMG welcomes the opportunity to provide ongoing technical assistance to support the development of an action plan and implementation of prioritized recommendations.

Appreciation for Collaboration

On behalf of TMG and the project team, we would like to thank CDCR leadership, the Female Offender Programs and Services (FOPS) division as well as the leadership, staff, and population housed at CCWF and community stakeholders. The strength of the recommendations in this report are due in large part to the thoughtful work CDCR has done in response to SB 132 and to the openness and candidness of those who contributed by sharing their experiences.

Assessment Overview

Introduction

The Moss Group, Inc. (TMG), a Washington, DC-based criminal justice consulting firm, was contracted by the California Department of Corrections and Rehabilitation (CDCR) in 2022, to assess implementation of its special housing mission in alignment with State Senate Bill 132 *Transgender Respect, Agency, and Dignity Act* (SB 132). The act became effective January 1, 2021. The assessment of CDCR interim policies and practices was designed to identify strengths and challenges in the agency's efforts to operationalize its demonstrated commitment to housing TGNBI incarcerated individuals in institutions that align with identity, as opposed to sex assigned at birth.

To complete this work, TMG conducted a review of relevant documentation, such as draft policy, memoranda, and training material; a process analysis of the Inmate Classification Committee (ICC); onsite observations of new or revised practices and their impact on institutions and those who work and live in them. CDCR selected Central California Women's Facility (CCWF) for TMG to conduct its onsite observation, which occurred April 5 – 8, 2022. While CCWF is the focus of the onsite observation, the outcomes and recommendations of this assessment have implications housing and management of TGNBI individuals agency wide. See **Attachment A** for the *Summary of Recommendations*.

Methodology

The TMG assessment model has been shaped by research and evidence-based literature, practitioner experience, knowledge of organizational culture dynamics, and collaborative partnerships with federal, state, and private entities. TMG's approach is built on nationally accepted operational and management best practice[1] and was customized to meet the needs of CDCR. The protocol for this assessment was aligned with SB 132, as well as related practice and cultural norms necessary for consistent and sustainable implementation. Specifically, the assessment protocol focused on policy, procedure, and practice as outlined below.

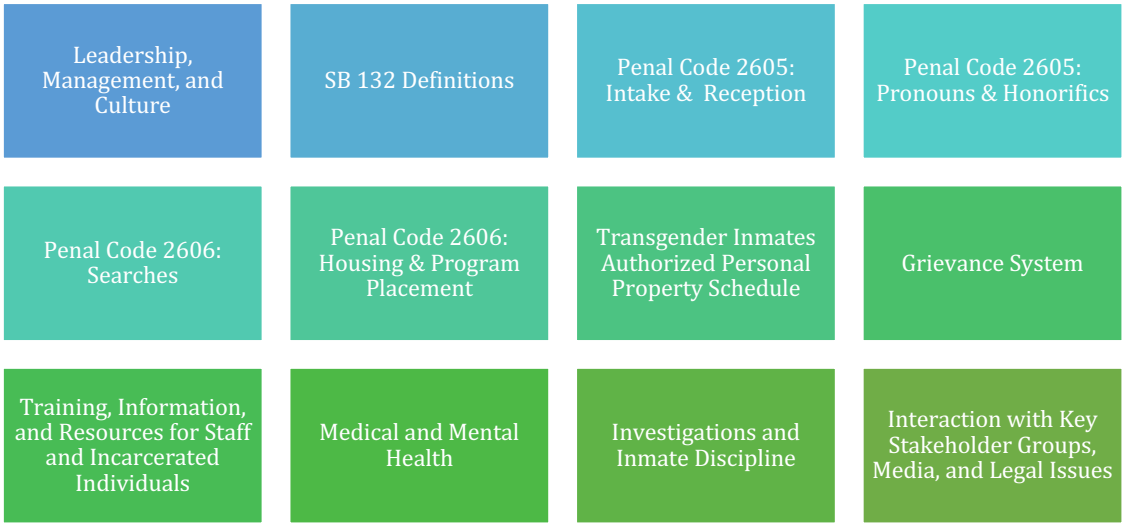


Figure 2: Assessment Areas of Focus

[1] Including research, selected American Correctional Association (ACA) Standards for Adult Correctional Facilities, selected PREA Standards for Prisons and Jails, National Commission on Correctional Healthcare, key DOJ Guidance in Restrictive Housing, and the National Resource Center for Justice Involved Women (NRCJIW), and resources, such as the *Gender-responsive Discipline and Sanctions Policy Guide for Women's Facilities* and *Using Trauma Informed Practices to Enhance Safety and Security in Women's Correctional Facilities*

The TMG seven-step assessment process which began with the initial meeting with the agency and facility leadership will culminate with the provision of assistance as the agency implements recommendations. The graphic below illustrates the process.

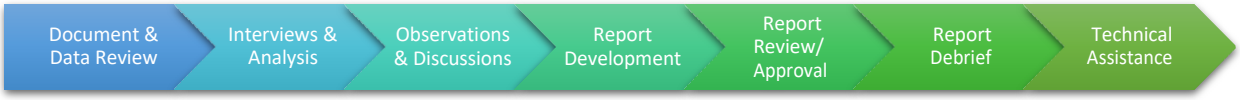


Figure 3: Assessment Seven-step Approach

The first phase, document and data review, assisted in understanding the language, terminology, acronyms, and formal guidance relevant to SB 132. It also informed areas to be explored further during onsite and offsite assessment activities. See **Attachment B** for the *Document & Data Request Lists.* The document and data review phase included the following activities:

- **Document Request & Review.** TMG submitted a detailed comprehensive request for documents, including reports, policies, procedures, training materials, and other relevant forms. FOPS provided a thorough and well-organized binder to each TMG team member with several of the requested documents in hard copy as well as electronically.
- **Data Request and Application Submission.** TMG submitted a detailed request for data, including demographic information and summary data for classification and placement, grievances and reporting, investigations, and discipline. To meet the requirements of CDCR regulations, TMG also provided sample protocols, submitted a research application to the Research Oversight Committee, and entered into a data sharing agreement to obtain data.
- **Classification Chronos and Documentation Review.** TMG requested and reviewed summary reports submitted to the ICC as well as classification chronos from the last 24 months. In addition, TMG reviewed the classification processes, instrumentation, needs assessment data, PREA screening for risk of sexual victimization or abusiveness, gender identity questionnaires, and any additional information taken into consideration for housing and placement decisions.

The second phase, interviews and analysis, included contact with agency and institution leadership, discussion of influencing factors, presenting issues, strategic plans, and intended outcomes. Virtual interviews were conducted and meetings related to SB 132 were observed. Specific activities included:

- **Headquarters and Stakeholder Interviews.** TMG conducted a series of interviews with key personnel at CDCR headquarters, including FOPS, classification counselors, ombudsman, legal affairs, community relations, and identified stakeholders, including community partners, advocates, and legal groups.
- **ICC Meeting Observations.** TMG observed two ICC meetings—one with the institution and one with headquarters—convened to review classification chronos for placement of transgender females in women's institutions. Observations allowed for review of strengths and areas of concern specific to summary reports and classification chronos, processes, instrumentation, assessment data, and overall outcomes.
- **Interviews with Classification Agency Personnel.** TMG conducted virtual interviews with key agency personnel, including ICC members, receiving and release custody supervisors who administer the GIQ, PREA compliance managers, caseworkers, classification & parole representatives, medical and mental health staff, and correctional counselor IIs.
- **Interviews with Voluntary Returns.** TMG conducted five interviews with transgender women who had been transferred to CCWF under SB 132 and later voluntarily returned to a male designated institution.

The third phase, observations and discussions, was completed at CCWF and included targeted interviews with key institution personnel, structured observations of operations and programs, focus groups with a random sample of custody and non-custody staff members, and individual and group discussions with a random sample of cisgender and TGNBI incarcerated individuals.

The fourth phase, report development, involved the synthetization of all document and data review, interviews and process analysis, and onsite observations and discussions with staff and incarcerated individuals. It is a snapshot of themes based upon the policies and documentation provided, operational procedures observed, and information reported at the time of assessment. Themes are noted in their respective sections throughout this report with accompanying recommendations for enhancement of practice. See Figure 4 for a description of report organization. To ensure both inclusion and clarity, when the report refers to transgender, non-binary, and intersex individuals, the acronym "TGNBI" will be used.



Figure 4: Report Organization

Influencing Factors

It is TMG's practice to consider major influencing factors that affect daily operations. Influencing factors at CDCR and CCWF are outlined below. While not an exhaustive list these areas were raised as important considerations in successfully implementing any proposed recommendations.

Innovation in an Emerging Area. The safe housing and placement of TGNBI incarcerated individuals is an important area of emerging practice being considered by correctional agencies, nationwide. Some states have responded to the need to improve practice in this area with legislation or policy that allows individuals to be housed in an institution that aligns with gender identity as opposed to sex assigned at birth. However, implementation of SB 132 requires implementation of change to longstanding correctional practices without existing models that have been tested and proven. The work being done at the agency and facility level will contribute to the developing body of best practice throughout the country. Leadership and staff at all levels are grappling with understanding both the intent of SB 132 and safe and effective methods of implementation. The complexities cannot be understated, and the fact that CDCR began the process of implementation prior to housing by gender identity being required by state statute is commendable.

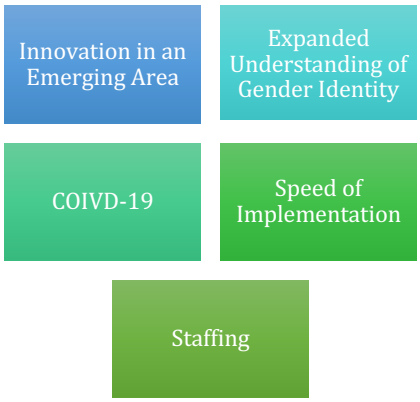


Figure 5: Influencing Factors

Expanded Understanding of Gender Identity. CDCR has a longstanding commitment to gender responsive practice in female designated institutions. In July 2005 CDCR was reorganized to effectively address inmate rehabilitative and reentry needs. As a part of this effort, the Female Offender Programs and Services (FOPS) office was established to oversee adult female programs designed to reduce recidivism for incarcerated women in the CDCR system. Along with the Gender responsive Strategies Commission, the *Master Plan for Female Offenders: A Blueprint for Gender-responsive Rehabilitation* was developed and published in 2008. As early as 2012 the agency began providing for placement by gender identity. SB 132 purposefully expanded the range of gender identities to be considered for changes in key operational practices such as housing, search preference, and property allowances.

The cultural dynamics of changing practice to manage TGNBI individuals safely and respectfully within corrections agencies are very similar to those that we see in our communities. The realities of transition are highly personal and sensitive but vital to understand and support. Some individuals must also grapple with how to manage their own personal or religious beliefs and conduct their job duties with professionalism and respect. In addition, many struggle to understand how to integrate their understanding of the needs of TGNBI individuals into gender responsive practice which until recently has focused largely on cisgender women.

COVID-19. While CDCR and CCWF have been creative in implementing practices to comply with national safety protocols, the consequences of COVID-19 have impacted the functioning of correctional institutions nationwide—altering the routine functioning of operational procedures, population movement protocols, exercise and recreation activities, programming, religious services, kitchen and cafeteria use, housing and bed assignments, medical and mental health services, and more. These challenges are compounded in a women's institution as women rely heavily on relational programming, and pro-social activities for rehabilitation. In addition, training schedules were widely interrupted due to pandemic related restrictions.

Speed of Implementation. The COVID-19 pandemic and the passage of SB 132 legislation occurred nearly simultaneously, creating unforeseen challenges that were further complicated by the required pace of implementation. These factors compounded an already challenging transition process by limiting the ability of multidisciplinary work groups to complete their work, expediting the process of engaging staff and incarcerated individuals in understanding the intent of SB 132 and resulting changes, and interrupted the processes outlined during implementation planning to support successful placement, such as *Right Person Right Prison* classes and case reviews. While early experiences were difficult, the agency can capitalize on lessons learned in early implementation efforts to strengthen practice moving forward.

Staffing. Nationwide, corrections agencies are facing an unprecedent staffing crisis requiring a fresh look at recruitment, hiring, and retention strategies to fill the need for qualified professionals. While these factors appear to be less pronounced in California, litigation and increases in workload (i.e., greater numbers of PREA reports and grievances) have contributed to staffing shortages. For example, SB 132 requirements have increased workloads and responsibilities for some staff, including shifting responsibility for more gender affirming medical care to CCWF with individuals transitioning to the facility, case work ups, and additional training. In addition, other changes in practice, such as revision of the grievance process, are reported to have added significantly to the workload of some who were also impacted by SB 132. Finally, where training opportunities continued, staff availability to attend has been negatively impacted by both time constraints and staffing availability. This limits opportunities for staff to develop professionally and gain confidence in new areas of practice. The combination of these factors makes prioritization and sequencing of new initiatives vitally important for sustainable change.

SB 132 Overview

As the community and the field expanded its knowledge of the TGNBI population, CDCR worked to align with emerging best practices, findings from formal reviews and audits, and input from external stakeholders. Key innovations include the following:

- In 2012 the department designated eleven—currently fourteen— institutions to house TGNBI individuals in an effort to meet their specific needs. Since then, the department has revised its classification process, allowed access to property and clothing items consistent with gender identity, such as bras and boxers, and in 2017 began providing gender-affirming healthcare.
- In 2019, the department formed its Transgender Housing and Search Working Group to address and strengthen its policy, procedures, resources, systems, and technology. This group met routinely and collaborated with external stakeholders to administer a survey to better understand the experiences and needs of incarcerated TGNBI individuals.

SB 132 Adoption and Announcement

On September 26, 2020, Governor Gavin Newsom signed SB 132, *Transgender Respect, Agency, and Dignity Act* into law. It became effective on January 1, 2021, added Sections 2605 and 2606 to the California Penal Code, and required CDCR to implement SB 132 in full. Key provisions of the act include:

- During initial intake and classification, and in a private setting, each individual entering into the custody of the department must be asked to specify their gender identity, whether the individual identifies as transgender, non-binary, or intersex, and their preferred gender pronoun and honorific. It prohibits the department from disciplining a person for refusing to answer or not disclosing complete information in response to these questions.
- Staff, contractors, and volunteers are prohibited from failing to consistently use the gender pronoun and honorific an individual has specified. This applies to verbal and written communications with, or regarding, that individual. Incarcerated individuals who are transgender, non-binary, or intersex must be searched according to the gender designation of the institution where they are housed or based on the individual's search preference.
- Incarcerated individuals are required to be housed in a correctional institution designated for men or women based on their preference.
- If CDCR has management or security concerns with an individual's search preference or preferred housing placement, the secretary, or designee, must certify in writing a specific and articulable reason the department is unable to accommodate that search or housing preference.
- CDCR must not deny a search preference or housing placement based on any discriminatory reason, including the anatomy or sexual orientation of the incarcerated person or a factor present among other people incarcerated at their preferred type of institution.

The department and FOPS have been intentional and thoughtful when building upon existing processes and incorporating SB 132 provisions into daily operations through activities including, but not limited to the following:

- Drafting revisions to current policy and practice,
- Developing and implementing the Gender Identity Questionnaire (GIQ),
- Convening an Institutional Classification Committee (ICC) chaired by women's facility wardens,
- Adding four specialist positions at headquarters to support the ICC,
- Developing training material and resources for staff and incarcerated individuals, and
- Updating electronic systems and databases to begin integration of new tools and practices.

The mission and changes to policy and practice were communicated to all institutions through various meetings, memoranda, and training. This messaging was tailored to staff and the incarcerated population. See the *Training and Preparation* section for additional information on the rollout of SB 132.

Themes and Recommendations

The following four sections outline key themes and recommendations for enhancing CDCR's current practice in the safe and effective management and housing for TGNBI individuals and overall safety within CDCR institutions. We begin with an overview of SB 132 transfer and operational processes, move to a discussion of preparation and training to support gender-identity-based transfers, explore leadership practices and cultural norms as a foundation for sustainable change, and conclude with a discussion of the pivotal role of data and research in continuing to innovate and support transition.

SB 132 Transfer and Operational Processes

This section of the report reflects the review of the overall SB 132 transfer process. While outcomes and recommendations provided below are influenced by the onsite observations, the information in this section is largely focused at the system level. Further, information below is supplemented or supported by interviews with agency leadership and relevant stakeholders.

Overall Process Summary. The agency has developed a roadmap to guide the transfer process of transgender individuals to an institution that is consistent with gender identity—see Figure 6.[2] The process is well thought out and addresses many key components for the safe and respectful management of transfer between institution placement based on sex assigned at birth and institution placement based on gender identity.

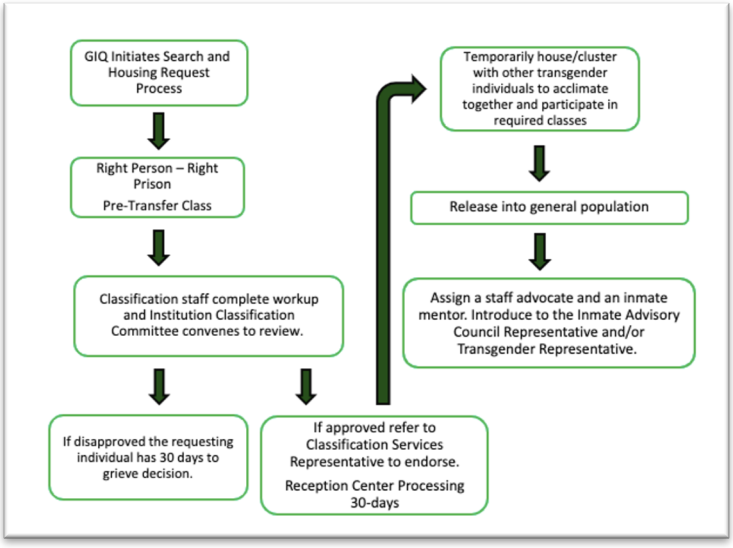


Figure 6: SB 132 Roadmap

The first of several steps designed to support transfer is to conduct the GIQ at reception. If an individual identifies as TGNBI, they are asked to identify a search and a housing preference. Upon identification, and indication of desire to transfer, three processes are initiated as follows:

- *Search Preference*: The PREA compliance manager reviews the search preference request and submits a recommendation for approval to the chief deputy warden for final action.
- *Pre-Transfer Class*: The incarcerated individual is placed in the pre-transfer class, titled Right Person Right Prison, which is designed to help them make an informed decision about placement by gender identity. See *Training and Preparation* for additional information.
- *Classification Workup and Review*: Housing requests are sent to the institution classification and parole representative (C&PR) who assigns it to classification staff for case workup. The ICC then reviews the request and makes a decision on institution placement.

If the request is denied an individual has 30 days to grieve the decision, the Office of Grievance meets with the incarcerated individual to evaluate the complaint; if no due process violations or additional information exists, it is referred to the Department Review Board (DRB) and the director or designee makes the final housing decision, which exhausts administrative remedies.

[2] Note that during the process of assessment policy was changed to allow an individual 60 days to grieve decisions about housing placement or search preference. At the time of assessment policy allowed 30 days which is reflected in the graphic and throughout the report. This revision strengthens the policy.

Upon approval of a request for housing consistent with gender identity and endorsement of the move, individuals are transferred to the institution of preference and participate in two stages of housing placement. First, they go to the reception center for thirty days. Upon completion of reception housing, an individual's case is again reviewed by the ICC for general population placement. By process, they are then to be housed in small cohorts with other individuals transferring in based on gender identity which are near, but not in, general population. See the *Reception Center Processing and Orientation Cohort* section below for additional information. Each step of this process is further discussed below.

Gender Identity Questionnaire. The GIQ is completed at reception by a custody supervisor and provides the opportunity for an incarcerated individual to disclose gender identity— whether they identify as transgender, non-binary, or are intersex—and specify preferred pronouns and honorifics. At the time of assessment, the questionnaire was completed as described in drafted changes to the Department Operations Manual (DOM) 54046.5.1. Gender Identity Questionnaire. This addresses the requirement of SB 132, Section 3. The questionnaire and administration process includes several strengths, including the following:

- The form includes an introductory paragraph to provide context to the questions.
- The interview was conducted in a private setting.
- The form is completed electronically.
- Policy states, and staff were aware, that individuals are not required to answer GIQ questions
- There is a brief explanation of the different types of search policies that the custody supervisor reads prior to asking the incarcerated individual their search preference.
- An e-mail is automatically generated, containing the search and housing preferences, to communicate requests to the PREA Compliance Manager and institutional C&PR staff.

Incarcerated individuals were aware they could go to staff to change their gender identity at any time.

During onsite observations, assessors noted an institutional challenge that is likely to occur agency wide. Specifically, while staff understood the requirement to administer the GIQ in a private setting, and had been doing so, a barrier to this practice emerged. Some of the medical operations had been temporarily moved to the Receiving and Release building, resulting in the custody supervisors being unable to use the private office where they had been conducting the GIQ. Another office was identified for use; however, concerns were raise about the location as it was a high traffic area, and the temporary arrangement was projected to last at minimum through the end of the year. Ongoing discussion of challenges to key components of practice, like privacy, will support effective, real time, collaborative problem solving.

Gender Identity Questionnaire Recommendations

1. Consider entering pronouns for all incarcerated individuals to normalize sharing and using and using preferred pronouns. At the time of assessment, information on preferred pronouns was collected for all incarcerated individuals but only entered for those who identify as transgender, intersex, or non-binary.
2. Map the automatic population of information from the GIQ to determine additional opportunities to provide staff with ease of access to preferred pronouns to support respectful interaction. For example, at the time of assessment, pronouns were populated into a banner at the top of an incarcerated individual's electronic file in one system, however, in other systems the information was reported to be more difficult to find.
3. Implement a process by which institution senior management regularly spot check the reception areas during intake processing to ensure the GIQ is being completed in a private setting as required by SB 132 to support collaborative problem solving in unusual circumstances where space or process challenges arise.

Search Preference Process Initiated by GIQ. Provisions of SB 132, Section 4, 2606 (a)(2) and DOM 54120.4 require the following:

- Transgender, non-binary, or intersex individuals be searched "according to the search policy for their gender identity or according to the gender designation of the institution where they are housed, based on the inmates' search preference."
- Search preference should not be denied "based on 1) anatomy, including, but not limited to, the genitalia or other physical characteristics or 2) the sexual orientation of the inmate.
- Incarcerated individuals be provided with a copy of any request not approved and can grieve the decision within thirty days.

DOM References

52010.17	*Staff Requirements/Urine Sample Collection*
52050.16.4	*Clothed Body Search of Female Inmates*
52050.16.5	*Unclothed Body Search of Inmates*
52050.16	*Unclothed and Clothed Body Searches of Transgender, Intersex, or Non-Binary Inmates*
52050.23.7	*Voluntary Bowel Movement*
54120.4	*Searching Based on Gender Identity*
54046.5.1	*Gender Identity Questionnaire*

Policy addresses the key components outlined in SB 132; however, opportunities exist to clarify policy now that practices have been implemented, such as the following in DOM 54120.4:

- There is repetitive language related to denial of requests.
- Procedural revisions are needed, such as an update where it specifies review of search requests are to be done by the PREA compliance manager to make a recommendation via form 128-B and submit to the deputy warden for final approval; however, in practice, these reviews appear to be done by the PREA coordinator.
- Incomplete sections, such as where it directs that "pertinent case factors" be reviewed but does not specify what should be considered or give any examples.

SB 132, Section 4(4)(d) indicates that if a housing or search preference is denied, individuals must be provided with a meaningful opportunity to verbally raise any objections to that denial, and have those objections documented. The agency and institution have robust processes in place for incarcerated individuals to submit grievances. The process is known by incarcerated individuals and provides a place within existing systems to address any concerns. Creating new processes when existing avenues to share concerns exist has the potential to be confusing to individuals seeking to appeal decisions. At the time of assessment, no search preference requests had been denied at CCWF; therefore, implementation of denial and grievance of decision policies could not be reviewed.

Staff concerns regarding search preferences may intensify as the need to conduct searches increases as COVID restrictions relax. Leadership monitoring of this potential dynamic will allow for coaching and support to be provided as needed to support staff implementation of new practices.

Search Preference Process Recommendations

1. Review policies listed to identify strategies to reduce repetition, enhance clarity, and identify modifications to be made post-implementation based on experience with the processes outlined.
2. Identify factors that should be considered when reviewing search preference requests.
3. Update staff job descriptions and performance evaluations to address consistent implementation of search preference policies to allow for staff performance and comfort to be monitored and coaching provided to support proficiency.
4. Submit a request to revise SB 132, Section 2606 (d) by substituting "the right to grieve and appeal" for "a meaningful opportunity to verbally raise any objections to that denial, and have those objections documented." The existing grievance process includes documentation of concerns and responses.

Transgender Access Cards and Property. Operational procedure *C-099 Transgender, Intersex, and Non-Binary Access Card and Gender Identity Questionnaire* was enacted in September 2021 to provide a process for TGNBI incarcerated individuals to access authorized property, canteen, and clothing, and allow them to designate a search preference. Information is gathered through the GIQ and documented by a Transgender Access Card (TAC). The rationale for development of the TAC was strong, however, the benefits do not appear to have been realized in practice. While policy indicates that individuals are not required to carry the card, there was confusion among both staff and the population about when, and if, the cards are required to be carried.

The one area where there seems to be uniformity in both policy and perception is the requirement that the card be presented to access property, canteen, and clothing consistent with gender-identity. An area of concern raised was routine delays in issuance of TACs leading to delays in access to property consistent with gender identity. This concern was supported by a review of grievances.

While most incarcerated individuals who identify as TGNBI indicated they are addressed in a manner consistent with gender identity or by last name, it did not appear staff were using the TAC to identify the appropriate pronoun or honorific, rather staff reportedly ask, consult SOMS, or use gender neutral terms.

Specific to property, 3190. General Policy states that "the Transgender Inmates Authorized Personal Property Schedule (TIAPPS) (4/4/18) identifies a separate list of allowable personal property afforded to transgender, intersex, and non-binary incarcerated individuals. Specifically, the *TIAPPS-Designated Male Institutions* applies to TGNBI incarcerated individuals who are housed at male designated institutions and *TIAPPS-Designated Female Institutions* applies to TGNBI inmates who are housed at female designated institutions."

This delineation is challenging because with a TAC a transgender man housed in a female designated institution can access commissary and property consistent with their gender identity. Often, women prefer men's items, such as t-shirts, which are reported to fit better. Some cisgender women appeared to be obtaining a TAC for the purpose of access to the male uniform t-shirts. In addition to cisgender women seeking to obtain a TAC, it appears that this issue has caused an administrative and operational burden—process confusion, delays, grievances, bartering, and inaccurate information on identity—similar to earlier challenges reported before the decision was made to allow women to purchase boxer shorts. Allowing boxer shorts was reported to have been successful at reducing the burden while not adversely impacting safety or operations. At the time of assessment, CCWF had submitted a budget request to support provision of the t-shirts customarily assigned to men for the women.

Transgender Access Card and Property Recommendations

1. Consider discontinuing the TAC and including preferred pronouns and search preference on state issued identification. This streamlines the process, removes the need for an additional card, and normalizes sharing and utilizing an individual's preferred pronouns.
2. Consider allowing individuals to select a male or female uniform at reception or when it is time for new uniform issuance.

Reception Center Processing and Orientation Cohort. As described Operational procedure *C-108 Senate Bill 132 Implementation, Processing, Orientation, Housing Expectations, and Removal, i*f a housing placement is approved, once endorsed, the individual is to be transferred to the appropriate reception center where they remain for thirty days. Those transferring to a female designated institution go to CCWF. Medical, nursing, and dental reception center processing are not required unless they are unassessed at the time of transfer. The identified purpose of this placement was to provide time for the individual transferring to acclimate to the women's institution, place them in a supportive orientation cohort of others also transferring in, and safeguard their privacy.

The objective of this placement is vital to successful transition as it allows for the transferring individual to 1) engage in support groups and self -help groups designed to aid individuals in understanding and adapting to the culture of the institution, 2) access to staff advocates, transgender, and cisgender mentors, and the inmate advisory council via representatives, and 3) become familiar with these resources, as well as education and healthcare resources specific to their gender identity that are designed to continue throughout their prison term. CDCR's understanding of this need to set aside time to support transition is commendable.

Several unanticipated challenges and unintended consequences of this placement were reported, including the following:

- Restriction of contact with the larger population that does not allow for acclimation to the institution culture and population.
- Restriction of individuals' access to property and opportunities based on reception status though the process is most often not required. Many grievances are received from individuals transferred under SB 132 related to initial placement into reception. Grievance categories included: property, housing placement, and discrimination.
- Inability to observe how the individual interacts in the general institution setting restricting opportunities to provide resources and support for practical challenges and restricting opportunities to reinforce adjustment.
- Inability of women in the institution to get to know the individuals transferring in heightening anticipatory anxiety related to room placements.
- The "orientation cohort" structure was not realized due in part to the pace of transfers, and in part to COVID restrictions on movement between institutions.

The experiences described post-implementation indicate that there may be other strategies that would meet the objective for this placement more effectively. Specifically, by providing a transition opportunity that permits contact with women in the institution, provides more routine access to property, classes, education, etc., and allows staff the opportunity to observe interaction and provide support for practical challenges while also reinforcing adjustment.

Reception Center Processing and Orientation Cohort Recommendations

1. Convene multidisciplinary transfer case conferences between sending and receiving institutions once an individual is endorsed.
2. Create a post reception[3] transition unit housing both TGNBI individuals as well as cisgender women who apply, and are selected, to live in the unit and serve as peer mentors[4]. Ensure that unit design includes the following:
    a. Clear and structured plan to include phase and overall program timelines. Opportunities progress from on-unit interactions to movement into the larger institution allowing experiences with programming and education while remaining in the transition unit. For example, first 30 days orientation and specialized programming, and the next 30 days ongoing support groups and education class attendance, and so on.
    b. Specially trained clinical, custody, and case management staff to support transition, ongoing case review, and eventual unit, bed, and program placement decisions.
    c. Routine multidisciplinary case reviews that include the individual transferring, to monitor the process of adjustment to the institution.
    d. Specialized programming, such as orientation, *Healing Trauma Plus*, and support groups.
    e. Structured quality assurance to ensure fidelity to the model, program curriculum, etc., planned engagement of feedback from staff and incarcerated individuals, and opportunities to adjust.

[3] In this model reception placement would be brief.
[4] As is current practice, individuals transferring would continue to have access to TGNBI mentors who had successfully transitioned to living in the receiving facility.

Institution Placement Process Initiated by GIQ. Provisions of SB 132, Section 4 (a)(3) and 54120.1 and 3 require the following:

- That "an inmate who is transgender, non-binary, or intersex, regardless of anatomy, shall be housed at an institution designated for men or women based on the individual's preference, including, if eligible at a residential program for inmates under the jurisdiction of the Department."
- That "an inmate who is transgender, non-binary, or intersex, regardless of anatomy, shall have their perception of health and safety given serious consideration in any bed assignment, placement, or programming decision within the institution in which they are housed: including, but not limited to, granting single-cell status, housing the individual with another incarcerated person of their choice, or removing the individual or individuals who pose a threat from any location where they may have access to the individual who has expressed a safety concern. If the inmate is not granted an alternative placement based on their concerns about health and safety, the department shall document the specific reasons for that denial and notify the inmate via a CDC form 128B. If an incarcerated individual raises concerns for their health or safety at any time, their housing and placement shall be reassessed."

DOM References

54046.4	*Review of Inmate's Case Factors*
54046.5	*Initial Screening*
54046.5.1	*Gender Identity Questionnaire*
54046.8	*Single-Cell Criteria*
54120.1	*TGNBI Inmates*
54120.3	*Housing Based on Gender Identity*
61010.1	*Policy*
61010.4	*RC Processing Staff Responsibility*
62010.3.2	*Institution Staff*
62010.4	*Considerations*
62010.8.1	*ICC Functions*
62010.8.2	*ICC Authority*
62010.9.1	*CDC Form 128-G*
62010.10.4	*Referral Criteria*

Policy differs from SB 132 requirements in that it does not specify that housing placement cannot be denied due to any discriminatory reason to include a factor that is present among other people at the preferred type of institution; however, a review of approval and denial of placement decisions indicate that there is an awareness of this regulation.

Classification Case Workup. Once a housing request is made, it is sent to the institutional C&PR. The C&PR assigns the request to a CCII from FOPS who conducts an interview of the individual requesting transfer and a complete file review to include "confidential reports" and prior interviews. There is then a meeting prior to the ICC that allows for discussion of any questions and recommendations and for collection of additional information prior to the formal ICC. Operational procedure *C-108 Senate Bill 132 Implementation, Processing, Orientation, Housing Expectations, and Removal* indicates that prior to ICC review medical conducts a review of health records to support a "warm handoff" with the prospective transfer institution and mental health completes a review and makes a housing recommendation. The process culminates in a summary report to be provided to the ICC for review.

Placement decisions are not about proving or disproving an individual's gender identity. Policy, process, and training must outline an approach to determine safe placement considering identity as well as management and security considerations.

Institution Classification Committee Review and Classification Criteria. The ICC is delegated primary authority for all classification actions within the institution. Review of all gender identity based housing transfer requests has been added as a case type to be reviewed by this committee. By policy, the ICC is a multi-disciplinary committee that must include the warden or chief deputy warden, assistant warden, psychiatrist or physician, captain, CCII or III, captain, assignment lieutenant, educational or vocational program representative, and others as required. When considering gender identity based housing transfer requests, the PREA coordinator, a mental health practitioner, and the warden from the receiving institution should be present.

This process has evolved and has clear strengths, including it being chaired by the wardens of the female institutions, the presence of the individual requesting transfer at the committee hearing, and the seriousness with which individual's own perception of safety is seriously considered. Observation of ICC meetings indicated that the individual is invited to discuss their perception of safety in their own words and from their own experiences. Further, mental health appears to be seriously considered. Mental health practitioners were observed to provide information related to status, risk factors, and adherence to treatment.

The key to implementation of SB 132 in a way that significantly and positively impacts safety is to recognize that safety has many meanings. Often when corrections professionals and community stakeholders reference the need for safety, they focus first on different definitions.

Corrections professionals are likely to first consider the threats to safety that are associated with criminogenic or anti-social behavior; community members are likely to first consider the threats associated with denial of identity.

Processes must be developed to mitigate risks where these forms of safety intersect.

Identification of criteria for consideration is vital to ensuring consistency in placement reviews. Common criteria recommended for consideration when determining housing placement based on gender identity include the following factors:

- Individual perception of safety
- Safety and health
- History of, and current, management and security problems
- Security level, criminal and disciplinary history
- Medical and mental health needs
- Vulnerability to sexual victimization and likelihood of perpetrating sexual abuse against others
- Gender identity and expression

Operational procedure *C-108 Senate Bill 132 Implementation, Processing, Orientation, Housing Expectations, and Removal* is clear that classification review must articulate and document the reason for the placement recommendations. It emphasizes that it is "critical this classification review be case factor driven and supported by source documentation and shall not rely upon personal conclusions of the caseworker." Focusing on case factors that are largely consistent with the factors above provides a strong foundation for a gender identity-based housing reviews that address both identity and safety. Case factors include the following:

- GIQ and history of identification as TGNBI
- Medical review
- Mental health review
- Pre-transfer education completion
- Criminal history
- Classification, custody level, program history, length and term to serve
- Cell, double cell, and dorm housing history
- In-Custody disciplinary history
- Victimization concerns
- Predatory behavior concerns
- Consultation with investigations
- PREA review
- Pattern of PREA allegations as a suspect
- Pattern of PREA allegations as a victim
- Co-defendants and enemy concerns at transfer institution
- Security Threat Group activity and validation
- Escape history
- Release date, proximity to release, and next BPH Review

At the time of assessment, CDCR classification professionals had access to information on all criteria listed above, however, they had not been trained on how to apply them to a decision about gender identity-based transfer requests. In the absence of clear training and criteria there appears to be a presumption of transfer. This is concerning given the serious challenges to safety based on institution type and staffing such as the following:

- Some individuals transferring from male to female designated institutions have custody classification scores that would contraindicate placement in CCWF[5] due to staffing patterns and housing options. CCWF is largely dorm living with few celled living options. At the time of assessment seventy to seventy-five percent of the population was level I or II.
- SB 132 prohibits CDCR from denying housing placement requests based on any discriminatory reason, including, a factor present among other people incarcerated at the institution. While there may be similar crimes or institutional misconduct findings present in a women's institution, there may also be distinctions between the scope and scale of those crimes and behaviors. Indications of a current risk of gender-based violence should be considered a key management and security concern. This is especially important considering the housing and supervision needed to manage such risks.

PREA standard §115.42 specifies that housing and institution placement for transgender and intersex people must be made on a case-by-case basis. To make a case by case, individualized decision, a variety of factors must be considered in the context of the individual and their current and proposed placement.

Institution Placement Trends

Based on a review of available documents and data, disciplinary charges related to violence, sexual behavior, enemy concerns, hesitancy of the requesting individual to transfer, safety of the current environment, and significant potential for adverse impact of the move (i.e., single cell to dorm) were the most common reason for denial of placement by gender identity.

While history of violence, diagnoses of gender dysphoria, and gender affirming therapies, all appeared to be considered as relevant in consideration for continuing care, none were treated as automatic inclusion or exclusion from gender identity based placement. This demonstrates case-by-case decision making.

The most common reason for approval of placement was described as "no case factors that were not currently present among individuals housed at a female institution."

Removal and Involuntary Return. Operational procedure *C-108 Senate Bill 132 Implementation, Processing, Orientation, Housing Expectations, and Removal* states that all decisions about removal from a placement made because of a gender identity based transfer shall be reviewed on a case-by-case basis if one of a variety of management and security concerns[6] are present. It is notable that none of the management and security concerns relate to gender identity; rather they relate to the ability of institutions designated for women to manage the level of risk presented by an individual.

Institutional Classification Committee Review and Classification Criteria Recommendations

1. Develop an interactive, practice based, training for CCII and IIIs to ensure consistency in case work ups, and for ICCs to support criteria-based decision making.
2. Develop, include in policy, and implement timelines for each step of the process from request for placement through arrival at receiving facility.
3. Ensure that case conferences convened to review potential alternate female designated housing placement or return to a male designated housing placement (or vice versa) includes representatives of medical and mental health.
4. Define clear criteria for consideration in case work up and ICC review to support consistency in decision making specific to institution placement. In addition to factors specific to identity, ability to manage risk through unit structure and staffing levels must be considered. After classification processes have been fully designed and implemented to ensure that placement decisions are made based on the individual's needs, and on the ability of an institution to safely house that individual, involuntary returns should be infrequent.

[5] CCWF is the only level four female designated institution in the state.
[6] Examples of identified management and security concerns include, but are not limited to, single cell or celled living requirement, enemy concerns, or safety concerns, and documented sexual behavior.

Housing and Access to Gender Affirming Medical Care. An additional important consideration in institution placement, and timing of placement, is proximity to gender affirming medical services and access to housing that provides necessary privacy during post-surgery recovery. Due to the geographic location of women's institutions in the state, access to these services often requires significant travel. CCWF is likely to be disproportionately impacted by transportation needs and staffing demands required to ensure safe and effective medical services. Further, staff referenced concern about the safety of travel post-surgery and access to the level of privacy needed in housing placement for recovery.

Housing and Access to Gender Affirming Surgery Recommendations

1. Ensure that proximity to gender affirming medical care and privacy needs are considered in institution placement.
2. Conduct an analysis of the travel and staffing costs of travel for gender-affirming medical care compared to defining a housing option closer to these resources. As a part of the analysis, engage medical experts to ensure clarity on travel safety and requirements.

Unit and Bed Placement. Once an individual is placed in a male or female designated institution, bed or unit placement at the receiving institution is an important consideration for safety. While there did not appear to be a difference in TGNBI individuals' access to programs, services, or out of cell time when successfully placed,[7] the experience of unit and bed placement in the institution was observed to have marked differences. Bedspace appeared to be a driving factor in dorm or bed placement. It was not clear what other factors, if any, were considered.

SB 132, Section 4, 2606 (a)(4) allows a transgender person to remove other individuals from a room if safety concerns are expressed. While all housing decisions should be predicated upon safety, this practice creates inconsistency and a perceived imbalance of power in the population. Incarcerated individuals who refuse a cell assignment face disciplinary action. For instance, in practice, if a cisgender woman raises personal safety concerns about having a transgender woman in the room, it was reported by staff and incarcerated individuals that she would be written up and removed from the room. This process has had a significant impact on all of the women in the institution. For some, housing stability was disrupted. This often evoked fear on the part of cisgender women and rejection of transgender women triggering a cycle of anger, divisiveness, and loss. These dynamics were at times activated by myths, anxiety or fear, and other times by misperceptions and misunderstanding. For example, a transgender woman was given a private room following gender affirming surgery and it was clear that the other women on that unit felt that was unfair and were not aware of the reason for the placement in this case, postoperative privacy. While maintaining confidentiality is important, so too is addressing misunderstandings through early education as a preventative measure.

The process for unit and bed placement of TGNBI individuals is not structured to support physical, sexual, emotional, or relational safety and does not include a formal review process. Allowing incarcerated individuals input into placement is important when considered as a component of a larger process and not an expectation that all requests will be granted. Direct selection of roommates is a risk to safety and security. It is notable that this process has been identified as problematic prior to SB 132 implementation and regardless of gender identity. SB 132 added complexity to the challenge.

Use of Administrative Segregation. There is concern that the lack of structure or review of institution unit or bed placement has increased the use of administrative segregation for TGNBI individuals transferring into CCWF. Reasons for placement in administrative segregation included enemy and safety concerns, evidence of romantic and sexual relationships, battery, allegations of sexual battery, and potential gang activity. It was consistently communicated that if there is a PREA allegation, the alleged suspect automatically goes to segregation until an investigation is completed. There is a widespread belief among staff and incarcerated individuals that allegations are often misused to remedy

[7] Access to out of cell time is difficult to interpret due to COVID restrictions. This statement is based on interviews and observations.

interpersonal or institutional issues. It is notable that concerns of this nature were not as common with transgender women who transferred in prior to SB 132; however, many believe that there has been an increase in PREA allegations made in bad faith coinciding with SB 132. It will be important to continue to monitor trends in this area as efforts continue to enhance safety in placements.

Unit and Bed Placement Recommendations

1. Submit a request to revise SB 132 by removing the following language from Section 2606 (a)(4) "bed assignments" and "pursuant to paragraph (3) of subdivision (a) or subdivision (b) including, but not limited to, granting single cell status housing the individual with another incarcerated person of their choice, or removing the individual or individuals who pose a threat from any location where they may have access to the individual who has expressed safety concerns." Include language that indicates that an incarcerated individual's preferences for who they are housed with be taken into consideration as a part the overall placement process.
2. Develop a structured process for institution-based unit and bed placement that includes clear guidelines for placement based on at minimum PREA screening, safety, and privacy considerations for housing transgender, non-binary, intersex, and cisgender women together.
3. Consider housing by custody level and behavior; separation of level III and IV would allow CCWF to determine staffing and resources according to population risk and need.
4. Construct or establish additional celled living capacity to support safe and effective management of individuals who are not appropriate for dorm-style living and where single cells are limited.

Staffing and Capacity. At the time of assessment several areas of concern were noted about staffing in relation to implementation and sustainability of SB 132. For instance, the workload for clinical professionals was reported to have increased due to the need for gender affirming care assessments and tasks. Further, it was reported that there was an additional workload due to the implementation of the new grievance procedure, and the time limited positions that were brought on to implement SB 132 are expiring. Finally, it is unclear if the standardized staffing model accounts for the staffing needs of women's institutions as a baseline.

Staffing and Capacity Recommendation

1. Conduct an analysis to identify staffing levels that consider custody, non-custody, and clinical needs based on the mission of the institution, safety, performance expectations, nuances of supervising women and TGNBI populations, and the workload created by operational changes.
    a. Consider a specialized case management structure for TGNBI care coordination.
    b. Consider maintaining the psychology and psychiatry positions created to support SB 132 implementation.

Preparation and Training

Consistent with the approach to making gender-identity based institution transfers, CDCR developed a thoughtful approach to preparing both staff and incarcerated individuals to support successful transition and respectful and safe management of TGNBI individuals in institutions that correspond with their gender identity. This approach was built on the foundational efforts of a long-term workgroup comprised of CDCR experts and diverse stakeholders.

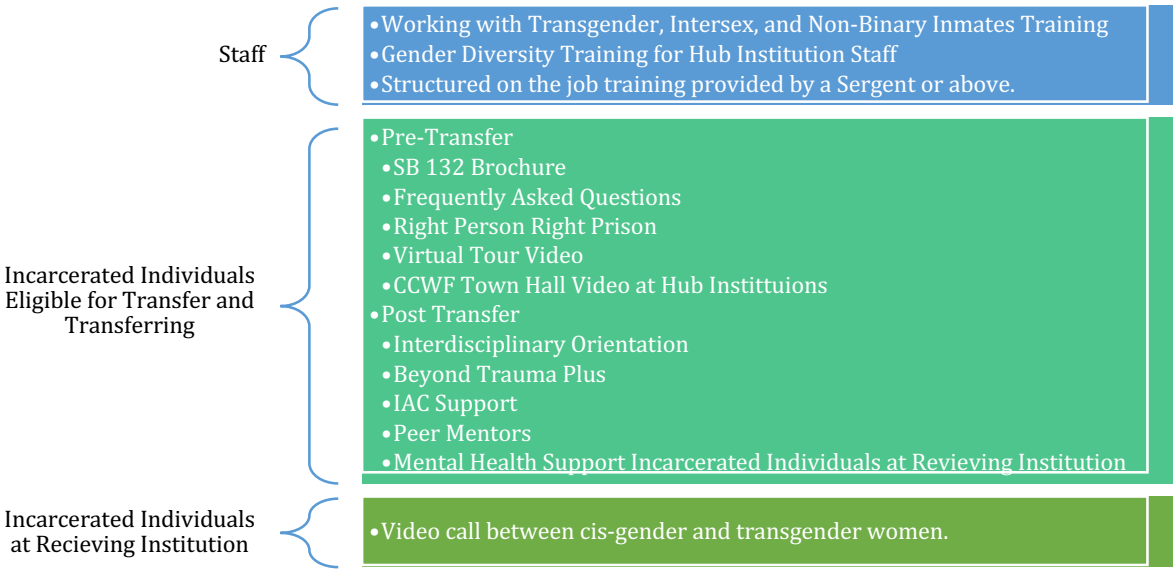


Figure 7: Preparation & Training Efforts

Leadership and Staff. Significant efforts were made to create multiple avenues for communicating and setting the tone for this critical transition. Several resources were provided for staff and leadership, including the following:

- *Overview of Senate Bill 132* as an on-the-job one-hour training module that included definitions, process flowcharts, direction on practices related to property and searches, and addressed frequently asked questions.
- *Working Successfully with Transgender, Intersex, and Non-binary Inmates* as an in-service one-hour training module that focused on culture, identifying pathways and experiences of a TGNBI population, and the resulting changes to policy and practice.
- *Transgender Cultural Fluency Training* was shared with the PREA compliance managers at the fourteen hub institutions.
- Development or delivery of flowcharts, talking points, presentations, memoranda, frequently asked questions, town halls, and other quick use resources.

During the onsite observation component of this assessment, it was clear through discussions and observations that many staff were grappling with implications of housing by gender identity that went beyond policy change into the deeper interaction of gender identity and gender responsive practice. Early communication was reported to be direct, quick and announcement driven rather than discussion based with many being unsure of where to ask questions.

Staff expressed that it had taken time and consistent training to shift the mindset of the institution to understand and treat women based on gender-responsive principles. While these changes do not negate the efforts expended to ensure use of a gendered lens, it will take time for staff to fully understand the implications for incarcerated TGNBI individuals. Additionally, the presence of transgender men in the institution complicates the issue for staff who are working to break habits such as referring to groups of individuals in the institution as "ladies."

There was some indication that trainers believed that as a result of SB 132 transfers they needed to prepare the staff at CCWF to work with and manage men, rather than women. While it is true that as transgender women transition into a female designated institution staff will need to understand the dynamics and processes these individuals are used to and become more flexible in their skills. However, messaging that indicates that men are coming into the institution reinforce harmful stereotypes. It is notable that this sentiment at its core was related to ensuring safety in the institution. Education and practice can enhance staff's comfort and confidence in managing the population. The expected challenges of the transition were complicated by the fact that at the time of assessment, staff were unclear on the full meaning and impact of the SB 132 legislation. The system of policy in California is complex, as draft policy is finalized, providing staff with easy-to-use resources directing them to appropriate guidance will help create consistency in understanding policy and procedure.

Incarcerated TGNBI Population. To prepare those transferring to the institution of gender identity, several levels of training and preparation were provided, including written material, interactive training, pre-transfer support, post-transfer support, and programming designed for TGNBI individuals.

Right Person Right Prison is a four-week pre-transfer course that by policy is mandatory for those who have indicated a desire to transfer to an institution that aligns with their gender identity. The course as designed includes eight, two-hour in-classroom instruction sessions as well as eight corresponding journal assignments. The goal is to support the population in deciding if the transition is the best choice for them by providing information about women's institutions and ensuring the differences are discussed and understood prior to transfer. It was reported by most transgender women who had transferred to CCWF that the course was either delivered at a time other than planned by process or lacked key information to support their preparation for the realities of living in female designated institutions. Specifically, they indicated a need for more information about interacting with the population at the receiving institution to include cisgender women and transgender men.

Incarcerated Cisgender Population. The type and scope of preparation differed widely for the population transferring into CCWF and the population already at the institution. The warden met early on with the with the executive body of the Inmate Advisory Council (IAC) to explain the bill and its impacts. The IAC was then asked to discuss SB 132 throughout the institution, collect feedback, and share the feedback with the warden. It is unclear if these women fully understood the changes associated with implementation and it was clear that there were concerns about the transition. This advisory body would benefit from additional education and opportunities to interact with TGNBI individuals as colleagues and community members. Further efforts included the department hosting a virtual meeting with the IAC executive body at CCWF and a group of transgender women who wished to transfer to a women's institution. This was a promising practice for both populations to ask questions and learn more about one another's concerns. However, the women who the IAC met virtually did not ultimately transfer to CCWF contributing to a level of mistrust and confusion about what to expect.

The difficult nature of this transition was exacerbated by the overlap of SB 132 implementation with the COVID-19 pandemic related lockdown of programming. There was a sentiment that the women's institution locked down in March 2019 and re-emerged as something else, with a sense of instability and fear that it will never be

CDCR continues to work on enhancing resources to support women at receiving institutions. For example, the agency is partnering with the PREA Resource Center and Just Detention International to create a video series designed to provide education about individuals who identify as transgender, non-binary, or intersex people to include a discussion of pathways and similarities of transgender and cisgender women.

Preparation and Training Recommendations

1. Incorporate data to demonstrate trends, successes, and challenges into messaging and training.
2. Continue to engage, or re-engage, community stakeholders as advisors and providers as the implementation process continues.
3. Expand education and preparation for incarcerated individuals at receiving institutions and engagement of cisgender women in creating a safe institution culture for both cisgender and transgender women.
4. Expand staff in person training to build on initial offerings with a focus on scenario practice.
5. Evaluate the effectiveness of the on-the-job training program to ensure that it provides practical, supported learning. There were indications that the current process is less focused on learning and more focused on proof of practice (i.e., signing policy, etc.).
6. Expand training for trainers to ensure trainer confidence in correcting, and not reinforcing, misconceptions about the population transferring into receiving institutions.
7. Create a quality assurance structure to support consistency in training and program delivery by qualified and trained facilitators.
8. Review processes for agency wide dissemination of information regarding the option to request placement by gender identity.
9. Provide incarcerated cisgender women additional education, opportunities to ask questions and get to know TGNBI individuals, and conversation with staff about strategies for safety.
10. Engage cisgender women in transitional housing planning and support for TGNBI individuals.
11. Assess the effectiveness of current training for current, new, and transferring employees as a baseline and foundation for development of focused, interactive, scenario-based training. Ensure any additional training is operationally driven and connected to policy.
    a. Clearly and concisely reinforce key components of initial training such as the distinction between gender identity and sexual orientation.
    b. Provide staff with training to support understanding of the various components of transition—social, emotional, and physical factors—and engage in discussions regarding the meaning of situations when behavior or characteristics may appear to contradict stated identity, such as medication and trauma.
12. Update the job shadowing checklist to include the adaptive skills that are required at a female institution in addition to considerations for TGNBI individuals and technical processes and procedures that are evaluated by the Field Training Officer.
13. Ensure that both policy and training definitions are consistent with those outlined in SB 132.
14. Develop a "quick guide" for staff that summarizes and provides reference to all policy and formal guidance to support staff in respectfully supervising TGNBI individuals.
15. Ensure that trainers and facilitators of programs are trained both in content delivery and facilitation of sensitive conversations regarding safety and individuals concerns. While education and programing is not designed to change an individual's personal beliefs, trainers, facilitators, and leaders must be able to communicate what professionalism entails in the institution setting regardless of personal beliefs.
16. Consider revisions to the current content and design of *Right Person Right Prison* class.
    a. Include input from those who have previously attended the course'
    b. Develop a structure that ensures that the *Right Person Right Prison* is consistently delivered at all institutions.
    c. Consider engaging facilitators with clinical expertise to facilitate the class. While the institutions themselves often impact decision making— based on housing and program options—so too can an individual's transition process, which may make the decision emotionally complex for some.
    d. Revise and update information on the transfer request process, housing layouts, and preparation for transfer.
17. Provide ongoing training specific to medical and mental health care for clinical professionals at CDCR and maintain resources for consultation and coaching that are currently in place.
18. Consider including a TGNBI representative to the Inmate Advisory Council (IAC).

Leadership and Culture: Sustaining Change

This section is focused largely on the onsite assessment of SB 132 implementation, policies and procedures developed to comply with requirements at CCWF, and its impacts on institutional culture and practice. See Figure 8 for a list of topics that will be further reviewed in this section. There are inferences from the CCWF assessment that will have implications agency wide. At all levels, the tone set by leadership, and creation of a culture to support new practices to improve safe and respectful housing and management of TGNBI individuals, are the keys to sustained change. Agency and institution leadership consistently demonstrated a commitment to safe placements that honor the identities of TGNBI individuals.

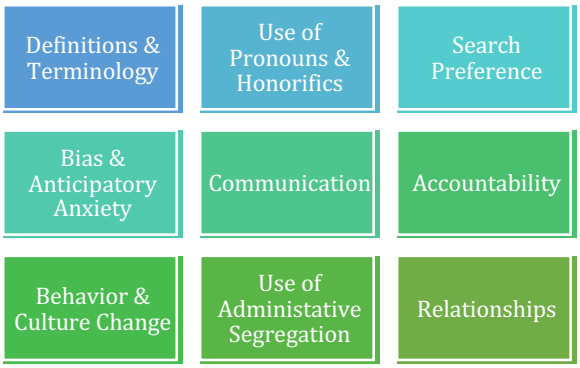


Figure 88: Leadership & Culture Indicators

Definitions and Terminology. Staff varied in understanding of key definitions and terminology related to the TGNBI population. While there was a broad understanding of what it means to be transgender, there are opportunities to build on this through training and formal guidance, such as the following:

- Clarify terms that staff may be less exposed to, such as non-binary and cisgender.
- Support a deeper understanding of the complexities of transition as not a one-time event but an individually driven constellation of social, emotional, and medical changes.

Existing policy definitions provided a general understanding of terminology, however, adoption of the definitions outlined in the legislation within department policy will support shared understanding and accurate use of terminology.

Use of Pronouns and Honorifics. It was reported by institutional leadership, institution staff, and the population that staff make sincere efforts to be respectful of preferred pronouns. In large part, it appeared that staff complied with this practice and the transgender population reported feeling comfortable addressing honest mistakes by both staff and the cisgender population. There were pockets of staff are reported to intentionally misuse pronouns, however, the efforts of the majority of staff signals an openness to not only compliance with, but eventual adoption of, comprehensive correctional best practice for the safe and effective management of TGNBI individuals.

Search Preference. A clear strength noted at the institution is that overall, individuals that assessors spoke with who had specified a search preference reported that it is honored. Some indicated that this is a clear difference from men's institutions where they were housed prior to transfer. While not all staff agreed with the search preference policy, they appear to have accepted it as part of their duties. This practice does present staff with the need to become proficient with practices that may not have been a routine part of their work prior to SB 132. Specifically, if a staff member has always worked at a women's institutions, they may be less comfortable with male search practices and vice versa.

Bias, Anticipatory Anxiety, and Fear of Manipulation. The shift from housing by sex assigned at birth to housing by gender identity represents a significant and important shift in philosophy and practice for correctional agencies nationally. It is to be expected that leadership and staff at all levels of an agency, and the incarcerated population, will be concerned about safe implementation of this new practice. Throughout the country, the practice of housing transgender individuals in an institution that aligns with gender identity has raised questions about the propensity for the system to be manipulated. SB 132 permits incarcerated individuals and those entering custody to be considered for housing aligned with their gender identity based on self-identification. Many worry that SB 132 will result in decreased physical and sexual safety because transgender women were transferring into female designated institutions. These fears reflect those that occur in community settings throughout the country as TGNBI populations become more visible and community members grapple with personal beliefs.

An important part of overcoming bias related to personal beliefs is to be aware of both implicit biases and confirmation biases. Implicit biases are the attitudes or beliefs that individuals hold about people, ideas, issues, etc. which are out of their conscious awareness but can impact their behavior. Confirmation bias is the unconscious tendency to seek and interpret information in ways that support existing beliefs or expectations. These biases are largely out of our awareness, however, there are ways to become aware of them to ensure that they do not impact our behavior in professional settings.

Issues of bias are complicated when there is significant anticipatory anxiety connected to a change. Anticipatory anxiety, in this setting, refers to the fear or worry that bad things will happen due to gender identity based housing. When a change feels out of an individual's immediate control, and when there are safety concerns, people can become fixated on the uncertainty. At CCWF, both staff and incarcerated individuals voiced concerns and anxieties prior to implementation, including physical and sexual safety concerns, contraband, and cultural changes that would shift to that of a male institution

Anticipation of challenges to plan and problem solve is an important practice; however, discussion of the fears without discussion of what is being done to promote safety is counterproductive. At the time of assessment, several staff and incarcerated cisgender women shared variations on the theme that their fears prior to the implementation of gender identity based housing were much worse than the reality. In reality, individuals transferred to CCWF have had a variety of experiences. Many have acclimated easily and reported feeling accepted, others faced hostility or felt ostracized.

Most staff reported having confidence and respect in institution leadership and reported appreciating the acknowledgement of their concerns about the implementation of SB 132. Similarly, most cisgender incarcerated women believed that staff and leadership understood their concerns. TGNBI individuals were mixed in the level of support that they felt from leadership and staff. Some felt supported, while others reported feeling that they were not wanted in the institution. It is likely that anticipatory anxiety and the unintended impacts of associated biases, myths, and misperceptions contributed to the difference in perceived attention to concerns between cisgender and TGNBI incarcerated individuals.

Direct experience, tracking and discussing very specific data will support continued enhancement of safety in the CCWF culture post-SB 132-implementation. These activities will help the people who live and work at CCWF, as well as other facilities housing TGNBI individuals, gain confidence in their understanding of strengths and challenges of the process. Recommendations in the *Research and Data* section of the report describe key considerations for streamlining the data needed to monitor processes and share outcomes. Continued education and attention to transition, as described in the *SB 132 Transfer Process* and *Preparation and Training* sections of the report, can build on the credibility institution leadership at CCWF has with staff and cisgender women, and increase trust and consistency of respectful interactions for TGNBI individuals.

Communication. In initial stages of implementation, CCWF leadership communicated directly with staff and incarcerated individuals about SB 132 and implementation efforts. Training was provided, and information was shared—see the *Preparation and Training* section for more information. As implementation has moved forward it appears that frequency of formal and direct communication on this topic has decreased. Information about operational functioning and incarcerated individuals is shared at the morning leadership meeting. However, because the agency does not have formal roll calls or musters, it appears that information is largely shared down the chain of command, via email, or on-the-job training. Due to the complexity of the transition to housing by gender identity, indirect communication can lead to misunderstanding and uncertainty as both validated and unclarified information is communicated verbally between staff. Supervisory communication is a vital part of supporting transition, however, with the complexity and sensitivity of issues related to identification as TGNBI, some may be fearful about saying the wrong thing.

At the time of assessment, staff at all levels and in all disciplines, as well as incarcerated individuals, referred to SB 132 as men moving to the women's institution. Clear and consistent messaging with ongoing coaching will be needed to shift that message to women transferring into an institution designated for women under SB 132. This will require broad messaging to staff and incarcerated individuals, as well as informal conversations about the impact of this mischaracterization and the leadership commitment to safety and respect. Intentional communication from leadership at all levels related to respect and adherence to policy, clear structures for accountability, and ongoing support for staff and incarcerated individuals through the transition is vital to sustained change.

Behavior and Culture Change. One consistent concern raised at all levels of the agency and institution was the potential of the changes associated with SB 132 to adversely impact the culture of the institution. For example, there were reported increases in possession and manufacturing of weapons, gang activity, PREA allegations, drug and alcohol use, and more sophisticated criminal behavior, such as a drone drop of drugs by a transgender woman who was transferred under SB 132. There were varying perceptions about violence and weapons increasing in the institution. Some believed the increase in violence and weapons to be rumors, others believe strongly that there have been increases. Further, while the prevailing fear was that transgender women would sexually victimize cisgender women, a few transgender women indicated that they were often sexually pressured or pursued, which indicates that there may be stereotypes threatening the sexual safety of transgender women.

Monitoring of trends in data that indicate broad changes in behavior or shifts in culture will be a key component of supporting the staff and incarcerated individuals in the institution through transition. Continually monitoring and contextualizing the data is one of the most effective tools leaders have to keep their institutions safe. For example, as indicated above, the institution reports an increase in deadly weapons. Specifically, in 2019 there were no infractions for possession of a deadly weapon, in 2020 there were five, in 2021, there were 8, and in 2022 there had been 5 at the time of assessment. Discussions with the institution indicated that the numbers do not directly correspond to possession by individuals transferring in under SB 132. Further exploration of the impetus for possession will help institution leaders and staff employ strategies to address presenting issues and enhance the safety of the institution. For instance, the increase in weapons may be related cisgender women being fearful due to the arrival of the transgender female population, it could also reflect transgender women who are fearful due to unsafe experiences in male institutions. It is even possible that the increase is due to factors unrelated to SB 132. Leadership action to support safety will vary depending on the root cause of any trend. Ongoing evaluation of this type would benefit from data system integration described in the *Research and Data* section of the report.

Accountability and Consistency. A clear theme identified through the discussions with institution leadership, staff, and incarcerated individuals was concern about staff's willingness to effectively hold TGNBI individuals accountable. It was reported some women who have transferred into the institution will push back when behavior is corrected by stating that they will engage an external resource such as an attorney or advocate. While these external resources are an important part of the system, staff should be empowered and know that if they are acting within policy and the code of conduct, they will have leadership support. Increasing the confidence of staff to hold all incarcerated individuals accountable appropriately and respectfully will require ongoing communication from leaders at all levels to reinforce support and coach staff on how to address these difficult interactions.

In addition, there were reported variations in how women perceived rules to be enforced. Some women who had transferred into CCWF indicated that while it is physically safer at the women's institution it is also much easier to receive a write up. Cisgender and transgender women assessors spoke with also reported that there is inconsistency in how rules are applied. For instance, some transgender women are reportedly not reprimanded for modifying clothing, while cisgender women are perceived to get written up for this routinely. Incarcerated individuals also noted that some individuals are never held accountable due to strong legal or community advocacy connections.

There was also a reported need for staff to intervene when inappropriate, disrespectful, or derogatory comments are made to TGNBI individuals. Assessors spoke with some cisgender women who reported hearing about incidents of violence or inappropriate sexual behavior by transgender women and being fearful even if they had not experienced these things. In part this was related to uncertainty of how they should react if something happens if staff are reluctant to step in. Addressing these concerns will require leadership to provide clear expectations that staff intervene, providing training on how to intervene in sensitive situations, and coaching in effectively interrupting bullying behavior.

Voluntary Returns

Interviews with transgender women who voluntarily returned to male designated institutions indicated the following as contributing factors for the return:

- *Feeling unsafe physically, sexually, emotionally, or economically*
- *Perceived pressure to return*
- *False allegations to be removed from room*
- *Hostile reception from staff or incarcerated individuals*
- *Issues with getting hygiene items, such as razors*
- *Challenges adapting to dorm living*
- *Incompatibility with roommates*
- *Sexualized environment, including being sexually pressured or pursued*

Relationships. Both cisgender and transgender women emphasized the importance of safe and healthy relationships, which is also a hallmark of effective gender-responsive practice. One concern that was reported is a perceived increase in domestic violence issues. Some attribute this increase to the implementation of SB 132, others believe it is a result of COVID-19 based restrictions access to domestic violence and healthy relationship programs. In either case, it is important to note that intimate or romantic relationships in the facility are not a new development with SB 132. They are reported throughout the institution to include relationships between cisgender women and between cisgender women and transgender men.

Overall, while some cisgender women report not feeling safe with transgender women, others have no safety concerns. Some cisgender women categorically do not accept identities outside of the binary as valid, others are clear that acceptance is about the person rather than the identity. Many individuals, however, remarked on the reality that, before SB 132, "transgender women were treated like women" and generally settled in well. It is likely that the pace and uncertainty surrounding implementation of SB 132 complicated the transition process for transgender and cisgender women.

Leadership and Culture Recommendations:

1. Develop a dynamic agency level "working" strategic plan as a tool to organize all the recommendations accepted in this report and additional priorities related to the management of TGNBI individuals in CDCR. We recommend a model of strategic planning that is action oriented with a mechanism to document progress and that builds on current goals.
    a. Engage institutions to develop an implementation plan consistent with the agency plan that supports the ongoing improvement of practice and safety. This will ensure that both staff and incarcerated individuals are clear on institution priorities and direction.
    b. Share successes and their impact routinely. For example, reinforce staff for honoring pronouns and search preferences and provide specific information on how those practices support safety for everyone. Recognizing what is going well increases the likelihood that staff will feel confident—and increase self-efficacy— in implementing other changes to enhance safety or safely manage TGNBI individuals.
2. Continue to track trends in discipline, assault, PREA incidents, and contraband in order to identify strategies to guide decision making, increase safety, and address myths and misperceptions about individuals transferring into the institution under SB 132.
3. From leadership levels, communicate with intentionally to keep the workforce, incarcerated individuals, and stakeholders informed. Committing to timely—daily, weekly, or monthly—systems of communication can significantly reduce anxiety and misunderstandings.

a. Ensure that communication systems have a feedback loop incorporated in them in order maintain leadership awareness of concerns and gain input on solutions to capitalize on the strengths of implemented processes and procedures.
b. Share operational and procedural adjustments, expectations, and provide clarification related to questions.
c. Communicate expectations about accurate and respectful communication. For example, rather than "bringing men into women's facilities" reinforce accurate messages such as: "Women are transferring into our institution from male designed institutions because female designated institutions are appropriate based on their gender identity."
d. Reinforce that leadership will support staff if they are operating within agency policy and the code of conduct to minimize anxiety about fairly and equitably holding incarcerated individuals accountable.
e. Address rumors and misperceptions, answer questions, identify areas of inconsistency and engage problem solving.
f. Conduct goal directed rounds. Both formal and informal interactions are key to promoting culture change to supporting safe and respectful management practices. Setting a specific goal to address during rounds creates powerful opportunities to intentionally communicate or reinforce expectations, seek feedback, or provide clarification. Evaluating the effectiveness of a change to practice or policy, answering questions about why the change occurred, and coming to understand the impact of change on staff facilitates buy-in and decreases the potential for a code of silence
g. Capitalize on rounds and forums such as shift briefings as opportunities for communication regarding safe and respectful management of TGNBI individuals. Methods may include the following:
    i. Leading discussion and observation practice or interaction during rounds
    ii. Providing information or brief skill-based scenario trainings

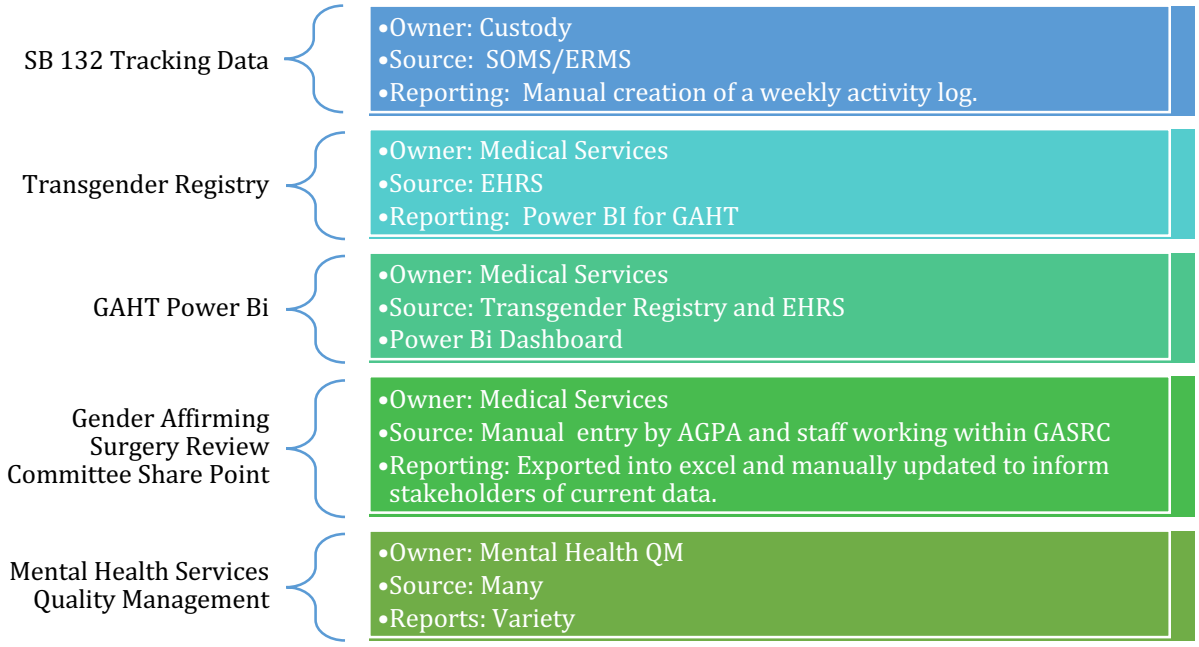
4. Consider providing interactive training to staff in the following areas to support ongoing culture change and professionalism for staff. Modified sessions may be appropriate to prepare incarcerated individuals at receiving institutions.
    a. The impact of implicit and confirmation bias on leading and acting with awareness and professionalism.
    b. Strategies for addressing and interrupting bullying and harassment.
5. As policies and procedures specific to SB 132 and the safe and respectful management of TGNBI individuals formalize and evolve, ensure that the culture supports true accountability rather than attempts to "cover oneself" with proof of practice. When a culture fully embraces accountability, you see a shift from staff being hesitant, complacent, or defensive. Rather you see people identifying a need or challenge, owning it, working to solve it alone or with others, and adopting new practices.[8]
    a. Key components to ensure accountability include clear expectations, performance planning, and ongoing coaching.
6. Identify and implement additional training for staff, and programming for incarcerated individuals, on domestic violence and healthy relationships. Ensure the training is inclusive of diverse relationship structures.
7. Identify ways to make policy, practice, and procedure designed to support safety for TGNBI individuals a routine component of good correctional practice.
8. Consider assessing at minimum a hub institution and male designated institution to clearly understand how SB 132 is being implemented across missions to develop and implement strategies for sustainability.

[8] Connors, R., Smith, T., & Hickman, C. R. (2004). *The Oz principle: Getting results through individual and organizational accountability*. New York, N.Y: Portfolio.

Research and Data

Throughout the report effective gathering and sharing of information, and ongoing monitoring of practice through examination of data, have been highlighted as key components of successful implementation and sustained change. Analysis of this kind supports effective practice by identifying successes and opportunities for course correction which is especially important when an agency is innovating in an emerging area of practice.

As a component of the document review TMG collaborated with the data and information experts at CDCR who worked diligently to provide clear and accurate data to facilitate assessment activities. It became clear during this collaboration that pulling data from the system specific to TGNBI individuals was complex and at times cumbersome. In addition, throughout the assessment, a variety of CDCR professionals with voiced concerns about the accuracy of the data. This was due in part to changes in the practice of gathering data or information in close proximity to the assessment, such as changes in grievance tracking and GIQ implementation, and in part to concerns about the accuracy of manual entered data, and the variety of different—and often unconnected—systems that data must be extracted from. In spite of a significant amount of work done to provide TMG with data, it was extremely difficult to create a cohesive picture of the TGNBI population across disciplines. See Figure 9 for a listing of current relevant data systems.



SOMS: Strategic Offender Management System; ERMS: Electronic Records Management System; EHRS: Electronic Health Record System; GAHT: Gender Affirming Hormone Therapy; AGPA: Associate Governmental Program Analyst; GASRC: Gender Affirming Surgery Review Committee; QM: Quality Management

Figure 9: Research & Data Systems

The lack of a central repository for custody management, housing placement, medical, and mental health information in the institution can hinder coordination of services. In addition, a comprehensive system for tracking data and information on TGNBI individuals could 1) help identify potential safety concerns or needs for individuals, as well as the population as a whole, so that they can be addressed proactively, and 2) allow for reviewing the effectiveness of programs, services, and interventions. Taken together, this information can provide a comprehensive and up to date summary of risks and needs of the population ultimately combatting anticipatory anxiety, implicit, and confirmation bias.

Gender Field. It is reported that there are challenges with consistent updates to the SOMS/ERMS gender field. While the GIQ triggers a change in the system, the change is manual, and it is reported that updates do not always occur in a timely way. This is particularly challenging because the electronic health record pulls from SOMS/ERMS; therefore, when the field is not updated, patient official medical records will be inaccurate, which reportedly make transferring to an institution even more challenging.

External Research. CDCR has an important opportunity to partner with external research experts to study the impact of evolving practice with TGNBI individuals. Because the agency is large and innovating in an emerging area of practice, the opportunity exists to contribute meaningfully to the literature on the safe and respectful management of TGNBI individuals. This will allow refinement of the practices implemented under SB 132 as well as provide a foundation for progress around the country. Streamlining data systems will support work of this nature, however, acting quickly to engage objective research is vital and challenges can be collaboratively overcome.

CDCR Numbers. The assignment of "WB" CDCR numbers was raised as a challenge agency wide. By way of summary, transgender women have been assigned "WB" numbers as a component of the transition to a women's institution due to data system issues. The reason for this is that SOMS is unable to automatically assign or generate a new CDCR number to an incarcerated individual if they currently have an active CDCR number. Headquarters Case Records maintains a block of reserved numbers for both male and female incarcerated individuals for different scenarios. The reserved block of numbers for female incarcerated individuals is WB1100-WB9999, and the reserved block of numbers for male incarcerated individual is AJ1000-AJ9999. When an individual has an active CDCR number in SOMS and requires a new CDCR number the next available number from the reserved block is manually entered into SOMS. When an incarcerated individual transfers between a male and a female institution, a new CDCR number from the reserved block is assigned to the individual to coincide with the gender designation of the institution to which the individual is transferring.

This method of assignment had the unintended consequence of compromising confidentiality and outing transgender women who transfer from an institution designated for men to an institution designated for women. Further, a small number of cisgender women have WB numbers. This causes conflict because they fear being mistakenly identified as a transgender woman. The concern expressed by cisgender women about these numbers illustrate the stigma attached to this WB designation.

CDCR has conducted extensive study around solutions to this challenge. The preferred solution identified was devising business rules for SOMS to have the capability to assign the next available (subsequent) number to an incarcerated individual upon arrival at the receiving institution. The clear strengths of this solution are that it would safeguard confidentiality and eliminate the need for manual entry. However, several challenges exist including potential system errors, such as movement, disciplinary, and gang validation, and key documents not being updated with new CDCR numbers adversely impacting holds, detainers, and CLETS/FBI rap sheets.

Research and Data Recommendations

1. Identify and implement an information technology solution to consolidate various sources of data into one system with the purpose of providing a comprehensive view of TGNBI individual, and population, characteristics and needs across disciplines.
    a. Include a process to ensure consistent updates of the gender field to support an individual's transition and ensure that their records are up to date and accurate.
2. Engage with external researchers at all stages of implementation to support refinement of the practices implemented under SB 132 contribute to providing a foundation for progress in safe and respectful management of TGNBI individuals around the country.
3. Identify solutions to address concerns with preferred method for assigning CDCR numbers for individuals who are transferring between male and female institutions.

Attachment A: Summary of Recommendations

Gender Identity Questionnaire Recommendations

1. Consider entering pronouns for all incarcerated individuals to normalize sharing and using and using preferred pronouns. At the time of assessment, information on preferred pronouns was collected for all incarcerated individuals but only entered for those who identify as transgender, intersex, or non-binary.
2. Map the automatic population of information from the GIQ to determine additional opportunities to provide staff with ease of access to preferred pronouns to support respectful interaction. For example, at the time of assessment, pronouns were populated into a banner at the top of an incarcerated individual's electronic file in one system, however, in other systems the information was reported to be more difficult to find.
3. Consider revising the GIQ to ensure that individuals are asked search and housing preference questions even if they have transitioned to the point where they no longer identify as transgender, but as their gender identity
4. Implement a process by which institution senior management regularly spot check the reception areas during intake processing to ensure the GIQ is being completed in a private setting as required by SB 132 to support collaborative problem solving in unusual circumstances where space or process challenges arise.

Search Preference Process Recommendations

1. Review policies listed above to identify strategies to reduce repetition, enhance clarity, and identify modifications that need to be made post-implementation based on experience with the processes outlined.
2. Identify factors that should be considered when reviewing search preference requests.
3. Update staff job descriptions and performance evaluations to address consistent implementation of search preference policies to allow for staff performance and comfort to be monitored and coaching provided to support proficiency.
4. Submit a request to revise SB 132, Section 2606 (d) by substituting "the right to grieve and appeal" for "a meaningful opportunity to verbally raise any objections to that denial, and have those objections documented." The existing grievance process includes documentation of concerns and responses.

Transgender Access Card and Property Recommendations

1. Consider discontinuing the TAC and including preferred pronouns and search preference on state issued identification. This streamlines the process, removes the need for an additional card, and normalizes sharing and utilizing an individual's preferred pronouns.
2. Consider allowing individuals to select a male or female uniform at reception or when it is time for new uniform issuance.

Reception Center Processing and Orientation Cohort Recommendations

1. Convene multidisciplinary transfer case conferences between sending and receiving institutions once an individual is endorsed.
2. Create a post (brief) reception transition unit housing both TGNBI individuals as well as cisgender women who apply and are selected to live in the unit and serve as peer mentors. Ensure that unit design includes the following:
    a. Clear and structured plan to include phase and overall program timelines. Opportunities progress from on-unit interactions to movement into the larger institution allowing experiences with programming and education while remaining in the transition unit. For example, first 30 days orientation and specialized programming, and the next 30 days ongoing support groups and education class attendance, and so on.

b. Specially trained clinical, custody, and case management staff to support transition, ongoing case review, and eventual unit, bed, and program placement decisions.
c. Routine multidisciplinary case reviews that include the individual transferring, to monitor the process of adjustment to the institution.
d. Specialized programming, such as orientation, *Healing Trauma Plus*, and support groups.
e. Structured quality assurance to ensure fidelity to the model, program curriculum, etc., planned engagement of feedback from staff and incarcerated individuals, and opportunities to adjust.
f. Structured quality assurance to ensure fidelity to the model, program curriculum, etc. and planned engagement of feedback from staff and incarcerated individuals, and opportunities to adjust.

Institutional Classification Committee Review and Classification Criteria Recommendations

1. Develop an interactive, practice based, training for CCII and IIIs to ensure consistency in case work ups, and for ICCs to support criteria-based decision making.
2. Develop, include in policy, and implement timelines for each step of the process from request for placement through arrival at receiving facility.
3. Ensure that case conferences convened to review potential alternate female designated housing placement or return to a male designated housing placement (or vice versa) includes representatives of medical and mental health.
4. Define clear criteria for consideration in case work up and ICC review to support consistency in decision making specific to institution placement. In addition to factors specific to identity, ability to manage risk through unit structure and staffing levels must be considered. After classification processes have been fully designed and implemented to ensure that placement decisions are made based on the individual's needs, and on the ability of an institution to safely house that individual, involuntary returns should be infrequent.

Housing and Access to Gender Affirming Surgery Recommendations

1. Ensure that proximity to gender affirming medical care and privacy needs are considered in institution placement.
2. Conduct an analysis of the travel and staffing costs of travel for gender-affirming medical care compared to defining a housing option closer to these resources. Include medical opinions on the impact of post – surgical travel for follow-up appointments.

Unit and Bed Placement Recommendations

1. Submit a request to revise SB 132 by removing the following language from Section 2606 (a)(4) "bed assignments" and "pursuant to paragraph (3) of subdivision (a) or subdivision (b) including, but not limited to, granting single cell status housing the individual with another incarcerated person of their choice, or removing the individual or individuals who pose a threat from any location where they may have access to the individual who has expressed safety concerns." Include language that indicates that an incarcerated individual's preferences for who they are housed with be taken into consideration as a part the overall placement process.
2. Develop a structured process for institution-based unit and bed placement that includes clear guidelines for placement based on at minimum PREA screening, safety, and privacy considerations for housing transgender, non-binary, intersex, and cisgender women together.
3. Consider housing by custody level and behavior; separation of level III and IV would allow CCWF to determine staffing and resources according to population risk and need.
4. Construct or establish additional celled living capacity to support safe and effective management of individuals who are not appropriate for dorm-style living and where single cells are limited.

Staffing and Capacity Recommendation

1. Conduct an analysis to identify staffing levels that consider custody, non-custody, and clinical needs based on the mission of the institution, safety, performance expectations, nuances of supervising women and TGNBI populations, and the workload created by operational changes.
    a. Consider a specialized case management structure for TGNBI care coordination.
    b. Consider maintaining the psychology and psychiatry positions created to support SB 132 implementation.

Preparation and Training Recommendations

1. Incorporate data to demonstrate trends, successes, and challenges into messaging and training.
2. Continue to engage, or re-engage, community stakeholders as advisors and providers as the implementation process continues.
3. Expand education and preparation for incarcerated individuals at receiving institutions and engagement of cisgender women in creating a safe institution culture for both cis and transgender women.
4. Expand staff in person training to build on initial offerings with a focus on scenario practice.
5. Evaluate the effectiveness of the on-the-job training program to ensure that it provides practical, supported learning. There were indications that the current process is less focused on learning and more focused on proof of practice (i.e., signing policy, etc.).
6. Expand training for trainers to ensure trainer confidence in correcting, and not reinforcing, misconceptions about the population transferring into receiving institutions.
7. Create a quality assurance structure to support consistency in training and program delivery by qualified and trained facilitators.
8. Review processes for agency wide dissemination of information regarding the option to request placement by gender identity.
9. Provide incarcerated cisgender women additional education, opportunities to ask questions and get to know TGNBI individuals, and conversation with staff about strategies for safety.
10. Engage cisgender women in transitional housing planning and support for TGNBI individuals.
11. Assess the effectiveness of current training for current, new, and transferring employees as a baseline and foundation for development of focused, interactive, scenario-based training. Ensure any additional training is operationally driven and connected to policy.
    a. Clearly and concisely reinforce key components of initial training such as the distinction between gender identity and sexual orientation.
    b. Provide staff with training to support understanding of the various components of transition—social, emotional, and physical factors—and engage in discussions regarding the meaning of situations when behavior or characteristics may appear to contradict stated identity, such as medication and trauma.
12. Update the job shadowing checklist to include the adaptive skills that are required at a female institution in addition to considerations for TGNBI individuals and technical processes and procedures that are evaluated by the Field Training Officer.
13. Ensure that both policy and training definitions are consistent with those outlined in SB 132.
14. Develop a "quick guide" for staff that summarizes and provides reference to all policy and formal guidance to support staff in respectfully supervising TGNBI individuals.
15. Ensure that trainers and facilitators of programs are trained both in content delivery and facilitation of sensitive conversations regarding safety and individuals concerns. While education and programing is not designed to change an individual's personal beliefs, trainers, facilitators, and leaders must be able to communicate what professionalism entails in the institution setting regardless of personal beliefs.
16. Consider revisions to the current content and design of *Right Person Right Prison* class.
    a. Include input from those who have previously attended the course'
    b. Develop a structure that ensures that the *Right Person Right Prison* is consistently delivered at all institutions.

c. Consider engaging facilitators with clinical expertise to facilitate the class. While the institutions themselves often impact decision making— based on housing and program options—so too can an individual's transition process, which may make the decision emotionally complex for some.
d. Revise and update information on the transfer request process, housing layouts, and preparation for transfer.

17. Provide ongoing training specific to medical and mental health care for clinical professionals at CDCR and maintain resources for consultation and coaching that are currently in place.
18. Consider including a TGNBI representative to the Inmate Advisory Council (IAC).

Leadership and Culture Recommendations:

1. Develop a dynamic agency level "working" strategic plan as a tool to organize all the recommendations accepted in this report and additional priorities related to the management of TGNBI individuals in CDCR. We recommend a model of strategic planning that is action oriented with a mechanism to document progress and that builds on current goals.
    a. Engage institutions to develop an implementation plan consistent with the agency plan that supports the ongoing improvement of practice and safety. This will ensure that both staff and incarcerated individuals are clear on institution priorities and direction.
    b. Share successes and their impact routinely. For example, reinforce staff for honoring pronouns and search preferences and provide specific information on how those practices support safety for everyone. Recognizing what is going well increases the likelihood that staff will feel confident (increased self-efficacy) in implementing other changes to enhance safety or safely manage TGNBI individuals.
2. Continue to track trends in discipline, assault, PREA incidents, and contraband in order to identify strategies to guide decision making, increase safety, and address myths and misperceptions about individuals transferring into the institution under SB 132.
3. From leadership levels, communicate with intentionally to keep the workforce, incarcerated individuals, and stakeholders informed. Committing to timely (daily, weekly, monthly) systems of communication can significantly reduce anxiety and misunderstandings.
    a. Ensure that communication systems have a feedback loop incorporated in them in order maintain leadership awareness of concerns and gain input on solutions to capitalize on the strengths of implemented processes and procedures.
    b. Share operational and procedural adjustments, expectations, and provide clarification related to questions.
    c. Communicate expectations about accurate and respectful communication. For example, rather than "bringing men into women's facilities" reinforce accurate messages such as: "Women are transferring into our institution from male designed institutions because female designated institutions are appropriate based on their gender identity."
    d. Reinforce that leadership will support staff if they are operating within agency policy and the code of conduct to minimize anxiety about fairly and equitably holding incarcerated individuals accountable.
    e. Address rumors and misperceptions, answer questions, identify areas of inconsistency and engage problem solving.
    f. Conduct goal directed rounds. Both formal and informal interactions are key to promoting culture change to supporting safe and respectful management practices. Setting a specific goal to address during rounds creates powerful opportunities to intentionally communicate or reinforce expectations, seek feedback, or provide clarification. Evaluating the effectiveness of a change to practice or policy, answering questions about why the change occurred, and coming to understand the impact of change on staff facilitates buy-in and decreases the potential for a code of silence
    g. Capitalize on rounds and forums such as shift briefings as opportunities for communication regarding safe and respectful management of TGNBI individuals. Methods may include the following:

        i. Leading discussion and observation practice or interaction during rounds
        ii. Providing information or brief skill-based scenario trainings
4. Consider providing interactive training to staff in the following areas to support ongoing culture change and professionalism for staff. Modified sessions may be appropriate to prepare incarcerated individuals at receiving institutions.
    a. The impact of implicit and confirmation bias on leading and acting with awareness and professionalism.
    b. Strategies for addressing and interrupting bullying and harassment.
5. As policies and procedures specific to SB 132 and the safe and respectful management of TGNBI individuals formalize and evolve, ensure that the culture supports true accountability rather than attempts to "cover oneself" with proof of practice. When a culture fully embraces accountability, you see a shift from staff being hesitant, complacent, or defensive. Rather you see people identifying a need or challenge, owning it, working to solve it alone or with others, and adopting new practices.
    a. Key components to ensure accountability include clear expectations, performance planning, and ongoing coaching.
6. Identify and implement additional training for staff, and programming for incarcerated individuals, on domestic violence and healthy relationships. Ensure the training is inclusive of diverse relationship structures.
7. Identify ways to make policy, practice, and procedure designed to support safety for TGNBI individuals a routine component of good correctional practice.
8. Consider assessing at minimum a hub institution and male designated institution to clearly understand how SB 132 is being implemented across missions to develop and implement strategies for sustainability.

Research and Data Recommendations

1. Identify and implement an information technology solution to consolidate various sources of data into one system with the purpose of providing a comprehensive view of TGNBI individual, and population, characteristics and needs across disciplines.
    a. Include a process to ensure consistent updates of the gender field to support an individual's transition and ensure that their records are up to date and accurate.
2. Engage with external researchers at all stages of implementation to support refinement of the practices implemented under SB 132 contribute to providing a foundation for progress in safe and respectful management of TGNBI individuals around the country.
3. Identify solutions to address concerns with preferred method for assigning CDCR numbers for individuals who are transferring between male and female institutions.

Attachment B: Document & Data Request List

Leadership, Management, and Cultural Indicators

- Department vision, mission, and values statements
- Department strategic or action plans specific to working with transgender, non-binary, and intersex inmates or detainees
- Staff demographics, including gender, age, tenure, education, position, etc. per institution
- Population demographics, including population numbers per institution, custody level, and projected length of stay
- List of management and security concerns referenced in early calls by Rosemary Ndoh
- Documentation and materials that describe the transgender hub model
- Provisions of union contracts that directly impact implementation of SB 132

Human Resources

- Code of conduct
- Staff discipline policy or procedures relevant to SB 132

Staff Training

- Orientation materials related to SB 132
- Training policy relevant to SB 132
- Relevant training curriculum and videos addressing key topics including PREA, LGBTI, gender responsivity, and trauma informed approaches.

Searches

- Policy on searches, including clothed, unclothed, cross-gender, and room searches
- Staff training material for conducting searches

Cross-gender Supervision

- Policy on cross-gender supervision
- Policy on opposite gender staff in living areas
- Staff training related to cross-gender supervision

Inmate or Detainee Intake and Orientation

- Intake policy revisions relevant to SB 132
- Revised intake forms relevant to SB 132
- Orientation policy and materials relevant to SB 132
- Inmate or detainee handbook

Healthcare Intake Services

- Policy on intake with accompanying forms
- Policy on intake exams and screenings
- Policy specific to care and treatment of transgender or intersex inmates

Classification and Placement

- Policy and documentation related to housing unit and/or bed placement
- Documentation or guidance related to bed move requests
- Policy on classification and accompanying tools
- Policy on risk need assessment and accompanying instruments
- Designation results from risk screening instruments relevant to SB 132 (See Data)
- Policy on PREA screening and accompanying instruments

- Policy on case management
- Training materials developed by the classification committee specific to transgender inmates
- Documentation of denial or placement of transgender, intersex, or non-binary inmates in a institution that aligns with gender-identity
- Transgender identity questionnaire

Grievances and Reporting

- Policy on inmate grievances
- Policy on reporting PREA incidents
- *Grievances from the last 24 months related to transgender, intersex or non-binary inmates

Investigations and After-Action Reviews

- Summary data from the last 24 months of investigations and outcomes for individuals who identify as transgender, non-binary or intersex and cisgender inmates
- *Investigation reports of sexual assault, harassment, and grievances reported by transgender, non-binary, and intersex offenders. (See Data)

Discipline and Sanctions

- Policy on the disciplinary process, including sanction grids (as applicable)
- Summary data for the last 24 months of disciplinary reports and outcomes for individuals who identify as transgender, non-binary, or intersex and cisgender inmates
- *Disciplinary reports of transgender, non-binary and intersex allegations (See Data)

Data*

- Information from investigative reports and databases relevant to transgender, non-binary, and intersex inmates, including institution, location, gender identity, risk assessment designation, incident date and time, and investigative finding.
- Information from the classification system database relevant to screening for risk of sexual victimization or abusiveness, including ID number, gender identity, DOB, race/ethnicity, initial intake date, institution assignment at intake, risk assessment designation at intake, override status and rationale if conducted, security level at intake, and subsequent reviews and results.
- Information from grievances filed relating to cisgender inmate grievances and/or other complaints or concerns about safety, reports about altercations between transgender and cisgender individuals, as well as PREA reports of sexual abuse or harassment.

Leadership, Management, and Cultural Indicators

The following information is requested to support understanding of the demographics of each institution and any differences that exist between or among institutions that may support cultures of safety. If differences are identified, training and resources will be recommended to build on identified strengths and mitigate challenges.

- Summary data:
    - Staff demographics, including gender, age, tenure, education, position, per institution.
    - Population demographics, including population numbers per institution, custody level, and projected length of stay

Classification and Placement

The following information is requested to support understanding of how the committee is using the process outlined in policy. For instance, what factors or considerations lead to approval or denial and how do the outcomes align with policy requirements.

- Documentation of denial or placement of transgender, intersex, or non-binary inmates in a institution that aligns with gender-identity

The following information is requested to support understanding of the population characteristics of transgender, non-binary, or intersex inmates.

- Summary data for individuals who identify as transgender, non-binary, or intersex.
    - Gender identity
    - Transgender identity questionnaire results for the last 24 months or since implementation
    - PREA screening for risk of sexual victimization or abusiveness.
    - Custody classification score or security level designation as well as any override status with rationale
    - Risk/need assessment score or designation as well as any override status with rationale
    - Any additional assessments or evaluation data the committee considers when determining housing placement

Grievances and Reporting

The following information is requested to support understanding of the type of grievances filed and ultimate resolution to allow for analysis of common concerns or challenges.

- Summary data from the last 24 months of grievances and resolution for individuals who identify as transgender, non-binary, or intersex and cisgender inmates.
    - Note: Focus on grievances filed relating complaints or concerns about safety, reports about altercations between transgender and cisgender individuals, as well as PREA reports of sexual abuse or harassment.
- Grievances from the last 24 months filed by transgender, intersex, or non-binary inmates and resolution.
- Grievances from the last 24 months filed by cisgender inmates that are related to placement of transgender, intersex, or non-binary inmates and resolution.

Investigations and After-Action Reviews

The following information is requested to support understanding of the type of investigations conducted in response to reports filed by or against transgender, non-binary, or intersex and ultimate resolution to allow for analysis of common concerns or challenges.

- Summary data from the last 24 months of investigations and outcomes for individuals who identify as transgender, non-binary, or intersex and cisgender inmates
    - Note: Include institution, location, risk assessment designation, incident date and time, and investigative finding.
- Investigation reports of sexual assault, harassment, and grievances reported by transgender, non-binary, and intersex offenders.
- Investigation reports of sexual assault, harassment, and grievances reported by cisgender offenders against transgender, non-binary, and intersex offenders.

Discipline and Sanctions

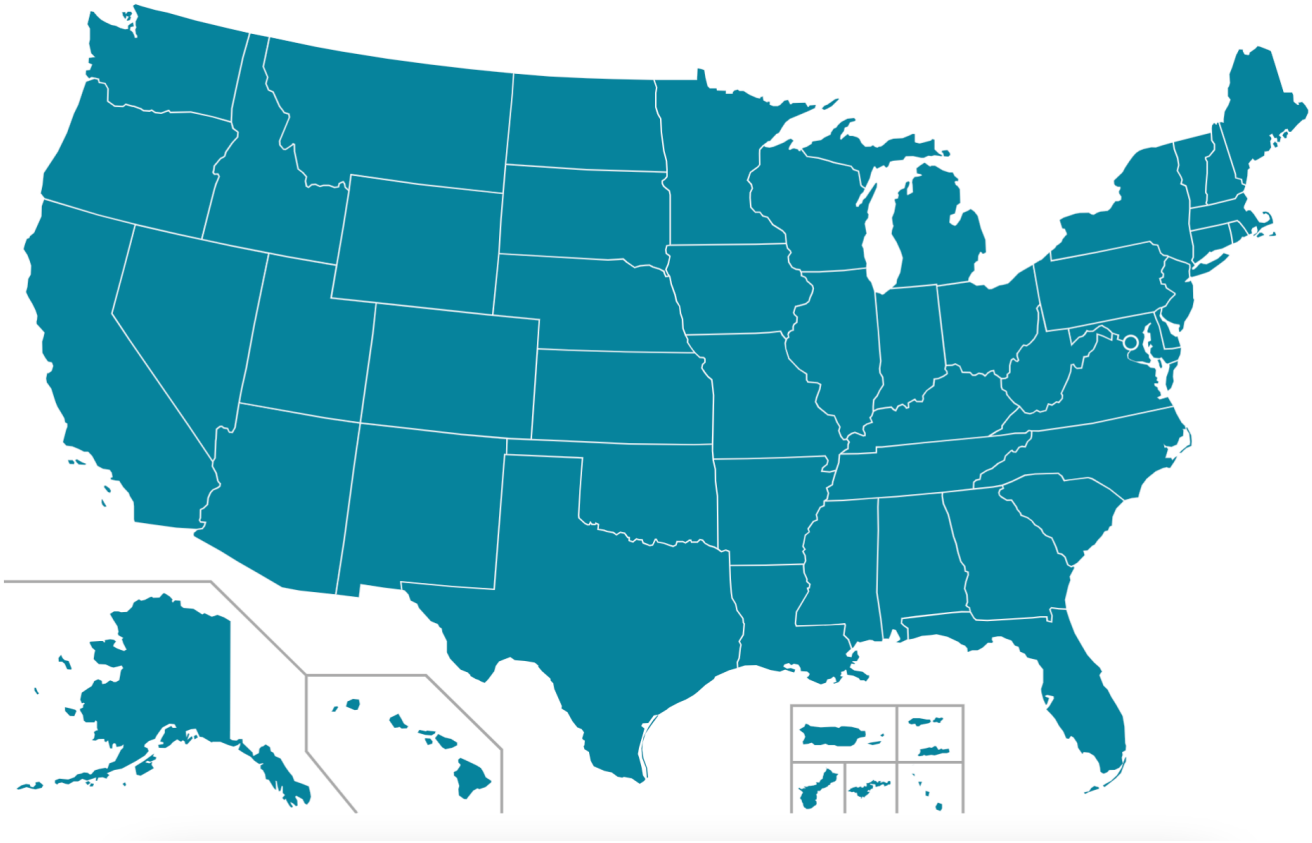
The following information is requested to support understanding of the type of disciplinary infractions filed by or against transgender, non-binary, or intersex and ultimate resolution to allow for analysis of common concerns or challenges, and how that differs for cisgender inmates.

- Summary data from the last 24 months of disciplinary reports and outcomes for individuals who identify as transgender, non-binary, or intersex and cisgender inmates
- Disciplinary reports from the last 24 months for transgender, intersex, or non-binary inmates and resolution.
- Disciplinary reports from the last 24 months for cisgender inmates and resolution.

Resource Guide to Improve Safety in Carceral Housing for Transgender People

A project of the National LGBTQ+ Bar Association

THE LGBTQ+ BAR



The National LGBTQ+ Bar, in partnership with Black and Pink and TGI Justice Project, is proud to share our Resource Guide to Improve Safety in Carceral Housing for Transgender People. The purpose of this guide is to support the critical work of advocates fighting for the safety and autonomy of transgender people in the carceral system.

Throughout the United States, transgender individuals in the carceral system are routinely misgendered and housed in a population that does not align with their gender. Not only does this practice place them at enormous physical risk, but the psychological and emotional damage of improper carceral housing cannot be overstated. Thankfully, in many jurisdictions, there are remedies to transfer transgender individuals to their preferred population. If you have additional questions please contact the National LGBTQ+ Bar Association at transjustice@lgbtqbar.org. We also encourage you to take a look at the Transgender Resource Guide, An Aid for People in the Custody of The Federal Bureau of Prisons, for additional information.

We are grateful to our partners at Gibson Dunn for their assistance with the project.

Links to full relevant policies for each state are available on the LGBTQ+ Bar's website at the following link: https://lgbtqbar.org/programs/ti-project/.

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Alabama

State Policy: State of Alabama Department of Corrections Administrative Regulation No. 454, Inmate Sexual Abuse And Harassment (Prison Rape Elimination Act [PREA]), effective Jan. 4, 2016.

H. The Warden/Director is responsible for: … **5.** Ensuring any LGBTI inmate's health and safety are considered, on a case-by-case basis, in making housing and program assignments in regards to management and security.

. . .

F. Intake Procedures. All ADOC facilities shall adhere to the following intake procedures when processing all inmates into all ADOC facilities:

1. All inmates, at initial intake, shall be screened within 72 hours utilizing ADOC Form 454-C, PREA Risk Factors Checklist, for potential risk of sexual vulnerability and potential risk of sexual aggression.

2. Upon transfer to another facility, all inmates shall be screened within 72 hours utilizing ADOC Form 454-C, PREA Risk Factors Checklist, for potential risk of sexual vulnerability and potential risk of sexual aggression.

. . .

9. Use of Screening Information

a. All information obtained during the screening process and PREA Mental Health Assessment shall be used to assist in the initial classification and institutional assignment of the inmate as well as determine work, education, and programs, in accordance with the ADOC Classification Manual, AR 433, Administrative Segregation and Housing for Close or Maximum Custody, and AR 435, Protective Custody, with the goal of keeping separate those inmates at high-risk of being sexually victimized from those at high-risk of being sexually abusive. . . .

c. ADOC shall not place LGBTI inmates in a dedicated facility, unit, or dorm solely on the basis of such identification or status.

d. Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year by the IPCM to review any threats to safety experienced by the inmate.

e. A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration.

f. In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, ADOC shall consider on a case-by-case basis whether the placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.

g. Transgender and intersex inmates shall be given the opportunity to shower separately from other inmates.

State Policy: State of Alabama Department of Corrections Administrative Regulation No. 637, Gender Dysphoria, effective May 9, 2018.

It is the policy of the ADOC to appropriately diagnose, treat, and manage inmates with Gender Dysphoria in a humane, safe, correctional environment, sensitive to their unique adjustment needs.

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Alaska

We were unable to locate state-specific policies related to carceral housing for transgender people. Please note, however, that on October 26, 2022, the Alaska Department of Corrections Public Information Officer provided us with the following information:

“We currently house prisoners according to their biological sex. Each new remand and transfer is screened and housed according to a scored potential for being victimized or for preying on others. Medical staff and Institution Probation Officers use the Prison Rape Elimination Act (PREA) Assessment Form which is reviewed after 30-days. If a transgender individual requests alternative housing, the facility reviews the request and makes a recommendation to a committee composed of staff from the Divisions of Institutions, Health and Rehabilitation Services and PREA to make a determination.”

Arizona

State Policy: Arizona Department of Corrections Rehabilitation and Reentry Department Order 810, Management of LGBTI Inmates, effective April 1, 2022.

2.2 Reception Centers shall process all inmates in the usual manner.

2.2.1 During the course of the intake process, all inmates shall be asked to voluntarily state gender identity, and the inmate's response shall be documented on the appropriate Arizona Correctional Information System (ACIS) screen. No discipline shall result from failure to respond or disclose. The name and Arizona Department of Corrections, Rehabilitation and Reentry (ADCRR) number of any transgender or intersex inmate shall be submitted by the Intake staff to the Transgender/Intersex Committee.

2.2.1.1 No transgender or intersex inmates shall be moved until the Committee has completed its review and made its housing determination as set forth in this Department Order.

2.2.2 All inmates shall be screened for the risk of being sexually abused by other inmates or sexually abusive toward other inmates in accordance with Department Order #811, Individual Inmate Assessments and Reviews.

2.2.3 Inmates identified as transgender or intersex shall be asked and afforded the opportunity to voluntarily provide the following information:

2.2.3.1 The appropriate personal pronouns for their gender identity.

2.2.3.2 Their own view of how they would be most safely housed, including female versus male housing.

2.2.4 Inmates identified as transgender or intersex shall be housed in accordance with Department Order #801, Inmate Classification.

2.2.4.1 At no time will identification as transgender or intersex be the sole factor in determining placement, including placement in administrative segregation or protective housing.

2.2.5 Staff shall not search or physically examine a transgender or intersex inmate for the sole purpose of determining the inmate's genital status. If the inmate's genital status is unknown, it may be determined during conversations with the inmate, by reviewing Medical Records, or, if necessary, learning that information as part of a broader medical examination conducted in private by a medical practitioner. This provision does not prohibit or otherwise affect searches of inmates to ensure the safe, secure and orderly operation of the institution.

. . .

2.5 Transgender/Intersex Committee

2.5.2 The Committee Chair or designee shall interview any inmate who identifies as transgender or intersex, and convene a meeting within seven calendar days of the inmate's arrival.

2.5.3 The Committee shall:

2.5.3.1 Determine for those inmates who are identified as transgender or intersex housing conducive to their needs.

2.5.3.2 Consider the inmate's own views with respect to his or her safety when determining placement and programming assignments for inmates identified as transgender or intersex.

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2.5.4 When an inmate initiates a formal written request to the Committee Chair or designee regarding his/her housing assignment, this request will be addressed on a case-by-case basis by the Committee, which will determine the appropriate housing assignment.
2.5.5 Each inmate will be reviewed at least twice each year to assess their individual institutional adjustment, or sooner if requested by the inmate or in the event of any alleged incident of victimization. This reassessment will include asking the inmate whether the inmate feels safe in his/her current housing assignment review any threats to safety experienced by the inmate and equal consideration will be afforded to any concerns expressed by the inmate population with consideration of PREA and pre-incarceration trauma experienced by vulnerable populations or any concerns with the inmate population.

State Policy: Arizona Department of Corrections Rehabilitation and Reentry Department Order 811, Individual Inmate Assessments and Reviews, effective Sept. 17, 2020, amended April 1, 2022.

2.10.5.2.1 In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments the Department shall consider on a case by case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.
2.10.5.2.2 Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experienced by the inmate.
2.10.5.2.3 A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration.
2.10.5.2.4 Lesbian, gay, bisexual, transgender, or intersex inmates shall not be placed in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.
2.10.5.2.5 Transgender and intersex inmates shall be given the opportunity to shower separately from other inmates. Accommodations made shall not interfere with access to programs, privileges, education, and work opportunities to the extent possible. [Revision – April 1, 2022]

State Policy: Arizona Department of Corrections Mental Health Technical Manual, Ch. 3, Sec. 10.0, Mental Health Service Delivery for Transgender, Intersex, and Gender Non-Confirming, effective Dec. 24, 2019.

2.0 Procedure
2.1 Assessments, reviews, and management of patients who identify as transgender, intersex, or gender non-conforming shall be done on a case-by-case basis, in a respectful manner, and in consideration of individual circumstances, including but not limited to current physical sexual characteristics, gender identification, physical presentation, behavior, and programming needs.
2.2 Identification – the identification can occur at the Reception Center or at any time during their incarceration. Information may be provided by the patient, a county jail, or other relevant collateral sources.
. . .
2.3 Assessment – the mental health clinician shall conduct a clinical interview in order to assess and determine identification of transgender, intersex, and gender dysphoria that are present and may require intervention.

2.3.1 Any identified housing concerns shall be relayed to the Transgender Committee as identified in DO 801.

. . .

2.4 Housing – facility and housing assignments shall be made on a case-by case basis, considering the patient's health and safety as well as potential programming, management and security concerns. A patient's own views regarding safety shall be given careful consideration.

State Policy: Arizona Department of Corrections Rehabilitation and Reentry Medical Services Division Medical Services Technical Manual (MSTM), P-F-01.03, Management of Transgender, Intersex, and Gender Nonconforming Inmates, effective Oct. 1, 2022.

PROCEDURES

The Transgender Committee is a multi-disciplinary team composed of all persons listed in Department Order #810, Management of LGBTI Inmates.

1.1. The Transgender Committee shall convene and perform services in accordance with the procedures outlines in Department Order #810, Management of LGBTI Inmates.

Maricopa County Sheriff's Office Policy: Maricopa County Sheriff's Office Policy and Procedures No. DI-2, Administrative Restrictive Housing, effective Aug. 2, 2022.

F. Inmates who are transgender or those at high risk for sexual victimization shall not be placed in involuntary administrative restrictive or security restrictive housing unless an assessment of all available alternatives has been made, and a determination has been made that there is no available alternative means of separation from likely abusers as specified in Office Policy GJ-28, Prison Rape Elimination Act (PREA).

Maricopa County Sheriff's Office Policy: Maricopa County Sheriff's Office Policy and Procedures No. GJ-37, Transgender and Intersex Interactions, effective Jan. 19, 2022.

4. Inmate Housing: Individuals identified as transgender, intersex, or gender-nonconforming shall be housed in accordance with Office Policies, DF-1, Inmate Classification and DI-1, Inmate Housing Categories.

A. Individuals that identify as transgender, intersex, or gender-nonconforming shall be interviewed by the PREA Housing Committee (PHC), within three working days, and a Detention Housing Plan shall be developed.

B. All decisions determining where transgender, intersex, or gender- nonconforming individuals will be housed, must be made on a case-by-case basis by the PHC. Transgender, intersex, or gender nonconforming individuals must be assessed individually to determine whether they should be housed with women or men. Classification and placement of transgender, intersex, or gender nonconforming individuals shall not be determined solely based on the individual's sex at birth, identity documents, or physical anatomy. A transgender, intersex, or gender nonconforming individual's gender identity and personal safety should also be considered when determining their housing location.

Maricopa County Sheriff's Office Policy: Maricopa County Sheriff's Office Policy and Procedures No. GJ-28, Prison Rape Elimination Act (PREA), effective Feb. 20, 2019.

B. Transgender and intersex inmates shall be housed, as specified in Office Policies DI-1, Inmate Housing Categories and DI-2, Administrative Restrictive Housing. A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration. Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats against the inmate, and to review the inmate's overall safety.

1. Inmates who identify as transgender or intersex shall be reviewed by the PHC, and a detention housing plan shall be developed.

2. All decisions determining where transgender and intersex inmates will be housed must be made on a case-by-case basis by the PHC. Transgender and intersex inmates must be assessed individually to determine whether they should be housed with males or females. Inmate classification and placement of transgender and intersex inmates shall not be determined solely based on the inmate's sex at birth, identity documents, or physical anatomy. A transgender and intersex inmate's gender identity and personal safety should be considered when deciding their housing location.

. . .

C. The Office shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated jail facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

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Arkansas

We were unable to obtain state-specific policies related to carceral housing for transgender people. However, on October 27, 2022, in response to a public records request for such policies, the Arkansas Department of Correction directed us to the A**rkansas Department of Corrections Secretarial Directive No. 2021-05, Prison Rape Elimination Act (PREA)**, effective date April 20, 2021. The Department also provided a copy of the **Arkansas Department of Corrections Administrative Directive No. 14-19, Gender Dysphoria and Intersex Inmates**, effective April 11, 2014. Neither directive explicitly discusses housing transgender inmates who do not have a Gender Dysphoria diagnosis.

State Policy: Arkansas Department of Corrections Secretarial Directive No. 2021-05, Prison Rape Elimination Act (PREA), effective date April 20, 2021.

> **G.** Screening for Risk of Victimization and/or Abusiveness
> In order to reduce the likelihood of Sexual Abuse while an Offender is in DOC custody, the DOC will take the following into account when assigning housing and jobs for every Offender, upon Intake, during Classification, or in any special circumstances:
>
> > **1.** All Offenders will be assessed at intake to determine whether they meet specific criteria indicating either likelihood of Victimization or predatory behavior. This requires the use of the appropriate screening tool by trained personnel.
> > **2.** This screening will be conducted within seventy-two (72) hours of the Offender's arrival at the DOC.
> > . . .
> > **5.** Offenders at high risk for sexual victimization shall not be placed in involuntary segregated housing unless an assessment of all available alternatives has been made, and a determination has been made that there is no available alternative means of separation from likely abusers. If a facility cannot conduct such an assessment immediately, the facility may hold the Offender in involuntary segregated housing for no more than 24 hours while completing the assessment.
> >
> > > **Note:** The appropriate Deputy or Duty Director will be immediately notified whenever an Offender is placed in involuntary segregated housing under these circumstances.
> >
> > **6.** Offenders placed in segregated housing for this purpose shall have access to programs, privileges, education, and work opportunities to the extent possible.
> > . . .
>
> **F.** The DOC shall not search or physically examine a transgender or intersex Offender for the sole purpose of determining the Offender's gender status. If the Offender's gender status is unknown, it may be determined during conversations with the Offender, by reviewing medical records, or, if necessary, by learning that information as part of a broader medical examination conducted by a medical practitioner in a setting designated for medical examinations.

State Policy: Arkansas Department of Corrections Administrative Directive No. 14-19, Gender Dysphoria and Intersex Inmates, effective April 11, 2014.

> **I. POLICY:** It is the policy of the Department to provide the appropriate treatment to inmates meeting the criteria for the current Diagnostic Statistical Manual (DSM) diagnosis of Gender Dysphoria. . . . The

Gender Dysphoria Management and Treatment (GDMT) Committee is responsible for determining the appropriate treatment referrals for identified GD and Intersex inmates.

V. HOUSING:

A. Housing placement of diagnosed GD or Intersex inmates will be made on a case-by-case basis taking into consideration the inmate's health and safety and whether the placement would present management or security problems, giving serious consideration to the inmate's own views regarding his or her own safety. Both GD and Intersex inmates shall be given the opportunity to shower separately from other inmates.

B. GD and Intersex inmates shall not be housed in dedicated facilities, units or wings of any Unit within ADC on the basis of such identification or status. The Department shall insure that these inmates have the same access to programming, recreation, and other activities as other inmates.

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California

State Policy: SB 132, The Transgender Respect, Agency and Dignity Act, effective on January 1, 2021. 2606.

(a) An individual incarcerated by the Department of Corrections and Rehabilitation who is transgender, nonbinary, or intersex, regardless of anatomy, shall:

(1) Be addressed in a manner consistent with the incarcerated individual's gender identity.

(2) If lawfully searched, be searched according to the search policy for their gender identity or according to the gender designation of the facility where they are housed, based on the individual's search preference. If the incarcerated individual's preference or gender identity cannot be determined, the search shall be conducted according to the gender designation of the facility where they are housed.

(3) Be housed at a correctional facility designated for men or women based on the individual's preference, including, if eligible, at a residential program for individuals under the jurisdiction of the department. These programs include, but are not limited to, the Alternative Custody Program, Custody to Community Transitional Reentry Program, Male Community Reentry Program, or Community Prisoner Mother Program.

(4) Have their perception of health and safety given serious consideration in any bed assignment, placement, or programming decision within the facility in which they are housed pursuant to paragraph (3) of subdivision (a) or subdivision (b), including, but not limited to, granting single-cell status, housing the individual with another incarcerated person of their choice, or removing the individual or individuals who pose a threat from any location where they may have access to the individual who has expressed a safety concern. If, pursuant to this paragraph, the individual is not granted an alternative based on their perception of health and safety, the department shall document the reasons for that denial and share them with the individual.

(b) If the Department of Corrections and Rehabilitation has management or security concerns with an incarcerated individual's search preference pursuant to paragraph (2) of subdivision (a) or preferred housing placement pursuant to paragraph (3) of subdivision (a), the Secretary of the Department of Corrections and Rehabilitation, or the secretary's designee, shall, before denying a search preference or housing the incarcerated individual in a manner contrary to the person's preferred housing placement, certify in writing a specific and articulable basis why the department is unable to accommodate that search or housing preference.

(c) The Department of Corrections and Rehabilitation shall not deny a search preference pursuant to paragraph (2) of subdivision (a) or a housing placement pursuant to paragraph (3) of subdivision (a) based on any discriminatory reason, including, but not limited to, any of the following: (1) The anatomy, including, but not limited to, the genitalia or other physical characteristics, of the incarcerated person. (2) The sexual orientation of the incarcerated person. (3) For a denial of a housing preference pursuant to paragraph (3) of subdivision (a), a factor present among other people incarcerated at the preferred type of facility.

(d) The incarcerated individual shall receive a copy of the written statement described in subdivision (b) and, within a reasonable time following the individual's receipt of the statement, the Department of Corrections and Rehabilitation shall provide the individual

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with a meaningful opportunity to verbally raise any objections to that denial, and have those objections documented.
(e) If an incarcerated individual raises concerns for their health or safety at any time, their housing and placement shall be reassessed.

State Policy: State of California Department of Corrections and Rehabilitation, Senate Bill 132 FAQs, Housing and Searching Incarcerated People Consistent with their Gender Identity, accessed Dec. 2, 2022.

> **Senate Bill 132**, The Transgender Respect, Agency and Dignity Act, became effective on January 1, 2021. It allows incarcerated transgender, non-binary and intersex people to request to be housed and searched in a manner consistent with their gender identity. . . . **Senate Bill 132**, a new law which took effect Jan. 1, 2021, allows incarcerated transgender, non-binary and intersex people to request to be housed and searched in a manner consistent with their gender identity. **The federal Prison Rape Elimination Act (PREA)** expressly prohibits housing decisions based solely on an incarcerated person's external genitalia. PREA standards require correctional agencies to consider on a case-by-case basis incarcerated people's requests to be placed in an institution consistent with their gender identity when different from their sex assigned at birth. . . . Since transgender, non-binary and intersex people may be singled out for violent attacks by other incarcerated people and are at a higher risk for victimization, CDCR must make every effort to protect this vulnerable population. Housing transgender people according to their gender identity, when safe to do so, increases safety in prisons, upholds CDCR's duty to protect all incarcerated people and promotes successful rehabilitation.

Policy: State of California Department of Corrections and Rehabilitation Operations Manual Policy 62080.14, Transgender or Intersex Inmates, revised May 15, 2018, manual updated though Jan. 1, 2022.

> Inmates who have been diagnosed as transgender or intersex, as documented on the Medical Classification Chrono, shall be referred to a classification committee for review of all case factors and determination of appropriate institutional placement and housing assignment. In order to ensure inmate-patients receive the necessary medical care/mental health treatment, transgender or intersex inmate-patients, to the maximum extent practical, shall be housed at the following institutions:
>
> 1. California Medical Facility (CMF)
> 2. Richard J. Donovan (RJD)
> 3. San Quentin State Prison (SQ)
> 4. Mule Creek State Prison (MCSP)
> 5. California Substance Abuse Treatment Facility (SATF)
> 6. California State Prison – Sacramento (SAC)
> 7. Salinas Valley State Prison (SVSP)
> 8. Correctional Institution for Men (CIM)
> 9. Kern Valley State Prison (KVSP)
> 10. California Men's Colony
> 11. California Health Care Facility
> 12. Central California Women's Facility (CCWF)
> 13. California Institution for Women (CIW)
> 14. Folsom Women's Facility

In cases where an inmate-patient has multiple case factors which make it difficult to house them in one of the above listed institutions, a case conference consisting of Health Care Placement Oversight Program, Classification Services Unit, California Correctional Health Care Services, and Population Management Unit staff, shall be conducted to determine the most appropriate level of care/institution suitable for housing consistent with the inmate-patient's case factors.

State Policy: State of California Department of Corrections and Rehabilitation Operations Manual Policy 54040.14.2, Transgender Biannual Reassessment for Safety in Placement and Programming, manual updated though Jan. 1, 2022.

On a bi-annual basis, Division of Adult Institutions (DAI) staff will send each PREA Compliance Manager (PCM) a list of identified transgender and intersex inmates, as known to the Department.
. . .
If an inmate is due to be seen for his/her annual classification review during the identified review period (August through January or February through July), the assigned caseworker will ask the inmate about any threats they have received during the pre-committee interview. In addition to interviewing the inmate, the assigned caseworker shall review the inmate's case factors in SOMS and ERMS for any additional information, which may indicate the inmate, has any placement or programming concerns. After the annual review is completed, the assigned caseworker will document his/her actions, as they relate to the PREA Biannual Assessment, in the Classification Committee Chrono. If the inmate is not scheduled to be seen for his/her annual classification review during the identified review period (August through January or February through July), the assigned caseworker shall conduct a Transgender Biannual Assessment-PREA and complete a pre-formatted CDC Form 128-B, General Chrono. This form includes information to be asked of the inmate during a face-to-face interview to assess any threats to their safety. In addition to interviewing the inmate, the assigned caseworker shall review the inmate's case factors in SOMS and ERMS for any additional information, which may indicate the inmate, has any placement or programming concerns. If, during the interview for either the annual review or the Transgender Biannual Assessment-PREA, the inmate discloses threats to safety, the assigned caseworker shall immediately notify a Custody Supervisor. Any information related to a PREA allegation shall be documented and forwarded to the institution's Locally Designated Investigator according to the DOM, Article 44, Prison Rape Elimination Policy.

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Colorado

State Policy: Colorado Department of Corrections Administrative Regulation No. 100-40, Prison Rape Elimination Procedure, effective date October 1, 2021.

f. In making facility, cell/unit housing and programmatic assignments for transgender or intersex offenders the DOC will consider on a case-by-case basis whether the assignment would ensure the offender's health and safety, and whether the assignment would present management or security problems (115.42(c), 115.242(c)).

. . .

3) DOC will not place lesbian, gay, bisexual, transgender, or intersex offenders in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such offenders. (115.42(g), 115.242(f))

. . .

6) Offenders will be placed in facilities based upon collaboration between the Gender Dysphoria Management and Treatment Committee, the health services administrator, and the office of Offender Services on a case-by-case basis.

State Policy: Colorado Department of Corrections Administrative Regulation No. 700-14, Practices Concerning Transgender Offenders, effective date April 1, 2022.

III. Definitions

A. Gender Dysphoria Treatment Committee: This committee will be established and maintained by Clinical Services. The purpose of the Gender Dysphoria Treatment Committee is to make individualized recommendations about Transgender Offenders' clinical treatment, privacy, housing and programming assignments in collaboration with mental health, medical and operations staff. Those recommendations will consider whether placement or accommodation in a facility designated for the offender's identified gender or for the offender's gender assigned at birth could potentially present management or security problems in order to ensure the transgender offender's safety.

. . .

B. Multidisciplinary Staffing Review: A case-by-case review process used to determine whether a transgender offender will be assigned to a facility consistent with their self-identified gender or gender assigned at birth. The review will occur when the offender enters the Department as an intake or when the Gender Dysphoria Committee refers the Transgender Offender for review. The review will involve a collaboration between the health services administrator(s) (HSA), the office of Offender Services, PREA coordinator(s), facility warden(s) and the Gender Dysphoria Committee

. . .

IV. General Information

A. The DOC will ensure that staff effectively interact professionally and respectfully toward transgender and intersex offenders. This population may require a more non-traditional approach to best satisfy their housing, security, programming and other needs.

. . .

C. When a new arrival offender self-identifies with a gender other than the one that was assigned at birth or the offender's genital status is unknown, a health care provider will determine at intake whether the offender shall be categorized as a transgender offender for purposes of this policy. The determination will be made by reviewing available medical records or, if necessary, as part of a broader medical examination conducted in private by a health care provider (115.15(e), 115.215(e)). DOC employees will not search or physically examine a transgender offender for the sole purpose of determining the offender's genital status (115.15(e), (15.215(e)).

. . .

V. Procedures

A. Facility / Housing Assignment

1. In making facility, cell/unit housing and programmatic assignments for transgender offenders, the DOC will consider, on a case-by-case basis, by and through a multidisciplinary staffing review, whether the assignment would ensure the offender's health and safety, and whether the assignment would present management or security problems (115.42(c), 115.242(c)).

2. Transgender offenders may be placed into general population of their assigned gender, general population of their identified gender, or placed in a support community.

3. Transgender offenders will be screened for facility placement during the initial intake process at DRDC. Post intake placement reassessments will occur at the currently assigned facility.

. . .

4. Placement Review Processes:

3) All offenders will be screened within 72 hours of their arrival into the reception and diagnostic facility and again upon transfer between facilities, for potential risk of sexual vulnerability or potential risk of sexually aggressive behavior utilizing the SAB and SVR Assessment in PCDCIS (28 C.F.R. §115.41(a) and 115.241(a)).

. . .

4) Without regard to whether an offender has been categorized as a transgender offender, pursuant to IV. C., an offender who self-identifies as transgender during the intake process will be seen by a mental health clinician, intake psychiatric provider, health care provider and a diagnostic programmer (CO III or equivalent) within three business days of the intake screening process. Initial assessments will be documented on AR Form 700-14A, Gender Review Intake Evaluation and any additional mental health information will be documented on the Mental Health Appraisal Form, in the electronic health record.

. . .

a) The Gender Review Intake Evaluation Form will include an assessment of the offender's treatment and life experiences prior to incarceration (including hormone therapy, completed or in-progress surgical interventions, real life experiences consistent with an offender's gender identity, and/or private expressions that conform to the preferred gender and counseling). If the diagnosis of Gender Dysphoria is considered, the offender will be referred for a comprehensive evaluation by a psychiatric provider. For purposes of this determination, the Diagnostic and Statistical Manual (DSM) diagnosis of Gender Dysphoria will not solely be used in

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the recommendation as this determination requires a more comprehensive evaluation, unless the diagnosis has been made previously by an outside consultant.

. . .

5) Once the Gender Dysphoria Treatment Committee has completed its review, a multidisciplinary staffing will be conducted within 3 business days of the offender's arrival to determine whether a transgender offender will be assigned to a facility consistent with their self-identified gender or gender assigned at birth for final placement.

. . .

1) Transgender offenders who have been assigned to a facility pursuant to the Intake Screening or Post Intake Screening process, will be re-assessed by the mental health clinician, primary health care provider and the living unit supervisor (CO III or equivalent) every six months using AR Form 700-14C, Gender Review Reassessment Form to review housing arrangements, program and work assignments and any threats to safety experienced by the offender. AR Form 700-14C, Gender Review Reassessment Form will be sent to the Gender Dysphoria Treatment Committee for review. The Gender Dysphoria Treatment Committee will then determine what cases are forwarded to the multidisciplinary staffing team for review. The multidisciplinary team will complete AR Form 700-14D, Gender Review Checklist for every offender reviewed.

. . .

5. Offenders being screened for facility placement will be reviewed by a multi-disciplinary team. This team will review the completed AR Form 700-14A, Gender Review Intake Evaluation Form or AR Form 700-14B, Post Intake Gender Evaluation Form or AR Form 700-14C, Gender Review Reassessment, the mental health appraisal, psychiatric evaluation and the medical exam. The Multidisciplinary Staffing Review will consider various factors, including but not limited to:

- Health and safety of the transgender offender to assist with mitigating risk to the transgender offender, to include but not limited to; cell and/or unit assignments, application of management variables and programming requirements.
- Whether placement would threaten the management and security of the institution and/or pose a risk to other offenders in the facility (violent conviction, violent assault, sexual conviction).
- Behavioral history and overall demeanor.
- Physical attributes of the transgender offender transferring (feminizing or masculinizing with noticeable
- results).
- Prior surgical procedures (initiated or completed).
- Adjustment to incarceration including the gender they adopted while incarcerated.
- Preference for assignment of gender facility.

. . .

7. . . . Upon consideration of all relevant factors the DOC will make a recommendation with respect to whether a transgender offender will be assigned to a facility consistent with their self-identified gender or gender assigned at birth and will document that recommendation in AR Form 700-14D, Gender Review Checklist.

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. . .

9. Transgender offenders will be housed in the least restrictive environment; while providing safety, security, and meeting the individual's medical or mental health needs.
10. A transgender offender's own views with respect to their own safety will be given serious consideration (115.42(e), 115.242(d)). A transgender offender can notify living unit staff of any safety issues verbally or in writing. Living unit staff will notify the facility PREA coordinator so that the offender's safety issues can be addressed.
11. DOC will not place lesbian, gay, bisexual, transgender, or intersex offenders in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such offenders (115.42(g), 115.242(f)).

. . .

13. Transgender offenders may request to be housed in a facility of their self-identified gender or an offender support community.
14. Transgender offenders who have been recommended for placement into a facility of their self-identified gender will be required to review and sign AR Form 700-14E, Preferred Gender Facility Assignment Agreement.

Local Denver Policy: Denver Sheriff Department Order No. 1.00.1024. Transgender And Gender Non-Conforming Persons in Custody, effective May 27, 2022.

G. Gender Identity Review Board

. . .

6. Decisions about where a transgender or gender non-conforming person is housed must be made on a case-by-case basis. Housing decisions will not be made solely based upon the person's anatomy or gender assigned at birth.

. . .

8. If needed, the Review Board may consult with an identified member of the gay, lesbian, bisexual and transgender (GLBT) or allied community who is knowledgeable with the issues surrounding transgender and gender non-conforming people to assist in forming and making a recommendation for housing to the Classification Unit and/or programs and services needed by the individual.

. . .

H. Long-term Housing and Classification:

3. Classification and placement of transgender or gender non-conforming persons shall not be determined solely based on their birth sex, identity documents, or physical anatomy. Classification and placement of transgender or gender non-conforming individuals should be made to maximize the health and safety of the individual and be based upon a determination of whether the placement would present management or security problems.
4. Transgender or gender non-conforming persons must be housed safely and in the least restrictive setting possible. Consideration shall be given on a case-by-case basis whether a placement would ensure their health and safety and whether the placement would present management or security problems.

a. Additional safety precautions may include (but are not limited to) access to private showers, single cells, etc., and will be offered if and when available.

. . .

b. Requests from a transgender or gender non-conforming individual to be placed in the same cell with another transgender or gender non-conforming person should be honored when possible.

c. The transgender or gender non-conforming person's own views with respect to safety shall be given serious consideration in placement and programming assignments.

. . .

5. Classification staff shall document in the jail management system (JMS) the choices and reasons regarding housing and additional safety precautions for all transgender/gender non-conforming persons.

. . .

8. Transgender/gender non-conforming persons who are placed in administrative segregation or other special management housing for their safety shall have the same access to the provisions of services and programs as any other person housed in a DSD facility. Additionally, as noted above, the reason for placing the individual into administrative segregation must be clearly documented and reviewed at least every thirty (30) days to determine whether a continuing need exists for separation from the general population. Medical staff shall be informed any time a transgender or gender non-conforming individual is place in administrative segregation or other special management housing.

9. Transgender or gender non-conforming persons shall have the right to request that their housing assignment be re-evaluated.

10. Placement and programming assignments for each transgender or gender non-conforming individual shall be reassessed every six months from initial intake, or at least two (2) times per year, to consider changed circumstances, including a review of any threats to safety they have experienced.

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Connecticut

State Policy: State Law CGS § 46a-71

Sec. 46a-71. (Formerly Sec. 4-61d). Discriminatory practices by state agencies prohibited.

(a) All services of every state agency shall be performed without discrimination based upon race, color, religious creed, sex, gender identity or expression, marital status, age, national origin, ancestry, intellectual disability, mental disability, learning disability, physical disability, including, but not limited to, blindness, or status as a veteran.

(b) No state facility may be used in the furtherance of any discrimination, nor may any state agency become a party to any agreement, arrangement or plan which has the effect of sanctioning discrimination.

(c) Each state agency shall analyze all of its operations to ascertain possible instances of noncompliance with the policy of sections 46a-70 to 46a-78, inclusive, and shall initiate comprehensive programs to remedy any defect found to exist.

(d) Every state contract or subcontract for construction on public buildings or for other public work or for goods and services shall conform to the intent of section 4a-60.

State Policy: State Law CGS § 46a-51

(21) "Gender identity or expression" means a person's gender-related identity, appearance or behavior, whether or not that gender-related identity, appearance or behavior is different from that traditionally associated with the person's physiology or assigned sex at birth, which gender-related identity can be shown by providing evidence including, but not limited to, medical history, care or treatment of the gender-related identity, consistent and uniform assertion of the gender-related identity or any other evidence that the gender-related identity is sincerely held, part of a person's core identity or not being asserted for an improper purpose.

State Policy: State of Connecticut Substitute Senate Bill No. 13, Public Act No. 18-4, An Act Concerning The Fair Treatment of Incarcerated Persons, approved May 14, 2018.

Sec. 8. Any inmate of a correctional institution, as described in section 18-78 of the general statutes, who has a gender identity that differs from the inmate's assigned sex at birth and has a diagnosis of gender dysphoria, as set forth in the most recent edition of the American Psychiatric Association's "Diagnostic and Statistical Manual of Mental Disorders", shall:

(1) Be addressed by correctional staff in a manner that is consistent with the inmate's gender identity,

(2) have access to commissary items, clothing, personal property, programming and educational materials that are consistent with the inmate's gender identity, and

(3) have the right to be searched by a correctional staff member of the same gender identity, unless the inmate requests otherwise or under exigent circumstances. An inmate who has a birth certificate, passport or driver's license that reflects his or her gender identity or who can meet established standards for obtaining such a document to confirm the inmate's gender identity shall presumptively be placed in a correctional institution with inmates of the gender consistent with the inmate's gender identity. Such presumptive placement may be overcome by a demonstration by the Commissioner of Correction, or the commissioner's designee, that the

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placement would present significant safety, management or security problems. In making determinations pursuant to this section, the inmate's views with respect to his or her safety shall be given serious consideration by the Commissioner of Correction, or the commissioner's designee.

State Policy: Connecticut State Department of Correction Administrative Directive No. 8.17, Gender Non-Confirming, effective Feb. 13, 2018.

4. Intake Screening. Upon intake to the CTDOC, an inmate who identifies as or is known to identify as gender non-conforming, or having an intersex condition will be assessed for placement. This initial assessment, by custody, will be based on the safety and security of the inmate, inmate population and staff at the respective facility. If this assessment can be completed prior to entry into the DOC as a new intake, the sending agency can transport the inmate to the appropriate facility. In [SIC] the intake facility receives an inmate believed to be intersex or gender non-conforming without forewarning from the Judicial Marshalls, other Law Enforcement Agency, or other sources, the receiving facility shall accept the inmate and the Unit Administrator will notify the appropriate District Administrator and a CN 81701, Referral for Gender Assessment will be initiated by the custody staff completing the PREA screen or the staff person to whom the inmate discloses as being gender non-conforming or as having an intersex condition and submitted to the unit supervisor for completion. The unit supervisor shall complete the referral form and submit to the Unit Administrator. The Unit Administrator shall forward within seventy-two hours of receipt to the CTDOC Chief Mental Health Officer or designee.

a. Upon receipt of the inmate at the designated DOC facility, the inmate will be secured in a cell with no other inmates until processed by custody and assessed by medical in accordance with Administrative Directive 9.3, Admission, Transfers and Discharges, and Administrative Directive 8.1, Scope of Health Services. The inmate shall not be medically or physically examined for the sole purpose of identifying the inmate's gender. In the event the inmate's status this has not been previously determined by the sending agency for appropriate housing/facility, the inmate will be housed separately based on classification needs, safety and security, and other risk needs until the Gender Non-Conforming Review Committee (GNCRC) is consulted.

. . .

i. During orientation phase, or until the appropriate facility has been determined, the current facility housing the inmate shall:

. . .

3. Determine the preferred gender of the officer who will conduct pat and/or strip searches.

a. In making this determination, the facility shall take into account the inmate's gender preference, facility needs, and safety and security.

. . .

4. Determine programming and housing assignments based on the facility's PREA Compliance Manager's recommendations.

a. Upon completion of the Gender Dysphoria Assessment or for other custodial reasons, programming and housing assignments may change.

. . .

5. Identification and Diagnosis of Inmates with Gender Dysphoria and/or Intersex related conditions. Upon admission to the CTDOC, or at any other time during an inmate's incarceration, if the inmate either self-identifies as being gender non-conforming or is referred as possibly having Gender Dysphoria, a CN 81701, Gender Non-Conforming Referral Form shall be initiated by the staff person

whom the inmate discloses such information or by any staff member that wants an inmate evaluated for Gender Dysphoria.

. . .

b. Upon receipt of the CN 81701, Gender Non-Conforming Referral Form, the CTDOC Chief Mental Health Officer or designee shall schedule a face to face interview with the inmate. The interview shall occur within ten (10) business days from the receipt of the CN 81701, Gender Non-conforming Referral Form. The purpose of the interview is to assess and determine if the inmate meets the criteria outlined in the DSM-V for a diagnosis of Gender Dysphoria. All inmates who meet the DSM V criteria for Gender Dysphoria will be referred to a licensed physician or APRN and facility psychologist for an evaluation to discuss possible medical and psychological interventions.

. . .

d. If the identified inmate does not meet DSM-V criteria for a diagnosis for Gender Dysphoria following the initial interview, a qualified mental health clinician within the CTDOC Health and Addiction Services Unit who was not involved in the initial interview of the inmate, will conduct a secondary interview within five (5) business days of the initial interview.

. . .

6. Gender Non-Conforming Review Committee (GNCRC) The Gender Non-Conforming Review Committee (GNCRC) is a multi-disciplinary group that shall provide recommendations regarding custodial management as it relates to inmates identifying as gender non-conforming and/or who have an intersex condition.

State Policy: State of Connecticut Department of Correction Administrative Directive No. 6.12, Inmate Sexual Abuse/Sexual Harassment Prevention and Intervention, effective July 20, 2015.

D. Transgender and Intersex Inmates. In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, the Department shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems. Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year by the unit counselor to review any threats to safety experienced by the inmate. The results of the review shall be documented on the inmate classification history form in section 5 of the inmate master file. A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration. Transgender and intersex inmates shall be given the opportunity to shower separately from other inmates. The Department shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status, unless placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

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Delaware

State Policy: Delaware Department of Correction Policy No. E-14, Treatment of Transgender Persons, effective Oct. 20, 2021.

A. It is the policy of the DDOC to respect the gender identity of a transgender person housed in any DDOC facility and under correctional supervision in the community. It is also the policy of DDOC to maximize the protection offered to offenders under the PREA statutes.

B. The DDOC shall provide each offender with an individualized assessment of their physical and emotional characteristics, their medical care needs and behavioral health needs. The individualized assessment may assist with housing assignments to provide the safest environment for the offender, the DDOC offender population and the security staff.

C. When an offender self-identifies a gender other than one that was assigned at birth, and the offender's genital status is unknown, the status shall be determined during the Intake Screening process by reviewing available medical records or, if necessary, by learning that information as part of a broader medical examination conducted in private by a medical practitioner during the initial medical examination or sick call appointment.

. . .

E. This policy does not include those offenders with a medical diagnosis of ambiguous gender (a rare genetic abnormality at birth in which the genitalia cannot be readily differentiated). These offenders shall be designated according to how they have identified during their lifetime or how they self-identify.

. . .

B. Urgent Behavioral Health evaluation

1. The purpose of the Urgent Behavioral Health evaluation is to assess the offender's suicide risk, the risk of becoming a victim of rape or "bullying", the offenders presenting emotional status, and the identification of the offender's statements about his/her gender as different from that assigned at birth. The Qualified Mental Health Professional (QMHP) shall document all statements and information, including the offender's actual statements that they identify their gender as different from that assigned at birth.

. . .

2. This evaluation will include an assessment of the offender's treatment and life experiences prior to incarceration as well as experiences during previous incarceration (including hormone therapy, completed or in-progress surgical interventions, real life experiences consistent with an offender's gender identity, private expressions that conform to the preferred gender and counseling). If the diagnosis of Gender Dysphoria is considered, the offender will be referred for a Comprehensive Behavioral Health Evaluation (CMHE) by an independently licensed behavioral health professional with experience in the evaluation and treatment of Gender Dysphoria.

. . .

C. Urgent Medical evaluation

1. The purpose of the urgent medical evaluation is to determine the presence or absence of characteristics that would increase risk of victimization of the transgender person in either the women's or men's facility.

2. In the case that the individual was receiving hormones prior to incarceration, enrollment in the Chronic Care Clinic and prescribing continuing hormone treatments should occur at this time to avoid the potential of any adverse effects of abruptly discontinuing the hormone treatments.

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D. Upon completion of Attachment A, Transgender Evaluation Recommendation Form, the recommendations of the Behavioral Health and Medical providers shall be forwarded to the Shift Commander, Warden, BOP Chief, BCC Chief, and BHSAMH Chief and the facility PREA manager to determine whether the offender could be safely housed in the current male or female facility, or whether discussion with a Warden of another facility is indicated.

State Policy: State of Delaware Department of Correction Policy No. 8.60A, Transgender Offenders, effective Oct. 19, 2016.

V. POLICY: It is the policy of the DOC to receive, evaluate, house and provide secure and humane custody of all persons who are lawfully committed or held for confinement by the Department. An offender's biological sex, and gender identity are recognized as factors in determining whether the inmate is likely to become a victim of abuse in the facility and shall be considered in applicable decision processes related to the offender. The DOC will screen offenders to help identify potential aggressors and victims.

A. Intake screening

1. A person's biological sex and their gender identity are two factors among many in determining the appropriate placement for every offender.

2. All offenders will be asked by DOC staff if they identify as transgender, using the PREA victimization/aggression screen. Medical will also ask this question during the medical intake questionnaire.

3. Prior to accepting an offender for the purpose of commitment from an external agency, the accepting receiving room staff shall review the following questions with the committing agency and offender:

a. Is the offender biologically male, female, or intersex?

b. Does the offender self-report as transgender?

. . .

5. When an offender self-identifies as transgender, the offender will be referred to medical for further evaluation prior to housing placement.

. . .

C. Housing and programs

1. Transgender offenders may not be assigned to gender-specific facilities based solely on their external genital anatomy.

2. In determining housing placement, the reviewing authority will consider physical layout and offender privacy issues when determining the location for a transgender offender.

3. In making housing and programming assignments, the reviewing authority shall consider, on a case-by-case basis, the least restrictive levels of security and custody needed to promote the health and safety of the offender, and whether such placement would present management or security concerns.

4. A transgender offender's own views with respect to their safety shall be given serious consideration, including whether they believe they would be more safely housed in a male or female facility.

5. Housing considerations will include all available housing options throughout the DOC.

6. Each facility will develop procedures to promote the safety and privacy of transgender offenders from other offenders in regard to showering and disrobing.

7. Facilities will not place transgender offenders in dedicated buildings, units, or tiers solely on the basis of such identified status.

8. The Bureaus of Prisons and Community Corrections will ensure transgender offenders are housed consistent with their sentence level (Level V or Level IV) absent exigent circumstances.

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District of Columbia

Policy: District of Columbia Department of Corrections Policy and Procedure No. 4020.31, Gender Classification and Housing, effective April 20, 2022.

2. POLICY

a. It is DOC policy to provide services in a humane and respectful manner to Transgender, Intersex, and Gender Nonconforming inmates while processing and housing them safely and efficiently to the greatest extent possible. For the safety, security, and order of the facility, the DOC houses male and female offenders in separate housing units. DOC shall house Transgender, Intersex, or Gender Nonconforming inmates in male or female units based on their preference, unless otherwise recommended by the Transgender Housing Committee and approved in accordance with this policy.

b. In order to address the specific needs of Transgender, Intersex, and Gender Nonconforming individuals, upon initial intake at the Inmate Reception Center (IRC), staff shall follow the guidelines in this policy in order to determine the inmate's housing in a male or female housing unit based on the inmate's preferred placement, safety/security needs, housing availability, gender identity, identity documents, and assigned sex at birth, if:

1) An inmate indicates that he or she is Transgender, Intersex, or Gender Nonconforming at any time during their custody.

2) An inmate's gender identity or gender expression differs from their assigned sex at birth.

3) A gender designation made by the medical service provider, government agency, or law enforcement agency indicates that the inmate is transgender.

. . .

10. INTAKE HOUSING UNIT

a. Inmates identified as Transgender, Intersex, or Gender Nonconforming shall initially be housed in protective custody (voluntary or involuntary protective custody) in a single cell in the intake housing unit consistent with the inmate's gender housing preference identified at intake. Within twenty-four (24) hours, excluding weekends, holidays, and emergencies, the inmate must receive a preliminary assessment by the PREA Victim Services Coordinator, consisting of an individualized initial safety and security assessment related to the gender housing preference of the Transgender, Intersex, or Gender Nonconforming inmate. Unless the inmate requests to remain in protective custody, or the PREA assessment concludes that the inmate cannot be housed in the intake unit of their preference consistent with the inmate's safety or the safety of others, the inmate shall be placed on that unit, and not in protective custody, upon the completion of the PREA assessment. Within seventy-two (72) hours, excluding weekends, holidays, and emergencies, after the preliminary assessment by the PREA Victim Services Coordinator, the Transgender Housing Committee shall conduct a formal classification and housing needs assessment for the Transgender, Intersex, or Gender Nonconforming inmate.

b. Inmates who Self-Report as Transgender, Intersex or Gender Nonconforming. Once an inmate makes known to DOC staff their Transgender, Intersex, or Gender Nonconforming status, staff shall:

1) Refer the Inmate to their assigned case manager or, on weekends, the captain or above.

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2) The case manager or the captain shall refer the inmate to the Transgender Housing Committee to determine the inmate's housing based on their gender housing preference, safety/security needs, gender identity and assigned sex at birth.

c. A case manager will be designated as "on call via remote assessment" on weekends, after hours, and on holidays, and that case manager will, as soon as practicable, contact Transgender, Intersex, or Gender Nonconforming inmates who enter intake at those times to make sure inmates are housed according to their preference at intake, pursuant to this Policy.

a. In accordance with PP 4090.3, Classification (Program Review), all Transgender, Intersex, or Gender Nonconforming inmates will be classified and assigned housing based on safety/security needs, housing availability, gender identity and sex assigned at birth. No inmate will be discriminated against based on their gender identity.

11. TRANSGENDER HOUSING COMMITTEE ROLE

a. As part of the housing assessment for vulnerability, the Transgender Housing Committee shall make a recommendation as to the Transgender, Intersex or Gender Nonconforming inmate's housing assignment after reviewing the inmate's records including the assessments (PREA and Risk Assessment) and interviewing the inmate.

b. The Committee shall ask the inmate to offer their opinion regarding whether they prefer to be housed in the male or female unit and any vulnerability they anticipate in the general jail population of the male or female unit. The Committee shall agree to house the inmate in the gender housing unit the inmate prefers– whether it corresponds to the inmate's gender identity or sex assigned at birth— unless the Committee has identified safety and security concerns with the inmate's preferred housing placement. The Committee shall attempt to reach a consensus, ultimately relying on majority vote when needed.

. . .

d. The Transgender Housing Committee's housing assessment shall address whether the inmate shall be housed in the general population or in a protective custody unit of the gender consistent with their gender identity or sex assigned at birth. If the Warden's opinion regarding safety and security concerns differs from the recommendation of the Transgender Housing Committee, the Warden shall justify the assignment in writing to the Director for the Director to make a final determination. Transgender, Intersex, and Gender Nonconforming inmates have the same right to appeal housing assignments as all inmates consistent with PP 4090.3, Classification (Program Review).

e. An inmate may request to come before the Transgender Housing Committee at any time by submitting an inmate request slip or an Inmate Grievance form.

f. If it is decided that the inmate can be housed in the general population, the inmate shall be transferred to the general population as determined by the Transgender Housing Committee after completion of initial classification and upon housing availability. Transgender, Intersex, or Gender Nonconforming inmates shall be housed in a single cell or with another Transgender, Intersex, or Gender Nonconforming inmate in their assigned housing unit.

g. A Transgender, Intersex, or Gender Nonconforming inmate shall be housed in protective custody when there is reason to believe the inmate presents a heightened risk to themselves or to others or where the inmate fears they will be vulnerable to victimization in any other housing setting. This assignment shall be only for the period during which the heightened risk and/or fear exists. Inmates in restrictive housing and protective custody shall have access to programs and services consistent with that status.

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h. If it is determined that the inmate requires protective custody, they shall be placed in such a unit and their custody shall be reviewed by the Transgender Housing Committee consistent with standard DOC policy.

i. Consistent with standard DOC policy, Transgender, Intersex, and Gender Nonconforming inmates may be placed in communal protective custody pursuant to the determination of the Transgender Housing Committee and subsequent reviews of the inmate's status from the Housing Board.

. . .

2) Inmate Detail Housing Assignment. Transgender, Intersex, or Gender Nonconforming inmates assigned to the detail or program unit shall be housed in a single cell or with another Transgender, Intersex, or Gender Nonconforming inmate. If accommodations cannot be made at the time of assignment, the Shift Supervisor shall be contacted immediately for appropriate housing.

. . .

CONTRACT HALFWAY HOUSE HOUSING PROCEDURES

a. Halfway House Referral

1) As part of the Halfway Housing assessment for vulnerability, the Transgender Housing Committee shall recommend a Transgender, Intersex, or Gender Nonconforming resident's housing assignment after review of all of the resident's records and assessments and an interview with the resident. The Transgender Housing Committee shall ask the resident to provide their her opinion of their vulnerability in the male and female halfway houses and determine the resident's housing assignment based on the resident's preference, unless the committee has safety or security concerns about the resident's preferred placement. The Transgender Housing Committee shall attempt to reach a consensus, ultimately relying on majority vote when needed. A written recommendation (Attachment C) by the Transgender Housing Committee shall be forwarded to the DOC Office of Community Corrections Program Administrator for approval and shall be maintained in the resident's institutional record.

2) The Transgender Housing Committee shall make a recommendation to the DOC Office of Community Corrections Program Administrator as to whether the resident should be housed in the male or female halfway house.

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Florida

Policy: Florida Department of Corrections Procedure No. 403.012, Identification and Management of Inmates Diagnosed with Gender Dysphoria, effective Nov. 13, 2019.

(1) GENDER DYSPHORIA REVIEW TEAM ROLE AND RESPONSIBILITY:

(a) The GDRT has the authority and responsibility to review recommendations for the treatment and management of inmates diagnosed with Gender Dysphoria to ensure individualization in the decision-making process.

. . .

(d) For those inmates receiving a formal diagnosis of Gender Dysphoria, further facility and housing assignments shall be made on a case by case basis with inmates being placed at one of the designated treatment facilities for Gender Dysphoria. The health and safety of the inmate, as well as all treatment, management, and security concerns will be examined. The inmate's own views regarding safety shall be given careful consideration.

Policy: Florida Department of Corrections Procedure No. 602.053, Prison Rape: Prevention, Detection, and Response, effective Sept. 7, 2021.

(2) PREVENTION/DETECTION

(a) Identification: . . .

6. Housing for transgender and/or intersex inmates will be determined on a case by case basis. The inmate's safety as well as the safety and security of the institutional compound will be taken into consideration when making the housing determination. Housing will be determined as outlined in this section below.

. . .

8. Transgender inmates, intersex inmates will be assessed biannually by classification. An interview will be conducted as well as a review of their housing, program and work assignments to determine if there are any necessary changes or threats to the inmate's safety.

9. A transgender and/or intersex inmate's own view, with respect to their own safety, shall be given serious consideration. A risk assessment may additionally be required, depending on the inmate's answers during the interview. Once identified the inmate will maintain the designation until classification completes the next biannual review.

10. Classification will screen all inmates within 72 hours of intake. Characteristics such as the inmate's age, criminal record, and prior identified history of sexual victimization or predation will be utilized to help determine s/he is at risk of future victimization of sexual abuse, sexual battery, or is at risk of committing sexual abuse or sexual battery. If s/he is identified as a potential victim or abuser (perpetrator); housing, bed, and work assignments will be appropriately assigned based on known information and established protocol.

. . .

v. Facility and housing assignments shall be made on a case by case basis, considering the inmate's health and safety as well as potential programming, management and security concerns. An inmate's own views regarding safety shall be given careful consideration.

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Sarasota County Policy: Sarasota County (FL) Sheriff's Office Corrections Operations and Services Bureaus Policy No. CO 440.04, Gender Identification Care and Custody, effective July 1, 2017, revised May 19, 2022.

C. Intake and Risk Assessment:

1. Booking and Admission:

b. If an incoming inmate identifies as an LGBTI or other gender identifying community member, they shall be given a Search Preference form. The booking sergeant shall then notify the classification sergeant and medical that the form has been completed. The operations bureau commander and watch commanders shall be notified of any special housing assignment for transgender and intersex inmates.

. . .

f. Classification is responsible for the initial determination of vulnerability using the PREA risk assessment and any other information available to decide housing.

g. The mere identification of an inmate's sexual orientation is insufficient to warrant an assumption of enhanced risk that the inmate will be sexually abusive or be sexually abused. Within 72 hours of arrival, the Possible Risk Factors and Possible Predatory Factors screening tools will be used to assess victimization and abusiveness [PREA 115.41 (a,b,c,d,e)].

. . .

D. Classification and Housing

1. Classification shall not classify inmates solely on the basis of their gender status or perceived gender status. Classification shall evaluate all available information, including inmate gender self-identification.

. . .

3. Inmates shall not be placed in segregation or dedicated housing units for the sole reason of their gender identity or status, unless the housing area has been established in connection with a consent decree, legal settlement, or legal judgment [PREA 115.42(g)]. Transgender, intersex, or other inmates who are placed in administrative segregation or other special management housing for their safety and security shall not have their privileges, programs, education and work opportunities restricted, without documentation listing limited opportunities, duration of the limitations, and non-discriminatory reasons for limitations [PREA 115.43(b)(1)(2)(3)].

4. Classification shall make individual determinations using the information from the risk screening to determine housing, bed, work, education, and program assignments with the goal of keeping separate inmates at risk of being sexually victimized from those at risk of being sexually abusive [PREA 115.42(a)(b), 115.62].

. . .

7. Transgender or intersex inmates may be housed according to their gender identity, rather than their birth sex. In deciding whether to assign a transgender or intersex inmate to housing for male or female inmates, as well as other programming assignments, classification and the operations bureau commander or his/her designee shall consider, on a case-by-case basis, whether a placement would ensure the inmate's health and safety, and if the placement would present management or security problems. If deemed necessary for the inmate's safety and emotional well-being, classification may place transgender or intersex inmates according to their birth sex and considering the facility's safety and security [PREA 115.42(c)].

8. All inmates may make requests to have their housing re-evaluated using the grievance system. A transgender or intersex inmate's own view with respect to his or her own safety shall be seriously considered. [PREA 115.42(e)].

9. The facility may consult with an identified member of the LGBTI or allied community to provide external resources and support in assistance with the LGBTI population or other gender identification.

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Georgia

State Policy: Policy: Georgia Department of Corrections Policy No. 507.04.68, Management and Treatment of Transgender Offenders, effective Feb. 1, 2022.

A. General Information . . .

2. When making housing and programming assignments, the medical, mental health, and facility staff shall consider on a case-by-case basis whether a placement would compromise the offender's health and safety and any management or security concerns.

3. Separate housing dedicated specifically to Transgender or Intersex offenders shall not be established.

4. Staff shall not physically examine an offender for the sole purpose of determining the offender's genital status. If unknown, it may be determined during conversations with the offender, by reviewing medical records, or if necessary, as part of a broader medical examination conducted in private by a medical practitioner.

. . .

6. To be diagnosed with Gender Dysphoria, the offender must meet the Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria.

. . .

B. Multi-Disciplinary Team Recommendations:

1. Within thirty (30) days of admission to the facility or within thirty (30) days of a report to staff that an offender reports they have or have been diagnosed with Gender Dysphoria or are Transgender, Intersex or Gender Non-Conforming and requesting accommodations, the facility Classification Committee Chairperson, or designee, shall convene a multidisciplinary team composed of medical, mental health, security and PREA Coordinator's office, as well as any other staff deemed appropriate.

2. This multi-disciplinary team shall make recommendations about the following:

a. Whether male or female housing is appropriate for the offender;

. . .

3. The multi-disciplinary team shall make recommendations based on all information available, including any evaluation for Gender Dysphoria and any relevant medical and/or mental health assessment.

. . .

4. The recommendations shall be based on, but not limited to the following:

a. The gender of the offender assigned at birth;

b. The offender's views with respect to his or her own identity and safety and whether or not those views have been consistent;

c. Any relevant characteristics of the offender, including physical stature, any tendency toward violence or predatory behavior, and any vulnerability to violence or predatory behavior;

d. Any relevant characteristics of other offenders with whom the person might be housed or come into contact;

e. Prior institutional history (for example, any previous management problems that impacted the safety or security of other persons or security within the facility);

f. Any co-occurring mental health issues; and

g. Any perceived risks to the continuing safety and health of the offender or others.

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5. The final decision on the recommendations shall be used in the development of the offender's case plan and classification.

6. It is the responsibility of the offender's treatment team to reassess all Transgender and Intersex persons in custody at least every six (6) months, or more frequently as deemed necessary.

State Policy: Georgia Department of Corrections Policy No. 208.06, Prison Rape Elimination Act – PREA: Sexually Abusive Behavior Prevention and Intervention Program, effective Dec. 1, 2014.

D. SCREENING FOR RISK OF SEXUAL VICTIMIZATION AND ABUSIVENESS

c) In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing or programming assignments, the Department shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.

d) Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experienced by the inmate.

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Guam

Policy: Guam Department of Corrections General Order No. 90.01, Prison Rape Elimination Act 203 (PREA), Aug. 21, 2020.

11. In deciding prisoner housing and programming assignments for transgender or intersex prisoners, the department shall consider on a case-by-case basis whether a placement would ensure the prisoner's health and safety, and whether the placement would present management or security problems.
12. If requested, transgender and intersex prisoners shall be given the opportunity to shower separately from other prisoners.
13. A transgender or intersex prisoner's own view with respect to his or her own safety shall be given serious consideration.
14. The PREA Compliance Manager will review placement and programming assignments for each transgender or intersex prisoner at least twice each year to review any threats to safety experienced by the prisoner.

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Hawaii

State Policy: State of Hawaii Department of Public Safety Policy No. ADM.08.08, Prison Rape Elimination Act, effective Nov. 15, 2021.

25. USE OF SCREENING INFORMATION

1. PSD shall use the information from the risk assessment screening for housing designations, work line, program assignment, or scheduling to keep separated those offenders at high risk of being sexually victimized from those at high risk of being sexually abusive. (115.42 a)

2. PSD shall use the risk screening tool information to make an individualized assessment about how to ensure the safety of each individual offender. (115.42 b)

. . .

26. LESBIAN, GAY, BISEXUAL, GENDER X, TRANSGENDER, AND INTERSEX (LGBTI) USE OF SCREENING INFORMATION

1. A gender X, transgender, or intersex offender will be housed based on their legal status as a male or female. Any deviation in the housing assignment of a transgender or intersex offender to a facility for male or female offenders will be determined by medical and mental health practitioners with input from program and security staff initially at the intake process.

2. In deciding whether to assign a gender X, transgender, or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, PSD shall consider on a case-by-case assessment of whether a placement would ensure the offender's health and safety, and whether the placement would present a management or security concern.

3. In the event that an offender's sex designation is changed as specified under Hawaii revised Statutes § 338-17.7, "Establishment of new certificates of birth" (effective July 1, 2015), then facility, housing, and programming assignments shall still be made as indicated in .2, but the PREA Coordinator shall be included in the case-by-case assessment.

4. Biannually designated facility staff identified by the Warden shall reassess the placement and programming assignment of each transgender or intersex offender for the purpose of assessing any threats to the safety of the offender.

5. This biannual assessment shall be documented by utilizing the PREA Mandated Reporting Form (PSD 8317) and/or may be conducted as part of a classification review for the transgender or intersex offender. The completed PREA Mandated Reporting Form shall be forwarded to the Department PREA Coordinator via email, fax, or mail within three (3) days.

6. A gender X, transgender, or intersex offender's own views with respect to his or her own safety shall be given serious consideration.

7. Gender X, Transgender, and intersex offenders shall be given the option to shower separately from other offenders in dorm shower situations, if so requested. This provision is applicable only when individual showers are not available at the offender's assigned housing unit.

8. PSD Facilities shall not place Gender X and LGBTI offenders in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such offenders.

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Idaho

State Policy: Idaho Department of Correction Standard Operating Procedure Control No. 149.01.01.001 (v.6), Prison Rape Elimination, adopted Aug. 17, 2004, approved Jan. 21, 2021.

> **6. Placement of Lesbian, Gay, Bisexual, Transgender, and Intersex (LGBTI) Residents**
>
> The department does not place lesbian, gay, bisexual, transgender, or intersex residents in dedicated facilities, units, or wings solely based on such identification or status. The IDOC considers the management and placement of transgender or intersex residents on a case by case basis. Health and safety, operational management, security, and mental health needs are considered. Serious consideration is given to the resident's own views regarding safety.

State Policy: Idaho Department of Correction Standard Operating Procedure Control Number 149.01.01.002, Prison Rape Elimination Screening and Cautions, adopted July 12, 2021, approved July 12, 2021.

> **b.** Security supervisors will assign staff to complete six-month checks on transgender, intersex, and gender non-conforming residents to ensure they feel safe in their housing and have programming access. If safety or placement concerns emerge, the security supervisor shall conduct a housing review. Case Managers shall follow-up on programming concerns. The six-month checks are documented in C-notes.

State Policy: Idaho Department of Correction Standard Operating Procedures Control No. 401.06.03.501 (v. 4.0), Gender Dysphoria: Healthcare for Inmates with, adopted Oct. 31, 2002, approved Oct. 5, 2018.

> **2. Referral and Placement of the Inmate for Evaluation Purposes**
>
> The chief psychologist will take the necessary action to transfer an inmate who is scheduled to be evaluated for GD to the appropriate facility for evaluation if a move is needed. When determining appropriate placement, the chief psychologist will consider factors such as the inmate's diagnostic needs, prior institutional adjustment, and safety and/or security concerns. In consultation with the warden, unless there are overriding security and/or safety concerns for the inmate, the chief psychologist will place the inmate (who either requests a GD evaluation or is diagnosed with GD) in a correctional facility consistent with the inmate's primary physical sexual characteristics.
>
> . . .
>
> **6. Management and Treatment Committee (MTC) Meeting**
>
> When convened, the MTC will develop and recommend a plan for the management and placement of the inmate. Copies of all reports authored by the evaluators will be provided to the MTC. The MTC will develop and recommend an individualized Management and Placement Plan for each inmate diagnosed with GD, which implements the treatment plan developed by the treating medical and mental health providers…Management and placement recommendations for inmates with GD will take into account both treatment and security needs, with a goal of least restrictive placement. As provided in section 2, facility placement will be based upon the inmate's primary physical sexual characteristics.

State Policy: Idaho Department of Juvenile Corrections Institutional Policy/Procedure Number 613, Prison Rape Elimination Act (PREA) Compliance, effective Jan. 30, 2009, reviewed Nov. 8, 2021.

A. Placement

1. LGBTIQ juveniles are not placed in a particular housing unit, bed or other placement based solely on the juvenile's LGBTIQ status, or perceived status.

2. The IDJC shall not consider a juvenile's LGBTIQ status, or perceived status, as an indicator or likelihood of being sexually abusive.

3. Transgender and Intersex Juveniles

a. Placement and programming assignments for transgender or intersex juveniles are reassessed at least every six months to review any threats to safety experienced by the juvenile.

b. When making a placement decision, placement staff consider whether a transgender or intersex juvenile would prefer to be placed with males or females and the reason for that preference, with the final decision for placement being made by the Clinical Supervisor and/or Program Manager. LGBTI and questioning juveniles will not be isolated or otherwise separated from other juveniles solely due to LGBTI or questioning status.

Local Canyon County Policy: Canyon County Sheriff's Office Prison Rape Elimination Act, 2014, revised July 2021.

In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.

Staff shall use all information obtained to make housing, bed, program, education, and work assignments for inmates with the objective of keeping all inmates safe and free from sexual abuse.

Lesbian, gay, bisexual, transgender, or intersex inmates shall not be placed in particular housing, bed, or other assignments solely on the basis of such identification or status.

In making other housing and programming assignments, the agency shall consider on a case by case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.

Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experienced by the inmate.

A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration when considering changing housing assignments.

Transgender and intersex inmates shall be provided with the opportunity to shower separately from other inmates.

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Illinois

State Policy: Illinois Department of Corrections Administrative Directive No. 04.03.104, Evaluation, Treatment and Correctional Management of Transgender Offenders, effective April 1, 2021.

2. Placement and Programming

a. Transgender, intersex and gender incongruent offenders shall not be assigned to gender-specific facilities based solely on their external genital anatomy.

b. A review of each transgender, intersex and gender incongruent offender's placement and programming assignments shall be conducted by the facility twice annually to review any threats to safety experienced or posed by the offender.

c. The Transgender Administrative Committee (TAC) shall make individualized determinations about how to ensure the safety of each offender including considering transfer from one gender-specific facility to an opposite gender facility and specifying the gender of staff which will perform searches of the offender. The determination shall consider, on a case-by-case basis, whether a specific placement would ensure the offender's health and safety, and whether the placement would present management or security concerns.

Note: The TAC shall make these determinations without the necessity of a referral for any offender identified as transgender, intersex, and gender incongruent. However, an offender may be referred for these reviews by written request of the offender, the offender's treating mental or medical providers, or the CAO.

d. A representative of the TAC shall interview the offender, review PREA allegations, offender grievances, criminal history, medical, psychiatric and disciplinary records and present findings to the TAC. Decisions shall be made by the TAC on a case-by-case basis with serious consideration given to circumstances including, but not limited to, the following:

(1) The offender's perception of whether a male or female facility is safest for him or her, as well as the preferred gender of staff to perform searches.

(2) The offender's prior institutional history (to include incidents and grievances).

(3) The offender's prior violent or sexual criminal history.

(4) The offender's gender expression including physical appearance, age and physical build.

(5) The offender's vulnerability to sexual victimization, including prior allegations of sexual abuse or harassment made by the offender.

(6) The offender's likelihood of perpetrating abuse against other offenders including consideration of prior allegations of sexual abuse or harassment made against the offender.

(7) The offender's compliance with medical and mental health treatment plans, including psychopharmacologic and hormone therapy compliance (if applicable).

(8) Any relevant information obtained about the offender from security staff or medical and mental health staff since arrival.

(9) The ability of security staff to house and supervise the offender to ensure his or her safety and the safety of the population in the current and requested environment.

(10) The services available to meet the needs of the offender in each environment.

(11) Any obstacles identified for the appropriate management of the offender in each facility.

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(12) Any other relevant information about the offender's ability to positively or negatively manage himself or herself in each type of environment.

e. The decision made by the Committee to transfer the transgender, intersex or gender incongruent offender to an alternative gender facility shall be documented and the offender shall be notified by letter from the Chairperson of the TAC or designee.

f. If after a transfer occurs the transgender, intersex or gender incongruent offender poses a significant threat to residents of the receiving facility or creates a disruption to the safe operation of that facility, the offender may be presented to the combined TAC and THAWC for placement consideration.

g. In the event where a transgender, inter-sex or gender incongruent offender is housed in a facility inconsistent with their gender identification, whether by their choice or decision of the TAC, accommodations shall be afforded to them as outlined below.

Local Cook County Policy: Cook County Administration Policy Manual Policy No. 125, Transgender and Intersex Subjects.

125.4 INTERAGENCY ACCOMMODATION PLAN COMMITTEE

(a) The Interagency Accommodation Plan Committee shall consider each transgender or intersex subject, and recommend appropriate accommodations for the subject on a case-by-case basis. The committee may also choose to consider subjects who are gender non-conforming.

(b) In its deliberations, the Interagency Accommodation Plan Committee shall ensure the dignity and respect of transgender or intersex subjects are taken into consideration. The transgender or intersex subject's views of his/her safety shall be given serious consideration.

. . .

(d) In deciding the housing assignment of a transgender or intersex subject, the committee shall consider the following:

1. Whether to place the subject in male or female housing;

2. Whether a placement will ensure the subject's health and safety; and

3. Whether a placement will present significant management, security or clinical challenges.

(e) A transgender or intersex subject shall not be housed separately (e.g., protective custody, administrative segregation) from other members of the jail population solely based on his/her status as transgender or intersex, nor shall such a subject be isolated as part of a group from other subjects solely based on his/her status.

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Indiana

State Policy: State of Indiana Department of Correction Policy and Administrative Procedure Number 02-01-118, Transgender and Intersex Offenders, effective July 1, 2019.

VI. HOUSING ASSESSMENTS: . . . After the facility PREA Compliance Manager receives the completed State Form 56492, "Transgender Evaluation," from the facility HSA, the PREA Compliance Manager shall convene the facility PREA Committee to complete State Form 56615, "Transgender/Intersex Placement Review" The PREA Committee shall consider the following information to complete State Form 56615:

A. The offender's own views of where he/she feels safe;
B. Medical and Mental Health assessment;
C. Security Threat Group (STG) affiliation;
D. Criminal history – sex or violent offense;
E. Conduct history – sex or violent offense;
F. PREA flag status;
G. Gender expression – gender non-conforming;
H. Policy and Administrative Procedure 01-04-101, "Adult Offender Classification;"
I. Security level; and,
J. Any other factors impacting safety and security.

The PREA Committee shall make a recommendation on State Form 56615 for the placement of the offender based on all information reviewed. The PREA Compliance Manager shall forward the completed State Form 56615, last completed SVAT and State Form 56492, "Transgender Evaluation" to the Executive Director of PREA. The Executive Director of PREA shall convene a committee …to discuss and determine the offender's placement. Serious consideration shall be given to the facility's assessment recorded on State Form 56492. The findings of this committee shall be documented and a recommendation forwarded to the office of the Deputy Commissioner of Operations for review and decision.

VII. HOUSING ASSIGNMENT: Transgender and intersex offenders may not be assigned to gender-specific facilities based solely on their external genital anatomy. While determining housing placement, the Department shall consider physical layout and offender privacy issues when determining location. In deciding whether to assign a transgender or intersex offender to a facility for male or female offenders, and in making other housing and programming assignments, the Department shall consider, on a case-by-case basis, whether a placement would ensure the offender's health, safety, and security; and whether the placement would present management or other safety or security concerns. Serious consideration shall be given to such an offender's own views with respect to his or her own safety. Facilities shall not place transgender or intersex offenders in dedicated buildings, units, or ranges solely on the basis of such identified status. The Division of Classification, in consultation with the Department's Executive Staff, including the Chief Medical Officer, shall ensure transgender and intersex offenders are housed in a manner consistent with their medical and mental health needs, sentencing level, and in accordance with Policy and Administrative Procedure 01-04-101.

State Policy: State of Indiana Department of Correction Policy and Administrative Procedures Number 02-01-115, effective April 1, 2020.

C. Use of Screening Information (115.42) . . .

2. The Department shall make individualized determinations about how to ensure the safety of each offender.

3. In deciding whether to assign a transgender or intersex offender to a facility for male or female offenders (see Policy and Administrative Procedure 02- 01-118, "Transgender and Intersex Offenders"), and in making other housing and programming assignments, the Department shall consider on a case-by-case basis whether a placement would ensure the offender's health and safety, and whether the placement would present management or security problems.

4. Placement and programming assignments for each transgender or intersex offender shall be reassessed twice each year to review any threats to safety experienced by the offender.

5. A transgender or intersex offender's own views with respect to their own safety shall be given serious consideration.

. . .

7. The Department shall not place lesbian, gay, bisexual, transgender, or intersex offenders in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such offenders.

State Policy: State of Indiana Department of Correction Policy and Administrative Procedure Number 01-04-101, Adult Classification, Effective Date, June 1, 2022.

XIII. CONSIDERATIONS FOR OFFENDER CELL ASSIGNMENTS

C. Upon the arrival of an offender following a transfer from another facility, staff shall thoroughly review the offender's packet, offender information system, IRIS, and any other pertinent information (e.g., Medical, Mental Health, STG, Investigations and Intelligence, gender identity issues, etc.) to determine whether there is any information that might require special consideration in the assignment of the offender to a particular housing unit, or a double-cell assignment.

In reviewing the offender's packet and offender information system screens, IRIS records, and any other pertinent information, staff shall pay particular attention to the following areas:

1. Gender Identity: Used to classify a person as male, female, both, or neither. Gender encompasses aspects of social identity, psychological identity, and human behavior.

2. Intersex Identity: Used to classify a person whose reproductive, genetic, or sexual anatomy does not seem to fit the typical definitions of female or male. Intersex identification does not necessarily mean the offender also identifies as Transgender.

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Iowa

State Policy: State of Iowa Department of Corrections Policy No. 00, PREA Standards for Adult Prisons and Jails, effective April 2018.

Screening for Risk of Sexual Victimization and Abusiveness

§ 115.41 Screening for risk of victimization and abusiveness.

(a) All inmates shall be assessed during an intake screening and upon transfer to another facility for their risk of being sexually abused by other inmates or sexually abusive toward other inmates.

. . .

§ 115.42 Use of screening information.

(a) The agency shall use information from the risk screening required by § 115.41 to inform housing, bed, work, education, and program assignments with the goal of keeping separate those inmates at high risk of being sexually victimized from those at high risk of being sexually abusive.

(b) The agency shall make individualized determinations about how to ensure the safety of each inmate.

(c) In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems and reassessed at least twice a year.

(d) Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experienced by the inmate.

(e) A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration.

(f) Transgender and intersex inmates shall be given the opportunity to shower separately from other inmates.

(g) The agency shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

State Policy: State of Iowa Department of Corrections Policy No. HSP-704, Management of Gender Dysphoria, effective March 2022.

B. Identification and Diagnosis of Patients with GD

1. Identification of patients with GD

a. All patients who self-identify themselves as GD entering IDOC custody shall be evaluated to confirm diagnosis by the mental health team.

b. Patients seeking treatment or accommodations for GD should be forwarded to psychology staff.

. . .

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5. Housing and Facility Transfers

a. Before transferring a transgender female patient from one male institution to another male institution, there should be a conference between the sending and receiving institutions to discuss the patient's case.

b. In deciding whether to reassign a transgender female patient to a female institution, or a transgender male patient to a male institution, and in making other housing and programming assignments, the patient's Institutional Classification Team, and Wardens from the sending and receiving institutions shall consider on a case-by-case basis whether a placement would ensure the patient's health and safety and whether the placement would present management or security problems. If approved internally, the case will be presented to the GD Clinical Supervision Group, Offender Services, and the Assistant Deputy Director – Reentry and Programs to review and make a final determination, then document such reasoning in writing.

c. All housing determinations shall be made in accordance with PREA and its implementing regulations.

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Kansas

We were unable to obtain Kansas state-specific policies related to housing transgender inmates. Please note, however, the Kansas Department of Corrections published **Prison Rape Elimination Act (PREA)** audits to its website that include summaries of relevant policies. For example:

PREA Audit: Lansing Correctional Facility PREA Facility Audit Report: Final, submitted June 24, 2022.

> Kansas Department of Corrections IMPP: Transgender and Intersex Offender Placement, dated July 7, 2019 page 2, section II. A. 1., "Transgender and Intersex offenders must not be assigned to gender-specific facilities based solely on their external genitalia. While determining facility placement, the Department must consider physical layout and offender privacy issues. 1. In deciding whether to assign a transgender or intersex offender to a facility for male or female offenders, and in making other housing and programming assignments, the Department must consider, on a case-by-case basis, whether placement would ensure the offender's health, safety, and security; and whether the placement would present management or other safety or security concerns."
>
> Kansas Department of Corrections IMPP: Transgender and Intersex Offender Placement, dated July 7, 2019, page 3, section II. A. 1., "For each transgender or intersex offender, the reassessment must be completed at least twice per year to review the appropriateness of placement and programming assignments and to assess any threats to safety experienced by the offender. (28 C.F.R. §§ 115.42 and 115.342)."
>
> Kansas Department of Corrections IMPP: Transgender and Intersex Offender Placement, dated July 7, 2019, page 2, section II. A. 2., "During the interview process to assess any safety concerns, serious consideration must be given to an offender's own views with respect to his or her own safety." (f) Kansas Department of Corrections, IMPP 10-143D: Transgender and Intersex Offender Placement, page 3, section IV. B. 1. a., states, "A transgender or intersex offender must be given the opportunity to shower separately from other offenders. a. This offer and their refusal or acceptance of separate shower times must be documented in a case note.

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Kentucky

State Policy: Commonwealth of Kentucky Corrections Policies and Procedures Policy No. 14.8, Lesbian, Gay, Bisexual, Transgender, and Intersex Offenders, effective Aug. 11, 2021.

A. Facility Determination

1. An assessment to determine the facility a transgender or intersex inmate shall be assigned to shall be made on a case-by-case basis via an individualized assessment of the inmate by the Therapeutic Level of Care (TLOC) committee, which includes input from medical and mental health staff, in consultation with the Director of Classification. A determination shall not be made based on genital status alone.

2. Staff shall consider if placement would ensure the inmate's health and safety and if the placement would present management or security problems.

3. Staff shall give serious consideration to the inmate's own views concerning his or her safety.

4. The individualized assessment shall consider the following:

a. Classification's housing decision;

b. The offender's documented choice of whether a male or female facility is safest for him or her;

c. The inmate's physical characteristics;

d. Whether the inmate identified as male or female;

e. The offender's prior institutional history, to include incidents and grievances;

f. The offender's prior violent or sexual crime history;

g. The offender's physical appearance, age, and physical build;

h. Any relevant information obtained about the offender from security, medical or mental health staff since arrival;

i. The ability of security staff to house and supervise the offender to ensure his or her safety in each environment;

j. Any management problems that can be identified in each facility; and

k. Any other relevant information about the offender's ability to positively or negatively manage his or herself in each type of environment.

5. If a transgender or intersex inmate already housed at a DOC facility requests transfer to a facility housing the opposite gender, the request shall be reviewed by the institutional treatment team prior to being referred to TLOC. The institutional treatment team shall complete the individualized assessment outlined in number 4 above. The TLOC shall then review and consider the information and recommendation provided by the institutional treatment team.

State Policy: Commonwealth of Kentucky Corrections Policies and Procedures Policy No. 14.7, Sexual Abuse Prevention and Intervention Programs, effective July 20, 2021.

F. Offender Risk Assessment

1. An offender shall be assessed during intake screening within seventy-two (72) hours of arrival at the Assessment and Classification Center and upon each transfer to another facility . . . Housing concerns shall be documented in the comments section on the assessment in KOMS. . . .

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4. The information gleaned from the intake screening shall be used to make housing, bed, program and work assignment decisions with the goal of keeping separate those offenders who are prone to sexual victimization from those who are prone to sexual aggression.

5. Within 30 days of arrival to each facility, the offender's risk level shall be reassessed based upon any additional information received since the intake screening. A reassessment shall also occur when any new information is learned that bears on an offender's propensity for sexual victimization or abusiveness, such as an incident or new disclosure of sexual abuse. Reassessments shall include consultation with the inmate.

. . .

10. Placement decisions regarding lesbian, gay, bisexual, transgender and intersex (LGBTI) offenders shall be individualized.

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Louisiana

State Policy: La. Admin. Code tit. 67, pt. V, § 7513 (Juvenile Detention Facilities—Admission and Release)

G. Classification Decisions . . .

4. Decisions for housing or programming of youth who are or are perceived to be gay, lesbian, bisexual, or transgender youth on the basis of their actual or perceived sexual orientation shall be made on an individual basis in consultation with the youth and the reason(s) for the particular treatment shall be documented in the youth's file. The administrator or designee shall review each decision.

14. USE OF SCREENING INFORMATION UPON INITIAL INTAKE: . . .

B. In deciding whether to assign a transgender or intersex offender to a facility for male or female offenders, and in making other housing and programming assignments, the unit shall consider on a case-by-case basis whether a placement would ensure the offender's health and safety, and whether the placement would present management or security problems. Transgender offenders will also be given the opportunity to shower separately and each unit shall maintain documentation of the efforts to offer separate showers utilizing a Shower Preference Statement (Form C-01-022-N). Questions regarding identification of a transgender or intersex offender's genital status shall be referred to the Department's Medical/Mental Health Director for review and, if needed, determination if a physical examination in a private setting by a health care provider is necessary. (§115.15(E) and 115.42(C))

. . .

16. USE OF SCREENING INFORMATION AT PERMANENT HOUSING ASSIGNMENT (§115.42):

. . .

B. Placement and programming assignments for transgender or intersex offenders shall be reassessed and documented at least twice each year utilizing the Transgender/Intersex Reassessment (Form C-01-022-O) by Classification staff to review any threats to safety experienced by the offender.

Note: It is prohibited to place a lesbian, gay, bisexual, transgender, intersex and gender nonconforming offender (LGBTI) in a dedicated unit or facility solely on the basis of LGBTI identification unless such placement is pursuant to a legal requirement for the purpose of protecting such an offender.

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Maine

State Policy: State of Maine Department of Corrections Policy No. 23.8 (Adult Facilities), Management of Transgender and Intersex Prisoners, effective Nov. 16, 2015, revised Nov. 30, 2015.

4. In general, a prisoner shall be placed in a facility and housing unit in accordance with his or her gender assigned at birth, except as set out below.
5. If a prisoner has fully completed sex reassignment surgery, then that person shall be housed and otherwise managed in accordance with his or her gender as reassigned.
6. The determination whether to assign a transgender or intersex prisoner who has not fully completed sex reassignment surgery to a facility for male or female prisoners and other housing and program assignments shall be done on a case-by-case basis, taking into account the views of the prisoner, and shall be based on protecting the prisoner's safety and mental health and preventing security issues, including, but not limited to, risks to the safety of others.
7. Separate housing dedicated specifically to transgender or intersex prisoners shall not be established.

State Policy: State of Maine Department of Corrections Policy No. 6.11.2 (Entire Department of Corrections), Sexual Misconduct (PREA and Main Statutes), Prevention, effective May 19, 2008, revised April 9, 2018.

Procedure G: Lesbian, Gay, Bisexual, Transgender, or Intersex (LGBTI) Prisoners and Residents

1. Facility staff shall not search or physically examine a transgender or intersex prisoner or resident for the sole purpose of determining the person's genital status. If the person's genital status is unknown, it may be determined by discussing the matter with the prisoner or resident, reviewing medical records, and, if necessary, by a health care provider performing a general physical health assessment that is not viewed by other staff.
2. The determination whether to assign a transgender or intersex prisoner or resident to a facility for male or female prisoners or residents and other housing and program assignments shall be individualized, take into account the views of the prisoner or resident, and be based on protecting the prisoner's or resident's safety and mental health and preventing security issues. These determinations shall be made in accordance with Department Policies (AF) 23.8 and (JF) 18.8, Management of Transgender and Intersex Prisoners and Residents, as applicable.
3. Facility, housing, and program assignments for a transgender or intersex prisoner or resident shall be reviewed through the facility classification process at least every six (6) months to consider any threats to safety experienced by the prisoner or resident.
4. If a facility does not have separate individual shower facilities for use by transgender and intersex prisoners or residents, then a transgender or intersex prisoner or resident shall be given the opportunity to shower at separate times from other prisoners or residents.
5. Lesbian, gay, bisexual, transgender, or intersex prisoners or residents shall not be housed in dedicated facilities, units, or wings solely on the basis of such identification or status.
6. All housing decisions for lesbian, gay, bisexual, transgender, or intersex prisoners or residents shall be clearly documented in the prisoner's or resident's housing unit file and in CORIS.

State Policy: State of Maine Department of Corrections Policy Number 18.8 (Juvenile Community Corrections), Management of Transgender, Gender Nonconforming, and Intersex Residents, effective Nov. 16, 2015, revised March 9, 2020.

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Procedure B: Housing and Programs

1. Separate housing dedicated specifically to transgender, gender nonconforming, or intersex residents shall not be established.

2. In general, a resident shall be placed in a housing unit in accordance with their sex assigned at birth, except that, in the case of a transgender or intersex resident, the decision about housing shall be made on a case-by-case basis, taking into account the views of the resident, and shall be based on protecting the resident's safety and mental health and preventing security issues, including, but not limited to, risks to the safety of other residents.

3. In the case of a transgender, gender nonconforming, or intersex resident, decisions about programs shall be made on a case-by-case basis, taking into account the views of the resident, and shall be based on protecting the resident's safety and mental health and preventing security issues, including, but not limited to, risks to the safety of other residents.

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Maryland

State Policy: Maryland Department of Public Safety and Correctional Services Executive Directive No. OPS 131.0001, Identification, Treatment and Correctional Management of an Inmate Diagnosed with Gender Dysphoria, effective Sept. 16, 2016.

J. Case Management.

(1) A Gender Dysphoric inmate's housing placement shall be made on a case-by-case basis seriously considering the inmate's opinion regarding the inmate's safety and the inmate's biological gender presentation and appearance considering:

(a) Intact external genitalia and secondary sex characteristics, such as pubic hair, chest hair, facial hair; and

(b) Specific factors, such as partial completion of sex reassignment surgery, removal or augmentation of breasts, or removal of testicles.

(2) Each inmate shall be evaluated on a case-by-case basis by the facility's Security Chief and Case Management staff with support from the Director, Clinical Services and Deputy Director of Mental Health or specialty consultation considering safety, security, or operational issues.

(3) Mental health staff may provide input as to clinical recommendations related to housing of a Gender Dysphoric inmate to the managing official and Case Management staff as part of the Regional Treatment Team's individualized treatment plan, however, final determination regarding housing placement is the responsibility of the managing official.

(4) If mental health staff input and recommendations and a managing official's decision on placement of a Gender Dysphoric inmate conflict, the final decision shall be made by the Deputy Secretary for Operations, or a designee.

K. Custody Issues.

(1) A Gender Dysphoric inmate shall be confined in accordance with provisions established under the Prison Rape Elimination Act of 2003 and all related Department policy and procedures.

(2) Consistent with an inmate's security level, a Gender Dysphoric inmate:

(a) Whose assigned gender is male and expressed gender is female and who is housed in a male facility is permitted to purchase and retain clothing items and other articles authorized for other male inmates at the facility, as well as items authorized for females at a female facility;

(b) Whose assigned gender is female and expressed gender is male and who is housed in a female facility is permitted to purchase and retain clothing items and articles authorized for other female inmates at the facility, as well as items authorized for males at a male facility; and

(c) May only purchase and retain personal property and commissary items that are authorized by established policy and procedures related to allowable inmate personal property.

State Policy: Maryland Department of Public Safety and Correctional Services Executive Directive No. OPS 200.0006, Assessment for Risk of Sexual Victimization and Abusiveness, effective April 4, 2018.

C. The PREA Coordinator shall ensure that the following issues are appropriately addressed in procedures for using information obtained during screening required under this directive:

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(1) Screening information shall be considered:

(a) When making decisions related to housing, bed, work, education, and program assignments with the goal of separating inmates who are determined to be at high risk of being sexually victimized from inmates who are determined to be at high risk of being sexually abusive.

(b) When making individualized determinations as how to ensure the safety of each inmate.

(c) When deciding to assign a transgender or intersex inmate to a facility for male or female inmates and in other housing and programming assignments and, on a case by case basis, determining if the placement or assignment:

(i) Ensures the inmate's health and safety; and

(ii) Presents management or security problems.

(2) Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review threats to safety experienced by the inmate.

(3) A transgender or intersex inmate's own views with respect to personal safety shall be seriously considered.

. . .

(5) Lesbian, gay, bisexual, transgender, or intersex inmates may not be placed in dedicated facilities, units, or wings solely on the basis of such identification or status, unless placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting inmates.

Local Montgomery County Policy: Montgomery County Department of Corrections and Rehabilitation Departmental Policy and Procedure Manual, Policy No. 3000-64, Implementation of the Prison Rape and Elimination Act (PREA), effective May 1, 2022.

V. Use of Screening Information:

(a) The Department shall use information from the risk screening to inform housing, bed, work, education, and program assignments with the goal of keeping separate those inmates at high risk of being sexually victimized from those at high risk of being sexually abusive.

(b) The Department shall make individualized determinations about how to ensure the safety of each inmate.

(c) In deciding whether to assign a transgender or intersex inmate to a housing unit or a programming assignment, the Department shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.

(d) Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experienced by the inmate.

(e) A transgender or intersex inmate's own view with respect to his or her own safety shall be given serious consideration.

. . .

(g) The Department shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

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Massachusetts

State Policy: Mass. Gen. Laws Ch. 127 § 32A, Prisoner Gender Identity, effective Dec. 31, 2018.

> A prisoner of a correctional institution, jail or house of correction that has a gender identity, as defined in section 7 of chapter 4, that differs from the prisoner's sex assigned at birth, with or without a diagnosis of gender dysphoria or any other physical or mental health diagnosis, shall be: . . . housed in a correctional facility with inmates with the same gender identity; provided further, that the placement shall be consistent with the prisoner's request, unless the commissioner, the sheriff or a designee of the commissioner or sheriff certifies in writing that the particular placement would not ensure the prisoner's health or safety or that the placement would present management or security problems.

State Policy: Massachusetts Department of Correction Policy No. 103 DOC 653, Identification, Treatment, and Correctional Management of Gender Non-Conforming Inmates, effective Oct. 26, 2022.

> **653.03 MANAGEMENT AND PLACEMENT**
>
> At the time of their commitment, sentenced individuals are court ordered into the custody of the Department of Correction and are transported to the Department's reception center for males or females based upon the court's order.
>
> Once committed to the Department of Correction, placement decisions, classification, and other programming assignments for gender non-conforming inmates shall be considered on a case-by-case basis. Factors which shall be considered include, but are not limited to, the inmate's stated request, whether a placement would ensure the inmate's health and safety, and/or whether the placement would present management or security problems.
>
> Placement and programming assignments for each gender non-conforming inmate shall be reassessed at least twice each year in order to review any threats to safety experienced by the inmate.
>
> A gender non-conforming inmate's own views with respect to his or her own safety shall be given serious consideration.
>
> **1. Initial Classification and Placement:** For all new commitments, an IMS Housing Risk Factor Assessment is completed which examines issues of risk of victimization and risk of violence/predatory behavior/abusiveness. Should an inmate identify as gender non-conforming, the additional process of the verification of the gender non-conforming status shall commence as outlined in 103 DOC 653.04. The findings of the verification of the gender non-conforming status process, along with the Housing Risk Factor Assessment, shall inform housing, work, education, and program assignments.
>
> **A. Bi-Annual Review:** A Housing Risk Factor Assessment will be completed at least every six months for all gender non-conforming inmates. In preparing for the status review, medical staff, mental health staff, and other security personnel will collaborate to assess appropriate programming and placement within the agency for each gender

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non-conforming inmate. The review shall assist with decisions regarding housing, work, education, and program assignments and shall focus on individual safety. Recommendations shall be considered on a case by case basis, and shall consider whether placement will ensure the inmate's health and safety, and whether the placement would present management or security issues. Security level, criminal and discipline history, medical and mental health assessment of needs, vulnerability to sexual victimization and potential of perpetrating abuse based on a history of being sexually or physically abusive, shall all be considered. The inmate's own views with respect to his or her own safety shall also be given serious consideration. This bi-annual review shall include a review of any threats to safety experienced by the inmate.

In addition, specific cases with partial completion of sex reassignment surgery, removal or augmentation of breasts, removal of testicles, etc., shall be evaluated on a case by case basis by the Program Medical Director. In the event that the Program Medical Director's recommendation may potentially present security, safety, or operational difficulties within the correctional environment, the Director of Behavioral Health shall refer the request to the Deputy Commissioner of the Prison Division and the Deputy Commissioner of Clinical Services and Reentry for a security review, pursuant to 103 DOC 653.08, Security Review.

B. Internal Placements: Site mental health directors may provide input as to their clinical recommendations related to housing gender non-conforming inmates within their respective institutions. Consideration of these clinical recommendations should be given by the Department of Correction when making determinations regarding such issues; however, final determination regarding internal housing placement is the responsibility of the Superintendent.

C. Gender non-conforming inmates will not be housed in dedicated institutions, units, or wings solely on the basis of their gender non-conforming identification or status, unless such placement is in a dedicated institution, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

653.04 VERIFICATION OF GENDER NON-CONFORMING STATUS

1. If, upon admission to the Department, or at any time during an inmate's incarceration, an inmate self-identifies as being gender non-conforming, a institution-based medical provider, or qualified mental health professional assigned to the inmate, shall review the inmate's gender non-conforming status to determine whether the inmate's gender identity is sincerely held as part of the inmate's core identity. This assessment shall include a thorough record review including obtaining releases of information for external providers as well as a face to face interview. Gender identity may be verified by providing to the medical provider or qualified mental health professional evidence of the inmate's gender non-conforming status which may include, but is not limited to, medical history, mental health history, care or treatment of the gender identity, consistent and uniform assertion of the gender identity, or any other evidence that the gender identity is sincerely held.

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For persons returned to the custody of the Department of Correction with a previously confirmed gender non-conforming status, a new gender identity verification process shall not be required unless indicated by the contracted medical provider or qualified mental health professional assigned to the inmate.

2. If an inmate's gender non-conforming status is denied by the contracted medical provider or qualified mental health professional assigned to the inmate, the inmate may appeal to the Statewide Medical Director within thirty (30) days of the denial. The Statewide Medical Director shall issue his/her/their decision for the appeal within sixty (60) days of receipt of the appeal. The grounds for the appeal decision shall be in writing and given to the inmate. The Statewide Medical Director's decision is final.

If an inmate's gender non-conforming status is denied, the inmate may request a re-verification process by the institution-based medical provider or qualified mental health professional assigned to the inmate after one year of the prior denial.

653.08 SECURITY REVIEW

1. A gender non-conforming inmate may request to be housed in a institution of the gender with which the inmate identifies. Upon receipt of the request, the site administration shall notify the Department's Director of Behavioral Health. In the event that a request may potentially present security, safety, or operational difficulties within the correctional environment, the Director of Behavioral Health shall refer the request to the Deputy Commissioner of the Prison Division and the Deputy Commissioner of Clinical Services and Reentry for a security review. The security review shall take into account the inmate's individual history of incarceration and present circumstances.

2. Arrangements for transition to the institution of the gender with which the inmate identifies shall occur unless the Commissioner certifies in writing that the particular placement would not ensure the inmate's health or safety or that the placement would present management or security problems.

The Commissioner shall articulate specific and justifiable reasons based on security, safety and/or operational concerns, in writing. The security review shall be completed within ninety (90) calendar days of the referral from the Director of Behavioral Health.

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Michigan

State Policy: State of Michigan Department of Corrections Lansing Director's Office Memorandum 2022-28, effective Jan. 1, 2022 (supersedes DOM 2021-33 (10/21/2021))

HOUSING REQUEST

Offenders with a gender identity defined above may make a housing request to be reviewed by the Gender Dysphoria Review Committee (GDRC). If there is a specific safety or security concern, the offender may request protection pursuant to PD 05.01.140 "Prisoner Placement and Transfer".

Housing assignments shall be considered on a case-by-case basis utilizing the below "Individual Risk Assessment of Housing Placement," including considering whether a placement would compromise the offender's health and safety and whether the placement would present any management or security problems.

The MDOC shall not place transgender or intersex offenders in dedicated facilities, units, or wings solely on the basis of such identification, status, or based solely on their external genital anatomy.

State Policy: Michigan Department of Corrections Policy Directive No. 03.03.140, Sexual Abuse and Sexual Harassment of Prisoner – Prison Rape Elimination Act (PREA), effective April 5, 2021.

RISK ASSESSMENTS

KK. All prisoners shall be assessed during an intake screening and upon transfer to another facility for their risk of being sexually abused by other prisoners or being sexually abusive toward other prisoners.

. . .

Prisoners shall be asked:

1. Questions relating to mental, physical, or developmental disabilities.

2. Whether they are, or are perceived to be, gay, lesbian, bisexual, transgender, intersex, or gender nonconforming.

3. Whether they have been previously victimized.

4. What is their perception of being vulnerable?

. . .

LL. Results of the risk assessment shall be considered when making housing, bed, work, education, and program assignments with the goal of keeping separate those prisoners at high risk of being sexually victimized from those at high risk of being sexually abusive. . . Employees designated by the Warden shall complete both PREA Risk Assessments if any of the following occur:

1. Within 72 hours of a prisoner's arrival at a correctional facility, including intake.

2. Whenever warranted due to a referral, request, incident of sexual abuse, or receipt of additional information that may increase the prisoner's risk of being sexually abused by other prisoners or being sexually abusive toward other prisoners.

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MM. In addition to the PREA Risk Assessments required in Paragraphs KK and LL employees designated by the Warden shall complete a PREA-Risk Assessment Review-Prison:

1. No earlier than 14 days but no later than 30 calendar days of arrival, including intake (unless the prisoner transfers from the facility prior to 30 days).

2. When it has been 12 months since the last review.

The review shall consist of review of the most recent victim and aggressor risk assessments, including asking questions relating to mental, physical, or developmental disabilities, whether they are, or are perceived to be, gay, lesbian, bisexual, transgender, intersex, or gender nonconforming, previous victimization, or their own perception of vulnerability.

NN. If the assessment/review indicates a change in designation, the PREA overall designation shall be updated in the Department's computerized database. If a prisoner self-identifies as an LGBTI prisoner, the specific category they identify shall be documented to ensure their safety and necessary services.

State Policy: Michigan Department of Corrections Policy Directive, No. 04.06.184, Gender Dysphoria, Effective June 26, 2017.

C. Gender Dysphoria Collaborative Review Committee (GDCRC) . . .

G. When making housing and programming assignments, the GDCRC and facility staff shall consider on a case-by-case basis whether a placement would compromise the prisoner's health and safety and any management or security concerns.

. . .

INDIVIDUAL MANAGEMENT PLAN AND PLACEMENT

L. If the evaluation(s) supports a diagnosis of Gender Dysphoria, the evaluator shall formulate an individual management plan in consultation with the referring integrated treatment team and GDCRC. An Individual Management Plan for Gender Dysphoria (CHJ-339) form shall be used for this purpose. The evaluator shall give consideration to all of the following in development of the plan:

1. Facility placement and housing in accordance with Prison Rape Elimination Act (PREA) standards (generally single-occupancy cell);

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Minnesota

State Policy: State of Minnesota Department of Corrections Policy No. 202.045, Management of Transgender/Gender Non-Conforming/Intersex Offenders/Residents , effective 6 Oct. 2020.

PROCEDURE

A. Screening

1. When an offender/resident identifies through kite or other communication as transgender, gender non-conforming, or intersex, facility mental health staff must complete a transgender psychological screening, including the offender's/resident's view with respect to their own safety.

2. Mental health or health services staff may not search or physically examine any offender/resident for the sole purpose of determining the offender's/resident's genital status. This prohibition equally applies to transgender, gender non-conforming, or intersex offenders/residents. If the offender's/resident's mental health or medical provider needs to know the offender's/resident's genital status for the purposes of treatment or the offender's/resident's safety, it may be determined through conversations with the offender/resident, by reviewing medical records or, if necessary, by learning that information as part of a broader medical examination conducted in private by a medical practitioner.

3. Facility health services staff must have an offender/resident (or a resident's guardian) sign a release of information to obtain medical/mental health records when the offender/resident:

a) Expresses a history of receiving care for gender dysphoria or other gender-related treatment;

b) Identifies as, or has self- reported to any staff member as, gender non-conforming; or

c) Has other medical/clinical conditions related to gender.

. . .

B. Placement

1. Facility staff determine the preliminary placement of an offender/resident who is transgender, gender non-conforming, or intersex upon intake screening, until the transgender committee makes a placement recommendation and the deputy commissioner – facility division determines placement.

2. In deciding whether to assign a transgender, gender non-conforming, or intersex offender/resident to a facility for male or female offenders/residents, the department considers on a case-by-case basis whether a placement would ensure the offender's/resident's health and safety, and whether the placement would present management or security problems. The department must not place lesbian, gay, bisexual, transgender, gender nonconforming, or intersex offenders/residents in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such offenders/residents from harm.

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3. Upon completion of the transgender psychological screening, the facility mental health director must forward the screening to the chair of the transgender committee and the offender/resident. The chair schedules a meeting of the transgender committee.
4. The transgender committee makes recommendations regarding facility placement and other matters that it deems necessary to maintain the offender's/resident's safety, such as single cell/room or shower restrictions. The committee must consult with the offender/resident and may seek consultation from outside health care providers to assist in making its recommendations. The committee considers factors such as the offender's/resident's security level, criminal/adjudication and disciplinary history, current gender expression, medical and mental health needs, vulnerability to sexual victimization, and the likelihood of perpetrating such abuse on other offenders/residents.
5. The transgender committee must promptly forward its recommendations regarding facility placement and other matters to the deputy commissioner – facility division for a final decision. The deputy commissioner should, whenever possible, review the committee's recommendations within five days and inform the committee chair whether the recommendations have been approved, denied, or modified. The deputy commissioner's determination is sent to the members of the transgender committee and to the offender/resident, and must be placed in the offender's/resident's health record.
6. A facility may seek reconsideration of the deputy commissioner's placement decision for any reason. The warden must contact the deputy commissioner, who may ask the transgender committee chair to convene another meeting and make recommendations if the deputy commissioner determines that further evaluation is needed.
7. Placement and programming assignments for each transgender, gender non-conforming, or intersex offender/resident must be reassessed at least twice each year by the deputy commissioner – facility division or designee, to review any threats to safety experienced by the offender/resident.

State Policy: State of Minnesota Department of Corrections Policy No. 202.105, Multiple Occupancy Cell/Room Assignment Policy, effective April 16, 2019.

B. Single cell restriction

1. Mental health and medical restrictions:

. . .

e) The transgender committee must review a transgender offender's need for a single cell and recommend placement as appropriate (see Policy 202.045, "Management of Transgender/Gender Non-Conforming/Intersex Offenders").

State Policy: State of Minnesota Department of Corrections Policy No. 202.057, Sexual Abuse/Harassment Prevention, Reporting, and Response, effective Aug. 21, 2018.

3. Offender screening

a) When an offender arrives at a DOC facility as a new commitment, release violator, department transfer, jail delegation, or non-department admission, a qualified staff person completes a PREA Intake Screening Tool in COMS, screens the offender's available file information, and interviews the offender to assess his/her potential for vulnerability to sexual abuse and/or tendencies to engage in sexually aggressive behavior.

. . .

PREA screening information is used to determine housing, bed assignment, work assignment, and the need for further referral based on the information (see Division Directive, 202.105, “Multiple Occupancy Cell/Room Assignment”). For additional information on placement options, see the Reference section for links on administrative segregation, offender incompatibility, and transgender offenders.

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Mississippi

State Policy: Mississippi Department of Corrections Policy No. 20-16, Management of Transgender and Intersex Offenders, effective May 1, 2021.

(b) The Transgender Committee shall assess, review, and manage inmates who identify as transgender or intersex on a case-by-case basis, in a respectful manner, considering each inmate's individual circumstances, including but not limited to the inmate's physical sexual characteristics, gender identification, physical presentation, behavior and programming needs.

. . .

PROCEDURE A: Intakes Screening Process

Prison Rape Elimination Act (PREA): MDOC states that its intake screening shall consider, at a minimum, the following criteria to assess individuals risk for sexual victimization – whether the individual is known or perceived to be gay, lesbian, bisexual, transgender, intersex or gender nonconforming.

1. Initial Designation

Staff will seek to identify inmates who present or identify as transgender or intersex upon delivery to MDOC during intake processing, based on available information from the county, the inmate (including the inmate's stated gender identity, if any) and as developed by staff.

2. Identification at Intake (Appropriate and Professional Questioning)

a. Staff will interview inmates regarding their sex and gender identity only when necessary to develop information for making appropriate intake and housing assignments, classification assignments, programming assignments; to provide healthcare and health assessments; and as necessary for the inmate's health or safety, or for the safe, secure, and orderly operation of the facility.

c. Designated staff will submit information to the Transgender and Intersex Committee for review and determination of appropriate housing placement.

. . .

3.Initial Placement in Holding Cell:

When staff identify an inmate who presents or identifies as transgender or intersex during intake processing, staff will place the inmate in a holding cell with no other inmates present to provide for the inmate's safety and to provide the inmate with a measure of privacy pending further review.

. . .

5. Intake Housing Assignment:

a. Following initial placement in a holding cell, an inmate who identifies as transgender or intersex during intake processing will be assigned to a single cell in the Infirmary, on a space available basis, until the appropriate housing for the inmate has been staffed by the Transgender Intersex Committee.

b. If there are no infirmary beds available, the functional unit manager or designee will assign the inmate to appropriate alternative housing in the facility, and document the reasons for the alternative housing assignment.

. . .

PROCEDURE B: Management of Transgender or Intersex Inmate Housing Assignment and Processing after Intake

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1. The Transgender and Intersex Committee will collect and review relevant information regarding inmates who identify as transgender or intersex and make appropriate facility and housing assignment decisions on a case-by-case basis.

2. The Transgender and Intersex Committee will notify staff at the receiving facility of the facility and housing assignment decisions regarding the inmate prior to the inmate's transfer.

3. When an inmate is assigned to a facility by the Transgender and Intersex Committee, designated facility staff will determine and assign the inmate to the appropriate housing within the facility unless the inmates' housing assignment has been specifically directed by the Transgender and Intersex Committee.

4. An inmate who identifies as transgender or intersex may not be transferred to another facility without the approval of the Transgender and Intersex Committee.

. . .

Identification after Facility Assignment:

If an inmate identifies as transgender or intersex after being assigned to a facility, staff will notify the Contract Health Provider (CHP) and the PREA Compliance Manager at the receiving facility. The PREA Compliance Manager will notify the Transgender and Intersex Committee and gather information for the Transgender and Intersex Committee's review.

Appropriate and Professional Questioning:

Contract Health Provider and PREA Compliance Manager will interview the inmate regarding the inmate's assigned sex at birth, gender identify, gender expression, and security concerns.

State Policy: Mississippi Department of Corrections SOP No. 20-14-01, Prison Rape Elimination Act of 2013, effective Feb. 1, 2015.

Use of Screening Information

Prisons and Jails: (a) The agency shall use information from the risk screening required by§ 115.41 to inform housing, bed, work, education, and program assignments with the goal of keeping separate those inmates at high risk of being sexually victimized from those at high risk of being sexually abusive.

(b) The agency shall make individualized determinations about how to ensure the safety of each inmate.

(c) In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.

(d) Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experienced by the inmate.

(e) A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration.

. . .

(g) The agency shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status,

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unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates. PREA [§ 115.42]

. . .

Community Corrections: (a) The agency shall use information from the risk screening required by § 115.241 to inform housing, bed, work, education, and program assignments with the goal of keeping separate those residents at high risk of being sexually victimized from those at high risk of being sexually abusive.

(b) The agency shall make individualized determinations about how to ensure the safety of each resident.

(c) In deciding whether to assign a transgender or intersex resident to a facility for male or female residents, and in making other housing and programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the resident's health and safety, and whether the placement would present management or security problems.

(d) A transgender or intersex resident's own views with respect to his or her own safety shall be given serious consideration.

. . .

(f) The agency shall not place lesbian, gay, bisexual, transgender, or intersex residents in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such residents. PREA [§ 115.242]

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Missouri

State Policy: Missouri Department of Corrections Department Procedural Manual IS5-3.3, Transgender and Intersex Offenders, effective July 6, 2019.

III. PROCEDURES:

A. RECEPTION AND DIAGNOSTIC

1. If the gender of the offender is unknown at the time of intake, staff members shall not search the offender for the sole purpose of determining the offender's genital status. Privacy considerations must be afforded to transgender and intersex offenders.

a. Genital status may be determined during conversations with the offender, reviewing medical records, or if necessary, through a broader medical examination conducted in private by the appropriate health care staff members.

. . .

B. TRANSGENDER COMMITTEE

1. Each institution shall have a transgender committee to make informed recommendations regarding the health and safety of transgender and intersex offenders.

2. The transgender committee shall meet with the offender within 10 working days of either the offender's arrival to the facility or upon learning the offender's transgender or intersex status and every 6 months thereafter.

. . .

3. Following the initial ITC meeting, the ICMHS or designee will:

a. Meet with the offender to discuss health and safety needs related to the offender's transgender or intersex status;

. . .

4. Within 10 working days of the meeting with the offender, the transgender committee review form shall be completed and forwarded to the transgender review team.

a. The transgender committee review shall include the following:

. . . (5) Review of programming assignments and accommodation needs; (6) Need for showering accommodations; and (7) The transgender committee's recommendations.

5. Within 10 working days of receiving the transgender committee review form the transgender review team shall complete the review and approve the recommendations as submitted, or with modifications to the PREA site coordinator.

. . .

C. INSTITUTIONAL PROTOCOLS

1. Housing assignments for transgender and intersex offenders shall be made in accordance with the institutional services procedure regarding offender housing assignments.

a. Offenders are not to be placed in restrictive housing solely based on gender identity or intersex status.

State Policy: Missouri Department of Corrections Institutional Services Procedural Manual 1S5-3.1, Offender Housing Assignments, effective Feb. 9, 2019.

III. PROCEDURES:

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A. HOUSING ASSIGNMENT CRITERIA

1. Offender housing assignments shall be made in an individualized, nondiscriminatory manner and not be made based on race, religion, nationality, political belief or sexual orientation.

. . .

C. TRANSGENDER HOUSING ASSIGNMENTS:

1. The transgender committee is responsible for determining a permanent housing assignment for each transgender or intersex offender, and prior to this assignment shall meet with each offender to determine his vulnerability within the general population and length of time living as the acquired gender.

2. Transgender and intersex housing assignments shall not be made based solely on genitalia but must consider the offender's health and safety and the security of the facility through a review of the respective classification, medical and mental health records.

State Policy: Missouri Department of Corrections Department Procedural Manual D1.8.13, Offender Sexual Abuse and Harassment, effective July 1, 2017.

b. Housing assignment for transgender and intersex offenders will be made as outlined in this procedure, on a case-by-case basis by the institutional transgender or intersex committee or designee of the community confinement facilities to ensure the health and safety of the offender in accordance with the institutional services procedure regarding offender housing assignments and the probation and parole procedure regarding risk assessment and housing assignments.

. . .

c. All housing, cell, bed, education, and programming assignments for transgender or intersex offenders will be made in accordance with the institutional services procedures regarding offender housing assignments and programming assignments.

. . .

D. TRANSGENDER COMMITTEE

1. Each institution will have a transgender committee to make informed decisions regarding the health and safety of transgender and intersex offenders assigned at that facility.

. . .

5. The transgender committee meeting and subsequent written report shall include the following:

. . .

g. recommendations regarding the offender's health and safety to include:

(1) housing assignment,

(A) Housing assignments for transgender or intersex offenders shall not be made based solely on genitalia but must consider the offender's health and safety and the security of the facility through a review of the respective classification, medical and mental health records.

(B) The transgender or intersex offender's own views with respect to his safety shall be given serious consideration when determining housing.

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Montana

State Policy: Montana Department of Corrections Policy Directive 1.1.17, Prison Rape Elimination Act of 2003 (PREA), revised June 22, 2021.

9. In deciding whether to assign a transgender or intersex offender to a facility, and in making other housing and programming assignments, the Department will consider on a case-by-case basis the placement's effect on the offender's safety, whether the placement would present management or security problems, and whether such placement would likely endanger the safety of other offenders.

A review committee consisting of a qualified health care professional, qualified mental health professional, PREA coordinator, chief legal counsel or designee, and the Montana State Prison and Montana Women's Prison wardens or designees will determine appropriate facility placement of transgender and intersex offenders based on their review of all relevant information.

a. The review committee will conduct an individual assessment of each transgender and intersex offender based upon their specific areas of expertise, knowledge, and control.

b. This assessment will occur as soon as possible following notification to the Department that a transgender or intersex offender has been committed to a Department secure facility but no later than 30 days after arrival at a facility.

c. The review committee may request information or participation from other subject matter experts as needed.

d. All documentation, information, and recommendations of the review committee are confidential and will be maintained in a secure location.

e. The recommendation for facility placement by the review committee will be given to the Director for final approval.

11. Placement and programming assignments for each transgender or intersex offender will be reassessed at least twice each year to review any threats to safety experienced by the offender. A transgender or intersex offender's own views with respect to his or her own safety will be given serious consideration.

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Nebraska

Please note that the Nebraska Department of Correctional Services publishes Prison Rape Elimination Act (PREA) audits to its website that include summaries of certain relevant policies. For example, please see: Nebraska Department of Corrections Prison Rape Elimination Act (PREA) Audit Report: Adult Prisons and Jails, Nebraska State Penitentiary, final audit date July 7, 2021. To put in a public records request for policies related to housing transgender inmates you may email DCS.PublicRecords@nebraska.gov.

State Policy: Nebraska Department of Correctional Services Policy No. 203.11, Sexual Assault/Abuse, revised July 31, 2022.

E. PREA Standard Secured Facility 115.15 a-f / Community Facilities 115.215 a-f Limit To Cross Gender Viewing And Searches

. . .

4. NDCS shall not search or physically examine a transgender or intersex inmate for the sole purpose of determining the inmate's genital status. If an inmate's genital status is unknown, it may be determined during conversations with the inmate, by reviewing medical records or, if necessary, by learning that information as part of a broader medical examination conducted in private by a medical practitioner.

. . .

6. NDCS will recognize the gender of an inmate based on the legal classification of that inmate as listed on their birth certificate as it is recorded on the inmate's birth state. When a transgender inmate has been approved to change their birth certificate to reflect how the inmate identifies and the birth certificate has been changed, and the NDCS has received an official copy of the new birth certificate, the inmate can be approved to have a pat search and a safety search conducted by the appropriate staff member. However, if an inmate has undergone gender transformation surgery and failed to change their gender on their birth certificate, the inmate's reproductive organs may be a factor in NDCS gender designation of the inmate (as determined by the initial medical screening). In the event a female post for male facilities and or a male post for female facilities is needed on shift to perform these pat/safety searches, the facility will adjust their staffing plan to adhere to the PREA standards.

7. Policy 204.01, Inmate Property Control states all inmates regardless of gender, have an option to choose one of the following state-issued underwear options: boxers, unisex boxers, or panties. Male inmates who have undergone hormone treatment, and, as a result, developed breasts, will be permitted to request a medical evaluation to determine whether a medical basis exists requiring the inmate be provided a bra. If the inmate disagrees with the result of the medical evaluation, he/she may appeal the decision of the Director.

. . .

Q. PREA Standard Secure Facility 115.42 a-g / Community Facility 115.242 a-g Use of Screening Information

1. Facilities will utilize information from the risk screening to inform housing, bed, work, education and program assignments with the goal of keeping those inmates who are at high risk of being sexually victimized from those who are at high risk of being sexually abusive. The institution's physical plant, staffing levels, size, and number of programs and services, as well as activity schedules, will determine the extent to which separation is possible or contacts minimized. Computer tracking of high risk inmates within an institution may be utilized. Facilities

will make individualized determinations about how to ensure the safety of each inmate. (ACI-3D-10, ACI-3D-12)

2. In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, NDCS shall consider on a case-by-case basis whether a placement would ensure the inmates health and safety, and whether the placement would present management or security problems.

3. Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year and shall consider any threats to safety experienced by the inmate. The PREA Compliance Manager will also complete an in person assessment and submit a written report that will be maintained in the inmates file indicating a review was conducted.

4. A transgender or intersex inmate's own views with respect to the inmate's own safety shall be given serious consideration.

5. Transgender and intersex inmates shall be given the opportunity to shower separately from other inmates.

6. NDCS shall not place lesbian, gay, bisexual, transgender or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

State Policy: Nebraska Department of Correctional Services Policy No. 201.03, Identification of Potential Aggressors and Victims, revised July 31, 2022.

I. SCREENING PROCEDURES: (PREA standard Secure facilities -115.41 a-c/ Community facilities-115.241 a-c)

All inmates shall be assessed during an intake screening at reception facilities and upon each transfer to another facility for their risk of being sexually abused/assaulted by other inmates or sexually abusive toward other inmates. This screening shall ordinarily take place within 72 hours of arrival at the facility and be conducted using an objective screening instrument.

. . .

C. The intake screening shall consider, at a minimum, the following criteria to assess inmates for risk of sexual victimization:

1. Physical condition/weakness makes him/her vulnerable (unrelated to age)

2. Slight physical stature (short and/or thin)

3. Smaller, unassertive, lacks self-confidence, timid or withdrawn

4. Vulnerable to sexual victimization due to nature of his/her crime (sex offender or all non-violent offenses in history)

5. Cognitive concerns/comprehension difficulties (difficulty answering questions/special education placement)

6. Reports history of sexual victimization

7. Age related vulnerability (young/naïve or older/fragile)

8. Detained for immigration purposes only

9. Inmate concerned about assault, pressuring, victimization

10. Inmate is or is perceived to be gay, lesbian, bisexual, transgender, intersex, or gender non-conforming

11. History of serious mental or physical disability

12. Passively acknowledges homosexuality

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. . .

E. Designated staff will notify housing unit, mental health and case management staff of inmates rated high for aggression or victimization for further review and monitoring.

F. If the screening indicates an inmate has experienced prior sexual victimization or has previously perpetrated sexual abuse, whether it occurred in an institutional setting or in the community, that inmate shall be offered a follow-up meeting with mental health staff within 14 days of the intake screening. Mental Health will complete the Mental Health Screening form (Attachment A).

II. FOLLOW UP ASSESSMENTS (PREA standard Secured facilities 115.41f/ Community facilities (115.241f)

Within a set time period not to exceed 30 days from the inmate's arrival at the facility, the facility will reassess the inmate's risk of victimization or abusiveness based upon any additional, relevant information received by the facility since the 72 hour intake screening. When an inmate is transferred to another facility the inmate must be screened within 72 hours of arrival and then again within a set time frame not to exceed 30 days.

. . .

V. REASSESSMENTS USING THE POTENTIAL FOR SEXUAL ASSAULT/SEXUAL VICTIMIZATION SCREENING INSTRUMENT (PREA standard Secured facilities 115.41g/Community facility 15.241g).

. . .

F. Review and rescore each known transgender inmate twice a year. If this rescore suggests any change in the inmate's aggression or victimization potential, changes to the inmate's housing, programming and work assignments shall be made as appropriate.

State Policy: Nebraska Department of Correctional Services Policy No. 010.08, Transfer Order, revised Dec. 31, 2021.

III. CLEARANCE FOR TRANSFER

Each inmate, whether on initial transfer from the DEC or the Nebraska Correctional Center for Women (NCCW) or an inter-institution transfer shall be thoroughly screened and appropriate clearance for transfer given by designated team members. Information required on either the Initial Transfer Order or the Inmate Transfer Order forms shall be accurately completed, with special attention given to the following:

. . .

C. Reason for Transfer

A specific explanation of the need for transfer is to be stated; i.e., routine transfer, inappropriate custody, pending disciplinary action (identify specific charges), approved for community programming, parole violation pending preliminary hearing/revocation hearing (identify specific charges, i.e. programming needs, pending investigation and/or restrictive housing placement needs, custody change, etc.).

D. Medical Clearance

Facility medical team members shall review each transfer to determine appropriateness for placement at the intended facility. Consideration should be given to specific medical needs, pending appointments, accessibility/accommodation needs, etc. Medical team members shall note specific details if their recommendation differs from the transfer order. Facility team members shall consult with Central Office classification team

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members when the medical review is in conflict with agency security needs and/or individual programming needs.

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Nevada

State Policy: Nevada Department Of Corrections Administrative Regulation 573, Prison Rape Elimination Act Screening and Classification, effective March 1, 2018.

573.01 PREA SCREENING AND CLASSIFICATION

1. All inmates shall be assessed, during intake and upon transfer to another facility, for their risk of being sexually abused by other inmates or sexually abusive toward other inmates in accordance with federal PREA standards.

A. Initial screening should take place as soon as possible, but shall be completed within 72-hours of arrival at an institution or facility.

C. Transgender/Intersex inmates will be reassessed every six (6) months for placement and programming needs.

. . .

573.02 INSTITUTIONAL PLACEMENT BASED ON GENDER IDENTITY

1. In deciding whether to assign a transgender or intersex inmate to a facility/institution for male or female inmates, and in making other housing and programming assignments, the agency shall consider, on a case-by-case basis, whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security risks. Reference should also be made to Administrative Regulation 494. the following factors will be taken into account for housing and programming:

a. A transgender or intersex's own views with respect to his or her own safety;

b. Transgender or intersex inmates shall be given the opportunity to shower separately from other inmates; and

c. Lesbian, gay, bisexual, transgender, or intersex inmates will not be placed in dedicated facilities, units, or wings solely on the basis of such identification or status.

2. A classification review committee consisting of a certified medical/mental health practitioner, Inspector General's Office, PREA management team member, and a designated staff member from Offender Management will determine appropriate institutional placement of a transgender or intersex inmate based on the review.

a. The classification review committee will conduct an individual assessment based upon their specific area of expertise, knowledge, and control.

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New Hampshire

State Policy: New Hampshire Department of Corrections Policy and Procedure Directive Statement No. 6.85, Standards for Treatment of Gender Dysphoria, May 2014, reviewed May 2015.

C. Housing and Facility Transfer

a. In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, the NHDOC shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems and document such reasoning in writing.

b. All housing determinations shall be made in accordance with the Prison Rape Elimination Act ("PREA") and its implementing regulations.

State Policy: New Hampshire Department of Corrections Policy and Procedure Directive No. 5.19, Prison Rape Elimination Act Procedures, March 2014, reviewed March 2020.

F. Classification

. . .

9. In deciding whether to assign a transgender or intersex inmate to a facility and in making housing and program assignments, classification should consider on a case-by-case basis whether the placement will ensure the person's health and safety, and whether the placement would present management or security problems. Placement and program assignments shall be reassessed at least twice each year to review any threats to safety experienced by the person. The person's own views with respect to his or her own safety shall be given serious consideration.

10. Lesbian, gay, bisexual, transgender or intersex inmates shall not be placed in dedicated facilities or housing units solely on the basis of such identification or status.

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New Jersey

State Policy: New Jersey Department of Corrections Internal Management Procedure No. PCS.001.TGI.01, Transgender, Intersex and Non-Binary Inmates, effective Dec. 15, 2019, revised July 1, 2021, to be reviewed on or about July 1, 2023.

III. POLICY

It is the policy of the NJDOC to address the needs of transgender, intersex, and non-binary inmates in a manner consistent with federal Prison Rape Elimination Act (PREA) standards, the New Jersey Law Against Discrimination (NJLAD), and in accordance with departmental regulations, policies and procedures.

Once the NJDOC learns and confirms an inmate's gender identity, using the procedures laid out in this document, it shall determine the inmate's facility and housing unit assignment, with a presumption that the inmate will be housed in line with their gender identity. The PREA Accommodation Committee (PAC) may deviate from the presumptive placement after an individualized determination and upon written certification that the placement would jeopardize the inmate's health and safety. When making such determinations, the inmate's own views with respect to their safety shall be given serious consideration.

. . .

B. Housing and Classification Reviews

9. The NJDOC considers whether the particular placement would present management or security problems in all housing and programmatic assignments. This consideration will be applied equally to all inmates, regardless of their sex or gender identity, and may justify a deviation from an inmate's presumptive placement in line with gender identity for cisgender, transgender, intersex, and non-binary inmates alike. Although this consideration therefore applies to Part IV.B of this document, under no circumstances will a transgender, intersex, or non-binary inmate's placement in line with their gender identity be considered a management or security problem solely due to their gender identity.

10. Once the NJDOC learns and confirms the gender identity of an inmate using the procedures laid out in this document, it shall determine the inmate's facility and housing unit assignment, with a presumption that the inmate will be housed in line with their gender identity. The PREA Accommodation Committee (PAC) may deviate from the presumptive placement after an individualized determination and upon written certification that the placement would jeopardize the inmate's health and safety.

a. In some cases, NJDOC may learn and confirm that an inmate's gender identity is neither male nor female. In such cases, inmates shall be housed in the most appropriate placement, taking into consideration whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems. The inmate's own views with respect to their safety shall be given serious consideration.

3. In deciding transgender inmates' precise housing and programming assignments, pursuant to PREA Standard 115.42 (b-e), the NJDOC makes individualized determinations about how to ensure the safety of each inmate, and considers on a case-by-case basis whether a particular placement would ensure the inmate's health

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and safety. When determining such assignments, the transgender inmate's views with respect to their safety shall be given serious consideration. At all times, the facility assignment will be in compliance with Parts IV. B.1-2 of this document.

4. A transgender, intersex, or non-binary inmate's housing assignment will be reviewed by the PREA Accommodation Committee (PAC) as follows:

a. At all times, the PAC will ensure that the inmate's facility assignment complies with Parts IV.B.1-2 of this document. If the PAC has a substantiated, credible, and non-discriminatory basis for believing that an inmate is not sincere in their assertion of their gender identity and is asserting it for an improper purpose, the PAC may ask further questions to better understand the inmate's identity and offer the inmate a fair opportunity to present additional information. The PAC must make a written record of the basis for its belief, which shall be included in the inmate's classification file and available to the inmate should they challenge the PAC's decision pursuant to Part IV.B.3(e) or other procedures.

b. Because multiple classifications and placements exist for male inmates within male facilities and female inmates within female facilities, in deciding the specific placement for a particular inmate, the PAC will consider:

i. All aspects of an inmate's social and medical transition when formulating recommendations to address safety and privacy concerns, including factors such as behavioral history, institutional adjustment, overall demeanor, and likely interactions with other inmates; and the inmate's own views with respect to safety.

ii. Whether a placement would threaten the orderly operation, management and security of the correctional facility and/or pose a risk to other inmates in the facility (e.g., considering inmates with histories of trauma, privacy concerns, etc.). This consideration will be applied equally to all inmates, regardless of their gender identity.

iii. The following factors on a case-by-case basis:

1. The Gender Identity Information Form, if completed;
2. custody level and sentencing information;
3. criminal history;
4. institutional disciplinary history;
5. current gender expression;
6. the inmate's own views regarding safety;
7. medical and mental health needs/information/status;
8. compliance with medically recommended treatments;
9. vulnerability to sexual victimization;
10. likelihood of perpetrating sexual abuse;
11. facility-specific factors including physical layouts; and
12. any other relevant information.

These factors are also considered on a case-by-case basis in deciding the specific placement for a cisgender inmate.

iv. The considerations outlined in Part IV.B.3(b)(i) through (iii) shall not apply to decisions to place a transgender inmate in a facility in line with their gender identity.

. . .

5. The housing assignment/transfer of inmates approved to be housed in a different facility due to their gender identity will be handled in accordance with all applicable operational policies and procedures and the provisions set forth in N.J.A.C. 10A.

6. In keeping with PREA standard 115.42, the particular placement of a transgender, intersex, or non-binary inmate shall be reassessed by the IPCM and supplemental staff as deemed appropriate by the facility Administrator, or the Administrator's designee, at least twice each year.

. . .

8. In accordance with PREA standards, all transgender, intersex, and non-binary inmates will receive an in-person review every six months to assess the inmate's institutional adjustment and safety. The PREA Compliance Manager will meet with the inmate prior to this review and complete the Gender Identity Information Reassessment form. This form will be maintained by the IPCM. A record of these reviews will be recorded and maintained in the inmate's iTAG Progress Notes.

9. In keeping with PREA standard 115.42, NJDOC shall not place transgender, intersex, or non-binary inmates in dedicated facilities, units, or wings solely on the basis of such identification or status.

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New Mexico

State Policy: New Mexico Corrections Department No. CD-150800, Transgender, Intersex, and/or Gender Non-Conforming, reviewed and revised March 11, 2022.

D. Inmates are screened within 24 hours of arrival at the facility for potential vulnerabilities or tendencies of acting out with sexually aggressive behavior. Housing assignments are made accordingly.
. . .
G. The facility shall not search or physically examine a transgender or intersex inmate for the sole purpose of determining the inmate's genital status. If the inmate's genital status is unknown, it may be determined during conversations with the inmate, by reviewing medical records, or, if necessary, by learning that information as part of a broader medical examination conducted in private by a medical practitioner. [§115.15e]
H. The agency shall use information from the risk screening required by § 115.41 to inform housing, bed, work, education, and program assignments with the goal of keeping separate those inmates at high risk of being sexually victimized from those at high risk of being sexually abusive. [§115.42a]
I. The agency shall make individualized determinations about how to ensure the safety of each inmate. [§115.42b]
J. Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experienced by the inmate. [§115.15d]
. . .

1. During intake and the initial classification screening and when determining whether inmates are transgender or gender non-conforming, the following shall be taken into consideration:

- **a.** Inmate appearance and behavior and whether or not it matches the gender marker on the inmate's arresting paperwork or identification materials
- **b.** Self-Reporting from the inmate
- **c.** Inmate's past history, if known
- **d.** Any alerts from the transporting agency

2. Any other documentation that may be available to intake and classification staff upon initial screening to include:

- **a.** Gender identity
- **b.** Gender marker on identification documents
- **c.** Social gender role in the community prior to incarceration (i.e. was the person living daily life as a man or woman)
- **d.** Any past diagnosis or treatment for Gender Dysphoria.
- **e.** The inmate's views regarding the safest placement option.
- **f.** An assessment by medical and mental health staff of the potential health impact of placement in a male or female setting (e.g. on PTSD or Gender Dysphoria).

3. The inmate should be temporarily housed in a single cell, for his or her own protection, and the paperwork be immediately and confidentially forwarded to The Cabinet Secretary or Director of Adult Prisons.
4. The inmate may choose to fill out a Transgender Preference Form documenting the individual's preferred pronoun and name. The form will be retained in the inmate's file in the classification section.

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5. If the intake process and classification has determined that an inmate is transgender, intersex, or gender non-conforming they will contact the Director of Adult Prisons in a confidential manner for further assessment in placing the inmate within seventy-two (72)

. . .

B. Transgender Advisory Group

1. The Cabinet Secretary or Director of Adult Prisons will assign a Transgender Advisory Group when notified by intake/classification that an inmate presents as transgender, intersex, or gender non-conforming to determine individualized placement in an appropriate facility. The group will take into consideration the needs, vulnerability and safety of the inmate as well as the safety of the current population at the receiving facility.

2. In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, the Transgender Advisory Group shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems. [§115.42c]

3. The agency shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.[115.42g]

4. The Transgender Advisory Group will review the intake and classification documentation and make a determination as to the placement of the individual in an expeditious manner.

. . .

5. A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration. [115.42e]

6. If needed, the Transgender Advisory Group may consult with an identified member of the Transgender Resource Center of New Mexico who is knowledgeable with the issues surrounding transgender and gender nonconforming people to advise on appropriate housing to the classification officer and/or the programs and services needed by the individual.

. . .

8. The Transgender Advisory Group will make decisions based on majority within fourteen (14) days of the inmate's intake date. The decisions made are for advisory only and can be overridden, changed, or enhanced by the [SIC] The Cabinet Secretary or Director of Adult Prisons at any time during the process.

. . .

Attachment C . . . To be filled out either by an offender or a staff member with input from the offender. Requests the following information: Birth Sex; Gender Identification; Transgender: MTF or FTM; Name Preference: Pronoun Preference (He/She); Housing Preference: Male Unit, Female Unit or no preference; preference to be searched by a male or female staff member.

State Policy: New Mexico Corrections Department, CD-150800, Transgender, Intersex, andor Gender Non-Conforming (March 11, 2022)

To be filled out either by an offender or a staff member with input from the offender. Requests the following information: Birth Sex; Gender Identification; Transgender: MTF or FTM; Name Preference: Pronoun Preference (He/She); Housing Preference: Male Unit, Female Unit or no preference; preference to be searched by a male or female staff member.

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State Policy: New Mexico Corrections Department No. CD-150100, Offender Protection Against Abuse; Sexual Misconduct; Reporting Procedures; PREA, revised May 29, 2020, reviewed March 26, 2021.

> **I.** Inmates shall be screened within 48 hours of arrival at the facility and reassessed 25 days after the inmate's arrival, for potential vulnerabilities or tendencies of acting out with sexually aggressive behavior. Inmates will be reassessed thereafter due to a referral, request, incident of sexual abuse or sexual harassment, or receipt of additional information that bears upon an inmate's risk of sexual victimization or abusiveness. Housing and program assignments will be made accordingly. Transgender and Intersex inmates shall be screened every six months. In the event of an incident, both the inmate perpetrator and/or inmate victim will be re-screened.[4-4281-2] [§115.41]
>
> . . .
>
> **K.** Transgender and intersex inmates shall not be searched or examined by non-medical staff for the sole purpose of determining the inmate's genital status. Genital status shall be determined by interviews or medical records reviews. A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration.
> [§115.15] [§115.42]

Local Bernarillo County Policy: Bernarillo County Metropolitan Detention Center No. SEC 8.17, Inmate Searches, revised May 2022.

> Staff are prohibited from searching of physically examining a transgender or intersex inmate for the sole purpose of determining the inmate's genital status.

Local Bernarillo County Policy: Bernarillo County Metropolitan Detention Center No. ICL 17.00, Classification / Screening / Housing Categories / Non-Discrimination, effective July 15, 2013.

> **H. General Housing Assignments:**
>
> . . .
>
> **2.** In addition to other relevant information, Classification staff will also consider the screening for risk of victimization and abusiveness conducted pursuant to Policy.
> **3.** In deciding whether to assign a transgender or intersex inmate to the MDC for male or female inmates, and in making other housing and programming assignments, the facility will consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.
>
> **a.** A transgender or intersex inmate's own view with respect to his or her own safety will be given serious consideration.
>
> **4.** Transgender and intersex inmates will be given the opportunity to shower separately from other inmates regardless of where they are housed.
> **5.** MDC will not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated units or pods solely on the basis of such identification of status, unless such placement is in a dedicated unit or pod established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

Local Santa Fe County Policy: Santa Fe County Adult Detention Facility No. J-B-05, Inmate Protection Against Abuse and Sexual Misconduct Reporting Procedures, revised Jan. 31, 2020.

8. Inmates must be screened within 24 hours of arrival at the facility by the case manager assigned to booking. Inmates must be re-screened within 30 days after the inmates arrival by the respective case manager assigned to the inmates unit, for potential vulnerabilities or tendencies of acting out with sexually aggressive behavior. In the event of an incident, both the inmate perpetrator and/or inmate victim will be re-screened within 14 days (conducted by the unit's assigned case manager). Inmates will also be re-screened due to a referral, request, incident of sexual abuse, or receipt of additional information that bears upon an inmates risk of sexual victimization or abusiveness. Housing and program assignments will be made accordingly. Transgender and Intersex inmates shall be screened every six months. [§115.41] [4-ALDF-4D-22-1] [SC-59]

. . .

14. Transgender and intersex inmates shall not be searched or examined by non-medical staff for the sole purpose of determining the inmate's genital status. Genital status shall be determined by interviews or medical records reviews. A transgender or intersex inmates own views with respect to his or her own safety shall be given serious consideration. [§115.15] [§115.42]

Local Doña Ana County Policy: Doña Ana County Detention Center No. SOP 2A-29, Prison Rape Elimination Act, dated March 1, 2020.

A. Cross Gender Viewing and Searches/Searches of Transgender Detainees [§ 115.15]

a. Searches . . .

iv. No staff member shall conduct a search of a transgender or intersex detainee solely for the purpose of determining genital status. If the detainee's genital status is unknown, it may be determined during conversations with the detainee, by reviewing medical records, or, if necessary, by learning that information as part of a broader medical examination conducted in private by a medical practitioner.

. . .

C. Use of Information Obtained from Screening [§ 115.42]

a. The Detention Center shall use information from the risk screening to inform housing, bed, work, education, and program assignments with the goal of keeping separate those detainees at high risk of being sexually victimized from those at high risk of being sexually abusive.

b. The Detention Center shall make individualized determinations about how to ensure the safety of each detainee.

c. In deciding whether to assign a transgender or intersex detainee to a facility for male or female detainees, and in making other housing and programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the detainee's health and safety, and whether the placement would present management or security problems.

d. Placement and programming assignments for each transgender or intersex detainee shall be reassessed at least twice each year to review any threats to safety experienced by the detainee.

e. A transgender or intersex detainee's own views with respect to his or her own safety shall be given serious consideration.

f. Transgender and intersex detainees shall be given the opportunity to shower separately from other detainees.

g. The Detention Center shall not place lesbian, gay, bisexual, transgender, or intersex detainees in dedicated facilities, units, or wings solely on the basis of such identification or status unless pursuant to a legal settlement or judgment.

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New York

State Policy: State of New York Department of Corrections and Community Supervision (DOCCS) Administrative Directive No. 4021, Inmate Reception/Classification, dated Jan. 23, 2019.

Transfer to a General Confinement Facility. . .

5. Each inmate shall be re-assessed by an ORC (Offender Rehabilitation Coordinator) for their risk of being sexually abused by other inmates or sexually abusive toward other inmates using the gender appropriate PREA Risk Screening Form #115.41M or Form #115.41F, in accordance with the facility-specific PREA Risk Screening Facility Operation Manual. Sexual orientation and gender identify information from the PREA Risk Screening shall be used to assign Other Security Characteristics as appropriate.

. . .

Transgender/Intersex Inmate Classification and Placement

1. An inmate who identified as transgender, intersex, or gender non-confirming during PREA Risk Screening, or who has a diagnosis of Gender Dysphoria or Intersex (identified via extended classification codes), shall be asked additional questions by their ORC using the "Gender Identity Interview," Form #115.41GI, regarding their gender identification, expression, and preferences. The interview will also document the inmate's statement regarding their safety in connection with decisions regarding their housing and placement. Information from the Gender Identity Interview will be used to assist the Department in making an individualized assessment of the inmates placement and program assignments in order to maximize the inmates safety.

2. Upon request from an inmate who identifies as transgender or intersex for a transfer from a male classified facility to a female classified facility, or vice versa, the ORD shall notify the Supervising Offender Rehabilitation Coordinator (SORC) upon completion of the Gender Identity Interview, Form #115.41GI. The SORC shall notify the Deputy Superintendent for Program Services and the facility's designated Assistant Deputy Superintendent PREA Compliance Manager. The Deputy Superintendent for Program Services/Deputy Superintendent for Reception/Classification shall notify the Director of Classification and Movement of the inmate's request via electronic mail, including the completed Form #115.41GI, and the most recently complete gender-appropriate PREA Risk Screening Form #115.41M or Form #115.41F, which shall be used to assist the Department in making an individualized assessment of the inmate's placement and program assignments, in order to maximize the inmate's safety. The request will be forwarded to the Central Office Transgender Placement Review Committee for a case-by-case assessment. Housing assignment by gender identify will be made when appropriate.

3. An inmate who identifies as transgender or intersex will not be placed in a gender-specific facility, housing unit, or program based solely on their external genital anatomy.

4. A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration.

Local New York City Policy: The City of New York Office of the Mayor Executive Order No. 16, Access to Single-Sex City Facilities Consistent With Gender Identity and Expression, March 7, 2016.

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WHEREAS, it is the policy of the City of New York that transgender and gender non-conforming people be assured of their right to access to single-sex facilities controlled by the City so that they enjoy equal treatment in the terms and conditions of City employment and the ability to access City services;

. . .

Section 2. Single-Sex Facility Policy. All employees of City agencies ("Agencies") and all members of the public using City services must be allowed to use the single-sex facility within facilities owned or operated by the City that most closely aligns with their gender identity or expression without being required to show identification, medical documentation, or any other form of proof or verification of gender.

Local New York City Policy: The City of New York Department of Correction (DOC) Administrative Directive 4498R-A, Lesbian, Gay, Bisexual, Transgender, Intersex, Gender Non-Binary and Gender Non- Conforming Inmates, with Attachments, dated December 3, 2014 effective October 22, 2019.

I. Purpose

This policy is intended to provide a housing determination process that most closely aligns with an individual's gender identity and provide supplemental guidelines to staff on operational issues related to LGBTI-GNC-GNB inmates, including identification, searches, housing and programming decisions, and access to programs, services, commissary, toiletries, and clothing items.

. . .

B. Guidelines

1. Facility Determination

a. In deciding housing placement for a transgender, intersex, or gender non-binary inmate, the Department shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security concerns. Persona shall be housed in the facility consistent with their gender identity, absent overriding concerns for the detained person's safety.

b. The SCDU (Special Consideration Determination Unit) is responsible for making case-by-case decisions about the housing and placement of a transgender/intersex inmate and gender non-binary inmates.

c. Decisions are based on, but not limited to, the following, when determining risk of vulnerability and safe placement of each transgender, intersex and gender non-binary individual:

d. The inmates own views of where they feel safest, as documents on the SCH form, shall be given serious consideration. If an inmate changes their mind of where they feel safest, a new form must be completed and submitted to the SCDU;

e. The inmates prior institutional history (to include incidents and grievances);

f. The inmates prior violent or sexual crime history;

g. Whether the inmate is at risk because the inmate is or is perceived to be gay, lesbian, bisexual, transgender, intersex, gender non-confirming, or gender non-binary;

h. The inmates gender identify including any designation from the PREA Intake Questionnaire (Form PREA-2);

i. Whether the inmate has previously experienced sexual victimization;

j. The inmate's physical appearance, age, and physical build;

k. Any relevant information obtained about the inmate from the PREA unit, security staff or medical and mental health staff, including information received since arrival;

l. Whether the placement would present management or security problems;

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m. Separation orders or requests between inmates and/or staff; and

n. Any other relevant information about the inmate, including information that would present management or security problems.

o. A final determination shall be made by the SCDU. The SCDU will provide its determination for appropriate housing within three (3) business days excluding holidays, unless extenuating factors exist which would require an extension of such time limit. Extenuating factors must be documented and verifiable. The SCDU must retain records concerning all housing applications and determination for no less than three (3) years.

p. LGBTI-GNC and GNB inmates will be processed identified by themselves or by facility staff (at any time while in custody), and processed according to defined procedures.

2. Identifying LGBTI-GNC and GNB Inmates

a. When identifying LGBTI-GNC and GNB Inmates the following should be taken into consideration:

i. Inmate self-reports

ii. Information provided by the PREA Unit.

iii. Information provided by the Health Care Provider.

iv. Information contained in the Securing Order.

b. Inmates who are known to the Department to identify as transgender, intersex, or non-binary, or who have self-identified as such, shall be given the opportunity to complete the “Special Considerations Housing Form” (Attachment – A) during intake, booking or at any time while in the Department’s custody. This is an ongoing obligation.

c. Inmates may request the Special Considerations Housing Form from the Department any time after intake, while in the Department’s custody.

d. The Department shall consider all Health Care provider referrals for placement in the SCU.

e. Process for Transgender, Intersex and Non-Binary Individuals

i. Inmates with securing orders that indicate male shall start their custody at a male housing facility. Those inmates who identify as transgender, intersex or non-binary during their PREA screening and meet the guidelines for facility level determinations set forth in paragraphs IV.B.1.c. shall be transferred to a female housing facility for intake and transgender/intersex new admission processing to await determination of the SCDU.

ii. Those individuals whose securing order indicate male; and who identify as gender non-binary during their PREA screening, shall continue through the intake and new admission process at the male housing facility to await a determination from the SCDU.

iii. Inmates with securing orders that indicate female or transgender female shall start custody at a female housing facility. Inmates who identify as transgender, intersex or gender non-binary during PREA screening and meet the guidelines for facility determinations set forth in paragraph III.B.1.c shall remain at the female housing facility, complete the intake and transgender/intersex new admission process and await determination from the SCDU.

iv. All inmates who identify or have been identified as transgender, gender non-binary or intersex must complete the SCH form (Attachment – A) during the intake process.

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v. The facility, command, or division accepting an inmate's written SCH form shall immediately forward the form to the SCDU for processing via email SCDUCommittee@doc.nyc.gov.

f. The Special Considerations Determination Unit will provide its written determination for appropriate housing within three (3) business days excluding holidays, unless extenuating factors exist, which would require an extension of such time limit. Extenuating factors must be verifiable, and the reason must be documented.

g. An inmate's self-identification as transgender, intersex, and gender non-binary shall be sufficient for consideration for housing by gender identity absent evidence that the inmate is requesting admission for reasons unrelated to identifying as such, or if there are security or management concerns preventing placement within SCU and/or female facility.

3. Inmates who qualify will be housed based on their gender identity in a facility determined by SCDU.

a. Inmates who have indicated a preference for a female facility will be housed either in SCU or considered for placement in an otherwise appropriate housing unit in the female facility (i.e., General Population Unit).

i. Admission to SCU will be on a voluntary basis.

ii. Inmates who do not qualify to be housed at a female housing facility and/or SCU or who have listed a preference to be housed at a male facility that is determined to be appropriate will be transferred to a male housing facility for processing.

iii. Such inmates should be interviewed for Protective Custody (PC).

b. Justification for denial to housing in the inmate's requested housing facility must be documented in writing and notice of the determination and their right to reconsideration provided to the inmate.

Local New York City Policy: The City of New York Department of Correction (DOC) Administrative Directive 5011R-A Elimination of Sexual Abuse and Sexual Harassment, effective May 31, 2019.

5. HOUSING LESBIAN, GAY, BISEXUAL, TRANSGENDER, AND INTERSEX INMATES

a. In deciding whether to assign a transgender or intersex inmate to a male or female facility and in making other housing and programming assignments, the Department shall consider on a case-by-case basis whether a placement would ensure the health and safety of the inmate and whether the placement would present management or security problems.

b. Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experiences by the inmate.

c. A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration.

d. Transgender and intersex inmates shall be given the opportunity to shower separately from other inmates.

e. The Department shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated facilities, units, or wings based solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit or wing established in connection with a consent decree, legal settlement or legal judgment for the purpose of protecting such inmates.

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d. For more information as it pertains to lesbian, gay bisexual, transgender, intersex, gender non-binary and gender non-conforming inmates, see Directive 4498, “Lesbian, Gay, Bisexual, Transgender, Intersex and Gender Non-Forming Inmates.”

Local Steuben County Policy: Steuben County Sheriff’s Office, General Order 16, Transgender, Intersex, Gender, Non-Binary, and Gender Nonconforming People is Custody, effective June 1, 2020.

E. Housing

1. Housing determinations shall be individually tailored and based upon classification factors and an evaluation of the inmate’s emotional and physical well-being and in compliance with NYS Commission of Correction regulations.

2. A person taken into custody shall, if that person so desired, have the right to request placement in a sex-segregated unit . . . that is consistent with that person’s gender identity and affirmed sex. The Sheriff and jail shall make a reasonable effort to grant such a request if in accordance with the security requirements of the facility, as set forth in paragraph (3) of this section.

3. If the Sheriff, Jail Superintendent, medical staff, or mental health staff have significant safety, security or health concerns related to a person’s stated housing preference pursuant to paragraph (1) above, the Sheriff or designee may, on a case-by-case basis, deny that person’s housing placement request

North Carolina

State Policy: North Carolina Department of Public Safety Policy and Procedure Ch. F Section .3400, Offender Sexual Abuse and Sexual Harassment Policy, issued June 9, 2022.

(M) The transgender or intersex offender, upon self-disclosure, may be housed temporarily in a single cell or bed with officer visibility until the Facility Transgender Accommodation Review Committee (FTARC) convenes and determines permanent housing placement based on the offender's concerns for safety, request for accommodations, screening information, and high-risk status.

. . .

(3) Use of Screening information:

(A) The information from the screening for risk of victimization and abusiveness shall be used to inform housing, bed, work, education, and program assignments with the goal of keeping separate those offenders at high risk of being sexually victimized from those at high risk of being sexually abusive.

(B) The following procedures will be followed to manage housing and bed assignments:

(i) Any offender identified as a high-risk abuser or high risk of being sexually victimized shall be restricted from double-cell housing (5-ACI-2C-02).

. . .

(iv) The facility shall make individualized determination for bed assignments, based on facility housing designs, to ensure the safety of each offender.

[. . .]

(E) In deciding whether to assign a transgender or intersex offender to a facility for male or female offenders, and in making other housing and programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the offender's health and safety, and whether the placement would present management or security problems.

(F) Placement and programming assignments for each transgender or intersex offender shall be reassessed by the case manager at least twice each year to review any threats to safety experienced by the offender.

(G) A transgender or intersex offender's own views with respect to his or her own safety shall be given serious consideration.

(I) The agency shall not place lesbian, gay, bisexual, transgender, or intersex offenders in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such offenders (5-ACI-4B-34).

State Policy: North Carolina Department of Public Safety Policy and Procedure Ch. F, Section .4300, Evaluation & Management of Transgender Offenders, amended July 13, 2021.

(f) A transgender offender requesting accommodation shall be scheduled for an interview with the Facility TARC.

. . .

(g) The Facility TARC process should reflect individualized consideration and review.

. . .

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(h) The transgender offender shall be informed of any Facility TARC privacy and housing recommendations within 48 hours of the meeting.

. . .

(A) When the transgender offender requests accommodation related to their gender identity, the multidisciplinary Facility TARC will convene.

(B) A diagnosis of Gender Dysphoria is not required for an offender to be considered for accommodation.

. . .

(G) All accommodation requests will be reviewed on a case by case basis considering the offender's medical and mental health history as well as risk safety profile.

. . .

(E) Facility housing considerations – Offender may be approved for alternate housing assignments within the facility to enhance staff supervision.

. . .

Non-routine accommodation requests shall be reviewed by the Facility TARC and forwarded to the Division TARC for review . . . When reviewing non-routine accommodations, the Division TARC will consider on a case-by-case basis whether an accommodation will ensure the offender's health and welfare without compromising facility safety and security.

All accommodation requests for surgical intervention or gender-identity-consistent facility transfer shall be reviewed by the Division TARC with recommendations referred to the Assistant Commissioner of Prisons and Director of Health & Wellness Services for review and determination.

. . .

The Division TARC will review non-routine accommodations to include but not limited to:

(B) Gender-consistent facility assignment – Decisions to transfer an offender to a facility consistent with their gender identity are not permanent and will be continually reassessed for safety and security considerations.

. . .

.4307 ADDITIONAL CONSIDERATIONS AND PROVISIONS

. . .

(4) An offender shall not be placed in Restrictive Housing on the basis of gender identity alone (5-ACI-4B-34).

State Policy: North Carolina Department of Public Safety, Policy and Procedures, Ch. E, Section .2600, Reasonable Accommodations for Offenders with Disabilities, issued March 31, 2021.

.2604 DEFINITIONS

(a) Disability . . .

(4) The following conditions do not constitute disabilities: transvestitism, transexualism . . . gender identity disorders not resulting from physical impairments. . .

.2605 POLICY

It is the policy of Prisons to establish procedures for an offender to request an accommodation for a qualified disability that affects a major life activity and to ensure that:

(a) Every offender, including an offender with a qualified disability, shall be housed in a manner that provides for their safety and security(5-ACI-2C-11);

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(b) Reasonable accommodations are made only if the accommodations pose no direct threat to the individual requesting the accommodation or cause an undue hardship on Prisons;
(c) Reasonable accommodations shall be made to the physical structure of housing for an offender with a qualified disability to accommodate for the physical limitations of the disabled offender and facilitate the offender's inclusion in facility life(5-ACI-2C-11);
(d) The Facility ADA Coordinator will ensure visually impaired offenders are assigned to bottom bunks in their assigned living area.
(e) Reasonable accommodations shall be made to facility jobs, programs, activities, and services to permit accessibility by a qualified offender with a disability(5-ACI-2C-11);
. . .

Please note, the Fourth Circuit rejected a reading of the ADA "that would exclude gender dysphoria from the ADA's protections." See Williams v. Kincaid, 45 F.4th 759 (4th Cir. 2022).

Local Mecklenburg County Policy: Mecklenburg County Sheriff's Office Classification Policy No. 4.35, PREA-Classification, effective Sept. 2020.

IV. Procedure:

A. Within 72 hours of incarceration, excluding holiday and weekends, the Initial Assessment Team (IAT) will review all collected information provided form the Intake and booking process; and that provided by the resident(s). Additionally, the Initial Classification Questionnaire (ICQ) shall be completed to further substantiate determinations made on identified LGBTI residents. Moreover, the residents' current charges, DCI, and past or present institutional behaviors, past or present history of Sexual Assaultive offenses will be considered as part of the housing process.
B. The IAT will make notification to the Classification Agent of an identified LGBTI resident whose gender is to be determined.
C. The Gender Committee shall conduct a hearing, which is to be documented in the Offender Management System (OMS). The Committee shall consider all available information and records when determining gender and appropriate housing. Identified LGBTI residents shall not be placed in segregated or protective custody based solely on their gender and physical characteristics. The identified LGBTI resident shall be present for the hearing regarding both gender designation, classification level, and housing; and has the right to speak and present information.
D. The Committee shall determine if the resident will be housed in general housing or protective custody consistent with the determined gender identity and/or genitalia. The Committee shall document the decision/recommendation action within the Medical section of OMS. The Major of the Facility shall be provided the information, and may approve, override, or amend the Committee's decision, in writing, to the Gender Committee. Once final determination has been deemed, the affected resident shall be made aware of the findings in writing by the Committee or Classification Section.
E. IAT will assess residents based on factual criteria and apparent needs, rather than personal biases, conflicts, values, or prejudices.
F. During the ICQ interviews, IAT members shall screen each LGBTI resident for individual placement decisions that prioritize the physical safety and emotional wellbeing of the residnet. Additionally, Form: CR 4.35 Attachment #1 shall be completed.

G. Additionally, residents will be assigned to housing units consistent with their custody levels, and with guidance from the Gender Committee.

. . .

V. Housing Managers:

A. Any LGBTI resident who remains in custody after their initial court appearance will be assigned a Housing Manager (HMR) based on housing location.

. . .

C. The HMR shall also consider each LGBTI resident's own views with respect to his or her safety while incarcerated.

D. Any identified LGBTI resident the HMR feels may be high risk for sexual victimization shall not be placed in involuntary segregated housing unless an assessment of available alternatives has been made, and there is no available alternative means of separation from likely abusers.

. . .

F. The Gender Committee or HMR shall assign such residents to involuntary segregated housing only until an alternative means of separation from likely abusers can be arranged, and such an assignment shall not ordinarily exceed a period of 30 days.

. . .

K. When making housing placement decisions, consider the host of issues specific to LGBTI residents.

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North Dakota

State Policy: North Dakota Department of Corrections and Rehabilitation Policy No. and Security 4B-07, Gender Non-Conforming Persons, effective Sept. 27, 2012, revised July 18, 2022.

4. POLICY: The Department shall provide access to evaluation, housing placement, and access to services for adults in custody who claim to be undergoing or claim to have undergone treatment for Gender Dysphoria; adults in custody who appear to be, or claim to be, gender-non-conforming; and adults in custody having other clinical conditions in which the biological sex or gender assignment is unclear. The Department shall offer appropriate gender-related behavioral health services and other medically care throughout the adult in custody's incarceration. (4-4305)

5. PROCEDURES:

A. Gender Identity Committee:

. . .

4. Functions:

a. The committee will discuss any requests from the adult in custody regarding specific treatment, services, housing, and property and determine the course of action.

. . .

c. The committee will develop an individual management plan that reflects specialized housing and property needs, if applicable.

d. If applicable, the Gender Liaison will work with the facility Treatment Coordinator to assign appropriate staff to develop an individualized treatment plan to address the adult in custody's specific medical, behavioral health, and adjustment needs and review and the facility Treatment Coordinator will approve the plan prior to its implementation.

. . .

4. Adults in custody who identify as gender non-conforming or transgender, but who do not meet criteria for a Gender Dysphoria diagnosis, may be given special property or housing accommodations based on their individual needs and safety considerations or by their request as required by PREA related policy. These may be done through the committee's development of an individualized plan without creating an individual treatment plan.

. . .

G. Placements of Adults in Custody:

1. In general, adults in custody are placed in facilities, in accordance with their sex assigned at birth, as determined by the gender indicated on their most recent form of government-issued identification.

2. Exceptions may be made to routine housing practices for adults in custody who identify as gender non-conforming or transgender based on individual needs and the safety concerns of others.

State Policy: North Dakota Department of Corrections and Rehabilitation Policy No. and Security 3C-04, (PREA) Prison Rape Elimination Act of 2003, effective Aug. 17, 2011, revised May 12, 2022.

15. § 115.41/115.341 Screening for Risk of Sexual Victimization and Abusiveness.

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c. Adults in custody and juveniles may not be disciplined for any refusal or nondisclosure during screening regarding gender identity, sexual orientation, intersex condition, disability status, or prior sexual victimization.

16. § 115.42/115.342 Use of Screening Information.

a. Adults – Refer to Policy 4A-01, Admission, Reception and Orientation, and Transfers; Policy 4B-07, Gender Non-Conforming Persons; PREA Rating Assessment Manual.

b. Juveniles – Refer to Policy 4A-01, Admission, Screening, Orientation, and Transfers; Policy 4B-07, Gender Non-Conforming Persons.

State Policy: North Dakota Department of Corrections and Rehabilitation Policy No. and Security 3A-06, Control of Contraband, Searches of Adults in Custody, Visitors and Facilities, effective March 28, 2011, revised Dec. 10, 2021.

f. Staff may not search or physically examine a transgender or intersex adult in custody for the sole purpose of determining the adult in custody's genital status. [PREA 115.15]

1.) If the adult in custody's genital status is unknown, it may be determined through conversation with the adult in custody, by reviewing medical records, or, if necessary by learning that information as part of a broader medical examination conducted in private by a medical practitioner.

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Ohio

State Policy: State of Ohio Department of Rehabilitation and Correction No. 79-ISA-05, Lesbian, Gay, Bisexual, Transgender, Intersex (LGBTI) Policy, effective July 13, 2015.

LGTBI Screening and Initial Placement

1. All inmates shall be screened for the risk of being sexually abused by other inmates or sexually abusive toward other inmates in accordance with Department Policy 79-ISA-04, PREA Risk Assessments and Accommodation Strategies.
2. In addition to the criteria in Department Policies 53-CLS-01, Inmate Security Classifications Levels 1 through 4; 53-CLS-04, Level 5 Classification; and 52-RCP-07, Reception Center Housing Assignments staff shall consider on a case-by-case basis whether the housing assignment for a transgender or intersex inmate would ensure the inmate's health and safety and whether the placement would present management or security problems.

The transgender or intersex inmate's own views shall be given serious consideration during the classification process and shall be documented. The PREA Accommodation Strategy Team (PAST), consisting of the Operational Compliance Manager, Unit Management Chief, medical and mental health staff, and other staff as necessary shall complete a PREA Accommodation Strategy in accordance with Department Policy 79-ISA-04, PREA Risk Assessments and Accommodation Strategies, for all transgender and intersex inmates.
. . .
3. LGBTI inmates shall not be placed in dedicated facilities, units, or wings solely on the basis of such identification unless placement in a dedicated facility, unit, or wing has been established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

State Policy: State of Ohio Department of Rehabilitation & Correction No. 69-OCH-07, Gender Identification and Treatment, effective August 15, 2021.

E. Evaluation and Treatment of Gender Dysphoria

b. If it is determined that the incarcerated individual satisfies the current DSM5 criteria for gender dysphoria, the diagnosis shall be recorded by Behavioral Health Operations in the incarcerated individual's EHR.
. . .
2. Referrals for additional accommodations shall be made to the institution's Accommodation Strategy Team and shall comply with ODRC Policies 79-ISA-04, PREA Risk Assessment and Accommodation Strategies, and 79-ISA-05, LGBTI Policy.

State Policy: State of Ohio Department of Rehabilitation and Correction No. 79-ISA-01, Prison Rape Elimination, effective November 15, 2021.

1. As set forth in ODRC Policy 79-ISA-04, PREA Risk Assessments and Accommodation Strategies, all incarcerated individuals shall be screened and assessed upon admission to ODRC and for all subsequent intra-system transfers for their risk of being a victim of sexual abuse or their likelihood of committing sexual abuse . . . As a result of these screenings, incarcerated individuals shall be assigned

a PREA classification. The UMC, or in their absence, the acting UMC, shall make appropriate housing assignments based upon PREA classifications by using a PREA accommodation strategy. The PREA accommodation strategy team (PAST) shall make appropriate housing assignments for transgender and intersex incarcerated individuals.

State Policy: State of Ohio Department of Rehabilitation and Correction No. 79-ISA-04, PREA Risk Assessments and Accommodation Strategies, effective April 1, 2021.

2. All transgender and intersex incarcerated individuals all receive a special screening at least every six (6) months as set forth in ODRC Policy 79-ISA-05, Lesbian, Gay, Bisexual, Transgender, Intersex (LGTBI) Policy.

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Oklahoma

Policy: Oklahoma Department of Corrections OP-030601, Prison Rape Elimination Act, effective Dec. 1, 2021, revised March 28, 2022.

VII. Screening/Assessment at Reception Centers (5-ACI-3D-10)

All inmates receive a mental health screening and/or evaluation, conducted by a trained mental health professional during the initial reception and assessment process within 24 hours of arrival in accordance with OP-140114 entitled "Screening New Arrivals."

. . .

1. The facility shall use information from the risk screening evaluation in accordance with "Cell Assessment Form" (OP-030102, Attachment A) in order to inform staff making housing, work, education, and program assignments; with the goal of keeping those inmates who are at risk of being sexually victimized separate from those at high risk of being sexually abusive.(PREA 115.42(a), 115.81(d))

a. Each facility shall make individualized determinations about how to best ensure the safety of each inmate. (PREA 115.42(b))

b. In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, the facility shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.(PREA (115.42(c), 115.242(c))

c. Placement and programming assignments for each transgender or intersex inmates shall be reassessed at least twice each year to review any threats to safety experienced by the inmate. (PREA 115.42(d))

d. A transgender or intersex inmate's own view with respect to his or her own safety shall be given serious consideration.(PREA 115.42(e))

e. Transgender and intersex inmates shall be given the opportunity to shower separately from other inmates. (PREA 115.42(f))

. . .

g. Management of gender nonconforming inmates will be handled in accordance with OP-140147 entitled "Determination and Management of Inmates with Gender Dysphoria."

h. The agency shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates. (PREA (115.42(g), 115.242(g))

State Policy: Oklahoma Department of Corrections OP-140147, Determination and Management of Inmates with Gender Dysphoria, effective June 24, 2021.

Inmates may self-identify as transgender, but not have gender dysphoria.

. . .

Following diagnosis of gender dysphoria, if the inmate requests specific treatment and/or reasonable accommodations, the inmate must submit a “Request for Health Services” (DOC 140117A) form for each housing or treatment request. Housing requests will be submitted to mental health services.

. . .

D. Housing

Housing will be in accordance with OP-030601 entitled “Oklahoma Prison Rape Elimination Act.” The agency shall not place transgender or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status. Health services staff may make housing recommendations to the facility head, after any necessary medical and/or mental health assessments have been completed. Complex cases that require a more extensive review will be submitted to the Personal Identity Administrative Review Authority (PIARA) by health services staff, a facility’s PREA compliance manager, or a facility/unit head.

. . .

IV. Initiating Review by Personal Identity Administrative Review Authority (PIARA)
Inmates with a confirmed gender dysphoria diagnosis may have their housing, clothing, and health care needs specific to their gender associated request assessed by PIARA. This committee will consider each inmate on a case-by-case basis to ensure fair, safe, and appropriate management of their gender associated requests. (PREA 115.42/115.242)

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Oregon

Policy: State of Oregon Department of Corrections DOC Policy 40.1.13, Prison Rape Elimination Act, effective Jan. 20, 2022.

C. SCREENING FOR RISK OF SEXUAL VICTIMIZATION AND ABUSIVENESS

. . .

f. In deciding AIC housing and programming assignments for transgender or intersex AICs, the department shall consider on a case-by-case basis whether a placement would ensure the AIC's health and safety, and whether the placement would present management or security problems.

(1) If requested, transgender and intersex AICs shall be given the opportunity to shower separately from other AICs.

(2) A transgender or intersex AIC's own views with respect to their own safety shall be given serious consideration.

2. The PREA Compliance Manager or designee will review placement and programming assignments for each transgender or intersex AIC at least twice each year to review any threats to safety experienced by the AIC.

3. The department makes individualized determinations about how to ensure the safety of each AIC including housing, work assignments and access to services.

4. The department shall use information from the risk screening to inform housing, bed, work, education, and program assignments with the goal of keeping separate those AICs at high risk of being sexually victimized from those at high risk of being sexually abusive.

Local Multnomah County Policy: Multnomah County Sheriff's Office, Corrections Division Special Order 14-32, December 31, 2014.

7.7.13 General Requirements

1. MCSO has zero tolerance for any staff sexual misconduct or sexual harassment directed toward LGBTQI arrestees/inmates. MCSO has zero tolerance for derogatory terms used toward LGBTQI inmates. . . .

2. When discussing an arrestees/inmates sexual orientation or gender identity, for the purpose of making placement and custody decisions, Corrections Division staff must recognize the sensitive nature of the topic and potential repercussions for the inmates. Appropriate staff sharing will be conducted through the CIMS system. Sharing this information with other inmates is inappropriate, and absolutely prohibited.

3. Conversations involving the transgender inmate in regards to their gender identity shall be conducted in private. Private areas may include; a medical exam room or single cell.

4. If an inmate discloses their sexual orientation or gender identity to staff without prompting during their custody, the staff member will report the information to their supervisor to ensure review of the inmate's classification.

5. In an effort to avoid confusion, and provide consistency from staff, an LGBTQI inmate's last name should be used when possible.

6. Staff shall not search, or physically examine a transgender-identified arrestee/inmate for the sole purpose of determining the inmate's sex at birth.

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7. Upon identification of a transgender inmate staff shall conduct searches in accordance with the inmate's identified gender, in accordance with Corrections Division Chapter 7.7 Searches.
8. Inmates may not be disciplined for refusing to answer or for not disclosing complete information in response to screening questions regarding gender identification.
9. Transgender Inmates will only be held in single cells for their protection. This housing option is to be non-punitive, and must not result in any unnecessary loss of privileges, programs or access to medical or mental health care.

. . .

7.7.14 Intake/Admissions . . .

3. When determining whether inmates identify as transgender, the following should be taken into consideration:

A. An arrestee's appearance or behavior does not match the gender marker on the arrestee's custody paperwork or identification;
B. The arrestee self- reports. If there is doubt or a question concerning the validity of the self-report, the deputy shall consult the Intake Sergeant;
C. The arresting/transporting agency has alerted the MCSO staff to the arrestee's transgender/gender identity;
D. Prior booking records/ medical records; and,
E. Identification carried by the person identifies their gender, or conflicting gender markers on identification.

4. Upon completion of the initial booking process the Sergeant shall determine placement of the arrestee in open holding or assignment to a single cell. This determination shall be made after consulting both medical staff and the arrestee.

. . .

7.7.16 Classification Criteria

1. Inmates identified as transgender shall be housed at MCIJ at dorm 18, or at MCDC in Module 4A, for up to 72 hours, excluding weekends and holidays, while the Transgender Review Board assesses appropriate housing options that address the following concerns:

A. Safety;
B. Protecting inmates at high risk for abuse;
C. Minimizing perceived or actual fear of becoming a victim of violence

2. In accordance with Corrections Division Operations Manual, Chapter 13, LGBTQI inmates will have opportunities to seek changes in classification through submission of a Service Request Form.

. . .

7.7.20 Transgender Review Board . . .

2. The Board shall meet to consider the case of each inmate who is identified as transgender within 72 hours, excluding holidays/weekends, from the time the inmate was booked into custody.
3. Prior to meeting, the Facility Commander, or their appointee, shall meet with the inmate to discuss the purpose of the Review Board and to explain the following:

B. Explaining the housing process;

. . .

4. The Transgender Review Board shall discuss the specifics of the transgender inmate's case to determine the most appropriate housing option(s).
5. The Transgender Review Board shall be given access to only the clinical information necessary to make a determination regarding the safe housing of the inmate.

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. . .

7. The Board will develop a Management Plan for the inmate which outlines the following:

A. Housing Assignment;

. . .

I. When developing the Management Plan, the Review Board shall:

J. Take into consideration preferences and requests made by the inmate. Such requests from the inmate shall be considered as part of the review board's discussions, but shall not be the only determining factors;

K. Consider the physical and psychological findings provided by medical staff; and

L. The safety and security issues as they relate to inmate and staff, as well as the operations of the facility.

. . .

8. The Board shall conduct reviews every 30 days to ensure transgender inmates remain appropriately housed.

. . .

11. The Transgender Review Board has the ultimate authority in regards to making any housing changes pertinent to a transgender inmate.

. . .

3. The Transgender Review Board will periodically review cases with approved community advocates. Names and medical conditions will be redacted from these reviews to ensure the inmate's rights within HIPPA are maintained.

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Pennsylvania

Policy: Pennsylvania Department of Corrections Policy DC-ADM 008, Prison Rape Elimination Act (PREA) Procedures Manual, Section 19 – Working with Transgender and Intersex Inmates, effective April 22, 2019.

A. General

1. Each facility shall ensure that staff effectively interact professionally and respectfully toward transgender and intersex inmates. (28 C.F.R. §115.31[a]) This specialized population may require a more non-traditional approach to best satisfy their housing, security, programming, and other needs.

. . .

5. Standards pertaining to the identification and management of transgender or intersex detainees are not applicable to Lockup facilities. When a detainee presents as gender nonconforming, the detainee shall not be double celled with any other detainee without direct sight and sound observation by staff in the Lockup.

B. Reception and Classification – General

Every inmate shall be assessed upon reception for potential risk of sexual abuse and victimization in order to identify at-risk inmates and ensure safety and security for all inmates committed to the custody of the Department. (28 C.F.R. §115.41) 1

1. The Prison Rape Elimination Act (PREA) Risk Assessment Tool (PRAT) shall be administered in accordance with Section 9 of this procedures manual. This assessment shall provide an opportunity for the inmate to self-identify as a transgender or intersex individual.

2. If an inmate identifies as a transgender in a State Correctional Institution (SCI), a DC-97, Mental Health Referral Form shall be completed and forwarded to the Psychology Department to initiate the procedures outlined in accordance with Department policy 13.2.1, “Access to Health Care Procedures Manual.”

. . .

e. The transgender or intersex inmate, upon self-disclosure, may be housed with a temporary Z-Code in SCIs or in single room status in Community Corrections Centers (CCCs) and Community Contract Facilities (CCFs) until the PCM and PAC convenes and determines permanent housing placement based on the inmate’s responses to the questions presented in the PAC Checklist.

f. If single room status is unavailable at the current CCC or CCF, the reentrant may, at the discretion of the Bureau of Community Corrections (BCC), be transferred to a facility that can accommodate single room status until the PAC is able to convene.

C. PREA Accommodation Committee (PAC)

1. The purpose of the PAC is to make individualized determinations about transgender or intersex inmates’ privacy, housing, and programming assignments to ensure their safety at the current facility. (28 C.F.R. §115.42[b])

2. PAC participants must consider all aspects of an inmate’s social and medical transition when formulating recommendations to address safety and privacy concerns affirmatively identified by the transgender or intersex inmate on the PAC Checklist.

. . .

5. PAC participants shall listen attentively to the inmate’s responses without interfering with the PCM’s line of questioning or challenging the inmate about any inconsistencies known to them by

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various sources. The PCM shall be responsible to ensure decisions of the committee remain consistent with applicable PREA Standards.

. . .

D. Administrative PREA Accommodation Committee (A-PAC)

1. In deciding whether to assign a transgender or intersex inmate to a facility that is consistent with his/her gender identity, and in making other privacy, housing, and programming assignments, the Department shall consider, on a case-by-case basis, whether a placement would ensure the health and safety of all impacted inmates and whether the placement or accommodation could potentially present management or security problems. (28 C.F.R. §115.42[c])

2. In SCIs and as requested by the BCC, the A-PAC shall be activated, and the local PAC shall meet as necessary when a transgender or intersex inmate has been identified and the facility or the inmate recommend or request the inmate be housed in a facility that is consistent with his/her gender identity.

3. A transgender/intersex inmate's own views, with respect to his/her own safety shall be given serious consideration. (28 C.F.R. §115.42[e]) (28 C.F.R. §115.242[d])

. . .

8. Decisions to transfer an inmate to a facility consistent with their gender identity are not permanent and shall be continually reassessed for their continued appropriateness

Local Sheriff's Office, City & County of Philadelphia Policy: Philadelphia Police Department Directive 4.15, Department Interaction with Transgender Individuals PLEAC 1.8.3, effective March 27, 2019.

4. GENDER CLASSIFICATION GUIDELINES FOR TRANSGENDER INDIVIDUALS WHO HAVE BEEN ARRESTED

A. An arrestee's gender will be classified as it appears on the individual's government-issued identification card.

1. If an individual explicitly informs personnel that they are transgender, and an officer finds a record for an individual (NCIC or any other law enforcement record) that lists a different gender from what the individual is currently presenting, the officer shall notify the cell block assistant (CBA) or police correctional officer (PCO) before delivering the individual into their custody. The CBA/PCO will document the information in the "Notes" section on the Prisoner Flow Chart/Medical Checklist and in the "Prisoner Log."

NOTE: If the individual refuses to provide their gender identity, the individual will be housed in a single cell according to their gender expression.

. . .

6. TRANSPORTATION, DETENTION, AND PROCESSING

. . .

B. Transgender arrestees will be housed in a secure single cell. The designated holding facility of adult transgender arrestees will be the Police Detention Unit (PDU).

. . .

D. Transgender juvenile arrestees shall be taken directly to Divisional Headquarters and housed in a secure single cell. The only exceptions will be for detainees suspected of sexual offenses or homicide, which will be handled by the pertinent investigative unit.

NOTE: If there is no empty cell for a juvenile prisoner at Divisional Headquarters, the ORS at Divisional Headquarters will call other districts within their division for secure holding placement.

1. Transgender juveniles taken into custody for Status Offenses only, will be taken directly to the designated non-secure holding facility for that division and be guided by Directive 5.5, "Juveniles in Police Custody, Appendix B."

. . .

NOTE: If the individual refuses to provide their gender identity, the individual will be housed in a single cell according to their gender expression.

Local Alleghany County Policy: Allegheny County Bureau of Corrections Policy No. 324, Guidelines for Detaining Transgender and Intersex Inmates, effective July 25, 2016, revised Feb. 21, 2019.

D. Housing

The following processes shall take place to determine appropriate initial and long-term housing of a transgender or intersex inmate:

1. Initial housing decisions shall be based on:

a. Inmate's responses to the Booking Observation Questions (BOQ);

b. Consideration of the inmate's health and safety; and

c. Consideration for placing the inmate in a location that minimizes management and security problems.

d. The Intake Sergeant will house the transgender or intersex inmate according to their legal gender identity until a committee appointed by the warden can determine long term housing.

. . .

E. Transgender/Intersex Housing Committee

1. The Warden shall appoint a committee to convene a housing meeting to determine long term housing for transgender and intersex inmates. This committee shall meet within 72 hours (excluding weekends and holidays) of the inmate being processed into the ACBOC. This committee will include representatives from the following departments: Administration, Medical, Mental Health, Classification and the PREA Compliance Manager.

2. The committee will determine whether to assign a transgender or intersex inmate to a male or female housing unit and in making other programming and security assignments. The ACBOC shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.

3. A transgender or intersex inmate own views with respect to his or her safety shall be given serious consideration. They will be given the opportunity to shower separately from other inmates.

4. To accomplish this, the committee will meet to discuss a recommended housing plan. The plan will be developed with consideration of an assessment completed by medical and mental health professionals, information obtained from the Booking Observation Questions, Classification process, PREA Assessment, and from an interview with the inmate. The written recommendation will be forwarded to the Warden for final approval.

5. The housing committee shall determine if the transgender or intersex inmate will be housed in the general population or in a protective custody unit of the gender consistent with their gender identity. The assignment shall be justified in writing and stored in the inmate's classification file. A housing plan will be developed and maintained by the Transgender/Intersex Housing Committee.

6. If it is determined that a transgender or intersex inmate can be housed in the general population, the inmate shall be transferred to a unit that matches his/her classification level.

. . .

8. A transgender or intersex inmate will be housed in administrative or protective custody when there is reason to believe the inmate presents a heightened risk to him/herself or others, or where the inmate fears he/she will be vulnerable to victimization in any other housing setting. This assignment shall be only for the period during which the heightened risk and/or fear exists. Transgender and intersex inmates in administrative segregation and protective custody shall have access to programs and services consistent with that status.

9. The Housing Committee will reassess placement and programming assignments for each transgender or intersex inmate at least twice a year to review any threats to safety experienced by the inmate.

. . .

Use of Screening Information/Confidentiality

2. Classification shall use this information to determine housing and bed assignments with the goal of keeping transgender and intersex inmates at high-risk to be victimized from those at high-risk to be abusive.

3. Classification and other Staff shall make individualized determinations on how to ensure the safety of every inmate.

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Puerto Rico

Policy: Orden Administrativa DCR-2018, Para Establecer La Política Pública Sobre Law Normas para el Afianzamiento del Respeto, La Adecuada Interacción y la No Discriminación con Personas de la Comunidad Lesbiana, Gay, Bisexual, Transgénero, Transexual, Queer, Intersexual y Asexual, fecha de efectividad, 5 diciembre de 2018).

VIII. NORMAS Y PROCEDIMIENTOS PARA LA ATENCIÓN ADECUADA DE MIEMBROS DE LA POBLACIÓN CORRECCIONAL Y JOVEN TRANSGRESOR DE LA COMUNIDAD LGBTTQIA

1. Al momento del ingreso de un miembro de la comunidad LGBTTQIA, el técnico de servicios socio-penales (TSS) o el trabajador social (TS) debe evaluar el riesgo de que pueda ser objeto de victimización y/o maltrato, reconociendo si la persona se percibe o expresa ser lesbiana, gay, bisexual, transgénero, transexual, intersexual, queer, intersexual, asexual o de un género no conforme, tomando las medidas que considere adecuadas con el apoyo de la Oficina de PREA y de Control de Población del DCR. [115.41]

2. La información recopilada como resultado de la evaluación de riesgo de victimización y maltrato, realizada al momento de ingreso, será utilizada para propósitos de ubicación en vivienda, cama, trabajo, educación y las asignaciones de programas, con el objetivo de mantenerlos seguro. [114.42 (a)]

3. Al decidir la ubicación de un miembro de la población correccional o joven transgresor miembro de la comunidad LGBTTQIA, en una institución, vivienda o programa para población masculina o femenina, se hará una evaluación individualizada considerando todas las características médicas y psicosociales del miembro de la población correccional o joven transgresor. Se debe tener en cuenta si dicha colocación aseguraría su salud y seguridad, a la vez que se examinará si la colocación presentaría problemas de índole administrativo o de seguridad, a los fines de hacer un balance de intereses coma parte de la toma de la decisión. [115.42 (c)]

4. La colocación y asignación en programas para cada miembro de la población correccional o joven transgresor de la comunidad LGBTTQIA, deberá ser reevaluada al menos dos (2) veces al año, para revisar cualquier amenaza a su seguridad [115.42 (d)] o al momento de sospechar que pueda existir una amenaza. Para esto se debe tener seriamente en cuenta la propia percepción de la persona en términos de su seguridad. [115.42 (e)]

5. Se le debe ofrecer la oportunidad a los miembros de la población correccional o joven transgresor que se identifican coma miembros de la población LGBTTQIA, a que utilicen las duchas separadas de otros miembros de la población correccional. [115.42 (f)] Para esto, se debe tener seriamente en cuenta si existe una amenaza a su seguridad; también, se debe incluir la percepción del miembro de la población correccional o joven transgresor que se identifica como de la comunidad LGBTTQIA.

6. No se podrán ubicar a miembros de la comunidad LGBTTQIA en unidades especializadas, con motivo único y exclusivo de dicha identificación, a menos que tal ubicación sea establecida coma resultado de consentimiento, acuerdo legal o juicio legal con el propósito de la protección a su persona. [115.42 (g)]

7. El aislamiento del miembro de la población correccional o joven transgresor en las instituciones, no puede ser motivado por su orientación sexual e identidad de género. No obstante, podrá aislarse en el ambiente menos restrictivo posible cuando se base en

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determinaciones de peligrosidad, seguridad, conducta o la naturaleza del delito que haya cometido. Deben existir motivos fundamentados para determinar el aislamiento.

8. El DCR proveerá áreas de vivienda habilitadas para la colocación voluntaria de aquellos miembros de la población correccional o joven transgresor de la comunidad LGBTTQIA, que así lo soliciten, teniendo en cuenta su identidad o expresión de género.

9. Cuando un miembro de la población correccional o joven transgresor de la comunidad LGBTTQIA se encuentre en un Centro de Ingreso o Centro de Detención, se le otorgará la oportunidad de solicitar ser ubicado en un área de custodia protectiva disponible cuando así lo solicite.

. . .

13. Se deberá adiestrar a los miembros del Cuerpo de Oficiales de Custodia sobre la manera adecuada de registrar a un Trans, según lo establecido en el Artículo VII de esta Orden Administrativa.

14. Las medidas en torno a ubicación aquí esbozadas serán aplicables a toda persona Trans, indistintamente a que institución correccional hubiese sido llevado por oficiales del Negociado de la Policía de Puerto Rico.

English Translation: *Administrative Order DCR-2018, To Establish a Public Policy on the Legal Standards for the Strengthening of Respect, Appropriate Interaction and Non-Discrimination with Persons from the Lesbian, Gay, Bisexual, Transgender, Transsexual, Queer, Intersexual and Asexual Community, effective date, Dec. 5, 2018.*

VIII. STANDARDS AND PROCEDURES FOR THE APPROPRIATE CARE OF MEMBERS OF THE CORRECTIONAL AND YOUNG VIOLATOR POPULATION OF THE LGBTTQIA COMMUNITY

1. *At the moment of a member of the LGBTTQIA community entering the facility, the socio-criminal services technician (SST) or social worker (SW) must assess the risk that he or she may be subjected to victimization and/or abuse, recognizing whether the person is perceived to be or expresses that he or she is lesbian, gay, bisexual, transgender, transsexual, intersexual, queer, asexual, or of a nonconforming gender, the technician taking whatever measures he or she deems appropriate, with the support of the Office of PREA and DCR Population Control. [115.41]*

2. *The information gathered as a result of the victimization and abuse risk assessment conducted at the time of entry will be used for purposes of placement in housing, bed, work, education, and program assignments to keep them safe. [114.42 (a)]*

3. *When deciding on the placement of a member of the correctional or young offender population who is a member of the LGBTTQIA community in an institution, housing, or program for the male or female population, an individualized assessment will be made considering all the medical and psychosocial characteristics of the member of the correctional or young offender population. Consideration should be given to whether such placement would ensure the person's health and safety, while examining whether the placement would cause administrative or safety issues, in order to balance interests as part of making the decision. [115.42 (c)]*

4. *Placement and assignment in programs for each member of the correctional or young offender population of the LGBTTQIA community must be re-evaluated at least twice (2) a year, to review any threat to their safety [115.42(d)], or when it is suspected that there may be a threat. For that purpose, the person's own perception of his or her safety must be taken seriously. [115.42 (e)]*

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5. *Members of the correctional or young offender population who identify themselves as members of the LGBTTQIA population must be offered the opportunity to use showers that are separate from other members of the correctional population. [115.42 (f)] For that purpose, it must be taken seriously into account if there is a threat to the person's safety. The perception of the member of the correctional or young offender population who is identified as part of the LGBTTQIA community must also be taken into account.*

6. *Members of the LGBTTQIA community may not be placed in specialized units for the sole and exclusive reason of being identified as such, unless such placement is made as a result of the person's consent, a legal agreement, or a legal judgment for the purpose of protecting him or her. [115.42 (g)]*

7. *Isolation of a member of the correctional or young offender population in institutions cannot be motivated by their sexual orientation and/or gender identity. However, the individual may be isolated in the least restrictive environment possible, when based on determinations of safety, security, conduct, or the nature of the offense that he or she committed. There must be substantiated reasons for determining the need for isolation.*

8. *The DCR will provide housing areas suitable for the voluntary placement of those members of the correctional or young offender population of the LGBTTQIA community, who so request, taking into account their gender identity or expression.*

9. *When a member of the correctional or young offender population of the LGBTTQIA community is in an Entry Center or Detention Center, they will be granted the opportunity to request being placed in an available protective custody area when he or she requests it.*

. . .

13. *Members of the Custodial Officer Corps must be trained in the appropriate way to search a Trans person, as set forth in Article VII of this Administrative Order.*

14. *Measures mentioned here about the placement of individuals shall be applicable to every Trans person, regardless of which correctional institution the person has been taken to by officers of the Puerto Rico Police Department.*

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Rhode Island

State Policy: Rhode Island Department of Corrections Standard Operating Procedure (SOP), Identification, Treatment and Management of Transgender and Intersex Inmates, rev. March 5, 2018.

D. Housing

1. If deemed appropriate, RIDOC may house transgender or intersex inmates according to their birth sex to protect their physical and emotional well-being, while assuring the facility's safety and security; however, RIDOC can also house transgender or intersex inmates according to their gender identity rather than their birth sex. All decisions to assign a transgender or intersex inmate to a facility for male or female inmates shall be made on a case-by-case basis by the Transgender and Intersex Review Board.

a. At no time will identification as a transgender or intersex inmate be the sole factor in determining placement.

b. Transgender and intersex inmates shall not be placed in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

2. Whenever an inmate is identified as transgender or intersex, the inmate shall complete a Gender Housing Request Form and request to be housed according to either their assigned sex at birth or their gender identity expression.

a. If an inmate requests to be housed according to their assigned sex at birth, housing placement shall not be delayed; however, the inmate will be subject to review by the Transgender and Intersex Review Board to determine that the placement meets the needs of the facility and the inmate.

b. If an inmate requests to be housed according to their gender identity expression, the inmate shall appear before the Transgender and Intersex Review Board.

. . .

3. The Transgender and Intersex Review Board shall meet within seventy-two (72) hours of a determination that an inmate is transgender or intersex, excluding weekends, legal holidays and emergencies. The Board shall conduct a review in order to assess the on-going and long-term medical, psychological and facility needs of the individual

. . .

4. The Transgender and Intersex Review Board will attempt to reach consensus, ultimately relying on majority vote when needed, to recommend a transgender or intersex inmate's assignment to a male or female facility. The Transgender and Intersex Review Board shall document its reasons for recommending placement in a male or female facility on the Housing Recommendation Form. The Board's written recommendation shall be forwarded to the ADIO for approval by the PREA Coordinator.

. . .

5. A transgender or intersex inmate shall not be placed in restrictive housing solely on the basis of such identification. Inmates at high risk for sexual victimization shall not be involuntarily segregated unless an assessment of all available alternatives has been made and it is determined that no feasible alternative exists.

. . .

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c. Every thirty (30) days the Warden/designee shall review the transgender or intersex inmate's circumstances and determine if it is still necessary to keep this inmate separate from the general population.

. . .

6. Placement and programming assignments for each transgender or intersex inmate shall be reassessed by the Warden/designee at least every six (6) months or more frequently as necessary. For those inmates who are housed according to their gender identity whose Gender Identity Housing Risk Assessment Score identified a Moderate or High Risk, their reviews shall be conducted every three (3) months. Specific attention shall be given to any threats to safety experienced by the inmate or any concerns with the inmate population.

. . .

a. If the Warden/designee recommends a change to a male or female facility, the Warden/designee shall notify the PREA Coordinator and the Transgender and Intersex Review Board will meet within seventy-two (72) hours of the Warden's recommendation, excluding weekends, legal holidays and emergencies. The Board shall conduct a review in order to assess the needs of the transgender or intersex inmate.

. . .

7. Transgender and intersex juvenile inmates shall be housed separate from adult inmates and afforded the same privileges as other juvenile inmates consistent with their classification. Please refer to the most recent version of RIDOC Policy 12.26 DOC, Special Management of Juvenile Offenders.

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South Carolina

State Policy: South Carolina Department of Corrections General Administration No. GA-06.09, Care and Custody of Transgender Inmates Diagnosed with Gender Dysphoria, issued Sept. 12, 2017.

2. THE MULTIDISCIPLINARY MANAGEMENT AND TREATMENT TEAM:

2.1. The Multidisciplinary Management and Treatment Team will, on a case-by-case basis, create individualized management accommodation plans that will provide for all medically necessary treatment, including personal adjustment and housing needs and search preferences, where deemed medically necessary.

. . .

2.3. The Prison Rape Elimination Act Coordinator will, with the assistance of the Chief Legal and Compliance Officer, oversee compliance with the individualized management accommodation plans created by the Multidisciplinary Management and Treatment Team.

. . .

3. HOUSING OF TRANSGENDER INMATES AND INMATES DIAGNOSED WITH GENDER DYSPHORIA

3.1. In deciding whether to house transgender inmates and inmates with gender dysphoria in a facility for male or female inmates, and in making other housing decisions (bathroom and shower access) and programming assignments, the Multidisciplinary Management and Treatment Team will consult with the Division of Operations as well as Central Classifications to create a plan with a reasonable outcome for the inmate and institution as a whole. Safety concerns will be taken into account.

3.2. The following factors, along with 3.1 above, must be given serious consideration in making housing and placement decisions:

- The inmate's views with respect to safety;
- The inmate's expressed gender identity;
- The inmate's current gender expression;
- The inmate's vulnerability to victimization;
- The likelihood that the inmate will perpetrate abuse;
- Facility considerations such as staffing patterns, physical layout, and inmate population;
- Length of sentence.

State Policy: South Carolina Department of Corrections General Administration No. GA-06.11, Prevention, Detection, and Response to Sexual Abuse/Harassment, issued Aug. 10, 2022.

1.2 Inmate Intake, Screening, and Assessment:

1.2.1 Screening for Risk of Sexual Victimization and Abusiveness: All inmates shall be assessed during an intake screening and upon transfer to another facility for their risk of being sexually abused by other inmates or sexually abusive toward other inmates.

. . .

1.2.1.2 Information provided from the screening assessment will be used to determine the inmate's housing, bed, education, and program assignments with the goal of keeping separate those inmates at high risk of being sexually victimized from those at high risk of being sexually abusive.

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1.2.1.3 Inmates who self-identify as transgender or intersex will be assessed and provided the minimally necessary accommodations on a case-by-case basis. For those inmates who self-identify as transgender, information will be provided to the Agency's Multidisciplinary Management and Treatment for individualized case management and review.

. . .

1.2.1.5 Those inmate cases that are brought before the Agency's MMTT will be discussed on a case-by-case basis with the intention of ensuring the inmate's health and safety, and whether the placement would present management or security problems.

1.2.1.6 No inmate will be placed specifically on their identity of lesbian, gay, bisexual, transgender, or intersex.

State Policy: South Carolina Department of Corrections General Administration No. GA-06.11B, Applying the Prison Rape Elimination Act, issued Nov. 23, 2021.

4.5: In determining housing and programming for inmates who identify as transgender, or intersex, assignment staff will complete the PREA Screening Application and will document the inmate's preferences in their assignment. Decisions on housing, programming, and other placements will be determined on a case-by-case basis. [PREA Standard(s) 115.42]

4.6: Inmates who identify as transgender or intersex during confinement will have their own perceptions of safety and housing documented and considered on a case-by-case basis. [PREA Standard(s) 115.42 (d)]

4.7: Those inmates identified by the MMTT as transgender, intersex, or diagnosed with gender dysphoria, will be provided an individualized accommodation plan. All individualized accommodation plans will be followed by SCDC Staff, absent exigent circumstances, whenever possible in consideration with employee, security, and safety concerns.

State Policy: South Carolina Department of Corrections Operations No. OP-21.04, Inmate Classification Plan, issued Oct. 22, 2020.

5.1.1 On a case by case basis, the Gender Dysphoria Multi-Disciplinary Team will determine whether to assign a transgender or intersex inmate to an institution for male or female inmates. The placement decision will be based on the inmate's own views with respect to his or her health and safety, and whether such decision will present a management or security problem. (PREA Standard 115.42)

. . .

5.1.7 Initial Housing of LGBT (lesbian, gay, bisexual, and transgender) inmates: Lesbian, gay, bisexual, transgender, or intersex inmates will not be housed solely on the basis of such identification unless placed for the purpose of protecting the inmate. Transgender and intersex inmates will be given the opportunity to shower separately from other inmates. Placement and program assignment of transgender and intersex inmates will be reassessed every six months to review any threats to safety experienced by the inmate. (PREA Standard 115.42)

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South Dakota

State Policy: South Dakota Department of Corrections Policy No. 1.4E.13, Management of Gender Dysphoria, effective June 2, 2021.

2. Placement and Programming: A. Facility housing and programming assignments for all inmates, including those that identify as transgender, intersex or who have a diagnosis of gender dysphoria, shall be made on a case-by case basis, consistent with the inmate classification system, taking into consideration the inmate's gender identity, crimes, disciplinary history, history of violence, medical and mental health needs, risk screening, individual safety, programming needs and legitimate penological interests of the DOC. An inmate's own view regarding individual safety shall be considered when determining placement and assignments.

1. Inmate housing is not based exclusively on external genital anatomy of those housed in the unit or facility.

B. Housing placement shall be consistent with the inmate's custody level/classification, PREA score (vulnerability to sexual victimization or perpetrating abuse) and AIMS code (male facilities only).

1. Requests by a transgender, intersex or gender dysphoric inmate to transfer to a facility inconsistent with the inmate's external genital anatomy (sex), may be considered. Requests will be forwarded to the Gender Dysphoria Committee for review.

. . .

C. Inmates who have underwent genital sexual reassignment surgery prior to incarceration, may be referred to the Gender Dysphoria Committee to identify appropriate housing. The Committee may provide recommendations for housing to the Director of Prison Operations. Any housing recommendation that seeks to place an inmate in a housing facility that is not consistent with the inmate's birth sex, must be reported to the Director of Prison Operations and Secretary of Corrections.

D. Inmates who have underwent partial genital sexual reassignment surgery, i.e. some removal or augmentation of breasts and/or some removal or modification of sex organs prior to incarceration, shall be reviewed by the Gender Dysphoria Committee. 1. The committee may consider housing that is not consistent with the majority results of an inmate's genital sexual reassignment surgery. 2. Exigent circumstances that may negatively affect safety and security shall be considered when considering housing placement. 3. Housing decisions shall be made on a case by case basis.

E. Self-inflicted genital mutilation and genital self-harm by an inmate does not constitute genital sexual reassignment and does not solely support referral of the inmate to the Gender Dysphoria Committee for housing review.

F. Housing assignments for transgender, intersex or gender dysphoric inmates shall be reviewed a minimum of twice a year by classification staff. Incidents or concerns that pose a threat to the inmate's safety may be reviewed by unit staff and/or forwarded to the Gender Dysphoria Committee (See DOC policy 1.4.B.2 Male Inmate Classification and DOC policy 1.4.B.1 Female Inmate Classification and PREA 115.42).

1. Inmates may be housed at any facility owned or operated by the DOC, contract facilities and outside housing approved for placement and housing of DOC inmates.

G. Transgender, intersex and gender dysphoric inmates shall not be placed in restricted housing solely on the basis of gender identity, intersex status or diagnosis.

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1. Transgender, intersex and gender dysphoric inmates considered for placement in protective custody for their own protection must consent to placement in protective custody unless no other housing options available and the placement is temporary.

. . .

l. The DOC shall not place inmates in dedicated facilities or units based solely on the basis of the inmate's gender identification or diagnosis of gender dysphoria, unless such placement is ordered through a consent decree, legal settlement or legal judgement.

State Policy: South Dakota Department of Corrections Policy No. 1.4.B.16, PREA Institutional Risk Screens, effective Sept. 1, 2021.

2. Individualized facility, housing and programming decisions for transgender and intersex inmates must be made based on consideration of all information available at the time, including the inmate's PREA Risk Screen score and individualized assessment. Placement shall be reviewed a minimum of twice a year and documented in COMS in the case notes.

State Policy: South Dakota Department of Corrections Policy No. 1.3.E.5, PREA Compliance with Prison Rape Elimination Act Standards, effective Sept. 21, 2021.

7. Transgender, Gender Dysphoria or Intersex Inmates:

A. Gender Nonconforming Committee.

1. The Committee will convene when:

a. Staff identifies or suspects an inmate is transgender or intersex (usually when an inmate is in A&O or following assessment by Behavioral Health staff or consultant).

b. When staff has identified safety concerns related to the inmate's placement. Staff shall complete a Gender Review Request form (Attachment 5). Forms may be completed at any time during the inmate's incarceration with the DOC.

c. When an inmate who identifies as transgender or inmates with gender dysphoria or intersex inmates submit a request concerning any issue which the Gender Review Committee has authority to take action on (Attachment 5).

1) Staff may assist the inmate in completing the Request form.

2. The Gender Review Committee has authority to approve and make recommendations on the following:

a. Housing placement, including transfer to a different facility, consistent with the inmate's external custody/risk classification and safety and security.

1) Transgender, gender dysphoric or intersex inmates shall not be placed in dedicated facilities or units solely on the basis of their identification or status, unless such placement is in connection with a consent decree, legal settlement, or legal judgement issued for the purpose of protecting the inmate(s).

2) The Committee may make recommendations for housing. Inmates will not be placed in involuntary protected custody housing unless all available alternatives have been reviewed and considered and a determination is made that there is no immediate alternative means of separating the inmate from likely abusers. Such placement will be temporary.

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3) Transgender, Gender Dysphoric or intersex inmates will not be housed in dedicated units or cells/units solely on the basis of their gender identification, diagnosis or complaints received by other inmates about the inmate's gender identity. Inmates will not be housed based exclusively on external genital anatomy. Housing shall be determined on a case-by-case basis, consistent with safety and security.

4) Housing placement will be reassessed a minimum of twice a year for all transgender (self-determined) and intersex inmates for any threats to the inmate's safety since the placement or last review. Reassessment of housing will be completed whenever a triggering event occurs, such as an incident documented by staff that may pose a risk to the inmate's safety or a report by the inmate describing concerns for their safety. Housing placement shall be based on consideration of all information available to staff at the time of the review.

5) The bi-annual reassessment of the inmate's housing placement will be documented in COMS under Case Management/Case Note/Note Type: Case Management/Sub Type: GNC Review. These will be completed every 6 months by the inmate's case manager.

6) Inmates with a diagnosis of gender dysphoria by the consultant, may request through Behavioral Health, to access certain personal property or commissary items. Behavioral Health staff will assess and forward recommendations to the GNC Committee for approval or denial. The accommodation will be documented in COMS by the Facility PREA Compliance Manager. Requests by an inmate for accommodations shall be considered on an individual, case by case basis, with consideration towards safety and security.

a) Inmates who do not meet the criteria of a Gender Dysphoria diagnosis, but have a recommendation from the consultant for accommodations, may request personal property or commissary items through Behavioral Health using the procedure identified in 6) above.

b. Transgender, gender dysphoric or intersex inmate requests for separate showers and separate dressing. Separate does not imply "single" showers or space and may include showering or undressing with inmate the of the same gender identity.

c. Transgender, gender dysphoric or intersex inmate's gender preference of staff performing hand pat searches of the inmate. Female staff may pat search any inmate. Inmates may not request to be searched by a particular staff member.

d. Transgender, gender dysphoric or intersex inmates may request to use their preferred title of Ms., Miss., Mrs. or Mr. in correspondence, provided the inmate's legal first and last name and DOC ID is included. Inmates may request to be addressed by staff with gender neutral reference.

3. The Committee will review an inmate's request within 30 calendar days of the request being received (Attachment 5).

a. The facility PREA Compliance Manager is the leader of the Committee and will coordinate with the other members to schedule a date and time for review or the request.

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b. The Committee will consider each request on a case-by-case basis. In each case, the Committee will consider safety and security interests and concerns.

c. The Committee must consider the following:

1) The inmate's gender identity;

2) The inmate's current genital status;

3) The inmate's own views of his or her safety and privacy concerns.

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Tennessee

State Policy: State of Tennessee Department of Correction Administrative Policies and Procedures Index 113.37, Gender Dysphoria, Transgender, Transsexual, Intersex, and Gender Non-Confirming Conditions, effective Jan. 15, 2019.

> **E. Placement:** Facility and housing assignments shall be made on a case-by-case basis, and documented on pages 1 and 2 of the PREA Housing and Programs Review, CR-4086, considering the patient's health and safety, as well as, potential management and security concerns. An inmate's own views regarding safety shall be solicited and considered.
>
> **1.** Inmates who have completed surgical sexual reassignment therapy prior to incarceration shall be placed in a correctional facility as determined by the Gender Dysphoria, Transgender, Transsexual, Intersex, and Gender Non-Conforming Accommodation Review Committee.
>
> **2.** For the purposes of facility placement, self-inflicted genital mutilation does not constitute surgical sexual reassignment therapy and does not qualify an inmate for placement in a facility for opposite-gender inmates.
>
> **3.** Placement and programming assignments shall be reassessed at least every six months at a re-classification hearing, or as warranted, to review any threats to safety experienced by the inmate.
>
> **4.** Lesbian, gay, bisexual, transgender, or intersex inmates shall not be placed in dedicated facilities, units, or wings, solely on the basis of such identification or status.
>
> **5.** An inmate will not be placed in restrictive housing on the basis of gender identity alone.
>
> **6.** The TDOC Statewide PREA Coordinator shall notify the Commissioner, Deputy Commissioners, and the applicable Assistant Commissioners of the Committee's action to approve an inmate's assignment to a given facility.

State Policy: State of Tennessee Department of Correction Administrative Policies and Procedures, Index 502.06.1, Prison Rape Elimination Act (PREA) Screening, Classification, and Monitoring, effective August 1, 2020.

> **C. Referrals and Monitoring:**
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> . . .
>
> **5.** Inmates identified as transgender or intersex shall be considered on a case-by-case basis. (See Policy #113.37) These identified inmates shall be reclassified every six months by the assigned counselor to review any threats to safety experienced by the inmate.

State Policy: State of Tennessee Department of Correction, Inmate Rules and Regulations, August 2018.

> Inmates having a diagnosis of Gender Dysphoria shall be governed by TDOC Policy #113.37.

Additional Policies:

> State of Tennessee Department of Correction Administrative Policies and Procedures, Index 502.06.2, Prison Rape Elimination Act (PREA) Allegations, Investigations, and Sexual Abuse Response Teams (SART), effective Aug. 1, 2020.

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State of Tennessee Department of Correction Administrative Policies and Procedures, Index 502.06, Prison Rape Elimination Act (PREA) Implementation, Education and Compliance, effective August 1, 2020.

Local Shelby County Policy: Shelby County Sheriff's Office Standard Operation Procedure, Unit: Transgender/Gender Variant Procedures, revised Apr. 16, 2021, signed Jan. 13, 2023.

V. GENERAL

. . .

C. In deciding whether to assign a transgender or intersex resident to a facility for male or female inmates/ residents/detainees, and in making other housing and programming assignments, SCSO shall consider on a case-by-case basis whether placement would ensure the inmate/resident/detainee health and safety, and whether the placement would present management or security problems. (PREA 115.342 (d) and 115.42 (c) Placement and programming assignments for each trans gender or intersex inmate/ resident/detainee shall be reassessed at least twice each year to review any threats to safety experienced by the inmate. A transgender or intersex inmate/resident's/detainees own views with respect to his or her own safety shall be given serious consideration. (PREA 115.342 (e-f) and 115.42 (d-e)

D. The SCSO does not house gay, lesbian, bisexual, transgender, or intersex inmates/residents/detainees in dedicated units based solely on such identification or status.

. . .

VII. PROTOCOLS

. . .

4. Housing

a. When assigning the inmate/ resident/detainee to a housing unit the Classification staff will take into consideration the inmate's/ resident/detainee concern about their own safety. Their own views with respect to his/her own safety shall be given serious consideration. However, the jail's/detention's decision for housing will prevail when dealing with concerns for the inmate's/ resident's/detainees safety and the normal day-to-day operations being disrupted.

b. Part of the Intake medical assessment will be to determine the transgender/intersex inmate's/ resident's/detainees vulnerability in general population. If the inmate/ resident/detainee expresses uncertainty about his/her gender, the medical professional will asses them to determine appropriate recommendation for housing.

c. A transgender inmate/ resident may be housed in Protective Custody or Administrative Segregation at the Administration's discretion if there are to reasons to believe the inmate/ resident/detainee presents a valid risk to themselves or others. Medical Staff will be notified to conduct appropriate mental health evaluations according to standard operating procedures.

d. Transgender and intersex inmates/residents/detainees shall be given the opportunity to shower separately from other inmates/detainees. (PREA Standard 115.42f).

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Texas

State Policy: Texas Department of Criminal Justice, Correctional Institutions Division, Safe Prisons/PREA Plan, Feb. 2019.

III. Offender Screening and Assessment

A. Intake

1. During the intake process, non-medical staff shall not search or physically examine a transgender or intersex offender for the sole purpose of determining the offender's genital status.

2. If the offender's genital status is unknown, it may be determined during conversation with the offender, by reviewing medical records, or, if necessary, as part of a broader medical examination conducted in private by a medical practitioner.

3. Offenders identified as transgender or intersex during intake shall be referred to medical in accordance with the TDCJ Intake Procedures Manual.

B. Obtaining Information from Offenders

1. All offenders shall be assessed during intake, and if transferred to another unit for permanent assignment, to determine the risk of being sexually abused by or sexually abusive toward other offenders.

2. Intake screening shall take place within 24 hours of arrival at the unit in accordance with the SPPOM.

3. Assignments shall be made through the collaborative efforts of intake staff, the USPPM, and medical and mental health services by using objective screening instruments.

a. The intake screening shall include, at a minimum, the following criteria to assess offenders for risk of sexual victimization:

(1) Any mental, physical, or developmental disability;
(2) The age of the offender;
(3) The physical build of the offender;
(4) Previous incarceration;
(5) Whether the criminal history is exclusively nonviolent;
(6) Prior convictions for sex offenses against an adult or child;
(7) Perception of the offender as gay, lesbian, bisexual, transgender, intersex, or gender nonconforming;
(8) Previous sexual victimization; and
(9) The offender's own perception of vulnerability.

. . .

C. Use of Screening Information

. . .

9. When deciding to assign a transgender or intersex offender to a unit for male or female offenders, and when making other housing and programming assignments, consideration shall be made on a case-by-case basis with regard to the health and safety of the offender and potential management or security problems. Housing determinations shall not be made solely on the basis of LGBTI status.

a. Placement and programming assignments for each transgender or intersex offender shall be reassessed semiannually to review any threats to safety experienced by the offender.

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b. A transgender or intersex offender's views with respect to his or her own safety shall be given serious consideration.

10. Offenders shall not be disciplined for refusing to answer, or for not disclosing complete information in response to, questions asked pursuant to Section III.B.3.

State Policy: Texas Department of Criminal Justice, Correctional Managed Health Care Policy Manual No. G-51.11, Treatment of Inmates with Intersex Conditions, or Gender Dysphoria, Formerly Known as Gender Identity Disorder, effective Jan. 10, 2017, reviewed July 2022.

To ensure that inmates with complaints consistent with intersex conditions or Gender Dysphoria are evaluated by appropriate medical and mental health professionals and treatment is determined on a case-by-case basis as clinically indicated.

Local Harris County Policy: Harris County Sheriff's Office Policy No. 413, Lesbian, Gay, Bisexual, Transgender and Intersex (LGBTI) Department, Nov. 2013, revised Aug. 2021.

3. At no time shall any search be conducted solely for the purpose of determining an inmate's or detainee's biological sex or gender. Any questions regarding an inmate's gender shall be referred to a gender classification specialist.

. . .

E. Intake Screening

. . .

3. LGBTQI prisoners may not be placed in segregated housing against their will due to the sole purpose of their sexual orientation. (See the Classification manual for procedures on reassessment periods).

4. Specially-trained gender classification specialists shall assist in the process upon which the Classification Division will base their housing decisions. The mere identification of an inmate as LGBTQI is insufficient to warrant an assumption of enhanced risk that the inmate will be sexually abusive.

5. Due to his or her vulnerability, a transgender prisoner shall be expedited through the entire booking process until Classification has determined housing in accordance with PREA standards. The Prisoner Processing Division supervisor on duty will be responsible for expediting the LGBTQI prisoner to Classification.

6. All inmates, within 72 hours of arrival at a HCSO detention facility, shall be assessed for their risk of being sexually abused by or sexually abusive towards other inmates in compliance with PREA standards.

7. If an indication of need arises, a gender classification specialist shall conduct a screening interview in a private and respectful manner. The gender classification specialist will only ask questions related to sexual orientation, gender identity, or gender expression for the purpose of making intake, housing, and classification assignments. If necessary, the inmate will be referred to HCSO Medical for screening.

. . .

F. Gender Classification Committee

The gender classification committee has the final authority in all matters related to the classification of LGBTQI inmates.

1. Additional responsibilities:

a. Gender classification specialist certification and assistance,

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b. Housing assignment arbitration, and

c. Required reporting.

2. Mandatory review meetings:

a. Placement of transgender inmates,

b. Gender classification specialist weekly documentation review,

c. Inmate housing appeals, and

d. 30-day reviews.

3. Monitoring and Reassessment: The housing and well-being of LGBTQI inmates shall be monitored and reassessed when needed by the gender classification committee. The committee will document and maintain records of all such monitoring and any reassessment deemed necessary.

. . .

I. Inmate Services

LGBTQI inmates shall have equal access to all available services to include mental health services, counseling, and support groups. Specialized LGBTQI services shall be developed based on identified needs.

J. Use of Screening Information and Confidentiality

1. A person's LGBTQI status is considered confidential information. This information, including electronic records, shall have strict dissemination controls. The HCSO shall keep LGBTQI screening information confidential except as necessary to conform to required protocols.

. . .

3. Classification shall use the information from the risk screening to determine housing, bed, work, education, and program assignments with the goal of keeping LGBTQI inmates at high risk of being sexually victimized separate from those at high risk of being sexually abusive.

4. Classification shall make individualized determinations on how to ensure the safety of each inmate.

5. In deciding whether to assign a transgender inmate to a facility for male or female inmates, and in making other housing and programming assignments, Classification shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety and whether the placement would present management or security problems.

6. The policy and procedure for and record of placements for transgender inmates shall be reassessed at least twice each year to review any threats to safety experienced by the inmates. Classification will record and keep these findings for permanent review and referrals for future training.

7. An LGBTQI inmate's own views with respect to his or her own safety shall be given significant consideration and recorded on his or her inmate record.

8. Classification shall strive not to place LGBTQI inmates in dedicated facilities, units, or wings solely on the basis of such identification or status unless such placement is necessary for his or her safety or such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

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Utah

State Policy: State of Utah Department of Corrections Vol. Operational Procedures: General, Ch. AG37 Diagnosis & Treatment of Offenders with Gender Dysphoria, effective Dec. 19, 2018.

AG37/01.03 Policy

1. It is the policy of the Utah Department of Corrections to appropriately diagnose and treat offenders with gender dysphoria in a humane and safe correctional environment. This shall be done in a way that is sensitive to the offender's unique adjustment issues, and is consistent with the core values, vision, and mission of the Department and its commitment to provide adequate health care and mental health services to all offenders in its custody.

. . .

AG37/01/04 Rationale

The Utah Department of Corrections recognizes the need to properly evaluate offenders who express transgender issues.

. . .

AG37/02.02 Procedure: Gender Dysphoria Offender

Upon intake into the Utah prison system, or at any other time during an offender's incarceration, if the offender self-identifies as transgender and requests a mental health evaluation through the ICR process:

A. The MHP shall meet with the offender within 14 working days from the date the referral is received.

B. The offender shall receive an initial evaluation from a MHP using the "Transgender Initial Assessment Form."

C. The MHP shall present the findings to the Gender Dysphoria Committee.

D. The Director of Clinical Services/designee shall have final approval whether or not to refer the offender for an assessment for gender dysphoria.

E. Offenders who are denied may apply to be reevaluated after one year.

F. If approved for an evaluation for gender dysphoria, a referral shall be sent to the contract psychologist.

. . .

H. The contract psychologist shall meet with the offender for an evaluation for gender dysphoria.

. . .

AG37/02.04 Procedure: Treatment and Services

A. The Director of Clinical Services/designee shall review and consider any recommendations made by the contract psychologist in developing a treatment plan.

B. The Director of Clinical Services/designee may require additional consults in the diagnosis and the development of the individual treatment plan.

State Policy: Utah Department of Corrections Department Manual Policy No. FC05, Inmate Housing Assignments, revised April 28, 2022.

01.00 POLICY & RATIONALE

01.01 Policy

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A. It is the policy of the Department that offender bed assignments are based on the consideration of all relevant factors which are necessary to appropriately assign offender housing, ensuring a properly functioning and safe institution.

B. Nothing in this policy or its corresponding procedure is designed or intended to confer due process rights on inmates or other individuals, revoke official discretion, or limit management flexibility.

. . .

02.00 HOUSING ASSIGNMENTS

02.01 Initiating a DPO Housing Assignment Change

A. Housing Assignment changes may be initiated by:

1. offender classification,
2. OMR recommendation,
3. management/safety concerns,
4. programming opportunities/CAP priorities,
5. bed space needs,
6. upcoming court hearings/BOPP hearings,
7. medical needs,
8. STG,
9. Pre-release,
10. PVP,
11. restrictive housing, or
12. any administrative need, (i.e., investigations, etc.).

State Policy: Utah Code Ann. § 64-13-47, Prison Rape Elimination Act Compliance, effective July 1, 2022.

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Vermont

State Policy: State Of Vermont Agency of Human Services Department of Corrections Directive 432.01, Gender Identification Care and Custody, effective Feb. 22, 2015.

d. Whenever an inmate is identified as transgender and/or intersex, the facility multidisciplinary team will meet within seventy-two hours of the inmate's arrival or intake and conduct a review in order to assess the on-going and long-term medical, psychological and facility needs of the individual, using and considering the following criteria:

i. The Gender Preference Form.

ii. Sexual Violence Screening Tool[n.16]

[n.16 Includes factors related to the inmate's emotional and physical well-being as well as the inmate's self-evaluation of his or her safety. Note than per C.F.R. § 115.42(e) a transgender and/or intersex inmate's own views with respect to his or her own safety shall be given serious consideration.]

iii. The anatomy of the inmate.

iv. The individual's incarcerated history.

v. Other psychosocial factors that may contribute to either the individual's resiliency or vulnerability.

vi. The inmates' privacy concerns.

vii. Available housing.

viii. Recommendations from the inmate's mental health providers.

ix. LGBTQI inmates can make informal requests to staff, or utilize the grievance system to express issues concerning privacy concerns, housing, factor's related to the inmate's emotional and physical well-being, and the inmate's self-evaluation of his or her safety.

e. LGBTQI inmates will not be placed in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

f. Classification determinations will be made using the information from the risk screening to determine housing, bed, work, education, and program assignments with the goal of keeping separate LGBTQI inmates at risk of being sexually victimized from those at risk of being sexually abusive.

g. The multi-disciplinary team will review the determination as necessary but within thirty days of the initial assessment to determine if any adjustments or reconsiderations need to be made.

h. The multi-disciplinary team will review placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice a year to review any threats to safety experienced by the inmate.

. . .

j. DOC can house trans gender or intersex inmates according to their gender identity rather than their birth sex. In deciding whether to assign an transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, DOC will consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems. DOC will consider the physical layout of the facility and privacy issues/concerns when determining the location of a transgender or intersex inmate. If deemed necessary for safety, DOC can place transgender or intersex inmates according to their birth sex to protect their physical and emotional well-being, while assuring the facility's safety and

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security. All determinations regarding the housing of a transgender and/or intersex inmate will be made by a management team consisting of the Director of Correctional Facilities; the Health Services Director; the Corrections Case Work Director; and a DOC employee with the ability and knowledge needed to represent LGBTQI interests.

k. LGBTQI inmates can make requests to have their housing re-evaluated using the grievance system.

l. If an indication of need arises, the facility may consult with an identified member of the LGBTQI or allied community to provide external resources and support in assistance with the LGBTQI population.

State Policy: State of Vermont Agency of Human Services Department of Corrections Directive 409.09, Prison Rape Elimination (PREA) & Staff Sexual Misconduct – Facilities, effective Feb. 22, 2015.

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Virginia

State Policy: Virginia Department of Corrections Operating Procedure 038.3, Prison Rape Elimination Act, effective Oct. 1, 2020.

D. Inmate and CCAP Probationer/Parolee Screening and Use of Screening Information

. . .

2. Staff will use information from the Classification Assessment to determine appropriate housing, bed, work, education, and program assignments with the goal of keeping separate those inmates or CCAP probationers/parolees at high risk of being sexually victimized from those at high risk of being sexually abusive. (§115.42[a], §115.242[a])

a. Staff will make an individualized determination on how to ensure the safety of each inmate or CCAP probationer/parolee. (§115.42[b], §115.242[b])

b. When deciding whether to assign a transgender or intersex inmate or CCAP probationer/parolee to a male or female facility and when making other housing and programming assignments, staff will take into consideration whether an assignment would ensure the health and safety, and whether the assignment would present management or security problems. (§115.42[c], §115.242[c])

i. A transgender or intersex inmate's or CCAP probationer's/parolee's own views with respect to their own safety will be given consideration. (§115.42[e], §115.242[d])

ii. Lesbian, gay, bisexual , transgender, or intersex inmates and CCAP probationer/parolees will not be placed in a dedicated facility, housing unit, or wing based solely on their identification or status. (§115.42[g], §115.242[f])

. . .

iv. The Gender Dysphoria Committee will make all specialized decisions when providing and CCAP probationers/parolees who are transgender, intersex, or diagnosed with Gender Dysphoria with specific individual accommodations.

3. Staff, in institutions, must reassess each transgender and intersex inmate's housing and programming assignments at least twice each year to review any threats to safety the inmate experienced. (§115.42[d])

a. The Institutional Program Manager (IPM) or designated staff at institutions without an IPM will print the Facility Offender Alert custom report from VACORIS in January and July to ensure staff complete the six month housing and programs reassessment for all transgender and intersex inmates.

b. The staff member must meet with the inmate to discuss their housing and program needs and verify their current assignments are still appropriate.

c. The staff member will place a note in VACORIS stating the "six month housing and program assignment reassessment completed" and documenting any necessary changes made to the inmate's housing and programs.

d. The IPM or designated staff member will refer the inmate to a Psychology Associate for follow-up, as needed.

e. Staff must complete all reassessments on the last day of January and July.

State Policy: Virginia Department of Corrections Operating Procedure 730.2, Mental Health and Wellness Services: Screening, Assessment, and Classification, effective June 1, 2021, amended March 1, 2022.

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C. The Psychology Associate will notify facility staff responsible for making housing and programming assignments for transgender or intersex inmates of any relevant screening results that would present management or security considerations so staff, on a case-by-case basis, can make a determination that best ensures the inmate's health and safety. (§115.42[c], §115.242[c])

State Policy: Virginia Department of Corrections Operating Procedure 830.5, Transfers, Institution Reassignments, effective Nov. 1, 2020, amended June 1, 2022.

C. Classification To Protective Custody Units

. . .

i. The institution will make individualized determinations about how to ensure the safety of each offender.

ii. In deciding whether to assign a transgender or intersex offender to a Protective Custody Unit, institution staff must consider on a case-by-case basis whether this placement would ensure the offender's health and safety, and whether the placement would present management or security problems.

iii. A transgender or intersex offender's own views with respect to their safety will be given serious consideration.

iv. Lesbian, gay, bisexual, transgender, or intersex offenders will not be placed in the Protective Custody Unit solely based on their identification or status.

State Policy: Virginia Department of Corrections Operating Procedure 720.2, Medical Screening, Classification, and Levels of Care, effective Oct. 1, 2020, amended Sept. 1, 2021.

Local Fairfax County Policy: Fairfax County Sheriff's Office Standard Operating Procedure 535, Prison Rape Elimination Act, effective July 20, 2022, revised July 2022.

6. Use of Information Obtained from Screening (PREA 115.42)

a. The Sheriff's Office shall use information from the risk screening to make informative decisions regarding housing, work, education, and program assignments with the goal of keeping separate those inmates at high risk of being sexually victimized from those at high risk of being sexually abusive.

b. The Sheriff's Office shall make individualized determinations about how to ensure the safety of each inmate.

c. In deciding whether to assign a transgender or intersex inmate to a housing unit for male or female inmates, and in making other programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.

1) Transgender and intersex inmates shall receive a Notification of Referral to Institutional Classification Committee Form within 24 hours of their initial interview and will have a 72-hour waiting period prior to the Formal Hearing being conducted.

2) The Formal Institutional Classification Committee shall conduct a hearing to determine appropriate housing for the inmate the day immediately following the 72-hour waiting period, excluding weekends, holidays or when the County is closed.

d. Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experienced by the inmate.

. . .

2) The Formal Institutional Classification Committee (ICC) shall conduct a reassessment of all inmates who identify as transgender or intersex on a quarterly basis beginning in January of each calendar year. This reassessment will include a review of placement and programming for each inmate.

e. A transgender or intersex inmate's own view with respect to his or her own safety shall be given serious consideration.

. . .

g. The Sheriff's Office shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated housing units solely on the basis of such identification or status unless pursuant to a legal settlement or judgment.

Local Fairfax County Policy: Fairfax County Sheriff's Office Standard Operating Procedure 606, Transgender and Gender Non-Conforming Inmates, effective May 13, 2021, revised May 2021.

B. Intake Housing

1. After completion of the initial intake process, an inmate identified as transgender, or gender non-conforming shall be afforded the opportunity to request and receive an isolated housing location. The inmate can then be housed in a single cell in the Receiving Unit, consistent with the gender identified at intake. They shall remain in their assigned cell until they can be fully classified.

. . .

C. Classification Process

1. The classification of transgender and gender non-conforming inmates shall follow procedures outlined in SOP 608 Classification Intake and SOP 535 Prison Rape Elimination Act.

2. During the classification interview, staff shall only ask questions related to sexual identity, gender identity or gender expression for making intake and housing assignments. Questions related to sexual identity, gender identity, or gender expression shall be asked in a private setting and in a respectful manner to preserve confidentiality, human dignity and to avoid subjecting the transgender or gender non-conforming inmate to abuse, humiliation or ridicule.

3. A transgender or intersex inmate's own view with respect to his or her own safety shall be given serious consideration. All transgender and gender non-conforming inmates shall be classified and assigned housing based on their safety/security needs, housing availability, and potential vulnerability, if assigned to general population.

4. In deciding whether to assign a transgender or intersex inmate to a housing unit for male or female inmates, and in making other programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health, and safety, and whether the placement would present management or security problems. Transgender and gender non-conforming inmates have the same right to appeal housing assignments as all inmates.

5. If it is decided the inmate can be housed in the general population, the inmate shall be transferred to the general population housing unit as determined by the ICC. If it is determined the inmate requires administrative housing due to substantial risk, staff shall follow protocol provided in SOP 535 Prison Rape Elimination Act (Section IV. I, Protection of Inmates Facing Substantial Risk).

6. A transgender or gender non-conforming inmate may be housed in administrative housing when there is reason to believe the inmate presents a heightened risk to themselves or to

others, or where the inmate fears they will be vulnerable to victimization in any other housing setting. This assignment shall be only for the period during which the heightened risk and/or fear exists and in accordance with PREA SOP 535.

7. Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experienced by the inmate.

8. Transgender or gender non-conforming inmates who were receiving hormone treatment and therapy at the time of their incarceration shall be referred to an appropriate medical doctor for further evaluation.

. . .

10. The Sheriff's Office shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated housing units solely on the basis of such identification or status unless pursuant to a legal settlement or judgment.

Local City of Richmond Policy: City of Richmond Sheriff's Office Standard 115.5-115.89, Policy 129, Prison Rape Elimination Act (PREA), effective May 2014, revised Jan. 2022.

v. All transgender or intersex inmates will be housed according to the appropriate housing unit to ensure their safety and security of the facility.

. . .

115.42 – Use of Screening Information

. . . Procedure

1. Information from the risk screening will be used to determine housing, bed, work, education, and program assignments to prevent inmates with the high risk of being sexually victimized from those at the risk of begin sexually abusive.

2. The agency makes individualized determinations about how to ensure the safety of each inmate.

3. The agency makes housing and program assignments for transgender or intersex inmates in the facility on a case by case basis to ensure the inmates health and safety; and whether the placement would present management or security problems.

4. Placement and programming assignments for transgender or intersex inmates will be reassessed at least twice each year to review any threats to the inmate's safety.

5. A transgender or intersex inmates own views with respect to his/her own safety shall be given serious consideration.

. . .

7. The PREA Coordinator or designee will assess all transgender or intersex inmates for housing to include:

i. Does the inmate feel comfortable being housed in general population?

ii. What gender of inmates does the inmate feel comfortable being housed with?

iii. Does the inmate feel comfortable showering around other inmates?

iv. Does the inmate prefer to shower away from other inmates?

v. Transgender or intersex inmates who prefer to shower separately will be taken to Transfer & Release or an occupied dayroom and allowed to shower.

vi. Transgender or intersex inmates in general population can submit a request form to the PREA Coordinator or Classification to request a change in housing or showering status.

vii. Lesbian, gay, bisexual, transgender or intersex inmates shall not be placed in dedicated facilities, units or wings solely on the basis of such identification or status,

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unless such placement is in a dedicated facility, unit or wing established in connection with a consent decree, legal settlement or legal judgment for the purpose of protecting such inmate.

We were unable to obtain Arlington County's policies relating to housing of transgender inmates. Please note, however, that the Arlington County Sheriff's Office publishes Prison Rape Elimination Act (PREA) audits to its website that include summaries of relevant policies. For example:

PREA Audit: Arlington County Sheriff's Office, PREA Facility Audit Report, Sept. 20, 2020

PREA Audit Language:

Policy – 8901 Intake Screening. The agency's Intake Screening policy requires staff to place an inmate whose gender-related expression, identity, appearance, or behavior that differs from their biological sex in a holding cell by themselves during the booking process. Staff are then required to perform the following to determine the sex of the inmate: (i) review commitment documents for gender assignment or notification that identifies the inmate as transgender or vulnerable, (ii) ask the inmate for verification of genitalia status, and (iii) if the sex cannot be determined or the inmate refuses to cooperate, notify a supervisor immediately so the inmate can be escorted to the medical unit for a physical examination and gender determination.

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Washington

State Policy: State of Washington Department of Corrections, Policy Number DOC 490.700, Transgender, Intersex, and/or Non-Binary Housing and Supervision, effective Feb. 13, 2020, revised March 9, 2022.

III. Intake Screening

A. DOC 02.420 Preferences Request will be completed if an individual identifies as transgender, intersex, and/or non-binary.

. . .

B. Housing decisions will be determined based on several factors as identified in DOC 420.140 Cell/Room Assignment.

1. If the arriving individual does not have a PREA Risk Assessment and DOC 02-384 Housing Protocol for Transgender, Intersex, and Non-binary Individuals on file, the individual will be evaluated by appropriate personnel and temporarily assigned to the least restrictive housing pending final outcome of the Multidisciplinary Team (MDT).

. . .

VI. Housing and Programming Reviews

A. Housing and programming will be reviewed at RDC intake and prior to any transfer by the facility MDT of all individuals who identify as transgender, intersex, or non-binary. Reviews will be documented on DOC 02-384 Housing Protocol for Transgender, Intersex, and Non-binary Individuals and scanned into the designated restricted section of the individual's electronic imaging file.

1. Initial housing reviews will completed, approved, and submitted within 10 business days of disclosure of the individual as transgender, intersex, or non-binary. A Prison or Reentry Center MDT will document housing reviews and make a recommendation on DOC 02-384 Housing Protocol for Transgender, Intersex, and Non-binary Individuals. The form, a completed and signed DOC 02-420 Preferences Request, and all related documentation will be forwarded to the PREA Coordinator and Gender Responsive Administrator.

. . .

B. The PREA Coordinator will review housing protocol recommendations and forward all related documentation to the Gender Responsive Administrator for final review and approval.

C. If DOC 02-384 Housing Protocol for Transgender, Intersex, and Non-binary Individuals is approved by the Gender Responsive Administrator indicating transfer to another Prison/Reentry Center, the receiving facility will complete Part II of the form.

1. The receiving facility MDT will conduct an interview with the individual, arranged by the sending facility.

. . .

D. A confidential PREA hold will be entered in the individual's electronic file as soon as an individual identifies as transgender, intersex, or non-binary. This hold will remain in effect until the individual's release or their status as transgender, intersex, or non-binary has been revised.

E. The facility MDT will reassess placement and programming assignments every 6 months using DOC 02-384 Housing Review for Transgender, Intersex, and Non-binary Individuals to review any threats to the individual's safety.

. . .

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F. Transgender, intersex, and non-binary individuals may appeal housing review decisions in writing to the:

1. Gender Responsive Administrator for decisions made based on facility recommendations, or

2. Appropriate Assistant Secretary/designee for decisions made by the Headquarters MDT.

State Policy: State of Washington Department of Corrections Policy No. 420.140, Prison/Reentry, revised Sept. 23, 2021.

B. Housing assignments will be made based on available information, including:

. . .

7. Risk assessment and housing assignment requirements per DOC 490.820 Prison Rape Elimination Act (PREA) Risk Assessments and Assignments and DOC 490.700 Transgender, Intersex, and/or Gender Non-Confirming Housing and Supervision.

State Policy: State of Washington Department of Corrections Policy No. 490.820, Prison Rape Elimination Act (PREA) Risk Assessments and Assignments, revised March 9, 2022.

VI. Housing Assignments

. . .

E. Individuals who identify as lesbian, gay, bisexual, transgender, intersex, and non-binary may not be placed in dedicated facilities/areas within a facility.

1. Superintendents will ensure:

a. Dedicated placements do not occur,

b. Individuals are not groups together within a facility based solely on this status, and

c. Employees who make housing assignments are aware of this prohibition.

2. The PREA Compliance Manager/designee will conduct periodic reviews of the housing assignments of these individuals to ensure dedicated placements do not occur.

Local King County Policy: Seattle Police Department Manual 16.200 – Interaction with Transgender Individuals, effective May 7, 2019.

This policy applies to all employees and establishes guidelines for the appropriate treatment of transgender individuals who come into contact with the Seattle Police Department. Officers shall consider a person to be transgender if the person identifies themselves as transgender or, if upon reasonable belief that a person may be transgender, the officer asks and receives an affirmative response. Officers will use their own discretion whether or not to ask a person of their gender identity.

. . .

Officers will house transgender suspects/prisoners in SPD holding cells alone. If there are no individual holding cells available, a supervisor will make arrangements for the transgender suspect/prisoner to have a cell, be transported, or released.

. . .

When officers transport a transgender individual to the King County Jail or otherwise transfer custody to another law enforcement agency, the officers will verbally advise the receiving agency/officer that the individual is transgender.

Local King County Policy: Seattle Police Department Manual 11.010, Detainee Management, effective March 1, 2021.

Detainees will not be searched to determine their gender.

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West Virginia

State Policy: State of West Virginia Department of Corrections and Rehabilitation Policy Directive No. 430.00, Prison Rape Elimination Act (PREA) Compliance, effective Oct. 7, 2022.

> **I.** The PREA screening assessments information shall be used to make decisions regarding housing, bed, work, education, and program assignments . . . The facility shall make individualized determinations about how to ensure the safety of each offender. (115.42 (a) (b)) (115.68)
> . . .
> **L.** All staff, volunteers, and contractors will communicate with, treat, and talk about any offender who is LGBTI, or perceived to be LGBTI, in a professional and respectful manner. Placement and programming assignments for each transgender or intersex offender shall be reassessed twice a year. Staff will take into consideration the facility population, staffing patterns, physical layouts and legal requirements. LGBTI offenders will not be placed in dedicated facilities or units solely based on such identification or status. A transgender or intersex offender's own views with respect to his or her own safety shall be given serious consideration. Transgender and intersex offenders shall be given the opportunity to shower separately from other offenders. (115.42 (d) (e) (f) (g))

State Policy: State of West Virginia Department of Corrections and Rehabilitation Policy Directive No. 411.00, Gender Nonconforming Inmates/Residents, dated Feb. 1, 2020.

> **II.** Facility and housing assignments of transgender and intersex inmates/residents shall be made on a case-by-case basis.
>
> **A.** Consideration shall be given to the inmate's/resident's health and safety as well as potential programming, management and security concerns. An inmate's/resident's own views regarding safety shall be given serious consideration.
> **B.** Facility and housing assignments shall be reassessed at a minimum of every six (6) months to review any threats to safety experienced by the inmate/resident.
> **C.** Placement may occur at any DCR Facility, in General Population, and in most cases a single cell is not necessary.
> **D.** Inmates/residents who have completed sexual reassignment surgery prior to incarceration shall be placed in a facility after the Superintended/designee consults with the Transgender Committee.
> **E.** For the purposes of facility placement, self-inflicted genital mutilation does not constitute sexual reassignment surgery and does not qualify an inmate/resident for placement in a different facility.
> **F.** Transgender and gender dysphoria inmates/residents shall not be placed in Restrictive Housing based on their gender identity alone, nor shall all gender nonconforming inmates/residents be housed together in housing units or facilities in an attempt to keep separate from other inmates/residents.

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Wisconsin

State Policy: Wisconsin Department of Corrections Executive Directive No. 72, Sexual Abuse and Sexual Harassment in Confinement (PREA), effective Jan. 11, 2016, date of approval Jan. 8, 2016.

E. Lesbian, Gay, Bisexual, Transgender and/or Intersex Offenders.

1. Lesbian, Gay, Bisexual, Transgender and/or Intersex Offenders shall not be placed in dedicated facilities, wings or units solely on the basis of such identification or status.

2. When making facility, cell/unit housing and programmatic assignments for transgender or intersex offenders the DOC shall consider on a case-by-case basis whether a placement would ensure the offender's health and safety and whether the placement would present management or security problems, in addition to serious consideration of the offender's own views with respect to their own safety.

3. Placement and programming assignments for each transgender or intersex offender shall be reassessed at least twice each year to review any threats to the safety experienced by the offender.

State Policy: State of Wisconsin Department of Corrections, Division of Adult Institutions Policy and Procedures No. 500.70.27, Transgender Inmates, effective July 19, 2021.

II. Placement of Transgender and Intersex Inmates

A. All sites are approved for transgender and intersex inmates except – Prairie du Chien Correctional Institution, Gordon Correctional Center, McNaughton Correctional Center, Chippewa Valley Correctional Treatment Facility, Flambeau Correctional Center and St. Croix Correctional Center.

B. Facility and housing assignments shall be made on a case-by-case basis, considering the inmate's health and safety as well as potential programming, management and security concerns. An inmate's own views regarding safety shall be given careful consideration.

C. Placement and programming assignments shall be reassessed a minimum of every six months at a reclassification hearing to review any threats to safety experienced by the inmate. The assigned OCS shall document in the WICS current offense description box: DAI Policy 500.70.27 applies to the management of this inmate with the requirement for classification review every six months.

D. When recommending transfer of a GD or transgender inmate, BOCM and/or the classification committee shall recommend a single approved GD or transgender site. Temporary sites may be used for transportation purposes.

E. Placement may occur at any approved site for transgender and intersex Inmates. For placements at minimum-security sites or correctional centers, PSU staff shall document on DOC-3474 the inmate does not require a single cell.

. . .

H. Inmates who have completed sexual reassignment surgery prior to incarceration shall be placed in a facility after consultation with the Transgender Committee. Placement shall be, in most cases, consistent with the reassignment treatment.

I. For the purposes of facility placement, self-inflicted genital mutilation does not constitute sexual reassignment surgery and does not qualify an inmate for placement in a different facility.

J. Transgender and GD inmates shall not be placed in RH on the basis of their gender identity.

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Wyoming

State Policy: Wyoming Department of Corrections Policy and Procedure No. 3.307, Management of Transgender or Intersex Inmates, Oct. 1, 2021.

A. General Policy. When deciding whether to assign a transgender or intersex offender to a facility for male or female offenders, and in making other housing and programming assignments, the WDOC considers on a case-by-case basis whether placement would ensure the offender's health and safety, and whether the placement would present management or security problems. The WDOC does not place lesbian, bisexual, transgender, gender-variant, or intersex offenders in dedicated facilities, or units solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or pod established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such offenders. (PREANS 115.42.g)

. . .

IV. PROCEDURE

A. Classification/Housing/Intake Procedure for transgender or intersex male or female inmates.

1. In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether placement would present management or security problems.(PREANS 115.42.c)

2. If during the intake process an inmate identifies as transgender or intersex the TRC will determine the housing assignments. The facility housing manager shall ensure the TRC is developed within three (3) working days from the inmate's arrival and/or identification as transgender or intersex. The committee shall document the review and determination for housing.

i. The TRC shall review all of the inmate's records; this includes the inmate's PSI, records received from the county jail the inmate was housed at, necessary medical and mental health records and assessments, and any other pertinent records to assist in determining housing. An interview with the inmate to include asking the inmate on his or her own opinion of his or her vulnerability in male or female units. At no time shall identification as transgender or intersex be the sole factor in determining housing. (PREANS 115.42.e)

ii. If the TRC deems it necessary the inmate may be recommended for an individual session with a psychologist/psychiatrist to assist in determining appropriate housing.

. . .

iv. Placement and programming assignments for each transgender or intersex inmate shall be assessed at least twice a year by the TRC to review any threats to safety experienced by the inmate. (PREANS 115.42.d)

v. Classification proceedings and decisions, including custody designation and facility, cell assignment, and housing decisions, are not subject to appeal under the Inmate Communication and Grievance Procedure (WDOC Policy and Procedure #3.100).

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State Policy: Wyoming Department of Corrections Policy and Procedure No. 3.302, Restrictive Housing, effective July 1, 2018.

D. Policy Regarding LGBTI and Gender Non-Conforming Inmates. Inmates who are LGBTI or whose appearance or manner does not conform to traditional gender expectations shall not be placed in restrictive housing solely on the basis of identification or status. (ACA-4-RH-0035)

State Policy: Wyoming Department of Corrections Policy and Procedure No. 3.402, Protection from Sexual Misconduct, effective May 15, 2021.

I. Transgender and Intersex Inmates

1. In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether placement would present management or security problems.(PREANS 115.42.c)

2. Placement and programming assignments for each transgender or intersex inmate shall be assessed at least twice a year to review any threats to safety experienced by the inmate. (PREANS 115.42.d)

3. A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration. (PREANS 115.42.e)

. . .

5. The agency shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.(PREANS 115.42.g)

State Policy: Wyoming Department of Corrections Policy and Procedure No. 2.200, Inmate Housing Areas, Feb. 1, 2018.

State Policy: Wyoming Department of Corrections Policy and Procedure No. 4.000, Inmate Housing Under Interstate Compact, effective May 15, 2019.

Local Johnson County Policy: Johnson County Sheriff's Office, PREA Policy, 2022.

III. Use of Information Obtained from Screening [DOJ §115.42]

• Detention deputies, in consultation with a supervisor, shall use information from the Initial Assessment, criminal history, behavioral observations, PREA Sexual Predator/Vulnerability Screening form, and all additional relevant information including their training and experience to inform housing, bed, work, education, and program assignments with the goal of keeping separate those inmates at high risk of being sexually victimized from those at high risk of being sexually abusive.

. . .

• In deciding whether to assign a transgender or intersex inmate to a cell block for male or female inmates, and in making other housing and programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.

• Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experienced by the inmate.
• A transgender or intersex inmate's own view with respect to his or her own safety shall be given serious consideration.
. . .
• The Detention Center shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated cell blocks solely on the basis of such identification or status unless pursuant to a legal settlement or judgment.

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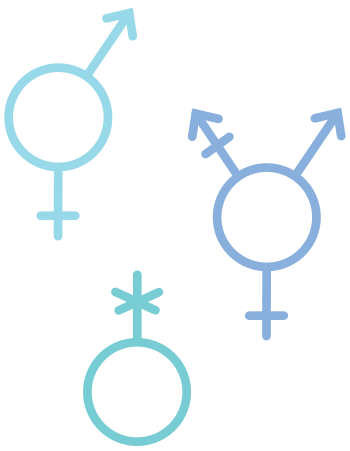
Roy W. Wesley, Inspector General

Bryan B. Beyer, Chief Deputy Inspector General

OIG | OFFICE *of the* INSPECTOR GENERAL

Independent Prison Oversight

September 2020



Special Report

The California Department of Corrections and Rehabilitation Has Taken Thoughtful and Important Steps to Address the Difficult Conditions of Confinement for Incarcerated Transgender, Nonbinary, and Intersex Individuals

AR-002502

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Roy W. Wesley, Inspector General
Bryan B. Beyer, Chief Deputy Inspector General

Independent Prison Oversight

Regional Offices
Sacramento
Bakersfield
Rancho Cucamonga

September 1, 2020

The Governor of California
President pro Tempore of the Senate
Speaker of the Assembly
State Capitol
Sacramento, California

Dear Governor and Legislative Leaders:

Enclosed please find the Office of the Inspector General's (OIG) Special Report titled *The California Department of Corrections and Rehabilitation Has Taken Thoughtful and Important Steps to Address the Difficult Conditions of Confinement for Incarcerated Transgender, Nonbinary, and Intersex Individuals*. Pursuant to California Penal Code section 6126 (b), the Inspector General may, under policies developed by the Inspector General, initiate an audit or review on the Inspector General's own accord. We chose to review the California Department of Corrections and Rehabilitation's (the department) efforts to address the difficult and evolving issues transgender, nonbinary, and intersex individuals face while in custody.

In this report, we summarize what we observed at some of the Transgender Housing and Search Working Group meetings, surveys, forums, and staff training sessions conducted by the department as well as through our conversations with external stakeholders and departmental leadership. We outline the concerns raised by incarcerated individuals through the surveys and at the forums; the concerns and insights of external stakeholders regarding the incarcerated population; and the department's thoughtful and important steps to address the issues voiced by both incarcerated individuals and external stakeholders, and to improve overall conditions of confinement for the incarcerated transgender, nonbinary, and intersex population. While we found that conditions of confinement for this incarcerated population are difficult, we commend the department for providing incarcerated transgender, nonbinary, and intersex individuals with an opportunity to share their stories and voice their concerns, and for adapting departmental policies and practices to improve conditions of confinement for this vulnerable population.

Based on our observations, we provide recommendations of additional steps the department should take to address the conditions we outline in this report.

Sincerely,

Roy W. Wesley
Inspector General

Gavin Newsom, Governor

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> The Inspector General may, under policies developed by the Inspector General, initiate an audit or review on the Inspector General's own accord.
>
> —*State of California*
> *Penal Code section 6126 (b)*

Terms Used in This Report	
Cisgender	Of, relating to, or being a person whose gender identity corresponds with the sex the person had or was identified as having at birth.*
Gender Affirming Surgery	Surgical procedures that change one's body to conform to one's gender identity.†
Gender Expression	The physical and behavioral manifestations of one's gender identity.*
Gender Dysphoria	A distressed state arising from conflict between a person's gender identity and the sex the person has or was identified as having at birth.*
Gender Identity	A person's internal sense of being male, female, some combination of male and female, or neither male nor female.*
Gender Nonconforming	Exhibiting behavioral, cultural, or psychological traits that do not correspond with the traits typically associated with one's sex: having a gender expression that does not conform to gender norms.*
Honorific	A form of address prefixing an individual's name, which signals politeness, respect, or social deference. Examples include Mr., Mrs., Ms., and Miss.
Intersexuality	The condition (such as that occurring in congenital adrenal hyperplasia or androgen insensitivity syndrome) of either having both male and female gonadal tissue in one individual or of having the gonads of one sex and external genitalia that is of the other sex or is ambiguous.*
LGBTQIA+	An abbreviation and umbrella term used to encompass the spectrums of gender and sexuality and refer to a diverse community. The term stands for lesbian, gay, bisexual, transgender, queer/questioning (one's sexual or gender identity), intersex, and asexual/aromantic/agender;* the plus sign represents every other identity on the gender and sexuality spectrum.
Locally Designated Investigator	The investigative services unit investigator or another designated institutional staff member who has been trained to conduct investigations into allegations of sexual violence and staff sexual misconduct.
Medical Classification Chrono (MCC)	The Medical Classification Chrono (MCC) is part of the Medical Classification System (MCS) and is used by California Correctional Health Care Services and California Department of Corrections and Rehabilitation (CDCR) as part of a system for considering medical factors in making patient placement decisions. The MCC is generated via an electronic database and is viewable in the Strategic Offender Management System (SOMS), and is also printed for the patient's records. It is primarily utilized to communicate the need for transmission-based precautions to custody staff.‡
Nonbinary	Relating to or being a person who identifies with or expresses a gender identity that is neither entirely male nor entirely female.*
Pronouns	Any of a small set of words in a language that are used as substitutes for nouns or noun phrases and whose referents are named or understood in the context. Examples include he/him/his, she/her/hers, or they/them/theirs.*

Continued on next page.

Terms Used in This Report (continued)	
Substantiated Allegation	An allegation that was investigated and determined to have occurred.§
Strategic Offender Management System (SOMS)	The Strategic Offender Management System. SOMS is primarily comprised of two complex software applications that assist CDCR staff in managing their offender population. These applications are the Electronic Records Management System (ERMS) and the Electronic Offender Management Information System (eOMIS). ERMS is used to manage an offender's central file (documentation) that is scanned into ERMS to be accessed by CDCR users anywhere in the state. eOMIS is the main web-based/centralized application that manages an offender's time with CDCR while either in custody or on Parole. Various components of eOMIS include: Intake, Movements, Counts, Offender Grievance Tracking/ Appeals, Visitation, Classification, Sentence Calculation, Discipline, Gangs, etc. CDCR continues to add significant functionality to eOMIS on a regular basis.‡
Transgender	Of, relating to, or being a person whose gender identity differs from the sex the person had or was identified as having at birth.*
Transgender Man	A person who was assigned female at birth, but identifies and expresses their gender as male.‖
Transgender Woman	A person who was assigned male at birth, but identifies and expresses their gender as female.‖
Transition	The period during which a person begins to live as their true gender. It may include changing one's name, taking hormones, having surgery, and altering legal documents.†
Unsubstantiated Allegation	An allegation that was investigated and insufficient evidence was obtained to determine if the allegation did or did not occur.§

* Merriam-Webster.com Dictionary, s.v. "cisgender," "gender expression," "gender dysphoria," "gender identity," "gender nonconforming," "intersexuality," "LGBTQIA," "nonbinary," "pronouns," and "transgender," accessed July 17, 2020, **https://www.merriam-webster.com/dictionary/cisgender**.

† Transgender Terminology, hr.cornell.edu, accessed July 17, 2020. **https://hr.cornell.edu/sites/default/files/trans%20terms.pdf**.

‡ The California Department of Corrections and Rehabilitation.

§ Prison Rape Elimination Act (PREA) Annual Report – Calendar Year 2018, cdcr.ca.gov, accessed July 17, 2020. **https://www.cdcr.ca.gov/prea/wp-content/uploads/sites/186/2020/01/PREA-Annual-Report-2018.pdf**.

‖ Your Dictionary.com Dictionary, s.v. "transgender man," and "transgender woman," accessed July 17, 2020. **https://www.yourdictionary.com/transgender-man**.

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Summary

The California Department of Corrections and Rehabilitation (the department) incarcerates approximately 1,200 transgender, nonbinary, and intersex individuals.[1] These individuals form a vulnerable population within the prison system, as they face fear, discrimination, and violence. For many years, the unique needs of this population had been overlooked by the department. However, more recently, the department has worked with external stakeholders, lawmakers, and the incarcerated transgender, nonbinary, and intersex population itself to develop policies, procedures, and training for staff with the intent to improve conditions of confinement for this incarcerated population.

To that end, the department established a working group with various external stakeholders and administered forums and surveys to query transgender, nonbinary, and intersex individuals directly. In addition, the department is currently working with lawmakers who are crafting legislation that can improve daily life for individuals within this population. The Office of the Inspector General (OIG) observed the department's working group and its efforts to obtain pertinent information from the transgender, nonbinary, and intersex incarcerated population. We also observed the development of the staff training that resulted from the working group, and the implementation of some of that training.

The department has made noticeable efforts to improve departmental culture. However, we believe there is much work to be done to improve the safety and security of the transgender, nonbinary, and intersex population and to afford these individuals basic respect. We believe the department should take steps to implement the mandates of Senate Bill 132, regardless of whether the bill is signed into law, and require that staff and incarcerated individuals comply with these mandates. In addition, the department should establish oversight of its compliance with departmental policies relative to this population, so that both staff and incarcerated individuals are held accountable for failure to comply with policies. The department should continually optimize shelf space in canteens and effectively manage the inventory of clothing and property items for transgender, nonbinary, and intersex people as demographics, trends, and purchasing fluctuates. Moreover, the department should acknowledge that the gender binary is a social construct and work to dismantle it within departmental culture to allow more equitable access to vocational training and property items and to improve overall conditions of confinement for the transgender, nonbinary, and intersex population.

1. We recognize that terminology regarding transgender, nonbinary, and intersex issues is rapidly evolving. Some terms or definitions may not be universally accepted, and there is some disagreement among professionals and communities regarding the correct words and definitions. We use terminology in this report carefully, with intent to shed light on the complex and difficult issues facing incarcerated transgender, nonbinary, and intersex individuals with fairness, integrity, and respect.



Photo 1. Senator Scott Wiener with incarcerated transgender, nonbinary, and intersex persons. Photo provided courtesy of Terry Thornton of the California Department of Corrections and Rehabilitation.

Introduction

"No one deserves to be treated disrespectfully because of their gender identity or expression."

—Secretary Ralph Diaz
California Department of Corrections
and Rehabilitation
January 2020

A transgender individual is a person whose gender identity differs from their assigned sex at birth.[2] As of June 4, 2020, the California Department of Corrections and Rehabilitation (the department) incarcerated approximately 1,176 individuals who identified as transgender or had symptoms of gender dysphoria.[3] Because the transgender population has unique needs and may also be at a higher risk of victimization than the cisgender population, it is imperative that the department comply with Federal and State laws and provide these individuals with safe housing, medically necessary treatment, and protection as it should for all other individuals in its custody.

Federal and State laws, State regulations, and departmental policies already impose obligations on the department to provide safe housing, medically necessary treatment, and protection for all incarcerated individuals, especially those who may be at a higher risk of victimization.[4] Under the Fourth Amendment, incarcerated individuals have a limited right to privacy and are protected from repetitive and harassing searches.[5] The Eighth Amendment imposes duties on prison officials to take "reasonable measures to guarantee the safety of inmates" and "protect prisoners from violence at the hands of other prisoners."[6] Under the Eighth Amendment, incarcerated people have a right to be free from "cruel and unusual punishment," and prison officials must not be "deliberately indifferent" to a "substantial risk of serious harm" to an incarcerated individual at the hands of anyone, including another

2. *California Code of Regulations*, Title 15, Section 3000; World Professional Association for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (7th Version, 2012).

3. The department determined this number by counting the number of incarcerated individuals with the "transgender" box checked on their Medical Classification Chronos. This number does not include transgender, nonbinary, or intersex individuals who do not have the "transgender" box checked on their Medical Classification Chronos.

4. *Farmer* v. *Brennan* (1994) 511 U.S. 825; *Doe* v. *District of Columbia* (D.C. Cir. 2016) 215 F.Supp.3d 62, 75.

5. *Bull* v. *City and County of San Francisco* (9th Cir. 2010) 595 F.3d 964, 974–975; *Michenfelder* v. *Summer* (9th Cir. 1988) 860 F.2d 328, 332.

6. Ibid. 833, citations omitted.

incarcerated individual.[7] Prison officials are also obligated under the Eighth Amendment to provide the incarcerated population with adequate medical care.[8]

Federal law, established through the Prison Rape Elimination Act (PREA) of 2003, set a zero-tolerance standard for prison rape and required the United States Attorney General to publish national standards to prevent, detect, and respond to sexual violence, sexual misconduct, and sexual harassment in all prisons. It also required that state prisons adopt standards consistent with national standards in order to receive federal funding.[9] In response, the California Legislature enacted the Sexual Abuse in Detention Elimination Act (SADEA) to protect California's incarcerated population from sexual abuse. The law mandates, through several core requirements, that the department establish policies and procedures to address the sexual abuse of incarcerated individuals.[10]

Following the model established by PREA and SADEA, the department promulgated regulations, policies, and procedures intended to provide all incarcerated individuals with safe housing and humane and respectful treatment.[11] Departmental policy requires that all staff—including employees, volunteers, and contractors—receive instruction on preventing, detecting, responding to, and investigating sexual violence, staff sexual misconduct, and sexual harassment. The department provides this instruction during its new employee orientation and annual training as well as in its training academy curriculum for new officers.[12] Furthermore, the department provides specialized training regarding PREA to locally designated investigators at each institution.[13]

In 2012, the department designated 11 institutions to house transgender, nonbinary, and intersex individuals to ensure they receive safe housing and necessary services, including medical and mental health treatment.

7. Ibid., 833–834.

8. *Edmo* v. *Corizon*, Inc. (9th Cir. 2019) 935 F.3d 757, 768-769; *Rosati* v. *Igbinoso* (9th Cir. 2015) 791 F.3d 1037; *Kosilek* v. *Spencer*; (1st Cir. 2014) 774 F.3d 63; *Fields* v. *Smith* (7th Cir. 2011) 653 F.3d 550; but see *Avilez* v. *Barr* (N.D. Cal., Feb. 5, 2020, No. 19-CV-08296-CRB) 2020 WL 570987; laws regarding transgender, nonbinary, and intersex individuals vary in federal jurisdictions and different states. Unless otherwise indicated, the law cited in this report is applicable to entities and individuals in California and will likely change as more cases are litigated and appealed.

9. 42 *United States Constitution*, Section 15601, et seq.

10. *California Penal Code* section 2635 et seq.; Sexual Abuse in Detention Elimination Act of 2005; US Department of Justice, National Standards to Prevent, Detect and Respond to Prison Rape, *Federal Register,* 77, no. 119, (June 20, 2012); California Department of Corrections and Rehabilitation, Department Operations Manual (hereafter referred to as DOM), Article 44, et seq.

11. DOM, Sections 33030.3.1, 31140.5, and 33030.3.

12. DOM, Section 54040.4.

13. Department of Corrections and Rehabilitation Training Materials: Specialized PREA Training for Locally Designated Investigators (June 2015).

That number has since grown to 14 institutions.[14] To the extent practicable, transgender, nonbinary, and intersex individuals are now housed at one of the 14 designated institutions. If individuals want to be housed at another type of institution (e.g., a transgender woman requesting housing at an institution for women), they can submit a request to their assigned correctional counselor. That request is then considered as part of the department's classification process.[15]

In 2015, a federal district court in California found the department violated the Eighth Amendment rights of Ms. Norsworthy, a transgender woman diagnosed with gender dysphoria and housed at an institution for men, when it denied her medically necessary gender affirming surgery.[16] The order was stayed while the department appealed the order to the Ninth Circuit, but Ms. Norsworthy paroled before the hearing.

Later in 2015, the department entered into a settlement agreement in *Quine* v. *Beard*. As part of the settlement, the department agreed to provide Ms. Quine with gender-affirming surgery and revise its policies to allow identified incarcerated individuals access to property items consistent with their gender identity and expression. The department amended its regulations to permit identified individuals at designated institutions to possess state-issued clothing consistent with their gender identity and expression and created the Transgender Inmates Authorized Personal Property Schedule (TIAPPS), which expanded the list of available items for these individuals.[17] The department's operations manual also provides that individuals identified as transgender on the Medical Classification Chrono shall, upon request, receive state-issued bras or boxer shorts via the institution's clothing room and be permitted to purchase such items as needed.[18]

To facilitate transgender individuals' access to proper clothing and other authorized items from canteens and approved vendors, the department established the Transgender Access Card (access card) program in June 2019. When requesting, purchasing, or picking up approved transgender, nonbinary, and intersex items, individuals must have a transgender access card and state-issued identification card.

14. The 14 institutions include California Medical Facility, Richard J. Donovan, San Quentin State Prison, Mule Creek State Prison, California Substance Abuse Treatment Facility, California State Prison Sacramento, Salinas Valley State Prison, California Institution for Men, Kern Valley State Prison, California Men's Colony, California Health Care Facility, Central California Women's Facility, California Institution for Women, Folsom Women's Facility; DOM, Section 62080.14.

15. *California Code of Regulations*, Title 15, Section 3269; DOM, Section 54040.1 et seq.

16. *Norsworthy* v. *Beard* (N.D. Cal. 2015) 87 F.Supp.3d 1164, appeal dismissed and remanded (9th Cir. 2015) 802 F.3d 1090.

17. *Quine* v. *Kernan* (9th Cir. 2018) 741 Fed.Appx. 358; *Quine* v. *Beard* (N.D. Cal., August 7, 2015, No. 3:14-cv-02726); *California Code of Regulations*, Title 15, Section 3000, Section 3030, subdivision (c), Section 3190, subdivision (d), Section 3269; Transgender Inmates Authorized Personal Property Schedule (TIAPPS) (April 4, 2018).

18. DOM, Section 62080.14.; *California Code of Regulations*, Title 15, Section 3030, subdivision (c).

An individual may request a transgender access card by submitting an Inmate Request for Interview, Item of Service form.[19]

Also, in 2019, the department formed its Transgender Housing and Search Working Group to assess and revise its housing and search policies and procedures specific to incarcerated transgender, nonbinary, and intersex individuals.[20] The OIG observed the working group meetings. Based on our observations, the working group remained steadfast in developing policies and procedures pertaining to housing and searches, and simultaneously addressed interrelated issues. Members engaged in frank discussions and robust analysis regarding the needs of the incarcerated population, departmental policies and procedures, technology, systemic problems, departmental culture and practices, resources, and potential solutions.

As part of the working group, the department collaborated with external stakeholders to develop and administer a survey at 18 institutions to query the incarcerated transgender, nonbinary, and intersex population. Information gathered through the survey has helped the department to better understand the experiences and preferences of this incarcerated population.[21] The survey included both structured multiple-choice questions and an opportunity to provide written comments regarding additional issues of concern. The surveys were voluntary and anonymous, but included demographics such as the institution where the department administered the survey, the gender identity participants most often use to describe themselves, and whether participants identify as a transgender man, a transgender woman, a nonbinary individual, an intersex individual, or other.

Following each survey session, the department invited incarcerated transgender, nonbinary, and intersex individuals to participate in a forum. During the forums, the OIG observed departmental personnel engaging in candid discussions with transgender, nonbinary, and intersex participants. Facilitators and departmental staff demonstrated professionalism, empathy, and a commitment to improving conditions of confinement for this incarcerated population. Facilitators acknowledged the department's shortcomings, provided candid

19. Department of Corrections and Rehabilitation, Form 22.

20. The working group, chaired by the Associate Director of the Female Offender Program, includes departmental employees from different disciplines, classifications, and institutions statewide, including chief deputy warden(s), associate warden(s), captain(s), lieutenant(s), sergeant(s), psychologist(s), and physician(s), a community resource manager, and an officer of transgender experience. Members of the group also include departmental executives and staff from the custody and health care headquarters, including the Assistant Secretary of Legislative Affairs, the Ombudsperson, the Public Information Officer, the Statewide PREA Coordinator, a correctional counselor, legal counsel, and employees from budgets and plant operations. Legislative staffers and external stakeholders also attended some of the working group meetings and consulted with departmental personnel between meetings.

21. External Stakeholders include but are not limited to American Civil Liberties Union (ACLU); Medina Orthwein LLP; Prison Law Office (PLO); Equality California; Gender-Variant Intersex Justice Project (TGIJP); and TransLatin@Coalition.

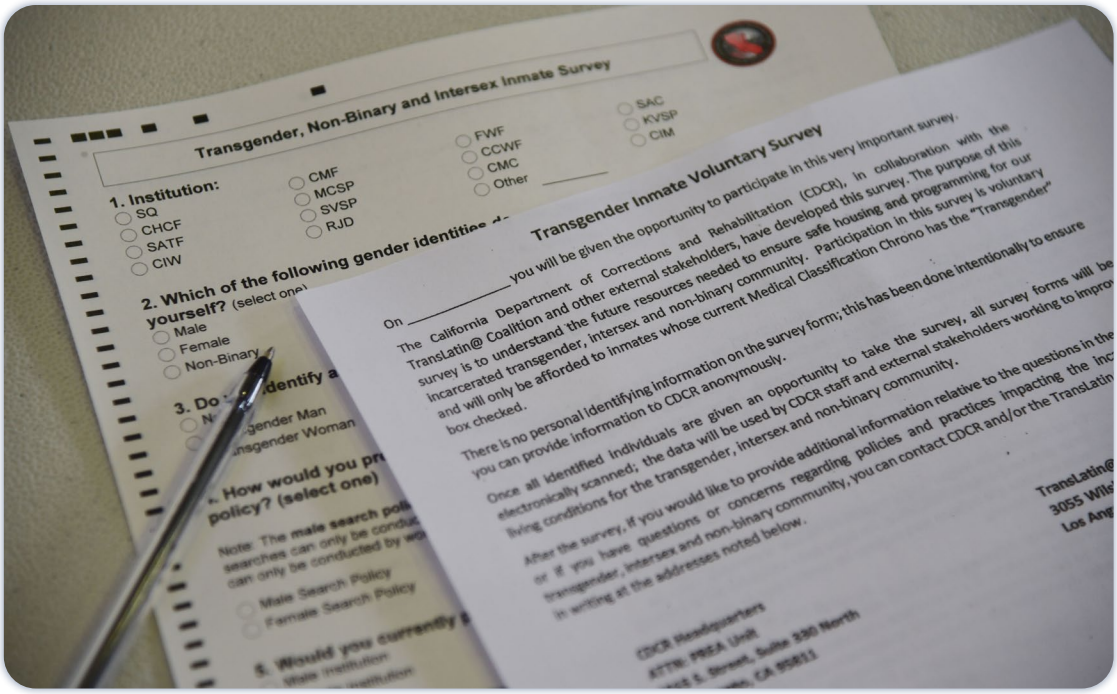


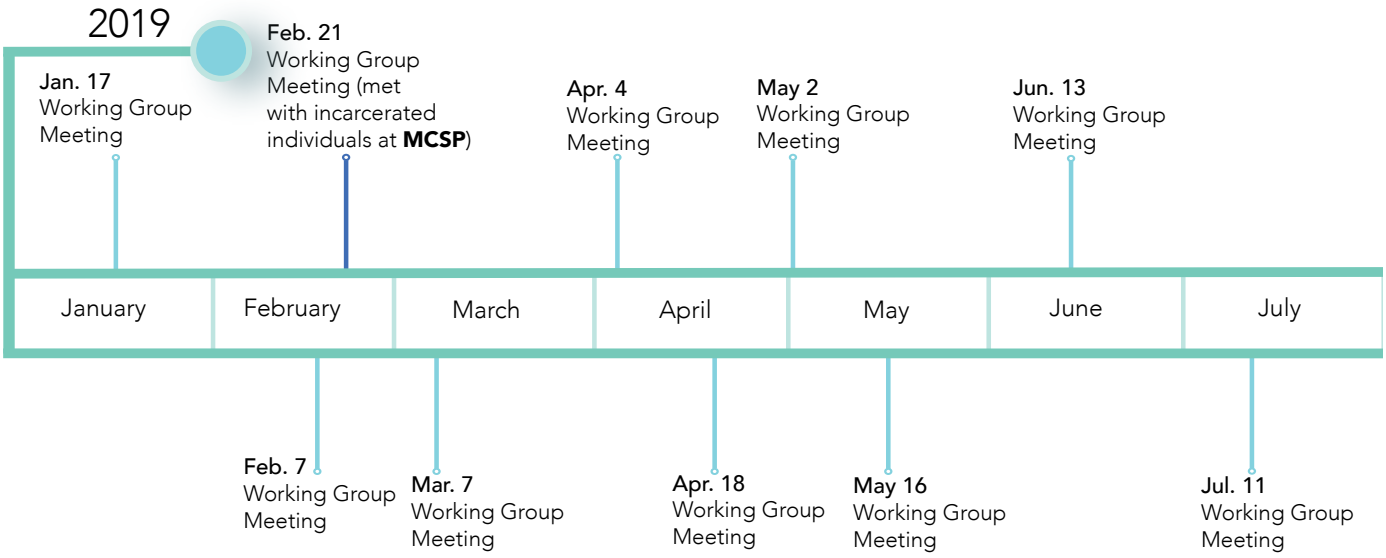
Photo 2. Transgender, nonbinary, and intersex inmate survey. Photo provided courtesy of Terry Thornton of the California Department of Corrections and Rehabilitation.

answers and, when feasible, took prompt action to resolve problems. They also invited external stakeholders to introduce themselves and the services they provide, respond to questions, speak privately with incarcerated individuals, and share their contact information for future correspondence.

We also observed the department's new Training-for-Trainers curriculum, called Working Successfully With Transgender, Intersex, and Nonbinary Inmates. During this time, the OIG engaged in ongoing dialogue with departmental representatives regarding the department's past, present, and planned efforts to improve the housing, services, and welfare of transgender, nonbinary, and intersex individuals. The OIG also consulted with external stakeholders to gain their perspective on the issues incarcerated transgender, nonbinary, and intersex individuals face.

In this report, the OIG sheds light on the experiences of transgender, nonbinary, and intersex individuals while incarcerated, conveys the concerns and advocacy of external stakeholders, and outlines the department's progress in addressing the varied and complex issues facing incarcerated transgender, nonbinary, and intersex individuals. We also make recommendations to the department to improve conditions of confinement for this incarcerated population.

Figure 1. Activities of the Transgender Housing and Search Working Group Between January 2019 and February 2020



Institutions

CCWF: Central California Women's Facility
CHCF: California Health Care Facility, Stockton
CIM: California Institution for Men
CIW: California Institution for Women
CMC: California Men's Colony
CMF: California Medical Facility
COR: California State Prison, Corcoran
DVI: Deuel Vocational Institution
FWF: Folsom Women's Facility
KVSP: Kern Valley State Prison
MCSP: Mule Creek State Prison
NKSP: North Kern State Prison
RJD: Richard J. Donovan Correctional Facility
SAC: California State Prison, Sacramento
SATF: Substance Abuse Treatment Facility
SQ: San Quentin State Prison
SVSP: Salinas Valley State Prison
WSP: Wasco State Prison

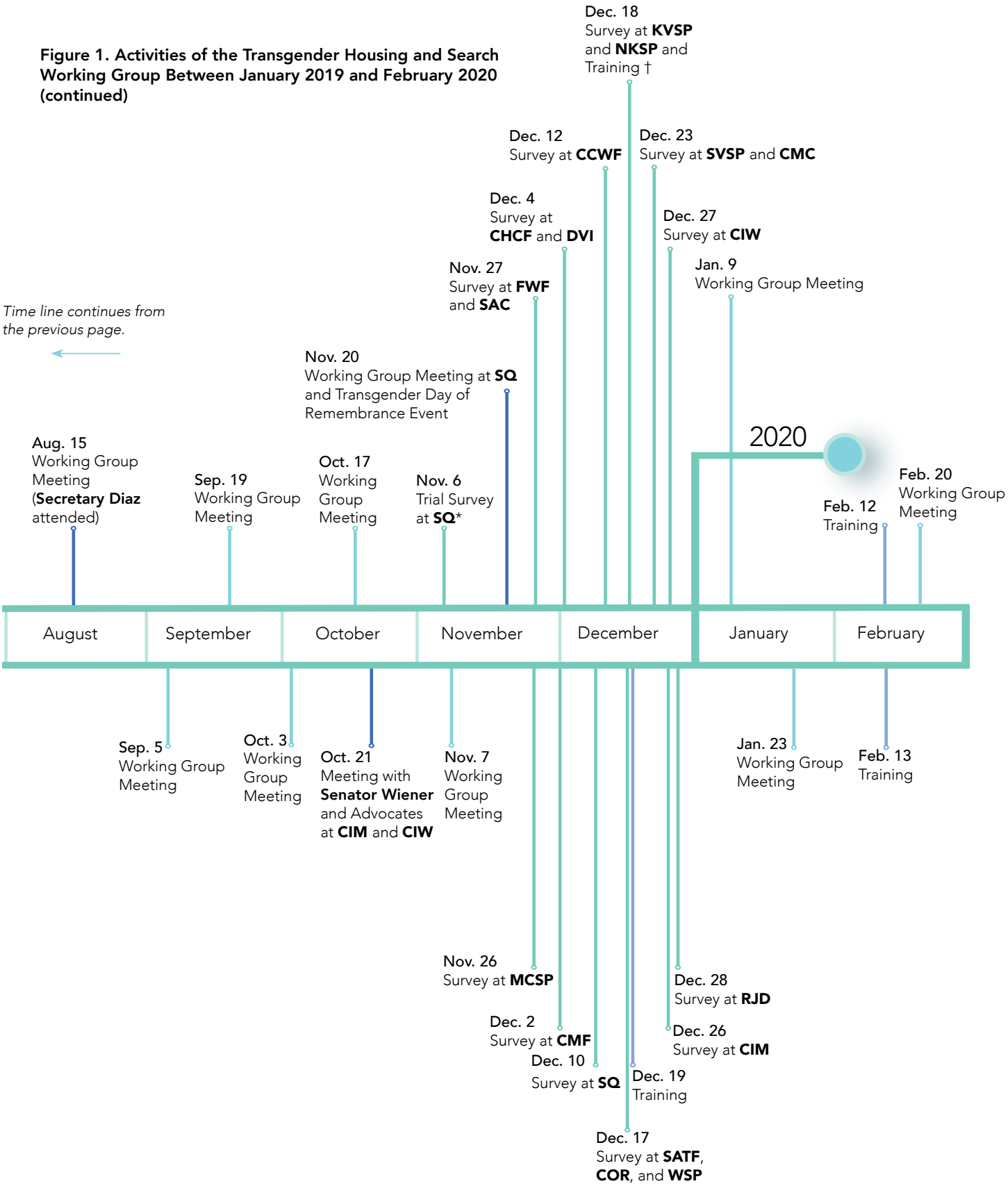
Time line continues on the following page.

* *Survey* refers to the Transgender, Nonbinary, and Intersex Survey through which the department queried the incarcerated population regarding housing preferences, search preferences, and other topics of concern.

† *Training* refers to the department's four-hour Training-for-Trainers sessions: Working Successfully With Transgender, Intersex, and Nonbinary Inmates.

Source: The California Department of Corrections and Rehabilitation.

Figure 1. Activities of the Transgender Housing and Search Working Group Between January 2019 and February 2020 (continued)



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Transgender, Nonbinary, and Intersex Individuals Reported They Are Vulnerable to Violence and Discrimination While Incarcerated

Transgender individuals have suffered a history of persecution, discrimination, and violence.[22] The Federal Bureau of Investigation's 2018 Hate Crime Statistics indicated that 85.6 percent of hate crimes committed on the basis of gender identity were motivated by an "anti-transgender bias."[23] The same trend occurs among the incarcerated population, as transgender people fall victim to maltreatment, sexual assault, and murder.[24] In 2018, the American Medical Association issued a press release noting that transgender individuals suffer disproportionately from sexual assault during incarceration. The press release cited a study of California prisons indicating "59 percent of transgender prisoners experience sexual assault, versus only 4.4 of the overall prison population," as well as another study reflecting "the proportion of transgender prisoners in California experiencing sexual assault to be as high as 75 percent."[25] The vulnerability of this population is echoed in the stories told by transgender, nonbinary, and intersex individuals during the surveys and forums we attended.

> "We are not treated like women or men. We are treated as less than human. Prison is a place to change, and a place to really figure yourself out and become a better person. The way we're treated hinders us from rehabilitation."
>
> —Incarcerated Transgender Woman December 2019

22. *Crowder* v. *Diaz* (E.D. Cal., Aug. 19, 2019, No. 2:17-CV-1657-TLN-DMC) 2019 WL 3892300; *F.V.* v. *Barron* (D. Idaho 2018) 286 F.Supp.3d 1113, citing *Adkins* v. *City of New York* (S.D.N.Y. 2015) 143 F.Supp.3d 134; *Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.* (7th Cir. 2017) 858 F.3d 1034, 1051; *Karnoski* v. *Trump* (W.D. Wash. Apr. 13, 2018, No. C17-1297-MJP) 2018 WL 1784464; *F.V.* v. *Barron* (D. Idaho 2018) 286 F. Supp. 3d 1131, 45; *Adkins* v. *City of N.Y.* (S.D.N.Y. 2015) 143 F. Supp. 3d 134, 139; *M.A.B.* v. *Bd. of Educ.* (D. Md. 2018) 286 F. Supp. 3d 704, 720; *Bd. of Educ. of the Highland Local Sch. Dist.* v. *U.S. Dep't of Educ.* (S.D. Ohio 2016) 208 F.Supp.3d 850, 874; *Evancho* v. *Pine-Richland Sch. Dist.* (W.D.Pa. 2017) 237 F.Supp.3d 267, 288; *Grimm* v. *Gloucester Cty. Sch. Bd.* (E.D. Va. 2018) 302 F. Supp. 3d 730, 749.

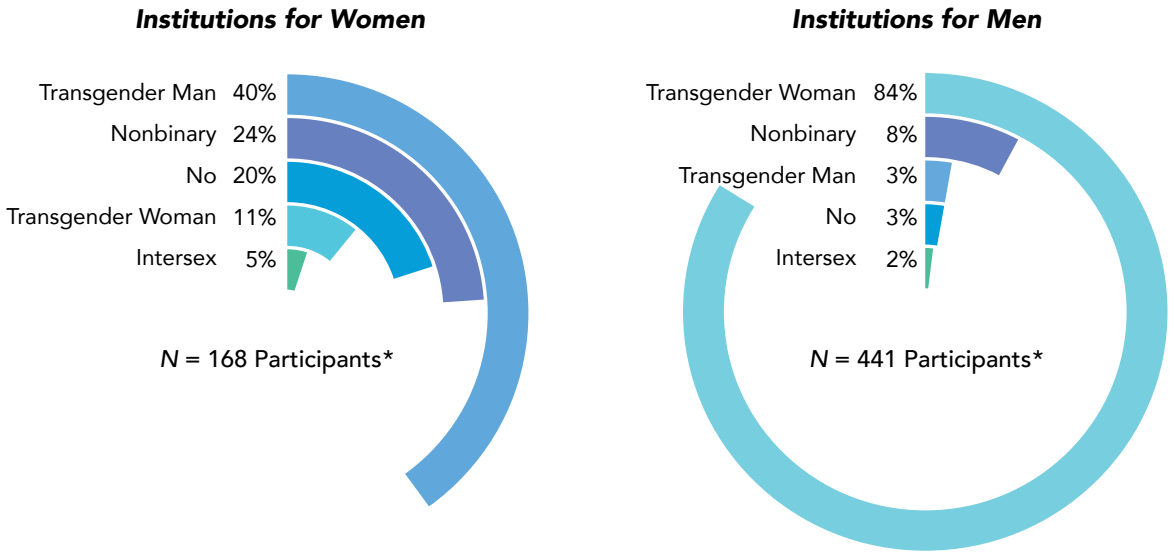
23. United States Department of Justice, Federal Bureau of Investigation: Hate Crime Statistics (2018), https://ucr.fbi.gov/hate-crime/2018/topic-pages/victims.

24. Prison Rape Elimination Act; "Classification and Housing of Transgender Inmates in American Prisons," *Harvard Law Review*, 127, no. 6 (2014), 1746; Sharon Dolovich, "Cruelty, Prison Conditions, and the Eighth Amendment," *New York University Law Review*, 84, no. 4 (2009): 881, 886–889; Gabriel Arkles, "Safety and Solidarity Across Gender Lines: Rethinking Segregation of Transgender People in Detention," *Temple Political & Civil Rights Law Review*, 18, no. 2 (2009), 515, 537–540.

25. American Medical Association, Press Release: "AMA Urges Appropriate Placement of Transgender Prisoners" (June 11, 2018), https://www.ama-assn.org/press-center/press-releases/ama-urges-appropriate-placement-transgender-prisoners.

Figure 2. Identities of Transgender, Nonbinary, and Intersex Inmate Survey Participants Between November 2019 and January 2020

Do you identify as transgender, nonbinary, or intersex?



Glossary

Transgender Man: A person who was assigned female at birth, but identifies and expresses their gender as male.

Transgender Woman: A person who was assigned male at birth, but identifies and expresses their gender as female.

Nonbinary: Relating to or being a person who identifies with or expresses a gender identity that is neither entirely male nor entirely female.

Intersex: Having both male and female gonadal tissue in one individual or of having the gonads of one sex and external genitalia that is of the other sex or is ambiguous.

No: Does not identify as transgender, nonbinary, or intersex.

* These figures represent the total number of individuals who participated in the Transgender, Nonbinary, and Intersex Inmate Survey at institutions for women and at institutions for men.

Source: The California Department of Corrections and Rehabilitation's analysis of the Transgender, Nonbinary, and Intersex Inmate Survey results between November 2019 and January 2020.

AR-002523

Incarcerated Transgender, Nonbinary, and Intersex Individuals Described a Culture of Disrespect by Both Staff and Other Incarcerated Individuals

Departmental policy acknowledges the role of "language used by staff toward inmates" in "creating a culture of safety and respect that can impact the emotional well-being of inmates, including transgender inmates."[26] It provides instruction on acceptable methods for communicating with transgender individuals, such as using gender-neutral language and the correct pronouns. Departmental policy makes clear that using "derogatory remarks, insults, and epithets," and "repeatedly calling a transgender inmate by the wrong pronouns or name, after the transgender inmate has provided notice of his or her gender identity to staff" is a violation of departmental policy.[27] Nevertheless, some staff are hostile, discourteous, unprofessional, and insensitive toward transgender, nonbinary, and intersex individuals, generating a culture of disrespect.

"Where are all my bitches at?"

—Incarcerated Individual Quoting an Officer December 2020

At the forums the OIG attended, incarcerated individuals explained that staff use epithets such as "faggot" and "fag," and other derogatory remarks toward transgender, nonbinary, and intersex people. One individual recounted a female officer asking "do you have your dick and balls tied to your back?" Another individual claimed that a male officer said "I have a real one." Another individual reported that while identifying transgender people at a male institution, an officer called out, "Where are all my bitches at?"

Incarcerated individuals shared stories of staff who intentionally misgender them by using the wrong pronouns. For example, some staff refer to transgender male individuals as "she" or "her." Officers also refer to individuals using first names that conflict with individuals' gender identity. Incarcerated individuals expressed less concern about the officers who tried to use correct pronouns, and sometimes made mistakes, but were troubled by officers who repeatedly, and appeared to purposefully, use the wrong pronouns.

The intolerance endured by transgender, nonbinary, and intersex individuals extends even further than verbal abuse. Two individuals reported that when the department transported them from an institution designated for transgender individuals to a non-designated institution, staff at the non-designated institution refused to accept them into the institution, grant them access to the bathroom, or allow them to exit the transportation vehicle. Instead, staff at the non-designated institution had them transported to another institution, nearly 380 miles away.

26. DOM, Section 54040.4.1.

27. Ibid.

Incarcerated transgender, nonbinary, and intersex individuals also described situations in which staff drew unwelcome attention to them. According to these individuals, the department's practice of scheduling hormone therapy and testing for transgender, nonbinary, and intersex patients on the same day and time each week draws unwelcome attention to them because it causes them to gather in waiting areas at the same time and become easily identifiable to other incarcerated individuals. The OIG observed similar attention being called to this population before a survey and forum at one of the institutions. A departmental staff member announced over the public address system for "all transgender inmates" to go to the meeting, which unnecessarily caused those who left to attend the survey and forum to be singled out and identifiable to other people. While changes to departmental policies and practices can mitigate the aforementioned issues, some forms of unwelcome attention can only be prevented through a cultural shift within the department. At one of the forums, an individual described that an officer displayed an old picture of the individual and called upon others to, "Look, this is what [the individual] looked like before."

"The C/Os single out all transgender, intersex, and nonbinary inmate[s], for no other reason than to make fun of us because of our gender. It's not right and need to be changes made to the treatment of this community."

—Incarcerated Nonbinary Individual Most Often Identifies as Nonbinary November 2019

Without minimizing the above-referenced experiences and concerns, it is important to note that a few transgender individuals acknowledged the department's effort to improve its culture and expressed that certain staff understand and support transgender, nonbinary, and intersex individuals. Individuals at one institution stated, "It is much better than 5 years ago," "It's getting better, "It's all going in the right direction," and "There are good staff, including [the investigative services unit]."

Incarcerated Transgender, Nonbinary, and Intersex Individuals Asserted That Staff Conduct Unprofessional Searches

The department has an obligation to comply with Federal and State laws, including the Federal Prison Rape Elimination Act (PREA), which provides that searches be conducted in the least intrusive manner consistent with security needs. Because of this, departmental policy requires that routine unclothed body searches "be conducted in a safe manner and in an area that allows the inmate to preserve some measure of dignity and self-respect."[28] However, transgender, nonbinary, and intersex individuals at the forums reported that officers target them with increased searches, deny them privacy during unclothed body searches, and make vulgar comments during the searches.

"Fuck that, bitch—bend over."

—Incarcerated Individual Quoting an Officer December 2020

At one institution, incarcerated individuals reported that officers intentionally strip search them in front of others, including routine strip searches conducted during work exchange. When individuals ask for privacy, officers respond with comments such as "Fuck that, bitch—bend over." One individual indicated that a female officer grabbed the individual's breast during a search rather than using the back of her hand

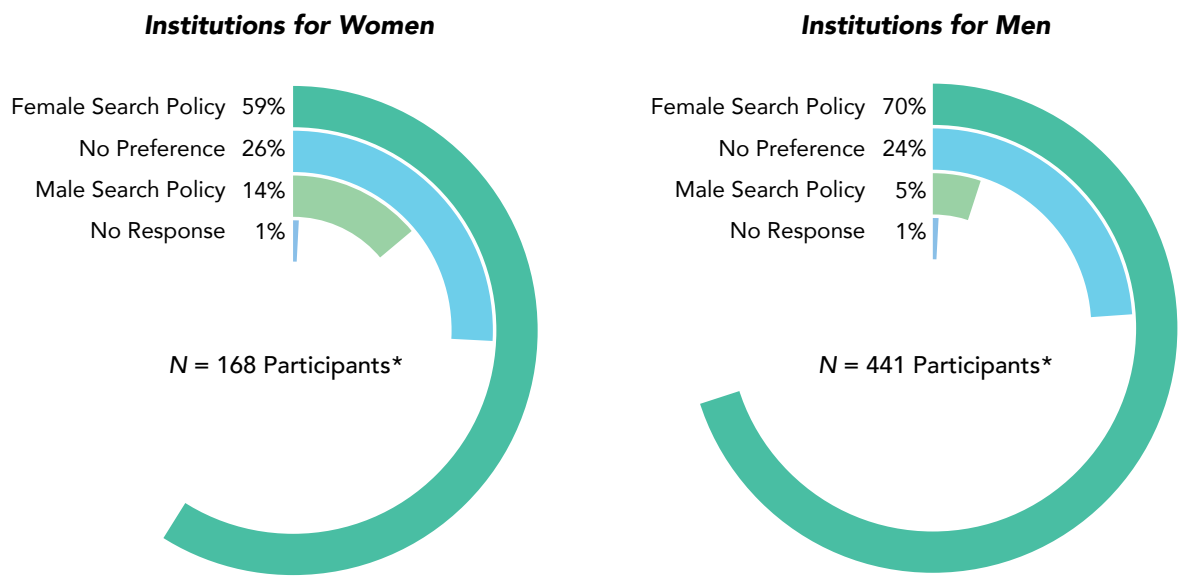
28. *Code of Federal Regulations*, Sections 115.15, 115.115, 115.215, and 115.315.

as required by departmental policy. When the individual complained, the officer replied, "Don't worry; it's not a big deal. I have those, too." An individual from another institution described an incident wherein the institution terminated the individual's job assignment and issued a negative write-up because the individual refused to be strip searched in front of other people during work exchange.

Although most transgender, nonbinary, and intersex individuals described unprofessional searches, one group shared the belief that officers would honor requests to be searched in a private setting.

Figure 3. Search Preferences of Transgender, Nonbinary, and Intersex Inmate Survey Participants Between November 2019 and January 2020

How would you prefer to be searched: with the male search policy or the female search policy?



Glossary

Male Search Policy: Clothed body searches can be conducted by men or women, unclothed searches can only be conducted by men.

Female Search Policy: Both clothed and unclothed body searches can only be conducted by women.

* These figures represent the total number of individuals who participated in the Transgender, Nonbinary, and Intersex Inmate Survey at institutions for women and at institutions for men.

Source: The California Department of Corrections and Rehabilitation's analysis of the Transgender, Nonbinary, and Intersex Inmate Survey results between November 2019 and January 2020.

Incarcerated Transgender, Nonbinary, and Intersex Individuals Expressed That the Department Does Not Provide Sufficient Privacy When They are Unclothed

"This is not asked [in this survey], privacy partitions that adequately keep others from seeing our genitalia and bodies like we shower at as the so called privacy partitions are a joke. You can walk up to a shower and see everyones bodies, i.e., genitalia. I get harassed on a daily basis. Guys walking by the showers looking in it causes problems. I'm 6'5" tall and the privacy partitions are a joke. These showers especially in C-15, need to be fixed and or tall movable privacy curtains need to be made and brought into all the housing units."

—Incarcerated Transgender Woman November 2019

The Fourth Amendment provides incarcerated individuals with a limited right to privacy, subject to limitation to maintain institutional security.[29] Both PREA and departmental policy are designed to limit cross-gender viewing when individuals shower, use the bathroom, and change clothes, to exigent circumstances or when viewing is incidental to routine cell checks.[30] PREA also provides that transgender individuals be allowed to shower separately.[31] Except in circumstances in which safety and security would be compromised, modesty screens (also referred to as privacy curtains) are placed strategically to prevent incidental viewing.[32]

Notwithstanding these policies, incarcerated individuals claimed the department denies them the basic self-respect and personal dignity of shielding their unclothed body from strangers of the opposite sex. To transgender, nonbinary, and intersex individuals, privacy is not only self-respect and personal dignity, but safety. These individuals voiced concern that the department does not provide them with sufficient privacy to take showers, use the bathroom, or change clothes. They reported that some institutions and facilities have privacy curtains while others do not; some have privacy curtains that are broken or altered; and others have curtains that are too small. They also reported that some officers do not provide them with separate shower times, thereby increasing the likelihood of cross-gender viewing. For this reason, some transgender, nonbinary, and intersex individuals forego showering altogether and instead take a "bird bath."[33]

Individuals housed in dormitory settings reported they do not have the same privacy to change clothes as individuals housed in a single or double cell. Those housed in a dormitory "have an audience" of other incarcerated individuals who stare at them and "play with themselves."

One group of incarcerated individuals indicated that officers in one facility afforded separate shower times for transgender, nonbinary, and intersex people, which provided them with more privacy.

29. *Bull* v. *City and County of San Francisco*, supra, 595 F.3d at p. 972; *Michenfelder* v. *Sumner*, supra, at p. 333.; *Bell* v. *Wolfish*, supra, 441 U.S. 520.

30. *Code of Federal Regulations*, Section 115.15, subdivision (d); DOM, Section 54040.4.

31. *Code of Federal Regulations*, Section 115.42, subdivision (f).

32. DOM, Section 54040.4.

33. A bird bath is similar to sponge bath; it constitutes bathing using water from an in-cell sink.

Incarcerated Transgender, Nonbinary, and Intersex Individuals Expressed That Reporting Sexual Harassment Is Futile

According to the Presidential Memorandum Implementing the Prison Rape Elimination Act, "the success of PREA in combating sexual abuse in confinement facilities" hinges on "effective agency and facility leadership and the development of an agency culture that prioritizes efforts to combat sexual abuse."[34] The department has made efforts to implement PREA through its policy and expectations for staff. Departmental policy requires that staff report any information indicating an incarcerated individual is being, or has been the victim of sexual violence, sexual misconduct, or sexual harassment from departmental staff, other incarcerated individuals, or both. Staff are also expected to show sensitivity and maintain professional behavior during interactions with victims.[35]

Despite the department's efforts to effectively implement PREA, incarcerated transgender, nonbinary, and intersex individuals expressed that PREA "is not effective at all." Several individuals shared accounts of being victims of sexual violence while incarcerated; some claimed they previously reported the incidents to staff, while others indicated they were reporting the incident for the first time.[36] Incarcerated transgender, nonbinary, and intersex individuals are reluctant to file complaints of sexual assault or harassment because staff do not take their complaints seriously, do not conduct interviews in private settings, and ridicule incarcerated individuals for complaining. Incarcerated individuals also relayed that staff retaliate against them when they complain—officers automatically place transgender, nonbinary, and intersex complainants in administrative segregation, which results in victims losing their jobs, educational programs, rehabilitative programs, and housing assignments. At one institution, incarcerated individuals explained that officers, including those in the investigative services unit, do not take allegations of sexual assault seriously and have responded with comments, such as "I thought you liked it that way."

> "I thought you liked it that way."
>
> —Incarcerated Individual Quoting Officers December 2020

Individuals at the forums also indicated that incarcerated cisgender individuals as well as other gender nonconforming individuals, misuse the PREA reporting process and protections by falsely accusing transgender, nonbinary, and intersex individuals of sexual assault to have them placed in administrative segregation, and cause the them to lose their desired job, education, rehabilitative programs, and housing

34. Memorandum of President Implementing the Prison Rape Elimination Act (May 17, 2017), https://obamawhitehouse.archives.gov/the-press-office/2012/05/17/presidential-memorandum-implementing-prison-rape-elimination-act.

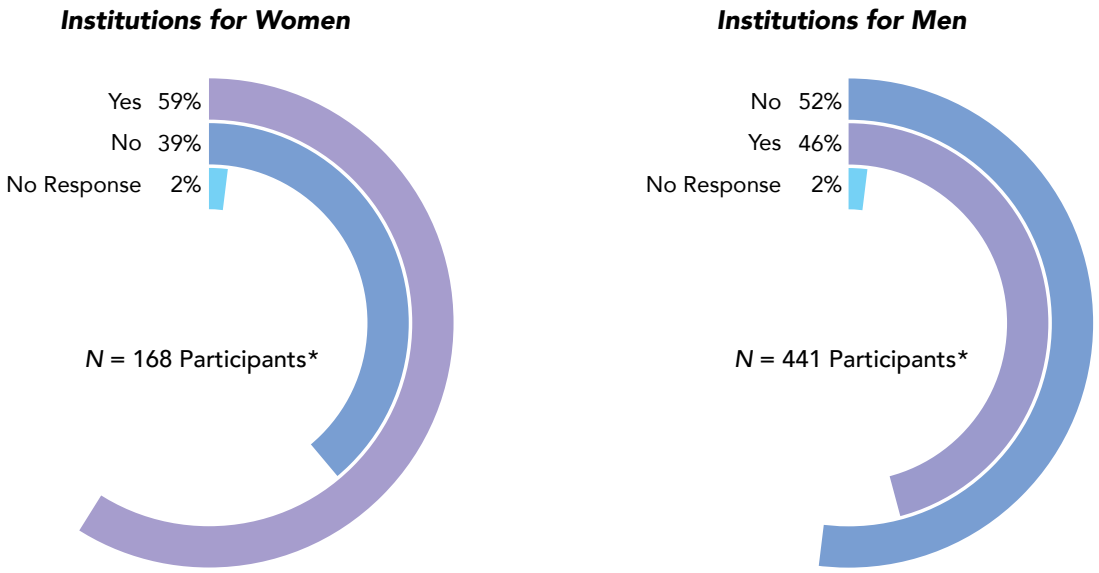
35. DOM, Section 54040.7.

36. Regardless of when the incident occurred, or whether the incarcerated person claimed to have previously reported the incident, members of the working group provided the information to the department's Statewide Prison Rape Elimination Act Coordinator or another appropriate departmental representative who obtained the necessary information to confirm an inquiry had already been conducted or to initiate an inquiry pursuant to the department's policies and procedures.

assignment. They explained that some people file false allegations against transgender, nonbinary, or intersex individuals to have them removed from a cell, room, or dorm.

Figure 4. Transgender, Nonbinary, and Intersex Inmate Survey Participants' Responses Regarding Safety in Reporting Discrimination, Harassment, and Violence Between November 2019 and January 2020

Do you believe you can safely report discrimination, harassment, or violence committed based on your status as a transgender, nonbinary, or intersex person?



* These figures represent the total number of individuals who participated in the Transgender, Nonbinary, and Intersex Inmate Survey at institutions for women and at institutions for men.

Source: The California Department of Corrections and Rehabilitation's analysis of the Transgender, Nonbinary, and Intersex Inmate Survey results between November 2019 and January 2020.

"Staff don't take your [PREA] cases serious[ly] and refuse you to make a complaint and staff harasses you and belittle you for alerting them, because of your status being transgender."

—Incarcerated Transgender Woman
November 2019

Incarcerated Transgender, Nonbinary, and Intersex Individuals Reported They Are at Risk of Violence Due to Unsafe Housing and the Department Does Not Respond Adequately to Their Concerns

Housing transgender, nonbinary, and intersex individuals with compatible cellmates is critical for ensuring the safety of those individuals while incarcerated. When the department overlooks incarcerated individuals' safety concerns or concerns regarding incompatibility with a cellmate, it puts these individuals' lives in jeopardy. On October 31, 2013, officers discovered a dead transgender woman in her cell, covered in a blanket with cloth ligatures looped around her neck three times, and both hands bound together and tied to her bunk. She died at the hands of her cellmate, hours after they became cellmates. Upon inspecting the cell, an investigator found two writings from the deceased: one indicating she was worried her new cellmate would rape her, and the other conveying a grim forecast—"Never mind tired of being abused better off dead." In December 2019, a judge sentenced the woman's cellmate to death. The cellmate had reportedly told officers he would kill the transgender woman if he were forced to share a cell with her.[37] In addition, the cellmate told the trial judge that he had previously attacked a gay cellmate, claiming "I had a restriction not to be housed with a [gay expletive]."[38]

During the forums we attended, incarcerated individuals reported the department does not provide them with safe housing or adequately respond to their safety concerns. They recounted situations in which officers dismissed their safety concerns and placed them in unsafe housing environments with incompatible cellmates. One individual claimed that, at the behest of officers, multiple incarcerated individuals attacked her from behind on an exercise yard, which resulted in her hospitalization and confinement to a wheelchair. Because she could not identify her attackers, officers ordered her to return to the same exercise yard where the attack occurred. When she refused to return to the exercise yard, officers placed her in administrative segregation.

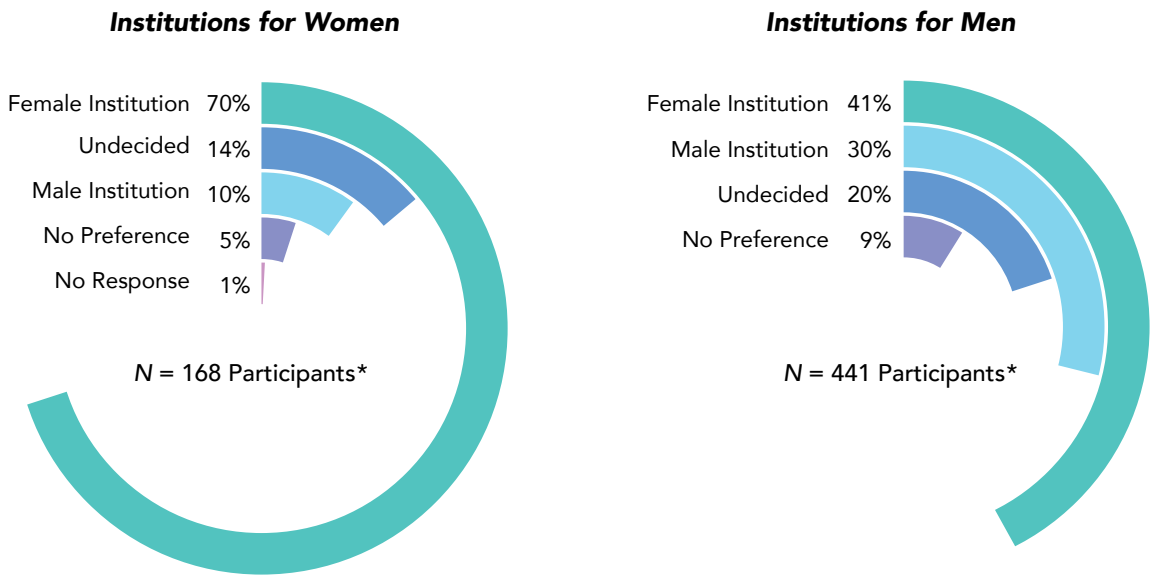
37. Miranda Leitsinger, "Transgender Prisoners Say They 'Never Feel Safe,' Could a Proposed Law Help?," KQED (January 8, 2020), **https://www.kqed.org/news/11794221/could-changing-how-transgender-inmates-are-housed-make-prison-safer-for-them**.

38. Tim Fitzsimons, "Man sentenced to death for killing transgender cellmate," NBC News (December 6, 2019), **https://www.nbcnews.com/feature/nbc-out/man-sentenced-death-killing-transgender-cellmate-n1097161**.

Another individual stated that officers housed her in a six-person room with "two serial rapists" who stood near her bunk at night and also watched her use the bathroom. Given her petite stature and the warnings she received from other incarcerated individuals regarding the cellmates' predatory nature, the individual felt unsafe and requested a room change. However, an officer denied her request to move, citing she had a physician's note for a lower bunk and had two options: "Go back to your cell, or go to the hole [a reference to administrative segregation]." Officers eventually permitted the individual to move to a different room after she abandoned her documented medical needs for her personal safety.

Figure 5. Housing Preferences of Transgender, Nonbinary, and Intersex Inmate Survey Participants Between November 2019 and January 2020

Would you currently prefer to be housed at a male or female institution?



* These figures represent the total number of individuals who participated in the Transgender, Nonbinary, and Intersex Inmate Survey at institutions for women and at institutions for men.

Source: The California Department of Corrections and Rehabilitation's analysis of the Transgender, Nonbinary, and Intersex Inmate Survey results between November 2019 and January 2020.

Other incarcerated individuals reported that officers dismiss their safety concerns and requests for safer housing with comments such as "Fuck or fight," "Fucking deal with it," and "This is a man's prison—deal with it like a man." They explained that, regardless of their safety concerns, refusing to be housed according to officers' determinations subjects them to disciplinary action, including being placed in administrative segregation.

> "This is a man's prison—deal with it like a man."
>
> —Incarcerated Individual Quoting Officers
> December 2020

Incarcerated individuals at the forums also explained they are often denied access to the grievance process, and if they do file grievances, the complaint is lost or discarded. As mentioned earlier, these individuals expressed that officers retaliate against those who file grievances. One individual reported that, after she filed a complaint against an officer, she was moved into a cell with "a homophobic inmate."

In contrast to the complaints shared nearly statewide, incarcerated individuals at one institution expressed that some officers would honor a request to move into safer housing.

> "Cellmates are a big issue. Some people are not compatible with transgenders and that is creating a hostile environment when the cellmate is forced just because a bunk is available and the institution needs to house an inmate. CDCR already allows inmates to choose housing according to race, gang affiliation, etc., but not gender identification."
>
> —Incarcerated Nonbinary Individual
> November 2019

Incarcerated Transgender, Nonbinary, and Intersex Individuals Reported They Face Discrimination in Access to Programs and Services

"It would be great to have a support group within each institution where we could gather (like and AA or NA type situation but just us) to discuss or get guidance from others who[se] experiences are like ours."

—Incarcerated Intersex Individual Who Most Often Identifies as Male November 2019

By listening to the stories incarcerated individuals shared at the forums, we found that the discrimination faced by transgender, nonbinary, and intersex individuals is far-reaching, and extends to all aspects of daily life. Bias against the transgender, nonbinary, and intersex incarcerated population not only results in hostile and unsafe conditions of confinement, but also in inequitable access to essential services and programs.

Incarcerated Transgender, Nonbinary, and Intersex Individuals Described Discrimination in Vocational Training, Job Assignments, and Other Activities

Within the department, incarcerated individuals are assigned a full day of work, education, or other rehabilitative programs, or a combination of work, education, and rehabilitative programs.[39] Vocational training and job assignments provide these individuals with an opportunity to increase their employment marketability upon release.[40] Job assignments also provide them with income for purchasing approved items and paying restitution.[41]

During the forums, incarcerated individuals indicated that departmental staff deny them access to desirable job assignments because of their transgender, nonbinary, or intersex status. For example, they explained that staff deny their requests to work as porters or in the culinary. They also reported that staff have told them that other incarcerated individuals do not want them serving food because of their perceived sexuality.

Incarcerated individuals also complained that the department's vocational training reflects outdated gender stereotypes in that it only provides vocational training that aligns with traditional gender roles. For example, at institutions for men the department offers vocational training or certificates in plumbing and welding, but not cosmetology, which the department offers at institutions for women.

Incarcerated transgender, nonbinary, and intersex individuals also explained that the department's religious leaders do not always accept them into faith-based programs or services. One individual described

39. *California Code of Regulations*, Title 15, Section 3040.

40. California's In-Prison Vocation Education, An Analysis of Program and Alignment to Labor Markets (2014). The department's career technical programs and certificates may be found at https://www.cdcr.ca.gov/rehabilitation/cte/ and https://www.calpia.ca.gov/offender-development/accredited-certification-programs/.

41. *California Code of Regulations,* Title 15, Section 3041.2.

that a reverend removed her from the choir after learning she was a transgender individual. The individual filed a successful appeal with the department. However, before the individual was allowed back into the choir, the reverend disbanded the choir entirely.

Incarcerated individuals also expressed that the department lacks sufficient support groups for incarcerated transgender, nonbinary, and intersex individuals. To the extent such groups exist, these individuals believe that officers allow agitators into the support groups with the intention of disrupting the meetings.

Incarcerated Transgender, Nonbinary, and Intersex Individuals Described Discrimination in Access to Clothing and Property Items That Align With Their Gender Identity and Expression

Clothing

The department is required to provide clothing to the incarcerated population.[42] However, incarcerated transgender, nonbinary, and intersex individuals expressed that institutions, including those designated for transgender individuals, lack a sufficient inventory of clothing, such as underwear congruent with individuals' gender identities. They also explained that some staff are confused about when, where, or how individuals may wear certain articles of department-authorized clothing.

> "I would like to bring up the clothes in prison we are judge[d] & forced to wear & look like a man. I would love it if us transgenders to be able to wear what we want to make us feel more like a woman & less like a man. Also I would like to mention how the C.O.s talk to us not all but there's a large amount of officers that mistreat us as transwomen."
>
> —Incarcerated Transgender Woman November 2019

Individuals at an institution for women explained that although the department issues boxer shorts to transgender men, officers only issue women's underwear to transgender men. Because incarcerated individuals are required to wear underwear to legal visits, transgender men must wear women's underwear if they want to visit with their attorney. One individual expressed that because he refuses to wear women's underwear, officers deny him legal visits.

Incarcerated individuals also explained that officers are confused about when, where, or how the incarcerated population may wear certain articles of clothing. For example, on exercise yards at institutions for men, some officers require women to wear a shirt over their sports bra while others permit them to wear a sports bra without a shirt. An associate warden at an institution for men highlighted this confusion during one of our visits at an institution for men when he told us he corrected an officer who required a transgender woman to wear a shirt over her bra while on the exercise yard. The associate warden said he told the officer that while transgender women are on the exercise yard, they are not required to wear clothing over their bras. However, the associate warden later found the officer was correct—both transgender women and cisgender women are required to wear clothing over their sports

42. *California Penal Code*, Section 2084; *California Code of Regulations*, Title 5, Sections 3030, 3031, and 3032.

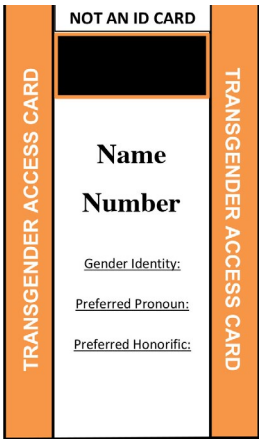
bras while on the exercise yard. The associate director corrected the associate warden and explained that at institutions for women, individuals must wear clothing over their sports bras while on the exercise yard and the same rule applies at institutions for men.

During one survey, an incarcerated transgender woman housed at an institution that is not designated for transgender people wrote the following:

> Even though [this institution] is not a transgender friendly facility they have done a good job making sure I am all right, notifying me of my rights as a transgender. They even got me female clothing from the womens prison on the same day that we gave them my sizes. They made me feel comfortable here.

Canteen

At each institution, the department maintains canteens where incarcerated individuals can purchase toiletries, candy, and other sundry items.[43] At the 14 designated transgender institutions, each institution's canteen must stock seven cosmetic or hygiene items for transgender individuals. To determine what items it would stock, the department polled incarcerated transgender individuals statewide. To optimize shelf space, the department selected the most popular items and mandated that all canteens at the 14 designated institutions carry those items.



During the forums, incarcerated individuals requested the department increase the type and variety of items that align with their gender identity and expression. For example, if the canteen at an institution for men sells combs, it should also sell hair brushes and more than one type of brush for women's hair; if a canteen sells foundation makeup, it should also sell more than one color of foundation.

In 2019, the department initiated a new program to improve incarcerated transgender individuals' access to authorized state-issued clothing, canteen items, and packages from approved vendors.[44] An individual may request a Transgender Access Card (access card; see Photo 3, left), which includes the individual's name, CDCR number, gender identity, pronoun, and honorific. An access

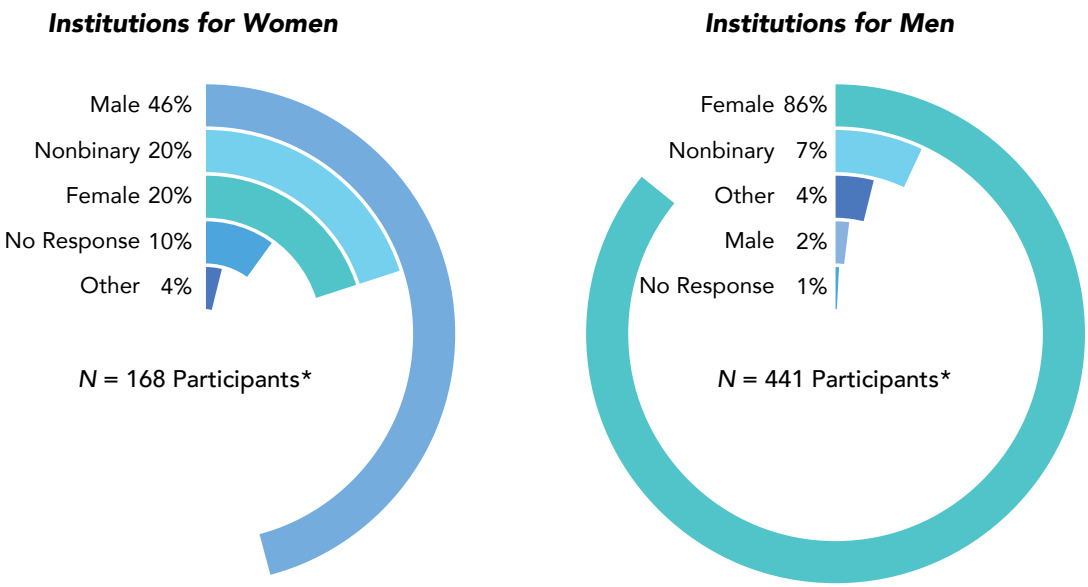
43. *California Penal Code*, Section 5005.

44. California Department of Corrections: Transgender Access Card for Transgender Inmates at Hub, Memorandum (June 19, 2019).

card is not an identification card and incarcerated individuals are not required to possess the access card on their person at all times. However, the access card is used to request, purchase, or receive items authorized only for incarcerated transgender, nonbinary, and intersex individuals.

Figure 6. Gender Identities of Transgender, Nonbinary, and Intersex Inmate Survey Participants Between November 2019 and January 2020

What gender identity do you most often use to describe yourself?



Glossary

Nonbinary: Relating to or being a person who identifies with or expresses a gender identity that is neither entirely male nor entirely female.

Other: Any gender identity that does not fall into the category of male, female, or nonbinary.

* These figures represent the total number of individuals who participated in the Transgender, Nonbinary, and Intersex Inmate Survey at institutions for women and at institutions for men.

Source: The California Department of Corrections and Rehabilitation's analysis of the Transgender, Nonbinary, and Intersex Inmate Survey results between November 2019 and January 2020.

During the forums, we learned that some institutions had not issued access cards or notified incarcerated individuals about the access card program. At one institution, transgender, nonbinary, and intersex individuals shared that the institution did not issue the access cards until the day before the working group's arrival to administer the survey. Individuals at another institution indicated that officers exhibited a dismissive attitude toward the access cards. For example, when they presented the access card, officers responded with comments such as "It's a male prison," and "You're a male in SOMS."[45] One individual reported that officers took her card during a search and did not return it to her.

Despite the department's efforts to improve access to property aligning with an individual's gender identity and expression, and despite the positive comments some incarcerated individuals voiced about these efforts, most expressed disappointment with the limited inventory and lack of access to preferred items. To increase transgender, nonbinary, and intersex individuals' access to preferred items, the department should devise ways to optimize storage space in the canteens.

Incarcerated Transgender, Nonbinary, and Intersex Individuals Indicated They Face Discrimination Because They Lack a Voice in Inmate Advisory Councils

"At this prison there is no MAC represent[ation for] the women here when th[ere] a[re] problem[s].*
—Incarcerated Transgender Woman
November 2019

* Inmate Advisory Councils (IAC) are also referred to as the Men's Advisory Council (MAC) and Women's Advisory Council (WAC).

According to regulations, wardens are required to establish an inmate advisory council that is representative of a facility's ethnic groups.[46] Council representation must include all ethnic segments of the general incarcerated population and of incarcerated individuals within a designated representation area or activity.[47] The incarcerated population at each institution selects council members to act in an advisory capacity to the warden in matters of common interest and concern.[48] When subcommittees of the council are established to represent specialized segments of the incarcerated population, only those within the particular area or segment may participate in the election.[49] Departmental policy does not require that wardens designate a position for a transgender representative or create a transgender subcommittee.

During the forums, incarcerated individuals at some institutions explained that councils do not have a transgender representative and the bylaws do not require the council to have a transgender, nonbinary, or intersex representative or subcommittee. These individuals expressed a lack of confidence that cisgender individuals would, or even could, adequately represent the transgender, nonbinary, and intersex

45. SOMS refers to Strategic Offender Management System.
46. *California Code of Regulations*, Title 15, Section 3230.
47. DOM, Section 53120.4.
48. DOM, Section 53120.1.
49. DOM, Section 53120.5.

incarcerated population during council meetings or in its interactions with the department's administration. These individuals want a representative from the transgender, nonbinary, and intersex population on the councils to allow their concerns to be heard and to improve communication with the administration.

Transgender, Nonbinary, and Intersex Incarcerated Individuals Expressed Frustration With the Department's Provision of Health Care

> "Are they normal, or like you?"
>
> —Incarcerated Individual
> Quoting a Health Care Provider

Adequate medical and mental health services is critical for all incarcerated individuals, including transgender, nonbinary, and intersex individuals. Some transgender individuals suffer from gender dysphoria because their gender identity does not align with their assigned sex at birth.[50] Transgender people often undergo a process known as *transition*, which is a period of time in which they transition from the gender associated with their assigned sex at birth to the gender with which they identify. For some, transition is limited to social changes, such as telling family, friends, and coworkers; using a different name and new pronouns; dressing differently; and, changing one's name or sex, or both, on legal documents.[51] For others, transition can include medical treatments, such as hormone therapy and gender affirming surgery.[52]

In February 2020, California Correctional Health Care Services revised and updated its transgender care guide. The care guide provides mental health and medical providers with an algorithm for patients seeking care. It delineates the process for assessing transgender patients for gender dysphoria as well as prescribing hormones to patients with gender dysphoria in a way that ensures that sex hormone levels are safe and appropriate for the patient's gender.[53] Using this guide, the department carefully considers an individual's request for gender affirming surgery on a case-by-case basis, taking the person's medical and mental health history and current medical and mental health conditions into account. However, during the forums the OIG attended, transgender, nonbinary, and intersex individuals shared their discontent with providers' medical acumen and the quality and availability of medical care and mental health services the department provides. They explained that many of the department's health care providers are insensitive about the

50. World Professional Association for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (7th Version, 2012), p. 5; American Medical Association: Resolution 122 (2008).

51. World Professional Association for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (7th Version, 2012), p. 16; GLAAD Media Reference Guide, 10th Edition (October 2016).

52. World Professional Association for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (7th Version, 2012), p. 5.

53. CCHCS/DHCS Care Guide: Transgender (February 2020), https://cchcs.ca.gov/wp-content/uploads/sites/60/CG/Transgender-CG.pdf.

medical, psychological, and social issues facing incarcerated transgender, nonbinary, and intersex individuals. In particular, these individuals reported that hormone regimens are changed when they transfer interdepartmentally. They also expressed frustration regarding the department's delay in reviewing requests for gender affirming surgery and its ambiguity in denying those requests.

At the forums, incarcerated individuals shared that some providers do not treat them professionally. For example, one individual reported that during an exam, a health care provider asked if the individual had any siblings and "Are they normal, or like you?" Incarcerated individuals also expressed suspicion that the department approves or denies hormone therapy based on positive or negative behavior—not on medical need.

Transgender, nonbinary, and intersex individuals at the forums also reported the department does not provide them with individualized treatment, access to endocrinologists, or information about the efficacy and side effects of hormone therapy. At one institution, transgender, nonbinary, and intersex individuals reported that the institution did not have an endocrinologist or offer telemedicine, leaving these patients without access to vital appointments.

Statewide, incarcerated individuals expressed frustration that the department does not provide information on the process for requesting and receiving gender affirming surgery and does not respond timely to requests for surgery. They shared the perception that it is difficult to obtain the department's approval for surgery and when the department denies a request, it offers no explanation for the denial. The department acknowledges the need to improve its process and communication with incarcerated individuals and is currently revising its guidelines for reviewing those requests.

> "We are being denied our requests to be seen by an endocrinologist here at [this institution]. The medical staff here does not manage our hormones properly. I have been told that an estrodial level of 39 is in the therapeutic range. My levels are so low my transition has stopped. We are also all denied our requests for gender affirmation surgery for any number of reasons such as 'your needs are being met with current treatment'."
>
> —Incarcerated Transgender Woman
> December 2019

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External Stakeholders Echoed the Concerns of Transgender, Nonbinary, and Intersex Incarcerated Individuals and Advocated on Their Behalf

External stakeholders amplify the voices of incarcerated transgender, nonbinary, and intersex individuals; provide them with education and services; and advocate on their behalf through open dialogue with the department, proposed legislation, and representation during litigation. These stakeholders were present during the forums and during some of the department's working group sessions.

In completing this report, the OIG engaged with external stakeholders outside of the forums and working group. In this section, we delineate the concerns these stakeholders raised regarding the incarcerated transgender, nonbinary, and intersex population.

External Stakeholders Reiterated Concerns That Transgender, Nonbinary, and Intersex Incarcerated Individuals Are Afraid to Report Sexual Assault Because Doing So May Subject Them to Being Housed in Prolonged Isolation

External stakeholders echoed the concerns incarcerated transgender, nonbinary, and intersex individuals raised about reporting sexual assault and harassment committed by both incarcerated individuals and departmental staff, and stressed that these individuals are housed in prolonged isolation as a result of reporting PREA-related incidents.

External stakeholders were aware of incarcerated individuals' fears that reporting sexual assault and harassment would subject them to misguided blame, retaliation, and coercion. They expressed that victims do not report sexual assault because they believe they would be blamed for the assault. Victims also fear that officers would share their complaints with other incarcerated individuals, thereby subjecting them to victimization and to being called a *snitch*. Incarcerated individuals also fear coercion, retaliation, and intimidation from officers in the form of false rules violations, excessive or humiliating searches, or unjustified seizures of personal property. The stakeholders explained that the inherent power and authority dynamic officers have over incarcerated individuals discourages these individuals from reporting sexual assault and harassment committed by officers or other staff.

External stakeholders suggested that the department violates PREA by placing victims in prolonged isolation. Pursuant to PREA, "Inmates at high risk for sexual victimization shall not be placed in involuntary segregated housing unless an assessment of all available alternatives has been made, and a determination has been made that there is no available alternative means of separation from likely abusers." PREA also provides, "If a facility cannot conduct such an assessment immediately, the facility may hold the individual in involuntary segregated housing for less than 24 hours while completing the assessment." Nevertheless, external stakeholders reiterated incarcerated individuals' fears that reporting sexual assault may lead to being placed in prolonged isolation. They stressed that the department continues to impermissibly house transgender and gender nonconforming individuals in isolation for prolonged periods of time, purportedly for these individuals' own protection, and not for disciplinary reasons.

External stakeholders stated their belief that even if safety is the true purpose for placing transgender and gender nonconforming individuals in administrative segregation, these individuals are denied access to rehabilitative programs, education, work, hormone treatment, and opportunities to earn credits to reduce their sentence during those periods of isolation. In addition, external stakeholders reasoned that isolation has an injurious effect on an individual's psychological and physical well-being.

External Stakeholders Reiterated That Incarcerated Transgender, Nonbinary, and Intersex Individuals Lack Access to Services

External stakeholders echoed concerns incarcerated transgender, nonbinary, and intersex individuals raised regarding access to services. They expressed concern regarding insufficient access to clothing and personal items as well as the department's provision of health care.

External stakeholders raised two issues regarding the provision of clothing and personal items for incarcerated transgender, nonbinary, and intersex individuals. First, they contended the department violates the *Quine* settlement by not allowing the incarcerated transgender, nonbinary, and intersex community consistent access to gender appropriate personal care items, such as muumuus, boxers, and eyeliner.[54]

Second, while stakeholders acknowledge that the *Quine* settlement is limited to designated transgender institutions, they are concerned the department does not extend its benefits to all transgender and gender nonconforming individuals. External stakeholders recommended that the department make these items, and more, available at every institution—not just institutions designated for transgender individuals.

External stakeholders also expressed concern with the department's performance in providing health care to this incarcerated population. They indicated that when incarcerated individuals on hormone therapy transfer into the department or within the department, the receiving institution often denies them hormone treatment or improperly reduces their hormone levels. The cessation or reduction of hormones can result in physical changes, causing psychological distress and physical pain.

54. *Quine* v. *Beard* (N.D. Cal., August 7, 2015, No. 3:14-CV-02726) Notice of Joint Settlement Agreement.

External Stakeholders Raised Additional Concerns Relating to Systemic Oversight of the Department's Handling of Grievances

External stakeholders highlighted concerns regarding the department's mishandling of grievances. Specifically, on December 5, 2019, an external stakeholder notified the department's Office of Legal Affairs that the department impermissibly prohibited a transgender woman housed at an institution for men from wearing a religious head covering. Even though the individual held a religious belief that she must cover her head, the department denied her request to purchase three scarves at her own expense. Although the individual previously filed appeals with the department, the department denied her request at all three levels of appeal, exhausting her administrative remedies.

On behalf of the individual, an external stakeholder requested that the department reconsider its denial and cited that "under Title 15, section 3213 (b), people in prison are permitted to possess any religious item listed on the Religious Personal Property Matrix, including 'religious headgear'." The external stakeholder noted that the department's "appeal response denying access to the headgear runs afoul of Title 15, as well as the Religious Land Use and Institutionalized Persons Act, 42 U.S.C. sections 2000, et seq." Thereafter, on February 13, 2020, the department's director of the Division of Adult Institutions issued a memorandum titled "Religious Head Gear Options," which provided clarification that transgender women housed in institutions for men are authorized to possess and purchase female head gear pursuant to the department's Religious Personal Property Matrix, and that transgender men housed in institutions for women are authorized to possess and purchase head gear pursuant to the same policy.

External Stakeholders Sponsored Senate Bill 132 to Improve the Lives of Incarcerated Transgender and Gender Nonconforming Individuals

Senator Scott Wiener, Senator Cathleen Galgiani, and Assemblymember Mark Stone, in consultation with external stakeholders, coauthored Senate Bill 132, the Transgender Respect, Agency, and Dignity Act, which is intended to improve conditions of confinement for incarcerated transgender, nonbinary, and intersex individuals.[55] If enacted, the law would address some of the concerns of external stakeholders and incarcerated transgender, nonbinary, and intersex individuals regarding respectful treatment, professional searches, and safe housing.

First, if enacted, the law would require the department to ask individuals entering its custody to specify "in a private setting" their gender identity, "whether the individual identifies as transgender, nonbinary, or intersex," and "the individual's gender pronoun and honorific." The law would prohibit "staff, contractors, and volunteers of the department" from "consistently fail[ing] to use the gender pronoun and honorific an individual has specified" and would also "prohibit the department from disciplining a person for refusing to answer or not disclosing complete information," and would provide that individuals may inform staff of this information at any time.[56]

Second, if enacted, the law would require that individuals in the department's custody "be housed at a correctional facility designated for men or women based on the individual's preference."[57]

Third, if enacted, the law would require that the department conduct searches on individuals "according to the search policy for their gender identity or according to the gender designation of the facility where they are housed, based on the individual's search preference." The bill's current language states that "if the incarcerated individual's preference or gender identity cannot be determined, the search shall be conducted according to the gender designation of the facility where they are housed."[58]

55. Senate Bill 132 is authored by Senator Scott Wiener (D-San Francisco), coauthored by Senator Galgiani, and Assemblymember Mark Stone, and sponsored by Equality California, TransLatin@Coalition, TGI Justice Project, Transgender Law Center, American Civil Liberties Union of California, and Lambda Legal.

56. Wiener, Scott, Cathleen Galgiani, and Mark Stone. "Bill Text." Bill Text – SB-132 Corrections., January 14, 2019: **https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200SB132**.

57. Ibid.

58. Ibid.

According to the legislation, which is pending approval as of the date of this report's publication, if the department "has management or security concerns with an incarcerated individual's search preference" or "preferred housing placement," the department must "certify in writing a specific and articulable basis why the department is unable to accommodate that search or housing preference." If enacted, the law would also require that the department provide the incarcerated individual with a "meaningful opportunity to verbally raise any objections to that denial, and have those objections documented."[59] The legislation would prohibit an individual's housing and search preferences from being denied based on discriminatory reasons.

Furthermore, if enacted, the law would require that gender nonconforming individuals' "perception of health and safety" be "given serious consideration in any bed assignment, placement, or programming decision within the facility in which they are housed, including, but not limited to, granting single-cell status, housing the individual with another incarcerated person of their choice, or removing the individual or individuals who pose a threat from any location where they may have access to the individual who has expressed a safety concern." The law would also provide that "if an incarcerated individual raises concerns for their health or safety at any time, their housing and placement shall be reassessed."[60]

If signed into law, this legislation is scheduled to take effect on January 1, 2021. One stakeholder expressed that Senate Bill 132 is a "life saver," and its passage would set a model for other states to "follow suit and validate the lives" of gender nonconforming individuals; another stakeholder described Senate Bill 132 as "long overdue."[61] Sponsors are hopeful that if this legislation passes, violence leveled against transgender and gender nonconforming individuals will be reduced, and a culture of respect and dignity within the department can be cultivated.

59. Ibid.

60. Ibid.

61. Senate District 11, "Senate Passes Senator Wiener's Legislation to Ensure Incarcerated Transgender People Are Housed According to their Gender Identity" (May 23, 2019), https://sd11.senate.ca.gov/news/20190523-senate-passes-senator-wiener%E2%80%99s-legislation-ensure-incarcerated-transgender-people-are.

Through the Working Group, the Department Took Thoughtful and Important Steps to Improve Its Policies and Practices

Drawing from insights gained through the working group, the department proposed policy changes, and developed and implemented new training to address the concerns raised by the incarcerated transgender, nonbinary, and intersex population. Through these efforts, the department's working group achieved several notable accomplishments. The group not only administered the Transgender, Nonbinary, and Intersex Inmate Survey and conducted the forums, but also made modifications to its policies and practices; proposed changes to the department's PREA screening form; developed a gender identity questionnaire and staff script; created a new training curriculum called Working Successfully With Transgender, Intersex, and Nonbinary Inmates; provided instruction statewide on the new curriculum; and effectuated positive change in other various ways.

In Response to Insights Gained Through the Surveys and Forums, the Department Proposed Modifications to Its Policies and Practices

Conducting forums enabled the department to discuss topics of concern directly with the incarcerated population. Doing so helped the executive team to better understand the struggles of transgender, nonbinary, and intersex individuals and more effectively address these individuals' concerns. The following examples demonstrate the department's initiative in addressing some of the issues raised during the forums.

Through the forums, departmental leaders were able to provide incarcerated individuals with clarifying information as well as address their concerns. For example, several incarcerated individuals expressed confusion about the process of finalizing a name change, stating it was difficult to get their name changes finalized. As a result, executive team members provided those individuals with additional information and clarification on the name-change process and requirements. When some incarcerated individuals inquired about misconduct allegations or incidents that occurred but may not have been reported, departmental executives followed up on the status of existing allegations or brought incidents to the attention of the warden so that inquiries could be opened.

During one of the forums, an incarcerated individual openly expressed concern about her rapidly deteriorating mental health condition and appeared physically distraught. Immediately following the forum, a

departmental executive member, a working group member, and the OIG notified an associate warden, who caused a mental health provider to personally meet with and evaluate the individual before the working group left the institution that day.

At an institution for women, transgender, nonbinary, and intersex individuals raised a concern about the institution's "Golden Girls" program. While the program allowed specific privileges beginning at the age of 55, access to those privileges was contingent upon individuals being identified as a "Golden Girl" on their department identification card—regardless of whether they identified as female. One individual noted that even though he would be entitled to the program the following week, on his 55th birthday, he refused to be identified as a "girl." His refusal to accept the new identification card would deny him access to the program's benefits. Following the forums, and before leaving the institution, executives raised the issue with the warden. By the following month, the warden renamed the program as the "Golden Program," revised the institution's applicable local operating procedures, and began issuing new identification cards.[62]

Incarcerated individuals appreciated the diversity of departmental staff members who attended the forums, the presence of external stakeholders and the OIG, and the open dialogue and prompt resolution of certain issues. During the forums, they repeatedly expressed gratitude to the department for its commitment to improving the lives of transgender, nonbinary, and intersex individuals. The department's actions were so well received that these individuals requested the department administer similar surveys and forums in the future.

> "Thank you for coming today and caring about our LGBTQ+ lives."
>
> —Incarcerated Individual
> December 2019

62. California Institution for Women, Operational Procedure 321, Golden Program (January 2020).

The Department's Working Group Proposed Modifications to Its PREA Screening Form, and Developed a Gender Identity Questionnaire and Script

All incarcerated individuals admitted to the department, or those who transfer to another institution, undergo a PREA screening. The goal of the screening is to aid the department in assigning individuals to cells, dorms, rooms, and beds by identifying an individual's risk of being sexually abused, probability of sexually abusing others, or both. The department also conducts an additional biannual assessment of transgender, nonbinary, and intersex individuals known to the department.[63]

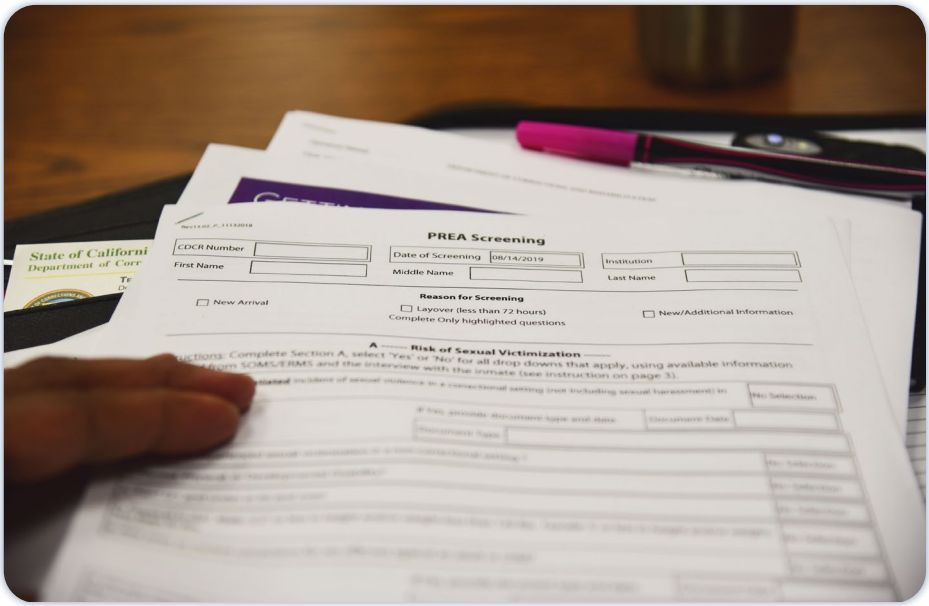

Photo 4. PREA screening form. Photo provided courtesy of Terry Thornton of the California Department of Corrections and Rehabilitation.

The department's Transgender Housing and Search Working Group proposed the department adjust the screening form to broaden the scope of information that may indicate an individual is vulnerable to sexual victimization. The group recommended the department amend the question pertaining to whether an individual has been a victim of a substantiated sexual violence incident in a correctional setting to include unsubstantiated incidents, too. The group also proposed adding a question of whether the individual has experienced sexual victimization in a correctional setting that was not reported. These proposed changes attest to the department's recognition that although some incidents of

63. DOM, Section 54040.14.2.

sexual victimization are not reported or cannot be proven, they are no less real.

The working group also developed a gender identity questionnaire and script to assist departmental staff in facilitating respectful communication and determining appropriate housing and services for transgender, nonbinary, and intersex incarcerated individuals. The questionnaire asks individuals their pronouns, honorific or title, and whether they prefer to be searched according to the men's policy or the women's policy. The script to be used in administering the questionnaire explains to participants that the questions may be personal because they relate to gender identity and that they are vital in appropriately placing them.

The Working Group Examined and Proposed Changes to the Department's Staff Training Relating to Transgender, Nonbinary, and Intersex Incarcerated Individuals

Members of the working group developed and assisted the department in its implementation of a new training curriculum for its employees—Working Successfully With Transgender, Intersex, and Nonbinary Inmates. The curriculum includes vital information for managing the unique set of challenges employees may face when communicating with and understanding the incarcerated transgender, nonbinary, and intersex population. The training includes information on safe housing as well as appropriate terminology, search procedures, pronoun usage, and clothing and personal property allowances. The curriculum was developed by subject matter experts within the department who have a passion for or lived experience with the transgender, intersex, or nonbinary community.

The department required every institution to send five trainers to a Training-for-Trainers session to receive instruction on how to provide staff with a basic understanding of the history, terminology, and needs of the transgender, nonbinary, and intersex incarcerated population. The training also provided an overview of laws and departmental policies specific to this incarcerated population. At different times, OIG staff from different classifications observed the department's four-hour sessions. They found the department's instructors to be knowledgeable about the subject, adept at presenting information and answering difficult questions, and skilled in facilitating group discussions. The instructors held different positions within the department and had personal experience within the LGBTQIA+ community. They not only offered definitions of key terms, but used personal examples to cultivate a greater understanding of the topic. They emphasized and reiterated the importance of maintaining professionalism and respect by using incarcerated individuals' correct pronouns, a core concern expressed during the forums.

The department now requires that employees at every institution attend a one-hour in-service training session that is co-taught by trainers who successfully completed Training-for-Trainers—Working Successfully With Transgender, Intersex, and Nonbinary Inmates. Every one-hour training session begins with a video-recorded address from Secretary Ralph Diaz, highlighting the department's commitment to "maintaining a culture where everyone is safe and all are treated with respect and professionalism." Diaz says, "This includes our fellow employees, incarcerated people, people on parole and community supervision, visitors, contractors, rehabilitation providers, and volunteers. This is more than a lofty goal or policy; this should be the norm." Secretary Diaz's address sets the tone for the training by letting participants know of the training's importance to the department and what the

"I am highly appreciative and grateful of the opportunity to create and implement the lesson plan, "Working Successfully With Transgender, Intersex and Nonbinary Inmates," in order to make the California Department of Corrections and Rehabilitation (CDCR) more in line with the LGBTQIA+ community. It is paramount for any business, including CDCR to become more inclusive with not only their workforce, but offenders as well. An important message in diversity training is for employers and staff to do all they can to create a safe and respectful working environment, which in turn can foster positive conversations for employees and reinforce the importance of empowering staff and offenders to do the right thing."

—Correctional Lieutenant Megan Cherinka

Subject Matter Expert and Department Trainer for Trainers

Transgender Housing and Search Working Group Member

Member of the LGBTQIA+ Community

April 2020

department's expectations are. Echoing what they learned during the new Training-for-Trainers sessions, the trainers provide instruction on topics specific to the transgender, nonbinary, and intersex incarcerated population, such as safety in housing, appropriate terminology, appropriate pronoun usage, proper search procedures, and authorized clothing and personal property.

"Regardless of our personal beliefs, it is the sworn responsibility of all departmental employees (and an expectation) that we treat each person with respect and professionalism. The foremost of which, for the transgender, intersex, and nonbinary community, is the use of correct names, pronouns, and honorifics."

—Officer Mandi Hauwert
Subject Matter Expert and Department Trainer for Trainers,
Transgender Housing and Search Working Group Member, and
Member of the LGBTQIA+ Community
April 2020

AR-002553

The Department Has Effectuated Positive Change by Hosting Provider Fairs, Providing Transgender, Nonbinary, and Intersex Individuals With a Voice in Inmate Advisory Council Subcommittees, and Holding Its First Transgender Day of Remembrance

Employees are the linchpin to the department's success. Due to the passion and dedication of some departmental staff, the department has made strides in improving conditions of confinement for transgender, nonbinary, and intersex individuals in various ways. The department hosted its first transgender provider fair for incarcerated females, took steps to provide transgender, nonbinary, and intersex individuals with representation in inmate advisory councils, and supported transgender, nonbinary, and intersex individuals at San Quentin in hosting their first Transgender Day of Remembrance event.



Photo 5. Kristoffer Applegate, Associate Director, Office of Correctional Policy Research, Division of Correctional Policy Research and Internal Oversight, California Department of Corrections and Rehabilitation, speaking with two incarcerated individuals.

Photo provided courtesy of Terry Thornton of the California Department of Corrections and Rehabilitation.

On April 29, 2019, the California Institution for Men hosted the department's first Transgender Provider Fair for Incarcerated Females. Those in attendance included external stakeholders, such as Asian Pacific AIDS Intervention Team; St. John's Well Child and Family Center; TransLatin@Coalition, Restorative Justice Minister Nora Jacob; and Urban Mission, Pomona. These stakeholders provided information on postrelease housing, employment, and medical and mental health services. Thirty-six transgender females, over half of whom were scheduled to parole in two years or less, participated in a two-hour event

"Over the past two years, I have been empowered to work with this underserved demographic at the California Institution for Men. The Hiring Authority has allowed services such as provider fairs, group counseling, and a Rehabilitative Achievement Credit approved group (CAGE, Cultural Awareness and Gender Education) to spread the work of inclusion and understanding to the entire population. The goal of our efforts is to develop a sense of community amongst our incarcerated population, understanding that if we effectively teach people to cohabitate with individuals unlike themselves in here, they have a greater chance of success upon release."

—California Institution for Men Community Resource Manager Delinia Lewis March 2020

"I have been with the department for 20 years. I recognize the hardships of being a transgender individual living in a prison. It's just common sense. . . . I am a professional employee and have always supported doing the right thing . . . and I am supported by my administration."

—Mule Creek State Prison Facility Captain and Transgender Coordinator, and Liaison March 2020

that included a presentation by service providers outlining the resources and services they offer, followed by an opportunity to visit the providers' display tables and collect information to assist them in transitioning back to society. The provider fair was well received by transgender, nonbinary, and intersex incarcerated individuals. External stakeholders recommended the department conduct similar fairs at all institutions.

When a facility captain at another institution found that transgender, nonbinary, and intersex individuals did not have representation on the inmate advisory council or access to the institution's management team to express concerns, the facility captain met with several transgender, nonbinary, and intersex individuals to develop a viable solution. Since then, the Inmate Advisory Council Bylaws for three facilities were amended to include six honorary members, including a transgender, nonbinary, or intersex representative, and eight Standing Committees, including a Transgender Committee.[64]



Photo 6. Amy Miller, Director of the Division of Correctional Policy Research and Internal Oversight, California Department of Corrections and Rehabilitation, speaking with three incarcerated individuals.

Photo provided courtesy of Terry Thornton of the California Department of Corrections and Rehabilitation.

"What the women of San Quentin put together was remarkable and emotional, and I am so proud of the hard work they did to make this event happen. Seeing their dedication, and the support of the rest of the incarcerated people and staff who attended was inspirational."

—Kristoffer Applegate Associate Director Office of Correctional Policy Research, Division of Correctional Policy Research and Internal Oversight, California Department of Corrections and Rehabilitation, and Member of the LGBTQIA+ Community December 2019

On November 20, 2019, the transgender, nonbinary, and intersex incarcerated population at San Quentin State Prison was supported by the department in holding its first Transgender Day of Remembrance, an annual observance honoring the memory of transgender, nonbinary, and intersex individuals who were fatal victims of violence. Audience members included Senator Scott Wiener and his aides, executive staff from the department, external stakeholders, members of the department's working group, San Quentin State Prison employees, and members of the incarcerated population.

64. Mule Creek State Prison, Inmate Advisory Council Bylaws (2019) Article IV, Section 1 and Article IX, Section 2.

Senate Bill 132 Will Require Further Changes to the Department's Policies

If signed into law, Senate Bill 132, authored by Senator Scott Wiener and supported by external stakeholders, would require improvements within the department to address many of the shortcomings identified in this report. The legislation was a topic of discussion during the forums and in the written comments incarcerated individuals submitted as part of their survey. Incarcerated transgender, nonbinary, and intersex individuals expressed widespread opinions regarding the proposed legislation and future housing policies. Appendix B of this report includes some of those opinions.

As of the date of the publishing of this report, Senate Bill 132 remains pending. However, we anticipate the legislation will soon be submitted for Governor Gavin Newsom's consideration. The department informed us that it is working with Senator Wiener's office to ensure it is ready to effectively implement Senate Bill 132 on January 1, 2021, if Governor Newsom signs the bill into law.

> "Incarcerated transgender people deserve to be housed in facilities consistent with their gender identity…When we house trans people based on their birth-assigned gender, we place them at high risk of sexual assault and violence. SB 132 will help ensure transgender individuals are treated with dignity and have their gender identity respected."*
>
> —Senator Scott Wiener
> California Senate District 11
> May 23, 2019

* Senate District 11, "Senate Passes Senator Wiener's Legislation to Ensure Incarcerated Transgender People Are Housed According to their Gender Identity" (May 23, 2019), https://sd11.senate.ca.gov/news/20190523-senate-passes-senator-wiener%E2%80%99s-legislation-ensure-incarcerated-transgender-people-are.

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Recommendations

We commend the department for soliciting input from the transgender, nonbinary, and intersex population when making decisions about policy. During the department's survey and forums, incarcerated individuals articulated their need for more dignity and respect, increased privacy to shield against cross-gender viewing, a meaningful path to report sexual violence, safe housing, equitable access to jobs and programs, additional clothing and items congruent with their gender identity and expression, and better medical care.

External stakeholders provide incarcerated transgender, nonbinary, and intersex individuals with a cogent voice. They expressed concern that individuals do not report sexual violence due to potential negative repercussions, that the department impermissibly places incarcerated people in prolonged isolation, that transgender and gender nonconforming individuals do not have sufficient access to clothing or property items congruent with their gender identity and expression, that the department provides these individuals with inadequate medical care, and that the department does not adequately handle grievances. External stakeholders support Senate Bill 132, which would enable gender nonconforming individuals to choose whether to be housed at an institution for men or an institution for women, and whether to be searched pursuant to the male or female search policy.

Unfortunately, the cruel, ignorant, or misguided behavior of some staff has had a negative impact on incarcerated transgender, nonbinary, and intersex individuals and overshadows the compassion and exemplary work of other departmental staff. That transgender, nonbinary, and intersex individuals are entitled to the same respect as other individuals is an attitude that must be conveyed from the top down. Hiring authorities, managers, and supervisors must continue to emphasize that abuse, ridicule, and other inappropriate behavior is a violation of departmental policy and will not be tolerated.

While incarcerated individuals and external stakeholders articulated a number of serious concerns, the department has made headway in addressing some of the issues critical to incarcerated transgender, nonbinary, and intersex individuals. While issues remain unresolved, the department has indicated it is committed to cultivating a safe and professional environment for these individuals. Doing so hinges on the department's collaboration with external stakeholders and communication with incarcerated individuals to examine potential policy changes that better protect and serve the incarcerated population and the public.

The OIG is hopeful the department will continue its work creating a safe environment for the incarcerated transgender, nonbinary, and intersex population and continue to seek input from external stakeholders and the

incarcerated community. However, we believe there are concrete steps the department should take:

- The department should implement system-wide oversight and monitoring of complaints made by incarcerated transgender, nonbinary, and intersex individuals against staff to ensure the complaints are properly investigated and discipline is taken against staff, when appropriate.
- The department should incite a clear, department-wide policy on how, when, and where articles of department-authorized clothing may be worn by transgender, nonbinary, and intersex individuals and implement that policy through regular staff training.
- The department should continually optimize shelf space in canteens and effectively manage the inventory of clothing and property items for incarcerated transgender, nonbinary, and intersex individuals as demographics, trends, and purchasing fluctuate.
- The department should consider staggering the scheduling of health care appointments for transgender, nonbinary, and intersex patients to reduce the unwelcome attention these individuals face.
- The department should fully implement the mandates of Senate Bill 132, regardless of whether the bill is signed into law.
- The department should review the new training curriculum annually and update it as needed.
- The department should establish an annual survey of the transgender, nonbinary, and intersex population to determine whether the implementation of the new training curriculum has meaningfully improved conditions of confinement.

Finally, we encourage the department to continue to support its staff in their dedication to effectuating positive change and working with external stakeholders and the incarcerated transgender, nonbinary, and intersex population. The department's efforts have not gone unnoticed by the incarcerated population.

> "I am thankful this is getting attention today. My view of self has impacted everything in life and probably a big factor to my crime and issues with addiction. Its great that we are getting a voice."
>
> —Incarcerated Individual
> November 2019

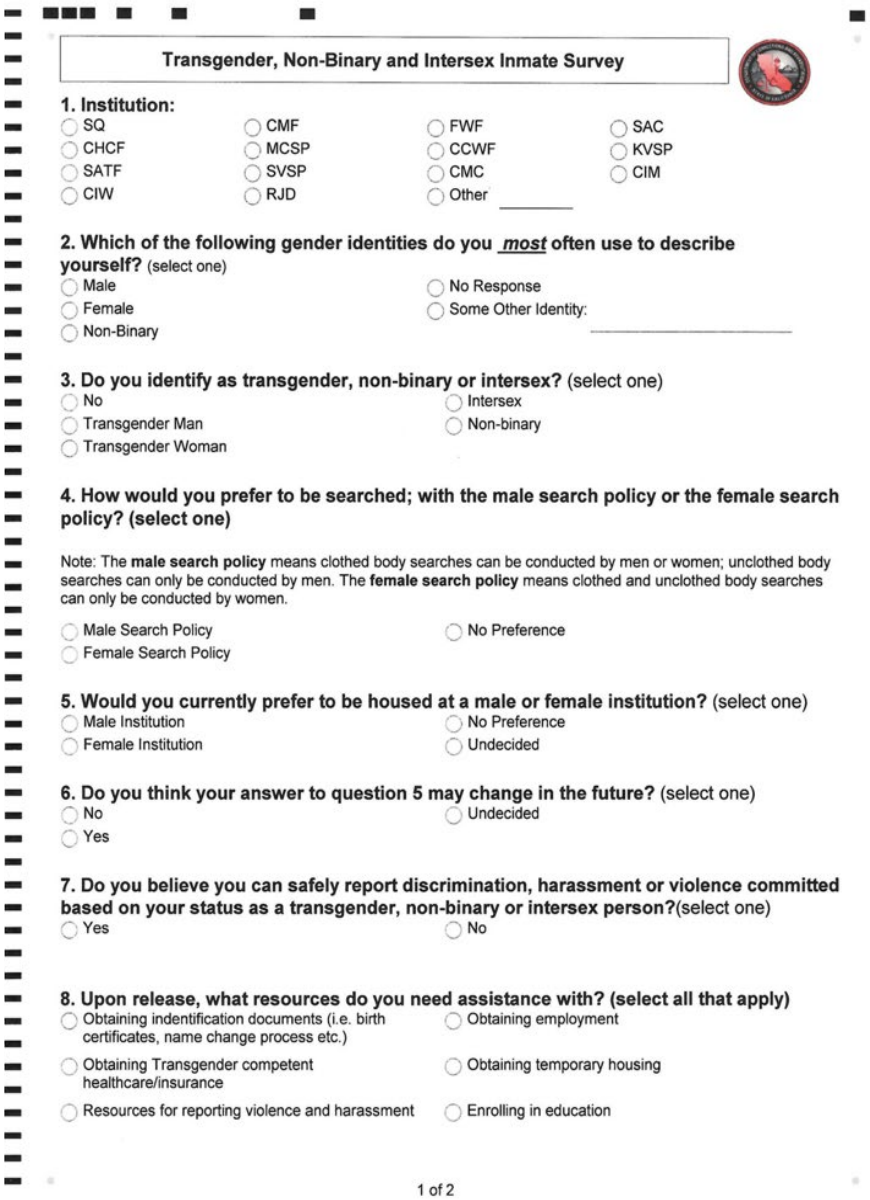
AR-002559

Appendices

Appendix A: The Department's Transgender, Nonbinary, and Intersex Inmate Survey

In this appendix, we include a copy of the department's Transgender, Nonbinary, and Intersex Inmate Survey as well as the department's analysis of the results of the surveys conducted between November 2019 and January 2020. We include this information to provide context on the information the department solicited directly from the incarcerated transgender, nonbinary, and intersex population and to share our source of information for some of the infographics included in this report.

Figure A–1. Transgender, Nonbinary, and Intersex Inmate Survey



Transgender, Non-Binary and Intersex Inmate Survey

1. Institution:

◯ SQ	◯ CMF	◯ FWF	◯ SAC
◯ CHCF	◯ MCSP	◯ CCWF	◯ KVSP
◯ SATF	◯ SVSP	◯ CMC	◯ CIM
◯ CIW	◯ RJD	◯ Other _____	

2. Which of the following gender identities do you *most* often use to describe yourself? (select one)

◯ Male
◯ Female
◯ Non-Binary
◯ No Response
◯ Some Other Identity: _____

3. Do you identify as transgender, non-binary or intersex? (select one)

◯ No
◯ Transgender Man
◯ Transgender Woman
◯ Intersex
◯ Non-binary

4. How would you prefer to be searched; with the male search policy or the female search policy? (select one)

Note: The **male search policy** means clothed body searches can be conducted by men or women; unclothed body searches can only be conducted by men. The **female search policy** means clothed and unclothed body searches can only be conducted by women.

◯ Male Search Policy
◯ Female Search Policy
◯ No Preference

5. Would you currently prefer to be housed at a male or female institution? (select one)

◯ Male Institution
◯ Female Institution
◯ No Preference
◯ Undecided

6. Do you think your answer to question 5 may change in the future? (select one)

◯ No
◯ Yes
◯ Undecided

7. Do you believe you can safely report discrimination, harassment or violence committed based on your status as a transgender, non-binary or intersex person?(select one)

◯ Yes
◯ No

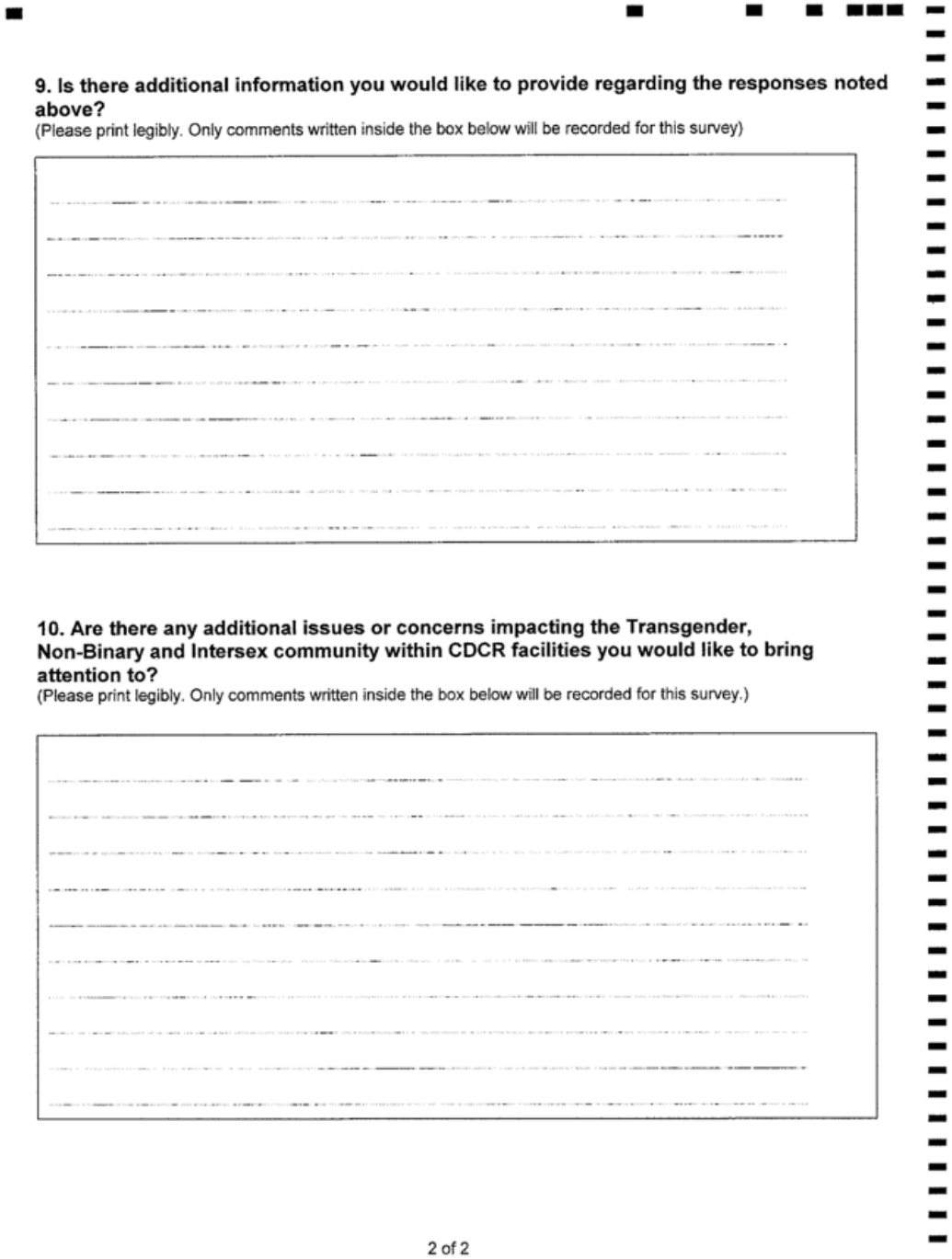
8. Upon release, what resources do you need assistance with? (select all that apply)

◯ Obtaining indentification documents (i.e. birth certificates, name change process etc.)
◯ Obtaining Transgender competent healthcare/insurance
◯ Resources for reporting violence and harassment
◯ Obtaining employment
◯ Obtaining temporary housing
◯ Enrolling in education

1 of 2

AR-002561

Figure A–1. Transgender, Nonbinary, and Intersex Inmate Survey (continued)



9. Is there additional information you would like to provide regarding the responses noted above?
(Please print legibly. Only comments written inside the box below will be recorded for this survey)

10. Are there any additional issues or concerns impacting the Transgender, Non-Binary and Intersex community within CDCR facilities you would like to bring attention to?
(Please print legibly. Only comments written inside the box below will be recorded for this survey.)

2 of 2

Figure A–2. The Department's Analysis of the Transgender, Nonbinary, and Intersex Inmate Survey Results at Institutions for Women

CCWF, CIW, FWF

Transgender Non-Binary Intersex November 2019 - January 2020
WOMENS INSTITUTIONS

Instructor
Associate Director A. Miller

1. Institution:

Response	Frequency	Percent
SQ	0	0.0%
CMF	0	0.0%
FWF	26	15.5%
SAC	0	0.0%
CHCF	0	0.0%
MCSP	0	0.0%
CCWF	96	57.1%
KVSP	0	0.0%
SATF	0	0.0%
SVSP	0	0.0%
CMC	0	0.0%
CIM	0	0.0%
CIW	46	27.4%
RJD	0	0.0%
Other	0	0.0%
No Response	0	0.0%

2. Which of the following gender identities do you most often use to describe yourself? (select one)

Response	Frequency	Percent
Male	76	45.2%
Female	34	20.2%
Non-Binary	34	20.2%
No Response	15	8.9%
Some Other Identity:	7	4.2%
No Response	2	1.2%

3. Do you identify as transgender, non-binary or intersex? (select one)

Response	Frequency	Percent
No	33	19.6%
Transgender Man	67	39.9%
Transgender Woman	19	11.3%
Intersex	8	4.8%
Non-binary	41	24.4%
No Response	0	0.0%

4. How would you prefer to be searched; with the male search policy or the female search policy? (select one)
Note: The male search policy means clothed body searches can be conducted by men or women; unclothed body searches can only be conducted by men. The female search policy means clothed and unclothed body searches can only be conducted by women.

Response	Frequency	Percent
Male Search Policy	24	14.3%
Female Search Policy	98	58.3%
No Preference	44	26.2%
No Response	2	1.2%

5. Would you currently prefer to be housed at a male or female institution? (select one)

Response	Frequency	Percent
Male Institution	16	9.5%
Female Institution	118	70.2%
No Preference	9	5.4%
Undecided	24	14.3%
No Response	1	0.6%

6. Do you think your answer to question 5 may change in the future? (select one)

Response	Frequency	Percent
No	109	64.9%
Yes	25	14.9%
Undecided	32	19.0%
No Response	2	1.2%

1

Figure A–2. The Department's Analysis of the Transgender, Nonbinary, and Intersex Inmate Survey Results at Institutions for Women (continued)

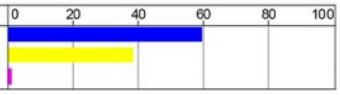
CCWF, CIW, FWF

Transgender Non-Binary Intersex
November 2019 - January 2020

Instructor
Associate Director A. Miller

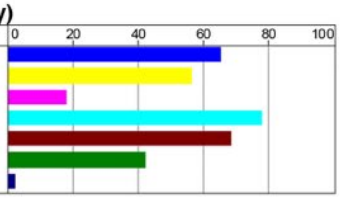
7. Do you believe you can safely report discrimination, harassment or violence committed based on your status as a transgender, non-binary or intersex person?(select one)

Response	Frequency	Percent
Yes	100	59.5%
No	65	38.7%
No Response	3	1.8%



8. Upon release, what resources do you need assistance with? (select all that apply)

Response	Frequency	Percent
Obtaining indentification documents (i.e. birth certificates, name	110	65.5%
Obtaining Transgender competent healthcare/insurance	95	56.5%
Resources for reporting violence and harassment	31	18.5%
Obtaining employment	131	78.0%
Obtaining temporary housing	115	68.5%
Enrolling in education	71	42.3%
No Response	4	2.4%



2

Figure A–3. The Department's Analysis of the Transgender, Nonbinary, and Intersex Inmate Survey Results at Institutions for Men

Transgender, Non-Binary, Intersex
November 2019 - January 2020
MENS INSTITUTIONS

1. Institution:

Response	Frequency	Percent
SQ	18	4.1%
CMF	16	3.6%
FWF	0	0.0%
SAC	26	5.9%
CHCF	20	4.5%
MCSP	76	17.2%
CCWF	0	0.0%
KVSP	26	5.9%
SATF	78	17.7%
SVSP	39	8.8%
CMC	21	4.8%
CIM	42	9.5%
CIW	0	0.0%
RJD	65	14.7%
Other	14	3.2%
No Response	0	0.0%

2. Which of the following gender identities do you most often use to describe yourself? (select one)

Response	Frequency	Percent
Male	8	1.8%
Female	381	86.4%
Non-Binary	33	7.5%
No Response	3	0.7%
Some Other Identity:	16	3.6%
No Response	0	0.0%

3. Do you identify as transgender, non-binary or intersex? (select one)

Response	Frequency	Percent
No	12	2.7%
Transgender Man	13	2.9%
Transgender Woman	371	84.1%
Intersex	10	2.3%
Non-binary	33	7.5%
No Response	2	0.5%

4. How would you prefer to be searched; with the male search policy or the female search policy? (select one)
Note: The male search policy means clothed body searches can be conducted by men or women; unclothed body searches can only be conducted by men. The female search policy means clothed and unclothed body searches can only be conducted by women.

Response	Frequency	Percent
Male Search Policy	21	4.8%
Female Search Policy	309	70.1%
No Preference	108	24.5%
No Response	3	0.7%

5. Would you currently prefer to be housed at a male or female institution? (select one)

Response	Frequency	Percent
Male Institution	130	29.5%
Female Institution	183	41.5%
No Preference	38	8.6%
Undecided	89	20.2%
No Response	1	0.2%

1

Figure A–3. The Department's Analysis of the Transgender, Nonbinary, and Intersex Inmate Survey Results at Institutions for Men (continued)

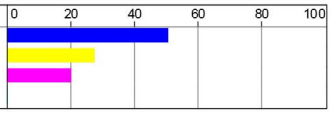
Mens Institutions

Transgender Non-Binary Intersex
November 2019 - January 2020

Instructor
Associate Director A. Miller

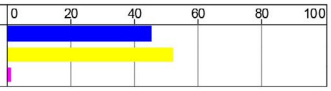
6. Do you think your answer to question 5 may change in the future? (select one)

Response	Frequency	Percent
No	225	51.0%
Yes	123	27.9%
Undecided	90	20.4%
No Response	3	0.7%



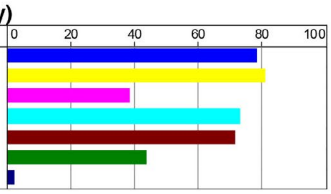
7. Do you believe you can safely report discrimination, harassment or violence committed based on your status as a transgender, non-binary or intersex person?(select one)

Response	Frequency	Percent
Yes	202	45.8%
No	231	52.4%
No Response	8	1.8%



8. Upon release, what resources do you need assistance with? (select all that apply)

Response	Frequency	Percent
Obtaining indentification documents (i.e. birth certificates, name	346	78.5%
Obtaining Transgender competent healthcare/insurance	358	81.2%
Resources for reporting violence and harassment	170	38.5%
Obtaining employment	323	73.2%
Obtaining temporary housing	317	71.9%
Enrolling in education	195	44.2%
No Response	11	2.5%



Appendix B: Comments Made by Incarcerated Transgender, Nonbinary, and Intersex Individuals Through the Surveys

In this appendix, we provide some additional comments made by incarcerated transgender, nonbinary, and intersex individuals as part of their responses to the survey. We include these additional comments to provide context regarding the varied experiences and concerns of the transgender, nonbinary, and intersex incarcerated population. These comments begin on the next page.

Incarcerated Transgender, Nonbinary, and Intersex Individuals Described a Culture of Disrespect by Both Staff and Other Incarcerated Individuals

Officers purposely refer to us as "him" or other types of disrespectful pronouns.

—Transgender Woman
November 2019

At this point in time CDCR officers at this facility think when you refer to a female as a him it's a joke.

—Individual Who Most Often Identifies as Female
November 2019

The issue should have been addressed. I have experienced staff officials not referring to me with appropriate pronouns and body searches/strip searches I've experience[d] are horrible, with officers staff making fun of me as a TG and making derogatory comments that Oh well, your a man and your in a mans facility punk. And so on. Some making ugly remarks and gestures expressed when searching me. I feel humiliated, violated and disrespected as a women having to go through this horrible traumatic experience. I'd appreciate that the transgender policy be made law to help prevent this type of on-going problem.

—Transgender Woman
November 2019

I'm a lifer and I would very much like to live where I'm not degraded by staff and their hurtful comments and actions. I'm daily referred to as a "him" even though I'm clearly a female. I'm really tired of all the hurt and degradation I go through everyday.

—Transgender Woman
December 2019

Some staff are still have a dislike and prejudice towards transgender inmates and how we dress.

—Transgender Woman
December 2019

Would like to see improved conduct from officers in professionalism in dealings with the transgender/non-binary/ intersex community.

—Transgender Man
December 2019

What most happens here with officers is "I" keep on being called "Ser" "Him," "He" or being made fun of by laughter by officers when I tell them to call me Ms, her, or she. They have no respect for transgenders.

—Transgender Woman
December 2019

C/Os being homophobic and trying to be funny by just putting anyone in our cells not caring about the dangers. Also the respect level CDCR has with the transgender community is not what it should be. They're shading our rights.

—Transgender Woman
December 2019

Being nonbinary is different than transgender. We shouldn't have to identify as trans with the box being checked. It is insulting. Can we get our own identification box?

—Nonbinary Individual
December 2019

I just wanted to say [this institution] is a transgender hub, however, it is NOT transgender friendly. We are hated, mistreated and publicly humiliated daily! We are not safe!

—Transgender Woman
December 2019

I would like if certain correctional officers have proper training when it comes to transgender inmate[s] and who are in the process because certain people may be anti-transgender and do[n't] view are option at life the same as theirs.

—Nonbinary Individual
November 2019

My concerns are, not enough meals, not being address[ed] correctly @ all times when in paperwork and in person. The officers begin to feel threatened by us who are on the shots. So we tend to be targeted more aggressively and more often. We are being treated very poorly due to us being trans.

—Transgender Man
December 2019

There should be constant training of staff for pronouns and the misgendering of transpeople.

—Transgender Woman
December 2019

I strongly feel staff needs to be retrained on how to address our transgender needs whether it comes to searching, being spoken to. I find alot of Hispanic C/O have a real problem with transgender Latinas. Its a cultural thing. And they (C/Os) become aggressive and offended like we embarrass the Hispanic race.

—Nonbinary Individual
December 2019

Incarcerated Transgender, Nonbinary, and Intersex Individuals Expressed That the Department Does Not Provide Sufficient Privacy When They Are Unclothed

It was pointed out that there is nothing but two partial partitions instead of doors on the showers. The partitions hid[e] very little. Lots of transgenders take "bird baths" in their cells instead of being exposed in one of these showers. There isn't any major security concerns with a door because a staff can still see and it provides privacy.

—Transgender Woman
November 2019

Using a urinal is degrading, we are forced to use the bathroom in the dayroom and yard. We should be given the opportunity to use the bathroom in private in our cell, and not in front of a yard or dayroom.

—Transgender Woman
November 2019

Getting shower time without the males looking in.

—Transgender Woman
December 2019

There are not enough privacy curtains in housing units.

—Transgender Woman
December 2019

Shower program: alot of times we are only allow[e]d showers with other inmates that are not transgender or even gay w[h]ich forces us to "bird bath" only in our cells to avoid problems.

—Transgender Woman
December 2019

Being housed in [this institution] theres no privacy in restroom areas. I feel that we should have doors on stalls.

—Transgender Woman
November 2019

Incarcerated Transgender, Nonbinary, and Intersex Individuals Expressed That Reporting Sexual Assault and Harassment Is Futile

There are problems with staff taking our reports of sexual misconduct and violence against us seriously, even when it is reported years later. They even are disrespectful when addressing us when we are addressed. I believe that staff need to be more professional in their actions with us and take our complaints seriously.

—Transgender Woman
November 2019

I do not believe I can safely report harassment, violation of law or violence committed based on my transgender status. As one who has received retaliation and retaliatory transfers as a result of filing 602s and staff complaints I am concerned about reporting staff misconduct. This prison has a reputation of such harassment. Also that threat of transfer to men's prison without volunteering.

—Transgender Man
December 2019

The PREA standards for transgender optional female housing assessments are not in compliance by CDCR nor is the prohibition of cross-gender strip searches. Even though I have a legal gender change and a new birth certificate as "female."

—Transgender Woman
November 2019

It isn't safe reporting harassment because staff, in indirect ways, still retaliate. Alot of times it's in the form of searches and "shake downs" that staff can say is perfectly in their right to conduct. They also use abusive language and are very hostile.

—Transgender Woman
December 2019

I feel as a transgender we cant report any discrimination or sexual harassment because Im being retaliated against.

—Transgender Woman
December 2019

PREA does not work and investigations are a joke and half investigated the same results of insufficient evidence even when there has been a crime.

—Transgender Woman
December 2019

When a PREA complaint is lodged they (staff) have a tendency to minimize your issues and let everyone know you made the complaint. They try to make you a pariah as if you are making complaints for personal reasons.

—Transgender Woman
December 2019

I believe that CDCR staff should take transgender concerns more seriously, including addressing those concerns by recording such concerns. (e.g., inmates harassing transgenders by inappropriate sexual conduct as requests, comments, exposing themselves to transgenders for wanting sex from us. This includes, staff always transferring out transgenders to other facilities who report incidents, instead of the male inmate violator's, especially when were innocent.

—Transgender Woman
December 2019

We cannot safely report discrimination, harassment or violence based on being a transgender because correctional staff retaliate by moving us or our cellies, stealing our property, fabricating RVRs, and intentionally placing us in situations where we will be harmed or have to use violence to protect ourselves.

—Transgender Woman
December 2019

Incarcerated Transgender, Nonbinary, and Intersex Individuals Reported They Are at Risk of Violence Due to Unsafe Housing and the Department Does Not Respond Adequately to Their Concerns

The staff will put anyone in your cell and that is a danger to transgenders. If a person refuses a celly that person gets disciplined. [This institution] has a surprising number of cell murders since I've been here. I myself will rather go to ad-seg than accept a stranger as a celly. I believe that because of the delicate nature of this, staff should give that person a reasonable amount of time to find a compatible celly instead of endangering us with involuntary co-habitation.

—Transgender Woman
November 2019

Being a M to F transgender, CDCR does not honor housing in choice of housing based on what feels safer for the individual and discriminates due to genital anatomy.

—Transgender Woman
December 2019

I would appreciate if staff would not force me to double cell with just anybody because I have been threatened because of my identity as a woman.

—Individual Who Identifies as Both Male and Female
December 2019

As a transgender [it] is hard to talk to staff when you feel unsafe in the cell with a celly. They do no listen to us all they do is write us 115s and punish us and we end up getting hurt.

—Transgender Woman
December 2019

As a transgender its hard to feel like we can go to staff because when we do they do not listen and write you up for being out of bounds.

—Transgender Woman
December 2019

Not getting 115s for refusing housing to other inmates due to people not being comfortable with living with a transgender.

—Transgender Woman
December 2019

When told I wasn't safe I was threatened with ad segregation (the hole) as the only place to keep me safe.

—Intersex Individual Who Most Often Identifies as Female
December 2019

I don't believe that gender identity and sexual preference are taken into consideration on the same level or to the same degree as other mental health and housing considerations. For example, you are asked if you mind being housed with other races and certain offenders. People are not asked if preference and identity impact their living conditions which creates room for one to live uncomfortabl[y] or get written-up for refusing housing.

—Nonbinary Individual Who Most Often Identifies as Male
December 2019

Incarcerated Transgender, Nonbinary, and Intersex Individuals Described Discrimination in Vocational Training, Job Assignments, and Other Activities

Transgenders are still being denied access to HRM and PIA laundry vocational skills.

—Individual Who Most Often Identifies as Female
November 2019

I am discriminated against when it comes to job assignments. I am good at any trades related work/repair but can only get low skill work.

—Transgender Woman
December 2019

Was wondering if female institutions could by chance get the ACT program that San Quentin has.

—Transgender Man
November 2019

There needs to be an LGBTQ class weekly that will inform and advise the community here at [this institution].

—Nonbinary Individual
November 2019

Work discrimination is a problem here as well.

—Transgender Woman
December 2019

More jobs for transgender, not yard crew.

—Transgender Woman
December 2019

Incarcerated Transgender, Nonbinary, and Intersex Individuals Described Discrimination in Access to Clothing and Property Items That Align With Their Gender Identity and Expression

> Will the state provide compression bras to indigent inmates[?]
>
> —Transgender Man
> November 2019

> I enjoy very much that the canteen [has] transgender makeup at all. The issue I have been having is the selection is very limited, what is on canteen here works well only for darker comple[x]ions. I think a few more color-type options would go over well.
>
> —Transgender Woman
> November 2019

> We should be able to get female i[t]ems on canteen.
>
> —Transgender Woman
> December 2019

> Access to more make-up, lingerie, razors.
>
> —Transgender Woman
> November 2019

> We need to have transgender clothing.
>
> —Transgender Woman
> November 2019

> I feel discriminated in the clothing distribution that we are given. The jean jacket is excellent most of the time except in the very cold months and we transgenders are not allowed sweatshirts. It would be very considerate of CDC[R] to allow us sweatshirts too, but if that is not possible would we be able to ask to wear our own catalog purchased sweatshirts?
>
> —Transgender Woman
> December 2019

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Need of plus size clothing and any resources available.

—Transgender Woman
December 2019

Inability to access razors or close shave razor like devices for indigent transgender inmates at this [Institution] 180 hub trans prison. M[o]re access to transgender literature.

—Transgender Woman
December 2019

More effemenent clothing and especially the boots and more variety in make-up it's almost racist, the choice available.

—Transgender Woman
December 2019

Being nonbinary is fluid. I personally switch genders every month or so. I need access to *both* male and female clothing in order to accommodate my fluidity.

—Nonbinary Individual
December 2019

I think not being allowed make-up and other feminin[e] products is damaging in the SHU to our ment[a]l state bec[a]use some of us are back here for 2–5 years at a time.

—Transgender Woman
November 2019

Incarcerated Transgender, Nonbinary, and Intersex Individuals Indicated They Face Discrimination Because They Lack a Voice in Inmate Advisory Councils

> [Facility] has no transgender MAC rep and it seems like a roadblock and hemming and hawing happens. Its an issue that isn't taken seriously.
>
> —Transgender Woman
> November 2019

> Transgender I.A.C. rep doesn't get the same access to administration as the other I.A.C. gets.
>
> —Transgender Woman
> December 2019

Transgender, Nonbinary, and Intersex Incarcerated Individuals Expressed Frustration With the Department's Provision of Health Care

Obtaining SRS surgery has been hard for me to get approved of an[d] I would like to have the surgery to complete the physical aspect of my transition.

—Transgender Woman
November 2019

I would like the sex change done because I've been denied twice.

—Transgender Woman
November 2019

I believe as transgenders we should be provided with more information about the shots. Also for those who stop taking them they should not stop them cold turkey. The side effects are really affecting people who stop them and aren't provided care for their bodys side effects without the shots.

—Transgender Woman Who Most Often Identifies as Male
November 2019

Educating staff on transgenders. Medical staff addressing you as gender you are especially if on hormones.

—Transgender Man
December 2019

I feel that only the inmates who are in the process of changing their preference should be documented as "transgender" meaning if they are taking the testosterone shot. Also, a lot of us who are transgender and are on the shots should have more resources regarding how to deal with the possible side effects, do we need to take certain vitamins, we need more food, etc. Also our clothing needs to be changed and if transgenders are considering breast removal, we should be able to begin the process after discussing it with a doctor.

—Transgender Man
November 2019

Mental health was very adamant on making sure I didn't get diagnosed GD here @ [this institution] and it took another institution to help me upon transfer.

—Nonbinary Individual
November 2019

I would like an in person transgender doctor so I could ask more questions and concerns about my body change. I also want to know how does my transgender continue on the outside world.

—Transgender Man
November 2019

I'm not sure if this is the box but I would like to address not being able to have the proper medical care that will initially go with being on testosterone shots. I say this because the nurses administering the shots really don't have the transgender knowledge or even being able to be monitored as directed by the shots. I just feel like I'm on the shots without having proper guidance and knowledge from my practitioner.

—Individual Who Most Often
Identifies as Male
November 2019

I am being refused my medical slips. I have brought it to their attention to give me my hormones pri[o]r to coming to [this institution] but still no answer.

—Transgender Woman
December 2019

Why is it so difficult to approved or even get approved gender reassignment surgery while housed in CDCR[?]

—Transgender Woman
December 2019

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Comments Regarding Safe Housing and Senate Bill 132

Housing needs to be sensitive to trans inmates' needs.

—Transgender Woman
November 2019

Hoping that [Senate Bill] 132 changes this so I can go to a women's facility where I would feel safe. Also [I] hope if discipline history is looked into, that consideration is given [to] "why" that resulted in discipline and that you not be excluded based on violence not directed at institution.

—Transgender Woman

I would opt to live in a male institution if I could get the bottom surgery—but the process seems to be denied for all the FTM trans I know, with only a few getting [a] mastectomy.

—Transgender Man
December 2019

My only concern with being housed at a female institution is whether or not I would be accepted by the female inmates.

—Transgender Woman
December 2019

The designation of being transgender should require a diagnosis of 'Gender Dysphoria' (through medical/trans specialist and also mental health) because men want to shower with us and have access to our property.

—Transgender Woman
December 2019

Housing transgender women by ourselves until we find somebody we are comfortable with. We as transgender women should have lower bunk chronos permanently!

—Transgender Woman
December 2019

I would prefer the *option* to chose (after reassignment surgery) to stay in a male institution.

—Transgender Woman
December 2019

I am afraid of going to a female prison because their policy is to treat us as a 'new commitment' and restrict access to razors and I have facial hair that if unshaven is upsetting my ability to function.

—Transgender Woman
December 2019

No female inmate (trans) should be housed in a mens prison. The risk is to[o] great to both the inmate and CDCR.

—Transgender Woman
December 2019

You should just make all prisons and jails in California co-ed meaning both men and women will be housed together.

—Individual Who Most Often Identifies as Female
December 2019

I would like to see SB 132 pass, because it is very helpful to help protect girls in CDCR.

—Transgender Woman
December 2019

I only want to be housed with female I/Ms or transgender females. I don't feel safe in the shower. Every day I am harassed by I/Ms & staff. Eventually I will be assaulted or in a fight.

—Transgender Woman
December 2019

It would be beneficial if we had the option to live at a womens facility but not mandatory.

—Transgender Woman
December 2019

As a trans-female I would like the option of only being housed with other inmates when a signed chrono (by both inmates) addresses compatibility.

—Transgender Woman
December 2019

I feel as though although I identify as trans male, I would become a rape victim being housed with men twice my size with a penis. Especially since I still keep getting denied breast removal and I am without a penis. I don't feel it would be a safe transfer.

—Transgender Man
December 2019

Miscellaneous Comments

Those of us taking the shots and holding our transgender cards are going thru a complete body change and [this institution] doesn't allow us to get fed sufficiently according to our body change. We should be getting the same portions as the men. Thank you.

—Individual Who Most Often Identifies as Female
November 2019

As FTM trans, my metabolism has changed with testosterone therapy, but [this institution] does not allow increased food portions—amounts that match the men's diet.

—Transgender Man
November 2019

More transgender survey and questionaires for future purposes.

—Transgender Woman
December 2019

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The California Department of Corrections and Rehabilitation's Response

STATE OF CALIFORNIA — DEPARTMENT OF CORRECTIONS AND REHABILITATION GAVIN NEWSOM, GOVERNOR

OFFICE OF THE SECRETARY
PO Box 942883
Sacramento, CA 94283-0001

August 27, 2020

Mr. Roy Wesley
Office of the Inspector General
10111 Old Placerville Road, Suite 110
Sacramento, CA 95827

Dear Mr. Wesley:

The California Department of Corrections and Rehabilitations submits this letter in response to the Special Report entitled "The California Department of Corrections and Rehabilitation Has Taken Thoughtful and Important Steps to Address the Difficult Conditions of Confinement for Incarcerated Transgender, Nonbinary, and Intersex Individuals."

The Department has reviewed the draft Special Report and appreciates how the Office of the Inspector General (OIG) recognizes the complexity of the issues that impact incarcerated transgender, nonbinary, and intersex people. As noted in the Special Report, the needs of this particular population are diverse and they are at greater risk of victimization both in the community generally as well as in a correctional environment. The experiences described by these individuals, some of which are laid out in the first two sections of this report, are very concerning, and emphasize why the Department proactively developed and engaged in these in person surveys to hear directly from the people the policy and law changes would impact as we work to improve their experiences. As your report notes, and the Department wants to reiterate, much of what is recounted in the first two sections of this Special Report was provided anonymously and did not include specific details that could be investigated. However, when Department staff were speaking to individuals during surveys and the subsequent group discussions, if statements were made that indicated misconduct or victimization, as noted in these sections of the Special Report, the Department staff immediately raised those issues to institution leadership so the concerns could be addressed appropriately through established processes. The Department is grateful to the incarcerated individuals who voluntarily participated in the survey and provided candid feedback on their experiences. The Department takes the kinds of allegations noted in these two sections very seriously, and maintains a zero-tolerance policy for sexual harassment, sexual violence, staff sexual misconduct and retaliation.

The Department appreciates the recognition this report provides for the many dedicated staff who have spent countless hours trying to proactively address and improve the experiences of incarcerated transgender, nonbinary, and intersex individuals in our care. When the Transgender Housing and Search Workgroup was initially established, the group set out to work solely on housing and search issues for this community, but as is made clear in the Special Report, the need for additional policy changes is apparent and the scope of the working group quickly expanded beyond these two distinct issues. This working group is also unique in that it is not solely an

The California Department of Corrections and Rehabilitation's Response (continued)

internal Department workgroup, but instead includes various external stakeholders, including Legislative staff, advocacy and legal groups, as well as OIG representatives. I am proud of the work that has been accomplished so far, and the Department is committed to continuing to engage with this community to ensure the gains made through this Workgroup are not lost, and that this important work continues. As your Special Report makes clear, continued work in this area is absolutely necessary.

If you have further questions, please contact me at (916) 323-6001.

Sincerely,

RALPH M. DIAZ
Secretary

Special Report

The California Department of Corrections and Rehabilitation Has Taken Thoughtful and Important Steps to Address the Difficult Conditions of Confinement for Incarcerated Transgender, Nonbinary, and Intersex Individuals

OFFICE *of the*
INSPECTOR GENERAL

Roy W. Wesley
Inspector General

Bryan B. Beyer
Chief Deputy Inspector General

STATE *of* CALIFORNIA
September 2020

OIG

The Public Health Crisis State of Transgender Health Care and Policy

Arjee Javellana Restar, PhD, MPH, Eric K. Layland, PhD, Bee Davis, MS, Hale Thompson, PhD, and Carl Streed Jr, MD, MPH

ABOUT THE AUTHORS

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The rise of antitransgender legislation in the United States[1] has reached unprecedented levels. At the time of writing (October 2023), there were 574 bill proposals explicitly directed at transgender populations in 49 US states, of which 83 have been signed into law.[1] These bills aim to restrict the rights and freedoms of transgender persons, particularly children and adolescents, in areas of health care and society such as employment, education, sports, and public facilities, effectively excluding transgender persons from participating in civic life.

HEALTH IMPACTS OF ANTITRANSGENDER LEGISLATION

For instance, according to the Transgender Legislation Tracker,[2] of the 83 laws passed, 22 were specific to restricting access to and provision of health care (e.g., making medically endorsed best practices of gender-affirming care to minors a felony crime), 19 were aimed at education restrictions (e.g., use of pronouns, updating gender marker and name in school records, undermining the privacy of transgender status disclosure involving parents), 12 were specific to sports participation bans, and 9 were related to bathroom bans. The impact of such antitransgender policies extends far beyond legal and political spheres; it is a critical public health crisis that threatens not only access to care but also the physical and mental well-being and survival of the more than 1.6 million transgender people in the United States.[3]

At the core of this crisis is the deliberate denial of basic human rights and autonomy of a population for a malevolent, politically convenient, and irrational agenda. While the provision of gender affirmation (i.e., services that encompass a range of psychological, behavioral, medical, or legal interventions designed to support one's gender identity) remains highly politicized, we, as scientific, medical, and legal communities must learn to combat the spread of disinformation and misinformation on this topic as well as policies that purposefully mischaracterize the science. The current wealth of evidence, as supported by multiple established medical organizations like the American Medical Association and the current standards of transgender health care,[4] point to published findings indicating that high-quality, gender-affirming care is an integral protective factor for the mental health and well-being of transgender persons. This evidence also supports the view that gender-affirming care is part of bodily autonomy such that decisions are to be made only between transgender patients, providers, and parents of transgender youths—prioritizing parental consent and youths' assent.[4]

The impact of antitransgender legislation on the mental health of transgender individuals cannot be overstated. Transgender people face significant mental health challenges because of discrimination and stigma, and the banning of gender-affirming care, in particular, can lead to trauma and other severe mental health consequences, such as suicide attempts, severe psychological distress, and depression. These outcomes are six, eight, and nine times more prevalent, respectively, in transgender populations compared with the general population in the United States.[5,6] The denial of basic rights and freedoms only exacerbates these linkages, putting transgender communities at greater risk of mental health conditions.[6] In recent studies examining the impact of state policies, state-level antitransgender policies were significantly linked to more past-month psychological distress and endorsement of past-year suicidal thoughts, plans, and attempts among transgender adults—after adjusting for individual (e.g., demographics), interpersonal (e.g., experiences of transphobic discrimination), and social environmental (e.g., state-level inequality, religiosity as a proxy to social stigma) factors.[7] In another recent study, state-level

and city-level protective policies were linked to significantly fewer experiences of discrimination.[8] These findings are concerning given their recency—that is, we are seeing these antitransgender policies drastically impacting mental health outcomes of transgender populations in the same year they are being introduced.

This is a crisis for public health and for mental health systems, in particular. Besides gender-affirming care itself, to our team's knowledge, there are currently no behavioral, social, or structural interventions tailored to transgender populations that have been demonstrated to prevent or reduce adverse mental health symptoms and outcomes.[6,9] To buffer the impact of antitransgender policies nationwide, greater resources must be invested in scalable interventions to improve family support, promote social connectedness, and build transgender individuals' and communities' capacity for empowerment and resistance.[10,11]

The physical and physiological health consequences of antitransgender legislation are equally devastating. For instance, the denial of gender-affirming care can trigger and lead to myriad adverse physical and physiological health outcomes and consequences, such as hormone imbalances, increased cancer risk, and increased risk of HIV and other sexually transmitted infections.[6] Indeed, some states have reported a chilling effect amid the enforcement of antitransgender policies, leaving providers and mental health professionals concerned that their practices might be penalized and that their patients' health and safety might be jeopardized.[12] Similar chilling effects have occurred in that transgender patients have hesitated to seek necessary care beyond gender-affirming care such as primary care or routine health checkups for fear of being targeted.[12] In addition, these antitransgender policies may force transgender persons who cannot flee to sanctuary states to conceal their transgender identities and disengage from lifesaving care, thus leading to unmitigated health-harming effects. These antitransgender policies can lead to increased rates of violence and victimization, too, which can result in physical injuries and trauma. As political motivations drive an antitransgender policy landscape, public sentiment follows, emboldening hate groups and dangerous subpopulations in society who wish to eradicate transgender people.

PUBLIC HEALTH ROLES AND EVIDENCE-BASED SOLUTIONS

We have at our disposal the ability and tools across scientific, medical, and legal armamentaria to proactively curb the impact of this legislation on the mental and physical health outcomes in transgender populations, and even dismantle the oppressive systems that uphold and reinforce these policies.[13] Strategic responses require us first to repair and heal relationships of historical distrust between transgender communities and scientific and medical communities. Forming meaningful collaborations and partnerships between transgender communities, stakeholders, and researchers entails establishing equitable team structures. These collaborative teams should prioritize transgender researchers and stakeholders as leaders in decision-making processes—while simultaneously being proactive in allyship, particularly those of us in leadership positions who are in power to amplify key and informed public health messages to make lasting changes.

Investing in community-engaged and community-led research, programs, and policy initiatives (e.g., the Trans Legislation Tracker, Center for Applied Trans Studies) is also crucial to ensure that such responses are community-driven and that they saliently address pressing health and legal needs and directly benefit transgender communities.[2,13] In addition, it is important to collaborate with other health equity scholars exploring and expanding concepts and strategies on resilience, racial equity, disability rights, Indigenous well-being, and reproductive health, among other topics, given the intertwining impacts of transgender health and policies in these areas,[13] and that health and legal professionals will also encounter transgender people among their target population.

Increased investments in rigorous research methodologies are necessary to strengthen evidence, address research and policy gaps, and combat misinformation. Specifically, these investments can begin with federal, state, and privately funded epidemiological studies or national surveys with gender-inclusive and gender-specific approaches that recognize and distinguish the health needs of all gender groups, longitudinal cohort studies that comprehensively map the impact of structural factors like protected policies on health, and interventions and clinical trials that are scalable and community-driven. These methodological and structural strategies can advance our responses and promote practices that are not only equitable but also just, on a larger scale.

Antitransgender policies reflect malicious attempts by those in power to pit the public against a highly marginalized group and avoid addressing critical economic and social issues that affect everyone (e.g., housing stability,

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infrastructure maintenance and expansion, climate change). The epidemic of antitransgender policies aims to regress decades of medical, public health, and policy progress, placing our achievements at a perilous crossroads. Where there is legislation that restricts a specific population's lives and human rights, there are multiple negative and inequitable consequences—as with the case of banning abortion rights, adverse birth outcomes and increased mortality were a consequence.[14] Respect for privacy, bodily autonomy, and the preservation of human rights for transgender people must be core ethical components of current and future health policies, and communities of medical, public health, and policy professionals must proactively oppose legislation that undermines public health responses. These actions are necessary components to achieving health equity for all.

AJPH

CORRESPONDENCE

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Note. This article does not represent the official view of the sponsors.

CONFLICTS OF INTEREST

C. Streed Jr reports consulting fees from EverlyWell (2020–present), L'Oreal (2023–present), and The Texas Health Institute (2022–present) unrelated to the work presented in this article.

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Continuation of Gender-affirming Hormones Among Transgender Adolescents and Adults

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Abstract

Introduction: Concerns about future regret and treatment discontinuation have led to restricted access to gender-affirming medical treatment for transgender and gender-diverse (TGD) minors in some jurisdictions. However, these concerns are merely speculative because few studies have examined gender-affirming hormone continuation rates among TGD individuals.

Methods: We performed a secondary analysis of 2009 to 2018 medical and pharmacy records from the US Military Healthcare System. We identified TGD patients who were children and spouses of active-duty, retired, or deceased military members using International Classification of Diseases-9/10 codes. We assessed initiation and continuation of gender-affirming hormones using pharmacy records. Kaplan-Meier and Cox proportional hazard analyses estimated continuation rates.

Results: The study sample included 627 transmasculine and 325 transfeminine individuals with an average age of 19.2 ± 5.3 years. The 4-year gender-affirming hormone continuation rate was 70.2% (95% CI, 63.9-76.5). Transfeminine individuals had a higher continuation rate than transmasculine individuals 81.0% (72.0%-90.0%) vs 64.4% (56.0%-72.8%). People who started hormones as minors had higher continuation rate than people who started as adults 74.4% (66.0%-82.8%) vs 64.4% (56.0%-72.8%). Continuation was not associated with household income or family member type. In Cox regression, both transmasculine gender identity (hazard ratio, 2.40; 95% CI, 1.50-3.86) and starting hormones as an adult (hazard ratio, 1.69; 95% CI, 1.14-2.52) were independently associated with increased discontinuation rates.

Discussion: Our results suggest that >70% of TGD individuals who start gender-affirming hormones will continue use beyond 4 years, with higher continuation rates in transfeminine individuals. Patients who start hormones, with their parents' assistance, before age 18 years have higher continuation rates than adults.

Key Words: transgender gender dysphoria, sex-hormones, treatment, adolescent, adult

Abbreviations: ICD, International Classification of Diseases; MHS, Military Healthcare System; TGD, transgender and gender-diverse

Approximately 1 in 250 adults or almost 1 million adults in the United States identify as transgender (1). The frequency of adults, and especially younger adults, reporting a gender-diverse identity has increased over time (1). Some persons who identify as transgender or gender-diverse (TGD) will seek treatment with gender-affirming hormones to align their bodies more closely with their gender identity (2). Medical treatment of people who identify as transgender improves body satisfaction, quality of life, and mental health (2, 3). However, many of these treatments are not entirely reversible (4).

Some adolescents or adults who take gender-affirming hormones subsequently elect to stop treatment (5, 6). Most adults who stop gender-affirming hormones report doing so for reasons unrelated to a change in gender identity, such as pressure from family, difficulty obtaining employment, or discrimination (7). Also, discontinuation of gender-affirming hormones does not necessarily represent a failure in treatment or initial decision-making. Some TGD adolescents and adults who start and then discontinue gender-affirming hormones experience use of hormones as an important part of consolidating their gender identity and experience no regret over the use of hormones despite some permanent effects (5, 7, 8). However, a portion of TGD individuals who pursue gender-affirming medical or surgical affirmation do express regret over the permanent effects of treatment (5, 9, 10). In a

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metanalysis of 7928 TGD individuals who had gender confirmation surgery, 1% expressed regret after surgery (9). The most prevalent reason for regret was psychosocial circumstances, particularly from a lack of social support or negative reactions from family and employers (9). Concerns about future regret after medical or surgical affirmation and the capacity of adolescents to provide informed assent for this treatment, with the assistance of their families, have led legislators and members of the judiciary in some locations to attempt to limit access to these interventions for youths (11-14). For example, in the United States, 16 states do not provide coverage for gender-affirming medical care through public insurance for those with incomes below the federal poverty line (Medicaid). Two states have outlawed gender-affirming care for minors, another state has taken administrative action to classify gender-affirming medical care for minors as child abuse, and 20 state legislatures are considering laws to make some or all aspects of gender-affirming medical care for minors illegal during the 2022 legislative session (13, 14). In the United Kingdom, a court ruled that gonadotropin-releasing hormone analogues could not be administered to transgender patients younger than age 16 years without obtaining a court order and suggested that older TGD adolescents should be required to obtain a court order before starting gender-affirming hormones (12).

Clinical guidelines for medical affirmation of persons who identify as TGD suggest that the rate of "de-transition" among postpubertal adolescents and adults is rare, but few studies have assessed the actual rate of treatment discontinuation (6, 7, 10). In a cross-sectional study of a self-selected sample of 27 715 TGD adults in the United States, 61.9% reported a history of social affirmation (ie, changing name, pronouns, appearance), 44.8% reported medical affirmation with hormones, and 19.5% reported surgical affirmation (7). A history of stopping affirmation and reverting to living in their sex assigned at birth for at least a little while was more common among people who only engaged in social affirmation (30.8%) than among people who had started medical (9.1%) or surgical (6.9%) affirmation (7). Among TGD adults who stopped affirmation, 82.5% reported at least 1 external factor, such as pressure from family and community or difficulty with employers as a reason to stop and 15.9% reported at least 1 internal factor, such as psychological distress and uncertainty or fluctuation in gender identity as a reason to stop. Only 5% of people who stopped affirmation reported stopping because they realized that changing gender was no longer desired. At the time of the survey, 68% of people who had discontinued affirmation had subsequently restarted (7). In a 1-year chart review of 174 adults treated at a national gender clinic in the United Kingdom, 12 (6.9%) patients discontinued medical affirmation during a 1-year period. Of these 12 patients, 4 later reengaged in gender-affirming care (6). At the Center of Expertise on Gender Dysphoria, a specialized gender clinic that provides > 95% of all gender-affirming medical and surgical care in the Netherlands, > 75% of TGD adults who started gender-affirming hormones between 1972 and 2014 had completed 1.5 years of gender-affirming hormones and met criteria for gonadectomy by the end of 2015 (10). However, this study did not assess hormone continuation rates directly.

Prior studies of treatment discontinuation rates among TGD adults undergoing medical affirmation have been limited to small samples of patients from specialized gender clinics who stopped coming in for appointments or a cross-sectional study of self-reported de-transition rates among adults who continue to identify as TGD and obtained hormonal therapy both in and outside the health care system (6, 7, 15). These studies found low levels of treatment discontinuation. The discontinuation that did occur was frequently temporary and unrelated to a change in gender identity. However, none of these studies have examined discontinuation rates among minors or assessed objective measures of medication continuation. Therefore, in the current study, we assessed the rate of treatment discontinuation after starting gender-affirming hormones among TGD adolescents and adults and identified demographic groups at higher risk of discontinuation of gender-affirming hormones. We hypothesized that gender-affirming hormone continuation rates will not differ between individuals who start hormones before or after reaching the age of legal majority.

Methods

This study is a secondary analysis of US Military Healthcare System's (MHS) medical and pharmacy billing records from October 2009 to September 2018 for family members of active-duty service members. Data were extracted from the Military Healthcare Data Repository, which includes insurance billing records of all inpatient and outpatient care and outpatient prescriptions provided to individuals enrolled in the military's health care benefit (TRICARE) both domestically and abroad at military and civilian treatment facilities.

We used the following inclusion criteria for our study:

- The patient was a child or spouse of an active duty, retired, or deceased servicemember at the time of the initial TGD-related diagnosis
- Patient had 2 or more medical encounters for a TGD-related diagnosis on different days (International Classification of Diseases [ICD] codes: ICD-9 302.6, 302.85 302.50, 302.51, 302.52, 302.53, and ICD-10 F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890)
- Patient received an initial prescription for gender-affirming hormones between 30 days before the date of their first TGD-related medical encounter and 90 days after their date of his or her last TGD-related medical encounter
- Patient received at least 2 prescriptions for gender-affirming hormones.

We excluded active-duty servicemembers and military retirees from our analysis because servicemembers are required to obtain permission from the military service to transition while on active duty (16) and follow rules governing gender affirmation and use of gender-affirming hormones. We felt this would make them a distinctly different population from their family members and it would be inappropriate to combine them.

Use of ICD 9/10 codes to identify TGD individuals is a validated methodology. In a previous study, these codes were well-matched with clinical text notes in identification of TGD individuals (17, 18). We required patients to have 2 or more encounters with an associated TGD diagnosis to limit false-positive identifications.

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We used medical and pharmacy records to identify TGD individuals who started gender-affirming hormones. We identified a TGD individual's sex assigned at birth using the sex recorded at the first encounter, for any reason, in our dataset. Then, we used pharmacy billing records to identify prescriptions and days supplied of gender-affirming hormones for both initial prescriptions and refills. We defined gender-affirming hormone prescriptions as prescriptions for testosterone issued to individuals coded as female at their first encounter and prescriptions for estrogens issued to individuals coded as male at their first encounter. We attempted to limit our sample to patients using gender-affirming hormones by requiring patients to obtain at least 2 prescriptions for gender-affirming hormones and obtain the initial prescription for gender-affirming hormones between 30 days before the date of their first TGD-related medical encounter and 90 days after their date of their last TGD-related medical encounter.

We collected patient age at the initial TGD-related encounter, age at the time of the first prescription for gender-affirming hormones, family role (spouse vs offspring), determined if the patient started gender-affirming hormones before or after gender-affirming health care became an officially covered military benefit for family members on September 1, 2016, and military rank of the insurance sponsor (16). We used military rank (enlisted vs officer) of the patient's insurance sponsor at the time of the last medical encounter in our dataset as a proxy for family income. Officers are required to have a 4-year college degree before military service, whereas enlisted servicemembers are only required to have a high school degree or equivalent. Officers also have a higher average base pay than enlisted servicemembers. In 2019, the average base salary for servicemembers with 10 years of military service was $48 864 for enlisted servicemembers and $86 832 for officers (19).

We used Kaplan-Meier analyses to estimate the rate of discontinuation of gender-affirming hormones after starting treatment (20). We identified patients as discontinuing their gender-affirming hormones if they failed to obtain another prescription for gender-affirming hormones more than 90 days after completing their most recent prescription. Patients were censored from further analysis if they were no longer obtaining health care in the MHS (reached the date of their most recent medical encounter in the database).

We used the log-rank test to assess the influence of sex assigned at birth, age at initiation of gender-affirming hormones (< 18 years vs 18 years of age and older), family income (officer vs enlisted insurance sponsor), family role (spouse vs offspring), and if the patient started gender-affirming hormones before or after gender-affirming care became an official TRICARE benefit on September 1, 2016 (16). We limited our analysis of the influence of official insurance coverage to the first 22 months after starting gender-affirming hormones because we only had 22 months of data after the change occurred. We also used Cox proportional hazard analysis to determine the independent influence of our demographic factors on discontinuation rates. This study was institutional review board-approved as a secondary analysis of preexisting records. Statistical significance was defined as $P < 0.05$.

Results

Of the 952 individuals in our study, 66% were assigned female at birth, 61% were ≥ 18 years old, 71% had an enlisted insurance sponsor, and 90% were children of active duty, retired, or deceased servicemembers (Table 1, Fig. 1). Patients who discontinued obtaining refills of gender-affirming hormones continued to obtain medical care in the MHS for an average of 324 days (SD, 274; range, 91-1602) after they completed their final prescription for gender-affirming hormones (Table 1). The number of patients initiating gender-affirming hormones increased during the study period, and 58% of patients had their first appointment for transgender-related care during the last 22 months of our study (September 2016-June 2018), after gender-affirming care was included as an officially covered TRICARE benefit for family members (14) (Table 1 and Fig. 2).

In our sample, 70.2% (95% CI, 63.9-76.5) of patients who started medical affirmation continued to fill prescriptions for gender-affirming hormone for at least 4 years (Fig. 1). Transfeminine individuals were more likely to continue obtaining gender-affirming hormones in the MHS than transmasculine individuals. The 4-year continuation rate for transfeminine individuals was 81.0% (95% CI, 72.0-90.0) vs 64.4% (95% CI, 56.0-72.8) for transmasculine individuals (log-rank test χ^2, 11.860) (Fig. 3). Patients who were younger than 18 years of age when starting hormones were less likely to discontinue use than patients who were 18 years of age and older. The 4-year continuation rate among people who started treatment under 18 years of age was 74.4% (95% CI, 66.0-82.8) and the rate among people who were ≥ 18 years was 64.4% (95% CI, 56.0-72.8) (log-rank test χ^2, 4.461) (Fig. 4). Family income (enlisted vs officer insurance sponsor; log-rank test χ^2, 0.013) and family member type (spouse vs child; log-rank test χ^2, 1.002) had no influence on continuation rates. Starting hormones before or after official coverage of gender-affirming medical care by TRICARE on September 1, 2016, also had no influence on continuation rates (log-rank test χ^2, 0.728).

Table 1. Sample demographics (n = 952)

Demographic group	%
Gender identity	
Transfeminine	34.1
Transmasculine	65.9
Age at Initiation of Gender-Affirming Hormones	
<18 years old	39.1
≥18 years old	60.9
Insurance sponsor rank	
Enlisted (high school or some college)	70.6
Officer (college education and beyond)	29.4
Family member type	
Dependent child	90.1
Spouse	9.9
Started gender-affirming hormones before or after approval of gender-affirming care as an official TRICARE benefit	
Before approval (October 2009-August 2016)	42
After approval (September 2016-June 2018)	58.0
	Mean ± SD (range)
Days between stopping gender-affirming hormones and last visit	324 ± 274 (91-1602)

Gender-affirming medical care became an authorized TRICARE benefit for dependents on September 1, 2016.

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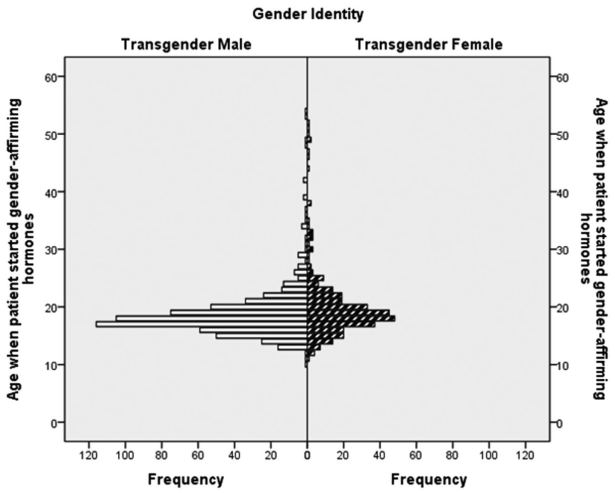

Figure 1. Age at initiation of gender-affirming hormones by sex assigned at birth.

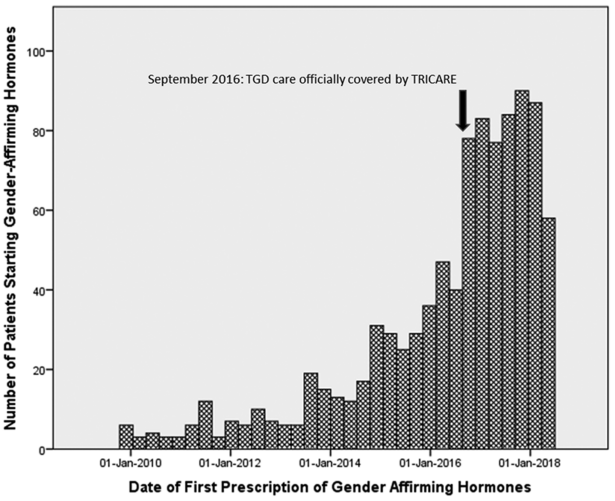

Figure 2. Incidence of gender-affirming hormone initiation over time.

In a Cox regression model containing assigned gender and age at initiation of hormones, transmasculine individuals were more than twice as likely to stop obtaining hormones in the MHS compared with transfeminine individuals (hazard ratio 2.40; 95% CI, 1.50-3.86) and people who started hormones after turning 18 years of age were more likely to stop obtaining gender-affirming hormones compared with people who started hormones before age 18 years (hazard ratio, 1.69; 95% CI, 1.14-2.52) (Table 2).

Discussion

Our study documented higher gender-affirming hormone continuation rates among transfeminine individuals and by patients who started hormones before reaching the age of legal majority in a population with universal insurance and access to low or no-cost medical and pharmaceutical care. Family socioeconomic status, family member type, and the official status of gender-affirming care as a TRICARE-covered benefit at the time the patient began taking gender-affirming hormones had no influence on continuation of gender-affirming hormones.

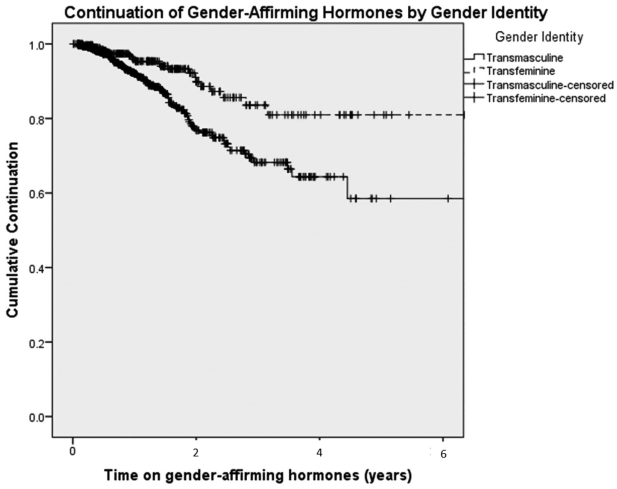

Figure 3. Continuation of gender-affirming hormones by gender identity.

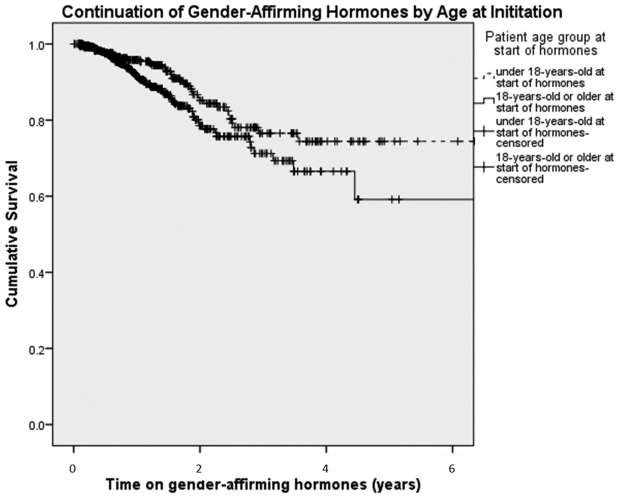

Figure 4. Continuation of gender-affirming hormones by age at initiation.

Table 2. Multivariate regression: independent association of age and gender identity on discontinuation of gender-affirming hormones

Demographic factor	Risk of discontinuing of gender-affirming hormones
Gender identity	Hazard ratio (95% CI)
Transfeminine	Reference
Transmasculine	2.40 (1.50-3.86)
Age at initiation of gender-affirming hormones	
<18 years old	Reference
≥18 years old	1.69 (1.14-2.52)

We noted a higher hormone continuation rate among TGD individuals who were younger than 18 years old at the time of first use of gender-affirming hormones compared with those who were aged 18 years and older when starting hormones. This has not been documented in previous studies.

The patients who started before turning 18 years would require parental consent for this treatment, whereas those aged 18 years and older do not. Parents who consent to use

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of gender-affirming hormones likely have a higher level of support for their child's gender affirmation on average than parents who do not. Parental support plays an important role in the mental health of TGD youth (21). A prior study of adults found that lack of family support for a TGD individual's gender was associated with a history of discontinuing social or medical gender affirmation (7). Higher parental support may explain the higher continuation rate among patients who start gender-affirming hormones as minors compared with people who start as adults.

Regardless of the reason for the higher hormone continuation rate among TGD youth, this finding provides support for the idea that TGD individuals below the age of legal majority, with the assistance of their parents or legal guardians and health care providers, can provide meaningful informed assent for gender-affirming hormones and do not appear to be at a higher risk of future discontinuation of gender-affirming hormones because of their young age alone.

There was a higher gender-affirming hormone continuation rate among transfeminine individuals compared with transmasculine individuals in our study. This has not been observed in previous studies. The reasons for this difference cannot be determined using the data from this study. If confirmed in future studies, this would suggest a need to ensure routine screening of transmasculine patients for osteoporosis risk after oophorectomy, especially if this procedure occurs at a younger age.

As in a previous study, there was an increase in the number of patients presenting for gender-affirming care over time (10, 22). However, unlike previous studies, the coverage status of gender-affirming care in our study changed over time. We noted a large increase in patients presenting for care after designation of gender-affirming care as a covered benefit in the MHS.

This leads to a concern that patients and providers who were engaging in gender-affirming care in the MHS before it was officially sanctioned were different than the patients and providers who did not start engaging in gender-affirming care in the MHS until after it was officially sanctioned. However, we did not see a difference in continuation rates between these 2 groups.

The large number of adolescents in our study, the longitudinal data for TGD individuals in a naturalistic and varied clinical setting, use of objective measures of ongoing hormone use, and comparison of gender-affirming hormone use among adolescents and adults are unique strengths of our study, but there are several limitations that must be noted.

We only collected information on medication refills obtained using a single insurance plan. If patients elected to pay out of pocket for hormones, accessed hormones through nonmedical channels, or used a different insurance plan to pay for treatment before and/or after obtaining gender-affirming hormones using TRICARE insurance, we did not capture this information. This means that our findings are likely an underestimate continuation rates among transgender patients.

We attempted to address our concern about overestimating discontinuation rates by only recording cessations among patients who stopped obtaining prescriptions for gender-affirming hormones while continuing to receive medical care using TRICARE insurance for more than 90 days. We would miscategorize patients as terminations if patients elected to obtain their gender-affirming medications using alternative payment options while continuing to receive other medical care using TRICARE.

However, the medication copay for generic medications purchased using TRICARE is quite low at $0 to $3 per prescription when compared with other private insurance programs in the United States. For example, a transgender woman using TRICARE insurance would pay a total of $0 to $72 for a 1-year supply of estrogen and spironolactone. For transgender women with private insurance in the United States, the out-of-pocket expenses for gender-affirming medications would be $230 per year and $500 per year for transgender men with insurance (23). This cost difference makes it less likely that a patient would continue to use TRICARE for medical care but elect to use a different insurer to obtain gender-affirming hormones.

This study was limited by reliance on accuracy of billing data and lack of patient-level data. We cannot know why patients in our study stopped obtaining refills of gender-affirming hormones using their TRICARE insurance. Many factors inform an individual patient's desire or ability to continue obtaining refills of gender-affirming hormones including gender identity, treatment intentions, difficulty finding a provider who offers gender-affirming care, satisfaction with treatment outcomes, or social context.

In a previous study, only 16% of TGD individuals who stopped gender-affirming hormones cited a change in gender identity or mental health concerns as a reason to discontinue social or medical gender affirmation (7). Many of the individuals who reported stopping gender-affirming hormones reported subsequently restarting treatment or the intention to restart treatment (7).

The lack of patient level detail in our study makes it impossible to predict individual patient outcomes with our findings. However, our findings can still be useful to inform policy makers or legislators when assessing the risk of transgender care for minors.

A related limitation is our reliance on the gender marker at the first medical encounter as a proxy for sex assigned at birth. It is possible that this information is wrong or reflects a change in gender marker that occurred before the beginning of our study interval. We attempted to address this concern using our inclusion criteria. For example, with our inclusion criteria, we would incorrectly include a cis-male patient who was assigned male at birth, changed the sex recorded in the electronic medical record to female, received a transgender-related diagnosis at 2 different medical encounters, and then elected to fill 2 prescriptions for testosterone during the same time period he had the 2 transgender-related medical encounters. This combination would likely be a rare event and, if present, have a minimal impact on the findings of the study.

Before September 2016, gender-affirming care was not an officially covered health care benefit under TRICARE (16). Patients may have had trouble finding a TRICARE-approved clinician who would prescribe hormones or a pharmacy that would fill the prescription in their area, especially in cases where they initiated care in 1 location and then they or their family moved. However, we did not see a difference in continuation rates between patients who started hormones before or after gender-affirming care becoming an officially covered benefit.

Determining if these differences in continuation rates exist in other groups of TGD individuals and determining if there

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are differences in reasons for discontinuation by gender identity or age is an important topic for future studies. Future prospective studies should investigate the rate of hormone discontinuation between transfeminine and transmasculine individuals to determine whether the same pattern of discontinuation is observed. The reasons for discontinuing treatment and whether patients anticipate restarting treatment at a future date would also be important to assess. Finally, it would be useful to prospectively assess the number of TGD individuals who experience regret after starting gender-affirming hormones and if there are any associated factors that can be used to identify patients at a higher risk of regret. This would assist clinicians in providing nuanced counseling regarding treatment options to TGD individuals before starting hormones.

Conclusion

In our study, transmasculine individuals were more likely to discontinue use of gender-affirming hormones during the first 4 years of use than transfeminine individuals. We also found that individuals who start gender-affirming hormones before reaching the age of legal majority are less likely to subsequently discontinue use when compared with individuals who start hormones after becoming a legal adult. If replicated in future studies, the improved continuation rate among patients who are not legal adults at the time of treatment should provide some reassurance to those concerned about the ability of minors to provide informed assent to use of gender-affirming hormones. A higher continuation rate among minors could also be used to inform the actions of legislators and judges who wish to prohibit gender-affirming treatment for minors to protect them from the consequences of health care decisions they make with the assistance of their parents and health care providers.

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Disclosures

The authors report no competing interests.

Data Availability

A deidentified copy of the dataset for this study is available from the authors on reasonable request

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DECLARATION OF KRISTOPHER E. KALIEBE, M.D.

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EXPERIENCE AND QUALIFICATIONS

1. I have been retained by Defendants in the above-captioned lawsuit to provide an expert opinion concerning mental health care, including care of Gender Dysphoria, within correctional environments. My opinion is based primarily on my own experience as a physician, psychiatrist, and professor in the field of psychiatry, as well as the relevant literature in this area. I have also reviewed documents and court filings in this case. I may wish to supplement my opinions or the basis for them as new evidence emerges or new research is published.

2. I am over the age of 18, am qualified to give this declaration, and have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion. I am being compensated at a rate of $450 dollars per hour. Testimony and depositions are billed in 4-hour increments. Any compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony that I provide.

3. I am Board Certified in Psychiatry, Child and Adolescent Psychiatry, and Forensic Psychiatry. My clinical work has been primarily in university-based clinics, community clinics, and correctional facilities.

4. I am a professor at the University of South Florida in Tampa, Florida, United States. I was promoted to the position on August 1, 2023. From 2016 to August 2023, I served as an Associate Professor at the University of South Florida, where my clinical roles included working in university clinics, providing consultative services at Tampa General Hospital, assessing and treating juveniles within correctional facilities, and supporting primary care physicians through the Florida Medicaid Psychiatric Medication hotline. From 2005 to 2016, I served as an Assistant Professor at the Louisiana State University (LSU) Health Science Center – New Orleans. I served as the training director of the LSU Child Psychiatry Fellowship for two years.

5. I received my medical degree in 1999 and subsequently completed general psychiatry, child and adolescent psychiatry, and forensic psychiatry training. This training included education in human biology, human sexuality, development, brain functioning, normal development, and psychopathology. Gender Dysphoria (then labeled "gender identity disorder") and Gender Dysphoria treatment were part of my professional training.

6. I have extensive teaching experience, including teaching medical students, general psychiatry residents, child and adolescent psychiatry fellows, and forensic psychiatry fellows. I have had years of extensive positive feedback from medical students and psychiatric residents. I have been awarded four resident teaching awards, including from the general University of South Florida residents in June 2023 and as the Forensic Psychiatry Fellowship Educator of the Year in June 2025.

7. I practice forensic psychiatry, working on both child and adult cases in both criminal and civil courts. I teach forensic psychiatry, and specifically I annually lecture forensic fellows on correctional psychiatry and on a biannual basis I lecture child and adolescent psychiatry fellows on correctional psychiatry.

8. I volunteer with direct patient care and resident supervision at University of South Florida's refugee clinic. I am also on call for nights, holidays, and weekends at Tampa General Hospital's consult service.

9. I work in two university-based training clinics. As a supervising physician at the University of South Florida's Silver Child Development Center, my role is to function as a clinical supervisor and instructor. Psychiatry residents and child psychiatry residents serve as primary patient evaluators and clinicians. I also evaluate new patients directly and then see patients as needed. I oversee the residents' work product and function as the physician of record. In this clinic, I evaluate

and treat pediatric patients with Gender Dysphoria. In addition to these direct clinical experiences, my duties at the Silver Child Development Center include training residents regarding the treatment of patients, including those with Gender Dysphoria.

10. Additionally, I am a supervising physician at the University of South Florida's general (adult) psychiatry clinic, the Outpatient Psychiatry Center. My duties at the Outpatient Psychiatry Center include supervising and instructing psychiatry residents. At this clinic, general psychiatry residents serve as primary patient evaluators and clinicians. I evaluate new patients directly and see them as needed afterward. I oversee the residents' work product and function as the physician of record. As part of my role in this clinic, I evaluate and treat adult patients with Gender Dysphoria.

11. I have experience working in adult corrections as part of my forensics training. In addition, I have experience working in Orleans Parish Prison and at the Elayn Hunt Correctional Center.

12. I have worked in juvenile corrections at various facilities since I graduated from the Forensics Fellowship in 2005. I also treat patients with Gender Dysphoria at the seven juvenile correctional centers I actively cover. I have also been consulted to provide a second opinion and coordinate care regarding a patient with Gender Dysphoria in the Louisiana juvenile correctional system.

13. I practice and support conventional medicine, and I have advocated for the expansion of Federally Qualified Health Centers, along with improved collaboration of mental health with primary care (Kaliebe 2016; Kaliebe 2017). I've presented at the Preventing Overdiagnosis conference in Oxford, England, in 2014, and at the National Institutes of Health in Bethesda, Maryland, in 2015. The Preventing Overdiagnosis conferences examine how physicians,

researchers, and patients can implement solutions to the problems of overdiagnosis and overuse in the healthcare system.

14. I am a member of the American Academy of Child and Adolescent Psychiatry, the American Academy of Psychiatry and the Law, and the American Psychiatric Association. I am also a member of the Open Therapy Institute, Therapy First, and Heterodox Academy. I co-chair the Heterodox Academy Campus Community at the University of South Florida.

15. I have been very active in the American Academy of Child and Adolescent Psychiatry (AACAP) since I joined in 2000 and have presented at its annual conference 26 times. I was awarded the status of a Distinguished Fellow at AACAP in 2016. I served as co-chair of AACAP Media Committee from 2013 to 2021 and was an author on AACAP's clinical practice guidelines for telepsychiatry. In addition, I served as the liaison between AACAP and the American Academy of Pediatrics from 2016 to 2022. I have also served AACAP through its state affiliates, acting as secretary-treasurer of the Louisiana Council for Child Psychiatry for four years and as president for two years. I was also a member of the Association for Behavioral and Cognitive Therapies from 2004 to 2016.

16. I have extensive experience in psychotherapy and have received additional training in Cognitive Behavioral Therapy and trauma-focused therapies. Throughout my career, I have provided psychotherapy and taught psychotherapy to psychiatry trainees. I currently routinely supervise psychiatry residents at the University of South Florida regarding psychotherapy. From 2007 to 2016, I created and taught a Cognitive Behavioral Therapy practicum for LSU residents.

17. My presentations related to Gender Dysphoria include:

- Psychotherapeutic Processes with Young People Experiencing Gender Dysphoria, Tampere, Finland, June 16, 2023. During this event, I presented and moderated a panel: "Working Psychotherapeutically in a Contested Space: Overcoming Challenges."

- Society for Evidence Based Gender Medicine Conference, New York, New York, October 9-12, 2023; Panelist: "The Etiology of Gender Dysphoria, The role of social and cultural context"; "Current Gender Dysphoria Guidelines, Assessing the Quality"; "Question and Answers, Next Steps."

- "Compassionate Care for Gender Non-conforming Youth" at Safe Children Coalition Conference, Sarasota, Florida, April 26, 2024.

- Society for Evidence Based Gender Medicine, Psychotherapeutic Approaches to Youth Gender Dysphoria, Athens, Greece, October 3, 2024; Panel Discussion, "The transgender zeitgeist: Exploring gender as a youth social movement."

- "The Chain of Trust is Broken in Gender Medicine," Heterodox Academy Conference, Chicago, Illinois, June 7, 2024.

- "When Perfect Storms Collide: The Ecological Origins of Youth Gender Medicine," Genspect, The Bigger Picture Conference, Lisbon, Portugal, September 27, 2024.

- "The Cass Review and its Implications for Approaching Youth with Gender Distress," Grand Rounds, University of South Florida, Department of Pediatrics, Tampa, Florida, November 14, 2024.

- "Power, Responsibility, and Truth: Increasing Open Expression Regarding Race and Gender in Medicine," as part of "The Battle to Remove Political Intentions from the Road to Scientific Truth: Three Physician Perspectives," Heterodox Academy Conference, New York, New York, June 23, 2024.

18. I have been a co-author on publications related to working with incarcerated populations:

- *Prescribing Psychotropic Medications for Justice-Involved Juveniles*, Journal of Correctional Health Care, Tamburello, A., Penn, J., Negron-Muñoz, R., & Kaliebe, K. (2023).

- *Telepsychiatry in Juvenile Justice Settings*, Child and Adolescent Clinics of North America, Kaliebe, K., Heneghan, J., Kim, T. (2011).

- *Clinical Update: Telepsychiatry With Children and Adolescents*, AACAP, Committee on Telepsychiatry and AACAP Committee on Quality Issues, Journal of American Academy of Child and Adolescent Psychiatry (Oct. 2017).

19. My recent publications related to Gender Dysphoria include:

- *Adolescent Onset Gender Dysphoria, Our Perspective*, AACAP News, with David Atkinson, MD (Nov/Dec 2023).

- *A Reply to Legal, Mental Health, and Societal Considerations Related to Gender Identity and Transsexualism*, Letter to the Editor, Journal of the American Academy of Psychiatry and the Law, Vol. 51 (2023).

- Letter to the Editor, in response to "*A reply to "The present state of housing and treatment of transgender incarcerated persons*," Journal of the American Academy of Psychiatry and the Law, Vol. 52 (2024).

- *Obstacles to progress in pediatric gender medicine*, European Journal of Developmental Psychology, Kozlowska, K., Hunter, P., Clayton, A., Kaliebe, K., & Scher, S. (2025).

OPINIONS

20. Hormone therapy is unproven and experimental treatment for Gender Dysphoria that generally should not be available to those in the custody of the Federal Bureau of Prisons ("BOP"). Though it is not medically necessary to provide hormone therapy to inmates who are diagnosed with Gender Dysphoria but not currently receiving hormone therapy, inmates currently receiving hormone therapy may be a more complex situation. In most circumstances, it is appropriate, after individual assessment, to discontinue hormone therapy for inmates currently receiving hormone therapy through an appropriate withdrawal process. In a limited set of circumstances, it may be appropriate, after individual assessment, to continue hormone therapy for inmates already being treated with hormones.

21. Cross-sex surgeries are not medically necessary and should not be made available in correctional environments.

22. "Social accommodation" is not medically necessary in the correctional setting.

23. It is not medically necessary to house inmates with Gender Dysphoria according to their asserted gender identity.

BACKGROUND

Definitions

24. Definitions and description of nomenclature in this report.

- "Social transition" is the process of changing one's sex-associated name, presenting oneself as a member of the other sex, and being referred to with third-person pronouns for the other sex.

- "Gender medicine" will be used for the clinical field that treats Gender Dysphoria, sometimes with medical interventions.

- The term "medical transition" will be used, as it is more accurate and clearer than the term "gender-affirming care."

- The term "cross-sex hormones" will be used, as it is more neutral and informative than the term "gender-affirming hormones."

- The term "medical necessity" refers to health care services that a physician and/or health care professional, exercising prudent clinical judgement, would provide to a patient for the purpose of preventing, evaluating, diagnosing, or treating an illness, injury, disease, or their symptoms. I use the term "medical necessity" as that term is used in the medical field, without regard to how that term may be used as applied to the Eighth Amendment or otherwise.

Sex and Gender

25. The basic biology of human beings is as a sexually dimorphic species. Biological sex is well-defined in all biological sciences, including medicine (Bhargava 2021). Sex is important in human development and throughout the lifecycle (Archer 2019). Sex is binary and determined at conception. Biological sex is programmed into every cell in the human body.

26. The term "gender identity" was introduced in the 1960s and meant the sense of knowing to which sex one belongs, the awareness of being male or female (Byrne 2023). More recently, however, the phrase "gender identity" is used differently by The World Professional Association for Transgender Health (WPATH), Standards of Care (SOC) 8, which defines "gender identity" as:

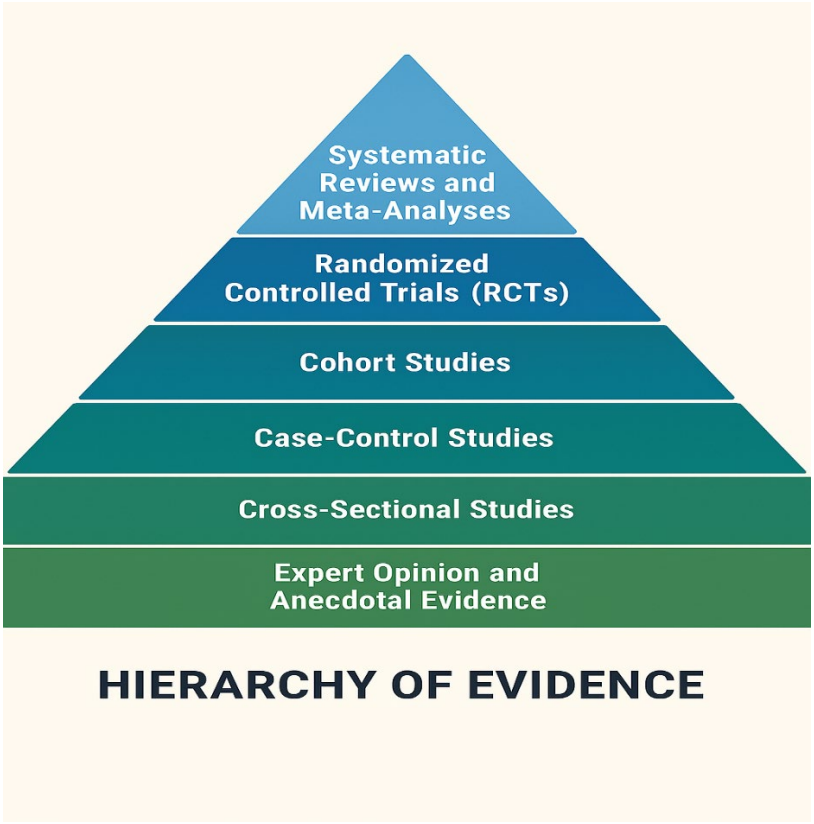
"A person's deeply felt, internal, intrinsic sense of their own gender." This definition is opaque because it refers to the amorphous term of "gender."

27. The term "transgender" is typically explained in terms of gender identity, i.e., that transgender people are those whose gender identities do not align with their sex.

28. This lack of clear definitions and shifting trends related to self-identified gender contribute to confusion about claims of medical necessity for the treatment of individuals with Gender Dysphoria, particularly in the correctional environment. While there are different uses of the term "gender" (Stock 2022 at 37-40), in this report, I will not use "gender" to refer to the distinction between men and women but will use the terms sex, biological sex, or natal sex for clarity.

Hierarchies of Evidence

29. In medicine, hierarchies of evidence are structured frameworks used to rank the reliability and validity of different types of research studies, guiding clinical decision-making, and evidence-based practice (Guyatt 1995, Evans 2003). Typically depicted as a pyramid, the hierarchy places systematic reviews and meta-analyses of randomized controlled trials (RCTs) at the top, as they synthesize high-quality data across multiple studies. Just below are RCTs, valued for their ability to minimize bias through randomization and control groups. Further down are cohort studies, case-control studies, and cross-sectional studies, which offer observational insights but are more susceptible to confounding factors. At the base lie expert opinions and anecdotal evidence, which, while sometimes useful, lack the rigorous methodology needed for strong clinical recommendations. This hierarchy helps clinicians prioritize the most trustworthy evidence when evaluating treatments, diagnostics, or prognostic tools.



30. In evidence-based medicine, grades like "low quality" or "high quality" evidence refer to how confident we can be that the research findings reflect the true effect of an intervention. These grades are part of the GRADE system (Grading of Recommendations Assessment, Development and Evaluation), which evaluates factors such as study design, risk of bias, consistency of results, directness of evidence, and precision of estimates. High-quality evidence typically comes from well-conducted randomized controlled trials and suggests that further research is unlikely to change our confidence in the results. In contrast, low-quality evidence—often from observational studies or flawed trials—means that future studies may significantly alter our understanding of the effect. These ratings help clinicians and policymakers make informed decisions by weighing the strength and reliability of the available data (Guyatt 2008).

Treatment Approaches for Gender Dysphoria

31. Gender Dysphoria is like depression, anxiety, and other mental disorders and is not among the most severe and persistent illnesses, such as schizophrenia, Level 3 autism, or bipolar disorder. The condition should not be assumed to be lifelong (Jorgenson 2024, Levine 2021). The Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) provides that the diagnostic criteria for Gender Dysphoria in adolescents and adults are (1) a "marked incongruence between one's experienced/expressed gender and assigned gender, lasting at least six months, as manifested by at least two of the [identified symptoms]," and (2) "clinically significant distress or impairment in social, occupational, or other important areas of functioning." DSM-5 (Gender Dysphoria). While Gender Dysphoria is viewed by some as a serious medical or psychiatric illness, others have also viewed it as a developmental adaptation to psychological problems, or an issue of sexual minority rights (Levine 2016, Castro-Peraza 2019). These beliefs about the nature of Gender Dysphoria will affect clinicians' treatment approach and the expectations of individuals experiencing Gender Dysphoria.

32. There are at least three different treatment models: (1) psychiatric comorbidities, (2) psychotherapeutic, and (3) affirmative.

33. The first clinical model is supportive and directly treats psychiatric comorbidities, such as depression and anxiety that frequently co-occur with gender dysphoria. This is a cautious approach based on the principle that not all human suffering should be a target of psychological or medical intervention. With any treatment, there is a potential for medical and psychological harm, wasted resources, and undermining patient independence and self-sufficiency. As gender non-conformity is not pathological, it is beyond the capacity and understanding of professionals to create interventions that are clearly beneficial and a reasonable use of resources. This approach treats

Gender Dysphoria as just another type of body-related distress that need not be over-emphasized or become a direct focus of treatment.

34. The second clinical approach is psychotherapeutic, aimed at alleviating distress by applying long-standing and evidence-informed tools of psychotherapy for patients suffering from Gender Dysphoria. Proper psychotherapy for gender distress does not impose the ideas of the clinician but can empower patients "to develop creative solutions to their difficulties and promotes agency and autonomy" (DeAngelo 2023).

35. The third treatment approach is the affirmation model (Coleman 2022), which promotes affirmation of the transgender identity immediately and decisively. Under this approach, social transition, i.e., living as the opposite sex, including changing the individual's name, preferred pronouns, and appearance, is encouraged. This approach considers the body parts and physical features that are associated with dysphoria as targets for treatment. Under this model, social transition, hormones, and surgeries would be provided without regard, or with minimal regard, toward factors associated with transgender identities, such as trauma, disorders of personality development, internalized or externalized homophobia, and neurocognitive disorders (e.g., autism).

A. <u>The affirmation model has many weaknesses and risks.</u>

36. In the community, the gender-affirming treatment options have become more common recently and are typically available for adults, and in some states, for minors. Yet affirmative treatment has significant known and unknown risks as discussed below and is based on low-quality evidence. These risks are amplified when applied to the correctional populations because such populations are highly unique and vulnerable due to higher rates of trauma, neurodevelopmental disorders, personality disorders, and psychopathy (Levine 2016, Liu 2021).

37. First, because the affirmative treatment paradigm emphasizes patient autonomy and the patient's desire to be treated as if they are the opposite sex, questions about the patients' self-identification are viewed as hostile and potentially harmful to the patient. This approach often overly credits patients' "rights", thus circumventing the scientific debate of evidence. It also tends to minimize discussion of harms and trade-offs, and risks patients harming themselves due to impaired decision-making, desperation, and/or exposure to misinformation that distorts informed consent of risk and benefit. Within the affirmation model, hormones or surgical interventions are provided despite that these treatments would not meet the usual clinical standards of providing treatments that improve health.

38. Second, the affirmation model treats Gender Dysphoria as a permanent disorder when it is better considered a temporary disorder like bulimia or depression. While some cases of depression or bulimia are long-lasting, most are not. The same is true with Gender Dysphoria. But once Gender Dysphoria is medicalized, it is more likely to become a long-lasting aspect of the individual, in part because patients are forever physically changed, and also due to patient self-justification, as will be detailed later in the report.

39. Third, much of the justification for affirmative treatment, such as cross-sex hormones and surgical treatments, comes from surveys indicating patient satisfaction. Although patient satisfaction is often used as an outcome measure in medical care, patient satisfaction can be influenced by factors unrelated to the quality of care (Richman & Schulman 2022), and prioritizing patient happiness and satisfaction may lead to inappropriate overtreatment (Mandell 2016, Lemke 2016), and undermine the importance of clinical outcomes and evidence-based practices, which are crucial for ensuring high-quality care (Fenton 2012).

40. As noted by Sirvoch (2012) at 412, "Fenton and colleagues followed more than 50000 adult participants in the National Center for Health Statistics' Medical Expenditure Panel Survey over a 2-year period (longer for mortality). Judging from patients' reported satisfaction with their physicians after year one, the authors found that, compared with patients in the lowest quartile of satisfaction, patients in the highest quartile were subsequently less likely to be seen in an emergency department, but more likely to be hospitalized, were responsible for more prescription drug and total health care expenditures, and were more likely to die." Sirvoch (at 413) goes on to note that: "Satisfaction with seemingly adverse outcomes of potentially excessive medical care appears to be the norm" and that "[m]ore aggressive practice, therefore, improves not only patients' perceived outcomes, but also those of physicians (reimbursement, performance ratings, protection against lawsuits), and the positive feedback loop of health care utilization is fueled at two ends."

41. Concerns about relying on patient satisfaction are especially acute when using affirmative treatments for Gender Dysphoria. There is sparse data to track in a controlled manner those who have embarked on these treatments and what their outcome has been. Retrospective recall is unreliable (Coleman 2024, Mazzoni 2003) and recall among patients expressing Gender Dysphoria may be particularly distorted by their current emotional state and beliefs (Kulatunga 2024). There is also a survivorship bias in surveys of those who remain transgender-identified, and large numbers of dropouts are frequently seen in studies purported to show long-term benefits (Shelemy 2023). And patients who have embarked on irreversible medical treatment would have the most self-justification, considering they have altered the trajectory of their lives, and for many, there is no return to their previous bodily state. This cohort would have the least propensity to factor in regret and look soberly at the outcome.

42. In sum, under the affirmation model, medical sex trait modification is patient-driven, voluntary, and sought-out treatment, but is supported only by low-quality evidence, is promoted by a field that has created publication bias, lacks a strong research foundation, and has failed to adhere to typical standards for clinical practice (Kozlowska 2025). The unknowns and risks, especially in carceral settings where practically no direct research evidence exists, are accompanied by an unreliable evidence base, ideological influences over care recommendations, and unknown long-term effects.

B. Psychotherapy is the preferred treatment approach for Gender Dysphoria, particularly within correctional environments.

43. While patient-driven medicine characteristic of the affirmation model carries significant risks because humans have immense powers to deceive themselves and because patients may be susceptible to clinicians' suggestions of affirmative treatment, both primary psychotherapeutic schools within mental health, Psychodynamic Therapy and Cognitive Behavioral Therapy, focus largely on identifying self-deception. A major target of treatment is helping patients identify how they deceive themselves.

44. In my opinion, the psychotherapeutic model is the most appropriate treatment model. That approach provides treatment aimed at alleviating distress by applying long-standing and evidence-based tools of psychotherapy. It enables the exploration of causative factors, enhances self-awareness and self-efficacy, and facilitates patients' coping with comorbidities.

45. The approach also provides support to reduce suicidality and self-harm and decrease symptoms of comorbidities, such as depression and anxiety. Psychotherapy practitioners do not directly challenge a claimed transgender identity, nor do they affirm the patient's narrative or theories. Instead, they permit the patient to continue to express a transgender identity (Hakeem 2012, DeAngelo 2021), while engaging in a dialogue with the patient regarding these matters

without providing the answer. Therapists (including psychologists, psychiatrists and a range of other mental health professionals) are all trained to appreciate that an individual is shaped by his or her upbringing, socialization, and life events. Therapists and patients work together to help the patient identify and address why the patient is uncomfortable with his or her sense of self, just as the therapist can help put the patient's other identities (such as racial and ethnic backgrounds, religious or spiritual affiliations, or professions) in perspective.

46. The dialogue in psychotherapy would look for adversity, abuse, and other traumas as potential contributors (Withers 2020). Therapy explores the influence of exposure to images, ideologies, and modeling, including online. This paradigm also considers fantasy, parental attachment, and psychosexual influences. Any of these factors can intermix with temperament, psychiatric symptoms, and neurocognitive disorders such as ADHD and autism, which are more common in those with Gender Dysphoria (Thrower 2020). Practitioners inquire about potential influences and encourage self-exploration, especially considering the increased rate of Gender Dysphoria and neurocognitive disorders.

47. This broad focus allows a full range of established treatments for the comorbidities typically present in correctional populations diagnosed with Gender Dysphoria. This approach avoids what Hillary Cass described as diagnostic over-shadowing (Cass 2024), or what is sometimes called gender exceptionalism, i.e., the focus on the gender-related distress deflects treatment away from other conditions.

48. While few studies have explored standard psychotherapy techniques in the context of Gender Dysphoria, psychotherapy is a longstanding mental health tradition with decades of accumulated wisdom regarding what works, how to approach and align with patients, goal setting, instilling hope, and establishing rapport. These and other common elements in various types of

psychotherapy are acknowledged to be healing, regardless of whether the orientation is psychodynamic, cognitive behavioral, or any other school of therapy (Feinstein 2015, Cuijpers 2019, Laska 2014).

49. Longstanding frameworks such as Psychodynamic Psychotherapy and Cognitive Behavioral Therapy have been used to treat an extremely wide range of mental health problems (David 2018, Hoffman 2012, Sanai 2024) and can be used to treat Gender Dysphoria. Psychodynamic Psychotherapy is a form of talk therapy that focuses on how unconscious processes and past experiences influence a person's current thoughts, feelings, and behaviors. Cognitive Behavioral Therapy is a type of talk therapy that helps individuals become aware of inaccurate or negative thinking patterns, enabling them to view challenging situations more clearly, take action to overcome symptoms, and respond to stressors more effectively.

50. Cognitive Behavioral Therapy, for example, is an effective treatment for Body Dysmorphic Disorder (Harrison 2016), which shares similar features as Gender Dysphoria, including body-related distress, a focus on appearance, increase in younger generations spending more time online (Gupta 2023), and significant comorbidities such as increased rates of self-harm, anxiety, and depression. Cognitive Behavioral Therapy's success in ameliorating Body Dysmorphic Disorder indicates applying similar approaches would be an effective treatment for Gender Dysphoria.

51. Cognitive Behavioral Therapy is also commonly used as a psychotherapy for eating disorders, such as Anorexia (Öst 2024). Eating disorders share features with Gender Dysphoria, as both are influenced by socio-cultural concepts of appearance (Choukas-Bradley 2022). Both disorders also have shown a potential for social contagion, i.e., the phenomenon where mental health symptoms, attitudes, or behaviors spread through a social network or population (Giedinghagen 2023, Alho 2023, Agostino 2021, Hacking 2006). This social contagion can happen

through various mechanisms, including peer influence, social learning, emotional mimicry, and the normalization of certain behaviors. In both Anorexia and Gender Dysphoria, patients seek to transform their bodies to align with the internalized image. Psychotherapy for Anorexia often includes Dialectical Behavior Therapy. Dialectical Behavior Therapy is a modified type of Cognitive Behavioral Therapy that focuses on teaching skills in four key areas: mindfulness, distress tolerance, emotion regulation, and interpersonal effectiveness (Cogodi 2024, Monteloeone 2024). In Anorexia, the distorted body image is never affirmed, and patients are not encouraged to alter their bodies to fit their embodiment goals (Korte 2023).

52. Because cross-sex identification can arise after trauma (Cosentino 1993), and gender dysphoric patients have experienced a higher incidence of trauma than the general population (Brewerton 2022, Gehring 2005), many effective psychotherapy treatments for post-traumatic stress symptoms can also be used to treat Gender Dysphoria. Cognitive Processing Therapy helps people challenge and modify unhelpful beliefs and thoughts that developed after the trauma. Prolonged Exposure Therapy is a specific type of Cognitive Behavioral Therapy that helps people with post-traumatic stress disorder by gradually and repeatedly exposing them to memories, feelings, and situations they have been avoiding since the traumatic event. Eye movement desensitization and reprocessing is a psychotherapy technique that helps people process and heal from trauma by using bilateral stimulation, often in the form of guided eye movements, while the individual recalls distressing memories.

53. These various treatments all use components of Cognitive Behavioral Therapy, which helps patients reconceptualize their experiences and tolerate body sensations associated with the stress response. Trauma-focused treatments, such as Cognitive Behavioral Therapy, can also ameliorate co-occurring depressive, anxiety, and grief symptoms.

54. Dialectical Behavior Therapy has the strongest evidence for reducing self-harm, but cognitive behavioral therapy and other approaches also show promise to reduce self-harm—a potential problem co-occurring with Gender Dysphoria. Dialectical Behavior Therapy has been shown to be the gold standard treatment for Borderline Personality Disorder, the criteria of which include changes in gender identity and along with frequent self-harm, emptiness, and unstable interpersonal relationships. Dialectical Behavior Therapy teaches patients to be present in the moment and aware of their thoughts and feelings without judgment. Patients learn distress tolerance techniques and strategies to manage intense emotions that often lead to self-harm.

55. There are higher rates of personality disorders among the patient cohort with Gender Dysphoria (Rodriguez-Seijas 2024, Kaila-Vanhatalo 2025), and higher levels of personality disorders in correctional populations (Levine 2016, Liu 2021). Psychotherapy is the treatment of choice for personality disorders, and there has been significant progress in developing approaches for this population (Stoffers-Winterling 2022, Emmelkamp 2025).

56. Because of the high levels of comorbidity of psychiatric disorders in patients with Gender Dysphoria, Cognitive Behavioral Therapy could be extremely helpful as the same approach and techniques have proven effective with so many problems including anxiety, depression, and in reducing self-harm. For instance, those with Gender Dysphoria may also suffer from anxiety. Cognitive Behavioral Therapy has been demonstrated to be helpful for the full range of anxiety disorders, and teaches patients to build on small successes, increase distress tolerance, and learn coping skills and self-regulation. Patient in Cognitive Behavioral Therapy face their fears and experiment with new experiences. Targets in Cognitive Behavioral Therapy for anxiety can include: (1) fears of the future; (2) feelings of tension, restlessness, and arousal; (3) social anxiety;

(4) thoughts focused on worry, impending danger, or panic; and (5) concentrating or thinking about anything other than the present worry.

57. Cognitive Behavioral Therapy, Interpersonal Therapy, Psychodynamic Psychotherapy, and mind-body therapies have all shown success in reducing depression, another comorbidity of Gender Dysphoria. These therapies can target (1) negative body sensations, (2) negative self-perception, (3) social struggles and isolation, (4) over-focus of the negative via persistent rigid or unrealistic thinking thoughts, (5) catastrophizing (expecting the worst possible outcome), and (6) overgeneralization (making broad conclusions from a single or few data points). Cognitive Behavioral Therapy has strong evidence for reducing depression, with a recent meta-analysis covering over 400 randomized controlled trials and 50,000 patients (Cuijpers 2023).

58. Psychotherapy can be combined with mind-body therapies that show promise to foster self-regulation and reduce body-related distress (Nejadghaderi, 2024, Brinsley, 2021, Deveci, 2023).

59. A significant benefit of psychotherapy is its ability to help patients without irreversible medical interventions. Patients with Gender Dysphoria may disfavor the cautious approach of psychotherapy in the short term and the effort involved, but the skills built and the perspective gained in psychotherapy can provide long-term benefits to the patients. Some patients will reassume the gender identity of their natal sex.

Regarding WPATH

60. WPATH and other affirmative guidelines regarding the care of people with Gender Dysphoria should neither be treated as authoritative nor be used to determine care for Gender Dysphoria. WPATH openly engages in ideologically-based political advocacy, systematically misrepresents evidence, and often bases its recommendations, no matter how impactful for the patient, on low-quality supporting evidence. WPATH's standards are even more unreliable when it comes to prisoners. "Inmates who seek treatment for Gender Dysphoria typically display little

resemblance to the patients who present for treatment in the community, and prison life bears little resemblance to life in the community. The SOC [WPATH Standards of Care] were not developed with the complexities, vulnerabilities, and life circumstances of incarcerated persons in mind" (Osborne 2016 at 1651).

61. Since its beginnings in 1979, WPATH—then known as the Harry Benjamin International Gender Dysphoria Association—has struggled to reconcile its goals of being both a scientific, clinical organization studying Gender Dysphoria and an advocacy organization. WPATH has made clear its desire to change policy toward gender identity and away from biological sex. For example, it endorses The Yogyakarta Principles, which urge the overhaul of sex- and gender-related legal frameworks to advance the human rights of gender-nonconforming individuals. *See* WPATH Statement on Yogyakarta Principles plus 10 and Healthcare Delivery (July 29, 2019), https://wpath.org/wp-content/uploads/2024/11/WPATH-Statement-on-Yogykarta-Principles-Plus-10.pdf

62. Some recent articles expose what has occurred at WPATH (Kozlowska 2025). This comes after the release of documents in a legal case in Alabama (*Boe v. Marshall*).

- Pamela Paul, New York Times, *Why is the US still pretending we know gender-affirming care works?* (July 12, 2024): "Recently released emails show the WPATH leaders told researchers that their work should 'not negatively affect the provision of transgender health care in the broadest sense.'"

- The Economist, *Research into trans medicine has been manipulated* (June 27, 2024):

    - "Court documents recently released as part of the discovery process in a case involving youth gender medicine in Alabama reveal that wpath's claim was built on shaky foundations. The documents show that the organisation's leaders interfered with the production of systematic reviews that it had commissioned from the Johns Hopkins University Evidence-Based Practice Centre (epc) in 2018."

    - "After wpath leaders saw two manuscripts submitted for review in July 2020, however, the parties' disagreements flared up again. In August the wpath executive committee wrote to Ms. Robinson [Associate Professor at Johns Hopkins] that wpath had 'many

concerns' about these papers, and that it was implementing a new policy in which wpath would have authority to influence the epc team's output—including the power to nip papers in the bud on the basis of their conclusions."

- "Ms. Robinson protested that the new policy did not reflect the contract she had signed and violated basic principles of unfettered scientific inquiry she had emphasised repeatedly in her dealings with wpath. The Hopkins team published only one paper after wpath implemented its new policy: a 2021 meta-analysis on the effects of hormone therapy on transgender people. Among the recently released court documents is a wpath checklist confirming that an individual from wpath was involved 'in the design, drafting of the article and final approval of [that] article'. (The article itself explicitly claims the opposite.) Now, more than six years after signing the agreement, the epc team does not appear to have published anything else, despite having provided wpath with the material for six systematic reviews, according to the documents."

- Benjamin Ryan, NY Sun, '*Damning' Information About Trans Medical Group Expected to Reach Supreme Court, as Justices Consider Challenge to Ban on Gender Treatments for Minors* (July 10, 2024):

  - "The unsealed documents indicate Wpath leadership caved to political pressure from outside groups and quietly crafted its pediatric guidelines with the intent of influencing public policy. Wpath leadership also balked at the potential publication of research findings the organization had commissioned that its leadership believed might negatively impact access to gender-transition treatment."

  - "Erica Anderson, a psychologist, transgender woman, and former head of WPATH's American branch USPATH, characterized the recent disclosures as 'damaging' to the organization. 'The backroom discussions cement the picture of ideological and political capture,' she told the Sun of how she saw her former colleagues as woefully compromised. She said their exposed communications 'hardly' portrayed them as 'scientists using evidence to develop best practices.' Many Wpath leaders, she added, 'clearly have lost their way.'"

  - "According to unsealed internal communications, WPATH also wielded a heavy hand after it in 2018 commissioned from evidence-based medicine experts at Johns Hopkins University a series of systematic literature reviews—the gold standard of scientific evidence—regarding various facets of trans medical care. After some of the Hopkins teams' findings raised concerns among WPATH leadership that they might 'negatively affect the provision of transgender health care,' WPATH compromised the independence of the Hopkins researchers. This included asserting the final say on the publication of any systematic reviews. To date, just two reviews have been published."

  - "The Cantor report [an expert report submitted in the Alabama litigation] further found that WPATH leaders crafted the language of its medical guidelines for the express purpose of influencing insurance coverage, policy, and litigation, which, according to Dr. Cantor, in at least some points, came 'even at the expense of scientific accuracy.'

> He also found that Wpath coordinated on the draft with the ACLU, which is behind many of the suits against state bans of such treatment."

63. These portrayals align with my review of the WPATH documents disclosed in the Alabama case (*Boe v. Marshall*, Kaliebe report; *Boe v. Marshall*, Cantor report). WPATH's internal documents clearly show that WPATH is an advocacy organization and not a scientific one. Scientific organizations do not pressure scholars to distort or suppress evidence that does not fit their narrative or systematically mislead the professional community and public regarding the treatments they support. WPATH has violated many principles underpinning medical ethics and research and contributed to widespread publication bias in gender medicine. Publication bias is the tendency for studies with positive or significant results to be published more frequently and rapidly than those with negative or inconclusive findings, leading to a distorted understanding of the evidence base. As noted in Murad at 85 (2018) publication bias is "one of the worst threats to the validity of scientific research."

64. Additionally, the recently released "WPATH files" are leaked internal discussions between WPATH members published by the think tank Environmental Progress (https://environmentalprogress.org/big-news/wpath-files). The site reports: "the WPATH Files reveal that the organization does not meet the standards of evidence-based medicine, and members frequently discuss improvising treatments as they go along." My review of the lightly redacted text and the video confirms this analysis. These files display that the internal discussions at WPATH do not match the simplistic affirmative guidelines WPATH produces.

65. The WPATH files further showed that there was minimal discussion of the tradeoffs involved in gender care, and prudent clinical caution is frequently derided as "gatekeeping." Activist members speak freely regarding their disdain for "cis normativity" and the

"gender binary" and their belief in patient self-determination regarding surgical body-modification.

66. Members of WPATH, and other advocates, which in total comprise a small number of physicians, have been able to leverage moralized claims and low-quality evidence to promote medical interventions for Gender Dysphoria. There has simultaneously been silencing, stigmatization, and censorship of more balanced and mainstream viewpoints (Bailey 2023, Ciszek 2021, Clark 2023, Clark 2024, Dreggor 2008, Gliske 2021, Soh 2021, Stevens 2020, Stevenson 2023), creating a mirage of general support for positions contrary to good medicine.

67. Public policy, including prison policy, based on the theories promoted by WPATH is unlikely to be good policy, as it arises from ideology more than evidence.

68. Dahlen reviewed WPATH's prior guidelines, SOC-7, as part of a systematic review and quality assessment of international clinical practice guidelines for gender minority/trans-identifying people. They noted that WPATH SOC-7 contained no auditable quality standards and scored poorly on editorial independence, applicability, and rigor of development. The reviewers noted that WPATH prioritized stakeholder involvement rather than methodological rigor. Among the principal findings was that WPATH SOC-7 "cannot be considered [the] 'gold standard'" (Dahlen 2021).

69. Yet despite the well-known methodological weakness of SOC-7, WPATH created SOC-8 with many of the same problems, only selectively using the conventions that are necessary to create a trustworthy clinical practice guideline. "It appears WPATH expects readers to faithfully accept potentially biased judgments of the literature rather than confidently submitting SoCv8 to open scientific scrutiny. SoCv8 could have been much better: its evidence base and recommendations cannot yet be relied upon" (Dahlen 2022).

70. WPATH's approach is contrary to the recommendation of the Institute of Medicine—the health arm of the National Academy of Sciences—that clinical practice guidelines should be informed by systematic reviews of evidence, which can help minimize potential harm created through guidelines supported mainly by the consensus of expert impression (Institute of Medicine 2011).

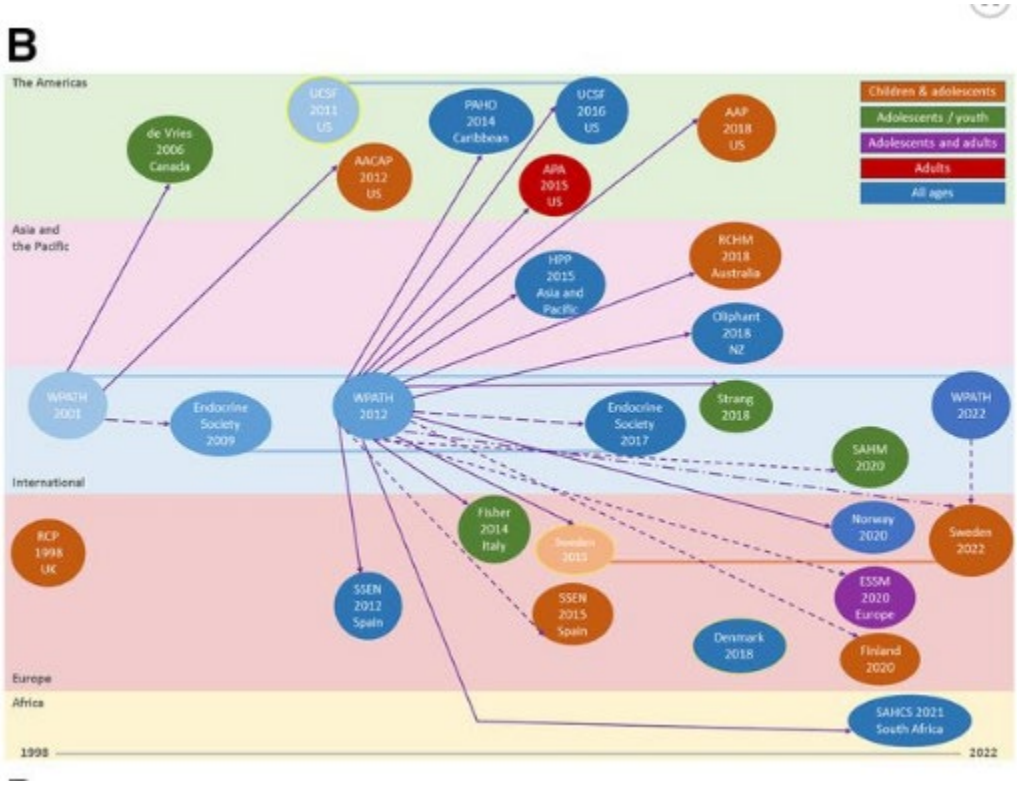
71. With recently unsealed court documents, we now know that WPATH SOC-8 did submit for likely more than a dozen systematic reviews of evidence but interfered with the researchers conducting the reviews, disallowed publication of most reviews, and undermined the publication of the available data (Kozlowska 2025, Economist 2024, Selin-Davis 2024, Ryan 2024). WPATH did what should be unthinkable; it has hidden, to this day, what systematic reviews were attempted, then stopped or buried them due to unfavorable results. (Kozlowska 2025, Economist 2024, *Boe v. Marshall* Cantor Report).

72. WPATH SOC-8 intentionally obscured the most important element required for a trustworthy clinical practice guideline: the assessment of the strength of the evidence used to make recommendations. Hiding the strength of evidence hides critical data from readers trying to evaluate the evidence base for an organization's recommendations (Murad 2017). This is especially concerning due to the lifelong implication and irreversible nature of the treatments WPATH advocates.

73. The British National Health Service's Cass Review of youth gender medicine, published in 2024, echoed these concerns. Dr. Hillary Cass conducted a systematic review of available clinical guidelines for children and adolescents experiencing Gender Dysphoria or incongruence. She reviewed 23 guidelines published from 1998 to 2022. "The findings from this review . . . raise questions about the credibility of currently available guidance, despite the majority being

published in the last 5 years. Most guidelines have not followed international standards for guideline development set out by the [Appraisal of Guidelines for Research and Evaluation II] initiative and/or provide insufficient information about their development. Because of this, the review team only recommended two guidelines for practice—the Finnish guideline published in 2020 and the Swedish guideline published in 2022" (Taylor 2024).

74. The Cass systematic review noted how the other guidelines cross-reference other guidelines to justify their recommendations, rather than citing actual evidence (see figure label B – below). Furthermore, the WPATH and Endocrine Society collaborated, meaning a very small, interconnected group of WPATH members led to the creation of multiple guidelines among multiple medical organizations. "The WPATH and Endocrine Society international guidelines, which like other guidance lack developmental rigour and transparency have, until recently, dominated the development of other guidelines. Healthcare professionals should consider the lack of quality and independence of available guidance when utilising this for practice" (Taylor 2024).



75. The above graphic from the Cass systematic review (Taylor 2024) shows that WPATH's unreliable and low-quality recommendations have infected other guidelines, causing a systematic distortion of clinical guidance.

76. While a complete review of WPATH's SOC-8 is beyond the scope of this report, I note a few concerns below:

77. First, SOC-8 does not analyze why it prioritizes affirmation of gender identity over affirmation and acceptance of the physical, sexed body. For all other mental health disorders, clinicians aim to help patients accept and feel comfortable in their body. Nowhere else do mental health professionals recommend changing the body to fit the mind's impression. SOC-8 treats the question as though it had a clear answer supported by the evidence: affirm self-reported gender identity. That unproven theory runs through the SOC-8 guidelines and underpins much of the assessment and treatment recommendations in the SOC-8, therefore making it untrustworthy.

78. Second, WPATH associates comorbidities, such as suicidality and depression, as being caused by society rather than individual psychopathology. This is often called the "minority stress" theory, the supporters of which advocate that it is the role of medical and mental health care to relieve that stress by affirming the patient's preferred gender. This unfortunate therapeutic stance is in tension with evidence that the victim mindset undermines the patients' mental health and impedes their healing (Kaufman 2025). Narratives that encourage those with Gender Dysphoria to develop a victim mindset may be especially detrimental in prison populations.

79. Third, SOC guidelines consistently recommend changes to institutions, such as prisons, without a review of the tradeoffs and harm involved. The SOC-8 suggestions regarding institutional care neglect the honest appraisals, stakeholder input, and nuance required to create a trustworthy recommendation regarding gender transition in carceral settings. WPATH overstates the benefit of an affirming and medicalized approach and does not adequately review the risks, particularly those associated with carceral settings.

80. Fourth, SOC-8 normalizes self-mutilation by devoting a chapter to "Eunuchs" (a castrated man) and treating it as just another non-binary category. It did so without the necessary warning that mental health assessments are needed before any consideration of chemical or surgical procedures and without acknowledging the damage associated with such self-harm.

81. Fifth, SOC-8 downplays concerns related to detransitioning, repeatedly using the term "rare" without definition or the methodology they used to determine that term is appropriate. Evidence suggests the more recently transitioned cohort with less-restrictive access to hormones and surgeries has a much higher rate of detransition, although the precise detransition rate is unknown (Cohn 2023, Jorgensen 2023).

82. As reflected in the WPATH SOC 8, within gender medicine, there has been a failure of "maintaining terminological and conceptual clarity" (Kozlowska 2025). This accompanies a failure to engage in appropriate scholarly discourse, a failure to publish research results in a timely manner, and a failure to frame outcomes and strength of evidence with accuracy. Reliance on WPATH has caused professional societies and government health authorities to break the "chain of trust" afforded to those who relied on WPATH (Kozlowska 2025).

CROSS-SEX HORMONES GENERALLY ARE NOT MEDICALLY NECESSARY

Weaknesses of Past Studies and Recommendations Related to Cross-Sex Hormones

83. Although used in affirming clinical practice, hormone therapy for Gender Dysphoria is not based on guidelines using best practice or systematic reviews of evidence. There are no controlled studies or high-quality evidence in the carceral setting that would lead to the recommendation of sex-trait modification, such as through cross-sex hormones, of inmates with Gender Dysphoria.

84. In 2012, the American Psychiatric Association (APA), along with members of WPATH within APA, decided to support affirmative treatments. At the time, the APA task force admitted, "The quality of evidence pertaining to most aspects of [hormone] treatment was determined to be low" (Byne 2012 at 759). Nonetheless, the APA used clinical consensus to support new recommendations for affirming treatment "[w]ith subjective improvement as the primary outcome measure" (Byne 2012 at 759). As such, the APA's recommendation is not based on established standards for creating quality treatment guidelines, but rather on clinical consensus that is based primarily on subjective self-report.

85. Similarly, WPATH's SOC-7 and SOC-8 guidelines regarding hormone therapy did not follow best practice and lack developmental rigor (Dalen 2021).

86. Recent large reviews and research into harms from hormone treatment for Gender Dysphoria raise increased concerns regarding the safety, efficacy, and prudence of this practice. A recent Danish review, for example, indicated that using cross-sex hormones to treat Gender Dysphoria yields mixed results, and a worsening of psychiatric diagnosis one year after initiation of hormones. Although the patient stabilizes thereafter, the patient at all times has increased mental health problems when compared to the general population, especially for males prescribed feminizing hormones (Glintborg 2025 at 336).

87. In 2020, the United States Department of Health and Human Services ("HHS") declined to "take a definitive view on any of the medical questions raised" "about treatments for Gender Dysphoria" because there was a "lack of high-quality scientific evidence supporting" the interventions. HHS characterized WPATH as "an advocacy group" and did not consider WPATH's guidelines as being based on "independent scientific fact-finding." Nondiscrimination in Health & Health Education Programs or Activities, 85 Fed. Reg. 37,160, 37, 186-98 (June 19, 2020).

88. A recent a systematic review and meta-analysis regarding patients up to age 26 noted the uncertain effects of cross-sex hormones across multiple domains. Specifically, the effects cross-sex hormones on Gender Dysphoria itself are noted to be "very uncertain," as are the effects on global functioning and depression. The authors conclude: "The best available evidence reporting on the effects of GAHT [cross-sex hormones] in individuals with [Gender Dysphoria] ranged from moderate to high certainty for cardiovascular events and low to very low certainty for the outcomes of [Gender Dysphoria], global function, depression, sexual dysfunction, BMD [bone mineral density] and death by suicide" (Miroshnychenko 2025 at 444).

89. Shelemy's review (2023) found 14 studies that met their inclusion criteria, showing a trend toward reduced depression and anxiety during hormone treatment. Yet this review specifically

excluded non-affirmative approaches and as such, sheds no light on whether the outcome would be the same, better, or worse with psychotherapy treatment alone. Furthermore, several of the 14 studies did not report dropout rates, while 31% reported *high* dropout (over 40%), and 28% of studies were assessed to have a *high* level of selection bias (less than 60% of the participants registered or approached completed the pretest measure). Moreover, the authors noted, "There is potential for authorship bias throughout much of the research literature as several studies were authored by clinical staff in which interventions are routinely offered." This noted bias highlights a major problem in the research on cross-sex hormones, which is that those involved in gender medicine research are already favorably inclined toward using affirmative treatment (Scott 2013, West 2012). Best practice to create reliable research regarding medical transitions would be to have neutral scholars design and conduct the research, thus correcting the authorship bias noted by Shelemy.

90. In any event, the noted reduction in anxiety or improvements in mood may be placebo effects (Clayton 2022). Placebo effects are positive changes based on expectations. Missing from the discussion of reviews like Shelemy is a discussion of what percentage of the improvement is placebo effects, which are broadly considered across other disorders. (Bschor 2024, Wager & Atlas 2015). Placebo effects are highest for internalizing disorders like depression and anxiety, which share similar symptoms as Gender Dysphoria. Furthermore, as placebo effects are bolstered by expectations, these placebo effects may be enhanced by clinicians' positive statements regarding the effectiveness of medical transition, just as patients with stronger belief in antidepressant medications' effectiveness receive a stronger placebo effect in anti-depressant studies.

91. Placebo effects also could arise from psychosocial support, which would be expected within affirming-gender clinics, and from allies in the community (Clayton 2023). That is, the

improvement noted in mood or anxiety could arise—not from the hormone treatment itself—but from the psychosocial support the patient receives in connection with the hormone treatment. This in turn would suggest that hormonal treatment within correctional settings cannot be expected to produce the same placebo effects because any psychosocial support will be significantly limited due to inherent restrictions in activities, movement, and self-association.

92. Until recently, medical transition for adults with Gender Dysphoria has been rare, and tracking long-term outcomes has been sparse; therefore, nominal long-term data exists. What long-term data does exist is mixed, with some of the most powerful data being unfavorable (Anckarsäter & Gillberg 2020, Dhejne 2011). Based on long-term data in Sweden, cross-sex interventions have not been shown to reduce self-harm; nor do they clearly reduce mental health problems (Bränström 2020).

93. The initiation of sex-trait modification through cross-sex hormones remains an experimental treatment that has been pursued at the expense of more cautious, holistic, and measured approaches. The rapid spread of these untested treatments has been called "runaway diffusion": sex-trait modification and affirmation entered clinical practice worldwide without rigorous research confirming the underlying hypothetical benefits (Abbruzzese 2023).

94. WPATH's commissioned systematic review reveals a high risk of bias in the available studies, and it appears to have been manipulated to frame the unimpressive results as supporting affirmative treatments. Even so, WPATH's own systematic review indicates hormone therapy has not been shown to reduce suicide risks (Baker 2021). This conclusion that there is a lack of evidence regarding any reduction in the risk of suicide is particularly pronounced in carceral settings, where no substantial research exists and no claim can be made whether hormone treatments increase, decrease, or do not change suicide risk.

95. Overstating the benefits of hormone therapy is particularly problematic in prison settings, with both vulnerable and potentially belligerent populations that have higher degrees of psychopathologies, such as trauma disorders, neurocognitive disorders, and personality disorders. The forced intimacy of a prison setting creates many risks and challenges not seen in the general community, and as such, the provision of hormone treatment has more profound effects on the prison community milieu.

Substantial Health Risks of Cross-Sex Hormone Therapy

96. Sex-trait modification through hormone therapy has substantial health risks and is one of the few instances, and the only psychiatric disorder, in which doctors intentionally harm healthy tissue. For years, there has been little data collection and scholarly discussion regarding the harms of cross-sex hormone therapy, yet this is changing.

97. A recent review analyzed 290 adverse drug reactions in the U.S. Food and Drug Administration Adverse Event Reporting System (FAERS) (Gomez-Lumbreras & Villa-Zapata 2024 at 1089). "For individuals assigned female at birth undergoing gender transition to male (transgender men), 82 reports (230 [Adverse Drug Reactions]) were analyzed, with an average age of 29.5 years. Transgender hormonal therapy was cited in 72% of reports, predominantly from the United States (67.1%). A striking 88% were categorized as serious [Adverse Drug Reactions], primarily SOC [System Organ Class] injury, poisoning, and procedural complications (26.5%), followed by psychiatric disorders (14.8%) and nervous system disorders (12.2%). Among those assigned sex male at birth transitioning to female (transgender women) (81 reports, 237 [Adverse Drug Reactions]), mean age was 33.3 years, with 58% indicating use for Gender Dysphoria. A significant proportion (53.6%) were serious [Adverse Drug Reactions], primarily SOC: injury, poisoning, and procedural complications (26.6%)." This included 2 deaths, 25 hospitalizations, and 4 categorized as life threatening. A significant number of these adverse reactions were

Psychiatric Disorders (14.8% in natal females and 8.9% in natal males), and most commonly included depression and anxiety, but also included a wide range of psychiatric complications including aggression, suicidal behavior, suicidal ideation, and suicide attempts. This raises the possibility that cross-sex hormones are associated with increased self-harm, a concern reflected by the two completed suicides in a small but well-controlled study of cross-sex hormones in young people (Chen 2023, Biggs 2023).

98. This FAERS data included adverse effects classified as Neoplasms benign, malignant and unspecified (10.9% in natal females and 9.7% in natal males), and adverse effects classified as Nervous System Disorders (12.2% in natal females and 7.2% in natal males) along with a range of cardiovascular complications such as pulmonary embolisms, cerebrovascular accidents, transient ischemic attacks, laboratory abnormalities of glucose, and atherosclerotic plaque ruptures, among others. For all these adverse reactions, the relative youthfulness of the cohort, mean age 29.5 for the natal males and 33.3 for the natal females, is especially concerning as young people will tend to be in better health, and their younger age limits the amount of time they could have been prescribed cross-sex hormones.

99. Beyond these concerns are the longstanding and well-known psychological and psychiatric complications from supraphysiologic amounts of sex hormones. Data about androgens from tumors that produce abnormally high amounts of androgens and from anabolic steroid use has shown psychiatric effects including mania, irritability, aggressiveness, and reckless behavior, which are more common and more severe with higher doses (Hall 2005, Laidlaw & Jorgensen 2024).

100. Regarding the cardiovascular risk from hormone therapy, much remains unknown and to be studied due to limited follow-up data and the complexities of the cardiovascular system and its interactions with cross-sex hormones (Getahun 2018, Aranda 2021, Nota, 2020, Dutra 2019).

101. Estrogen therapy (natal males): Estrogen, often combined with anti-androgens, increases the risk of venous thromboembolism, including deep vein thrombosis and pulmonary embolism. Studies indicate a 2- to 5-fold increased venous thromboembolism risk, particularly with oral estrogens like ethinyl estradiol, due to hepatic metabolism and prothrombotic effects. Transdermal estrogen may pose a lower risk. Estrogen can also elevate triglycerides and reduce HDL [High-Density Lipoprotein] cholesterol, potentially increasing the risk of atherosclerosis and coronary artery disease. Hypertension is another concern, as estrogen can cause fluid retention and blood pressure elevation. Limited data suggests a slight increase in stroke risk, though evidence is less conclusive.

102. Testosterone therapy (natal females): Testosterone use is associated with increased red blood cell mass (erythrocytosis), which can elevate blood viscosity and the risk of thromboembolism. Studies show mixed results, but some report a 1.5- to 2-fold increase in cardiovascular events like myocardial infarction, particularly in older individuals or those with pre-existing conditions. Testosterone can lower HDL cholesterol and raise LDL cholesterol, potentially contributing to atherosclerosis. Hypertension is also a concern, as testosterone may increase blood pressure.

103. There is also concerning data for females using masculinizing hormones, especially across the lifespan (Gosiker 2024). A meta-analysis of 35 studies reported that masculinizing hormone therapy "was associated with significant changes in serum lipids from baseline up through the 60-month timepoint with meta-difference of means (95% CI) estimates of 26.2mg/dL (23.3,29.0) for

LDL-C, 26.1mg/dL (22.8,29.4) for total cholesterol, 30.7mg/dL (6.9,54.6) for triglycerides and –9.4mg/dL (–12.1, –6.7) for HDL-C." They noted studies evaluating the effects of feminizing hormones on balance demonstrated no notable changes in HDL-C or triglycerides while the results for LDL-C and total cholesterol were inconsistent." This data was reassuring regarding natal males on feminizing hormones, but not for females using masculinizing hormones. This was largely consistent with Leemaqz's longitudinal study (2023).

104. Also consistent is Allgayer's systematic review of the effects of cross-sex hormones on subclinical atherosclerosis, which concluded that androgens are associated with an increased risk of subclinical atherosclerosis in natal females. In contrast, natal males may experience either neutral or beneficial effects regarding atherosclerosis from estrogenic agents, even though many unknowns remain.

105. For natal females taking androgens, there is also a substantial risk of Pelvic Floor Dysfunction (PFD) (Da Silva 2024). PFD encompasses a range of symptoms including urinary incontinence, bowel dysfunction, sexual dysfunction, and pelvic pain, all of which can significantly impact quality of life. In natal females undergoing cross-sex hormone therapy with testosterone, research indicates a notably high incidence of PFD. A cross-sectional study conducted between September 2022 and March 2023 involving 68 females administered cross-sex testosterone therapy found that 94.1% experienced at least one PFD symptom.

106. Specifically, the study reported: 86.7% of participants had urinary issues, with 69.1% experiencing storage symptoms such as urinary incontinence, frequent urination, or bed-wetting. Among those with urinary incontinence, symptoms were reported as moderate in severity, impacting quality of life. Urinary control complications have more profound impacts within the forced intimacy and restricted movements of correctional environments. Among all participants,

74% reported bowel-related issues, including constipation, anorectal symptoms (45.6%), and flatal incontinence (39.7%). As for sexual dysfunction, defined by criteria such as reduced sexual interest, arousal difficulties, or orgasmic disorders, with some reporting pain during sexual intercourse, it was experienced by 52.9% of the participants.

107. The high incidence of PFD in this population is hypothesized to result from testosterone-induced changes, such as vaginal mucosa atrophy, which mimics a hypoestrogenic state similar to postpartum or postmenopausal conditions, potentially weakening pelvic floor muscles. The implications of PFD in females taking androgens are multifaceted, affecting physical, psychological, and social domains, including: anxiety, embarrassment, or reduced self-esteem, especially in younger individuals (average age 28 in the referenced study), who may face symptoms typically associated with older populations. However, the extent to which testosterone affects pelvic floor muscles remain understudied, and long-term effects on pelvic organs are not fully understood.

108. Marks (2018) found that 45% of females on masculinizing hormone therapy experienced hair loss. Testosterone is associated with hair loss (alopecia), and a percentage of natal females taking androgens will experience significant hair loss, which is often associated with significant distress and may prompt the desire for further medical procedures and medications. This hair loss can be especially distressing in younger populations (Gao 2023).

109. While incarcerated individuals rarely have access to procreative sex, most are not housed throughout their reproductive spans. As such, risks related to infertility from hormone therapy may be overlooked while incarcerated. After discharge, those who wish to procreate may have difficulty if they have been prescribed cross-sex hormones (De Roo 2025). For males taking estrogens, some patients only retain limited sperm production, while many no longer have sperm production and

exhibit testicular atrophy, hyalinization, and fibrosis. These histological changes may lead to an elevated risk of cancer. Taking estrogen alongside testosterone blockers was linked to sperm abnormalities and azoospermia (complete loss of sperm). These effects may or may not be reversible, and tissue studies following surgical removal of the testis show widespread damage (Schwartz 2025).

110. Schwartz highlights potential cognitive risks, including memory loss and early-onset cognitive impairment. Longer-term research on older natal females taking hormones has found poorer performance on tasks involving memory and processing speed. Again, it will likely be decades before firmer data emerges regarding these risks.

111. Medical harms occur from cross-sex hormone therapy. At the same time, there is little reliable data supporting that hormone therapy produces meaningful long-term mental health benefits. Accordingly, hormone therapy should not be available to those in BOP's custody, unless an exception is determined to be appropriate especially in the short term as discussed below.

A Reasonable Approach for Those Already Receiving Hormones Is to Assess Them Individually on Whether and How to Discontinue Therapy

112. While it is appropriate to not initiate hormone therapy on inmates who are not currently subject to hormonal therapy, there are complex questions about whether to continue these treatments for inmates already receiving hormones.

113. Some inmates arrive at BOP with prescribed hormone treatment from the community, and others start on these treatments while in custody. These cases can be individually assessed, with allowance for exceptions under certain circumstances.

114. This clinical approach reflects the reality that once a treatment has been provided, its removal can, but does not necessarily, cause physiological and psychological stress. And the benefits of ending treatment—through an appropriate way—could outweigh the short-term

physiological and psychological stress from ending the treatment. The amount of this stress can be estimated clinically and individually, taking into account factors such as the duration of treatment, the initial rationale for treatment, and the treatment response. Accordingly, under this approach, it is reasonable for dysphoric patients to be divided into different patient populations with different clinical approaches. A rapid discontinuation is appropriate for those who recently started treatment, but a slow withdrawal could be appropriate for others, and still others may be allowed to continue treatment indefinitely.

115. Standard psychiatric medications have withdrawal effects, and their abrupt cessation causes both physiological and psychological effects. The cessation of cross-sex hormones will have a similar impact. Just as the length of treatment predicts difficulties stopping a Selective Serotonin Reuptake Inhibitors, it can be expected that the duration of cross-sex hormones would be a pertinent clinical factor in assessing whether and how to cease hormone therapy (Kalfas 2025, Gøtzsche 2024).

116. Moreover, it is likely rare that an inmate should continue hormone therapy indefinitely. It could be reasonable for prison officials to adopt a strong presumption in favor of ending hormone therapy for all inmates (through the appropriate method of withdrawal), given the unproven medical benefits of continued hormone therapy and the potential negative effects of hormone therapy. This strong presumption would only be rebutted by exceptional cases.

117. Based on the above, there are multiple reasonable approaches to determining whether and how to discontinue hormone therapy for inmates diagnosed with Gender Dysphoria.

CROSS-SEX SURGERIES ARE NOT MEDICALLY NECESSARY

118. Cross-sex surgeries have not been shown to be medically necessary. There is widespread uncertainty with regards to whether cross-sex surgeries provide mental health benefits or, on the

whole, worsen mental health. These surgeries have substantial risks, and there is little, if any, reliable data supporting that such surgeries cause meaningful long-term benefits in improving mental health or reducing suicide risks. This is particularly true in prison settings. Indeed, there are no controlled studies, high-quality evidence, or reliable evidence on sex-trait modification, such as through cross-sex surgery, of inmates with Gender Dysphoria in the carceral setting.

119. Much of the research regarding cross-sex surgery shares weaknesses with hormone therapy data, in that short-term individual studies are insufficient to support the hypothesis of benefit, and longer-term population studies show mixed results and raise concerns about long-term outcomes.

120. A recent a systematic review and meta-analysis regarding Mastectomy for individuals younger than 26 years with Gender Dysphoria (Miroshnychenko 2025) "found limited evidence about aesthetic satisfaction and surgical complications (i.e., nipple necrosis, hematoma, and hypertrophic scarring)" and noted that "evidence regarding psychological outcomes is missing." This review highlights the sparse and "very low-certainty evidence on mastectomy effects."

121. A recent national database study (Lewis 2025), involving 107,583 patients and using matched cohorts, examined mental health risks after cross-sex surgery and found that those undergoing surgery were at significantly higher risk for depression, anxiety, suicidal ideation, and substance use disorders than those patients with Gender Dysphoria who did not have without surgery. Males with surgery showed a higher prevalence of depression (25.4% vs. 11.5%, RR 2.203, $P < 0.0001$) and anxiety (12.8% vs. 2.6%, RR 4.882, $P < 0.0001$). Females exhibited similar trends, with elevated depression (22.9% vs. 14.6%, RR 1.563, $P < 0.0001$) and anxiety (10.5% vs. 7.1%, RR 1.478, $P < 0.0001$). Feminizing individuals demonstrated particularly high risk for depression (RR 1.783, $P = 0.0298$) and substance use disorders (RR 1.284, $P < 0.0001$).

122. Another large retrospective patient data analysis with over 90 million patients compared cross-sex surgeries and concluded, "Patients who have undergone gender-affirming surgery are associated with a significantly elevated risk of suicide," and "patients who have undergone gender affirmation surgery are associated with significantly higher risks of suicide, self-harm, and PTSD compared to general population control groups in this real-world database" (Straub 2024).

123. A 2020 review of Swedish data showed that there was no significant benefit following cross-sex surgery, and in fact raised concerns of increased suicidality in the year after surgery (Bränström & Pachankis 2020). This study published in the American Journal of Psychiatry initially suggested that surgery was associated with improved mental health outcomes. But a later re-analysis and correction of the data indicated that there was "no advantage of surgery" compared to a control group of transgender people who had not had surgery. There were at least 9 MDs or PhDs who responded to the significant flaws when this article was initially published and erroneously claimed that the data supported cross-sex surgery. The references to these letters can be found listed under the original article in PubMed or in the August 2020 American Journal of Psychiatry.

124. As noted by Wold, "among the individuals examined in the study, the risk of being hospitalized for a suicide attempt was 2.4 times higher if they had undergone gender-corrective surgery than if they had not" (Wold 2020). Ring and Malone noted that the data suggested "that sex reassignment surgery is in fact associated with increased mental health treatment" (Ring & Malone 2020).

125. The Bränström and Pachankis study confirms the strong association between psychiatric morbidity and Gender Dysphoria. It does not demonstrate that either hormonal treatment or surgery has any effect on this morbidity. One caution that can be taken is that the incidence of mental health

problems and suicide attempts are especially high in the year after the completion of gender-affirming surgery.

126. The Dhejne review of long-term follow-up of medical transition surgeries in Sweden (Dhejne 2011) "found substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts, and psychiatric hospitalisations in sex-reassigned transsexual individuals compared to a healthy control population."

127. These concerns are especially elevated in a carceral setting. As noted by Levine, "The request for SRS [sex reassignment surgery] is fraught with legal, safety, clinical, political, and policy concerns." "Most inmates requesting SRS through litigation are serving very long or life sentences. Their backgrounds are quite unlike most transgendered individuals encountered in the community" (Levine 2016 at 236)

128. For example, as Elizabete Stahl, the BOP Medical Director recently stated, "Inmates have higher rates of certain chronic conditions and infectious diseases compared to people living within the community. They have higher rates of hypertension, asthma, arthritis, and tuberculosis. They also suffer from higher rates of mental illness" (Stahl Decl.).

129. Cross-sex surgeries can have serious complications, some of which are lifelong. Complications are especially prevalent in populations with poor general health status. Vaginoplasties require dilation protocols which, even when strictly followed, may not prevent stenosis, and may require follow-up surgeries, or lead to long-term wound care due to fistulas or infection. Vaginoplasties can also result in chronic pain and altered or absent sensations due to nerve damage or scarring. Phalloplasty can result in chronic pain, loss of sensation, scarring, infections, and urethral complications, such as strictures and fistulas. Similarly, metoidioplasty can also have urethral complications, limited size or function, chronic pain, and sensory changes.

Cross-sex mastectomies use techniques to create a chest that is made to appear more like the other sex, and the lateral chest contour involves increased risk of iatrogenic injury (Ferrin 2025).

130. With newer data, the utility of cross-sex surgeries and long-term outcomes has become more doubtful, which in any event is based on low-quality evidence base. As such, with the known harms to healthy tissue, potential increased risk of psychiatric decompensation, technical issues such as wound care, potential surgical complications, potential life-long health complications, and unclear mental health benefits, cross-sex surgeries within the correctional environment are not medical necessary.

SOCIAL ACCOMMODATIONS ARE NOT MEDICALLY NECESSARY

131. Social transition is understood as the process by which a person begins to live and present in a way that aligns with their internal gender identity, rather than their sex. This typically involves various non-medical actions, such as:

- Changing one's name and/or pronouns: Using a name and pronouns (e.g., she/her, he/him, they/them) that reflect their gender identity.
- Altering appearance and expression: This can include changing clothing, hairstyles, or other elements of their outward presentation to align with their gender identity.
- Coming out to others: Sharing their transgender or nonbinary identity with family, friends, and their community.
- Engaging in gendered activities: Participating in social activities or using facilities (like restrooms) that correspond to their affirmed gender.

132. Social transition is theorized to be helpful as it appears empathetic to gender distressed individuals by allowing them to live in the role of the other sex. But social transition is not medically necessary, particularly in correctional facilities**.** As can be seen from the list of activities related to social transition, none are related to healing medical illness or disease. Moreover, there

are no reliable study or high-quality evidence showing any benefits of social accommodations for individuals with Gender Dysphoria who are currently incarcerated.

133. The only systematic review of evidence regarding social transition is in children and adolescents, revealing minimal evidence to guide practice (Hall 2024). The evidence is overall low quality, and "[t]his review has shown that we have little evidence of the benefits or harms of social transition for children and adolescents." Concerningly, in children and adolescents, social transition appears to prolong transgender identification and continue Gender Dysphoria (Steensma 2013, Olson 2022, Rae 2019, Zucker 2020). Social transition is thus not associated with better outcomes but is related to future harms and risks due to the increased likelihood of later sex-trait modification. As noted by Zucker regarding social transition in children: "if one conceptualizes gender social transition as a type of psychosocial treatment, it should come as no surprise that the rate of Gender Dysphoria persistence will be much higher as these children are followed into their adolescence and young adulthood. If this is, in fact, the case, one might ask why would one recommend a first-line treatment that is, in effect, iatrogenic [illness cause by treatment]" (Zucker 2020 at 37).

134. Based on this data, we should consider the risk that social transition may increase the desire for cosmetic medical interventions to appear as the other sex, and these treatments harm healthy tissue and pose significant risks, without clear benefit.

135. Social transition may also undermine an individual's desire to participate in psychotherapy to explore why they have their body-related distress, thereby undermining the process of exploration and self-reflection that can lead to relief of the gender-related distress. Inmates with Gender Dysphoria tend to have significant trauma-related experiences and may have been treated poorly by family, peers, primary caretakers, and others, due to their gender non-conformity.

Sometimes incarcerated males identifying as transgender females have assaulted women and may be searching for an escape from their masculinity. All of these are important topics that require exploration in psychotherapy. It has been my experience that inmates (adults and juveniles) of both sexes with Gender Dysphoria often do not want psychotherapy because they are convinced that affirmation and medical interventions are the best and only treatment for their Gender Dysphoria. This misinformation has created an unfortunate "nocebo effect" in gender medicine, undermining psychotherapy (Clayton 2022). The nocebo effect is a phenomenon where negative expectations about a treatment or experience led to worse outcomes. The nocebo effect does occur in psychotherapy (Locher 2019). The nocebo effect in patients with Gender Dysphoria is created through promotion of affirmative treatments and derogatory proclamations, such as the claim that psychotherapy is "conversion therapy", creating the conditions that many patients with gender dysphoria have expectations that the psychotherapy is useless, inappropriate, or harmful.

136. There is limited evidence suggesting that allowing cosmetic and clothing items, such binders, undergarments, makeup, wigs, and other accessories and items stereotypically associated with the opposite sex, would improve or resolve symptoms associated with Gender Dysphoria. And there is no evidence-based study or reliable evidence showing that access to such items improves or resolves symptoms in inmates with Gender Dysphoria, regardless of whether the inmate is in a facility that aligns with the inmate's biological sex or gender identity. The fact that some social-transitioning items are psychologically pleasing to inmates with Gender Dysphoria does not mean that such interventions are medically necessary. Such social-transitioning items are not medically necessary, as they can prolong the symptoms and undermine psychotherapy, and there is no clear evidence of medical benefit.

137. In the correctional context, making social transition items available can work against the patients' overall mental health because having such items likely will prolong the symptoms of Gender Dysphoria for the already vulnerable inmate-patient population with significant co-morbidities, and because they may enhance the patients' reluctance to receive psychotherapy, when such treatment could have long-lasting benefits.

138. "Concept creep" is the principle that psychological and psychosocial concept start with a valid narrow idea that can arise out of a desire to help but, applied in new contexts and with less extreme forms, it can enfeeble those it is intended to assist (Haslam 2016). Those who advocate for social transition functionally lowers the bar for what is expected of individuals with gender dysphoria, such that we are led to believe they cannot handle routine experiences such as wearing clothing consistent with their sex, accepting their appearance, and being addressed by their biological sex. Medical necessity now is claimed by advocates of gender affirmation to include assisting with a preoccupation with appearance and avoidance of accurate but distress-provoking words. The psychological over-protection of social transition sends an institutional-wide message that inmates with gender dysphoria are unable to cope with knowing their own sex or appearing as they appear. There is no clear evidence that social transition does, in fact, lead to functional or mental health improvement in inmates. It may more often contribute to distress by prioritizing accommodating the distress rather than engaging the process of overcoming the distress.

139. The same is true with male inmates' requests to be housed in female facilities as part of the male inmates' social transition. To the extent that transfer to a prison facility matching the inmate's gender identity rather than the inmate's biological sex is asserted to be a treatment for Gender Dysphoria, transfer is not medically necessary. There is no reliable study or high-quality evidence suggesting that an inmate being housed in a facility in line with the inmate's gender identity rather

than the inmate's biological sex has any meaningful benefits (let alone long-term benefits) to the inmate's Gender Dysphoria symptoms. Even if there were evidence suggesting social transitioning in society at large treats Gender Dysphoria, the secure prison environment is fundamentally different. There may also be other concerns, such as security and prison administration concerns, with such transfers that could outweigh the speculative medical or mental health benefits of transfer for inmates with Gender Dysphoria. For example, highly relevant is the fact that the presence of a biological male in close quarters in a female prison could significantly harm the emotional and physical well-being of certain female prisoners, such as female victims of sexual abuse. This concern is particularly acute since female prisoners suffer from extremely high rates of sexual trauma. Placing these vulnerable female inmates with biological males could have meaningful negative effects on female inmates.

140. Unlike many other mental health treatments, where the focus is on the patients themselves, requiring prison officials to allow social transition as "treatment" for Gender Dysphoria is asking the administration, staff, and other inmates to validate the inmate's gender preference without any proven benefits. Again, while social transition might decrease inmate-patients' discomfort in the short term, it ultimately may cause long-term harm, such as continuation of Gender Dysphoria. Having correctional policies along the lines of biological sex can help set inmate-patients' expectations such that they may be amenable to proven mental health treatments discussed above. That is, maintaining neutral stances, rather than stances that validate the inmate-patient's preferred gender, can reasonably be expected to benefit the inmate-patient in the long term, as prison officials seek to balance competing interests in safeguarding the inmate's welfare.

PRISON RELATED SPECIAL TOPICS

141. Incarcerated people tend to have histories, characteristics, and vulnerabilities that differ substantially from community-dwelling people with Gender Dysphoria. Thus, different considerations apply when assessing the appropriate medical treatment for inmates. "Inmates who seek treatment for [Gender Dysphoria] typically display little resemblance to the patients who present for treatment in the community, and prison life bears little resemblance to life in the community. The [WPATH] SOC were not developed with the complexities, vulnerabilities, and life circumstances of incarcerated persons in mind" (Osborne & Lawerence 2016 at 1651).

142. The concept of social transitioning through social accommodations, hormones, or surgery is out of place in the correctional context because an inmate does not live in society at large but a secure prison environment.

143. And as noted above, the inmate population generally also has poorer health status. "These factors coupled with the safety and security concerns found in a carceral setting, provide challenges to BOP medical providers that are not present to medical providers who provide treatment outside of a prison setting" (Stahl Decl.).

Unavailability of Certain Treatment in Prison

144. Simply because a treatment may be available in the community does not mean that it should be provided in a prison setting. This situation is not exceptional. Prisons and correctional systems have formularies, lists of approved medications and supplies that determine what will be available for medical providers to use. For instance, the medication quetiapine (brand name Seroquel) is "off formulary" in many prisons, despite being routinely available in the community. This is because quetiapine has abuse potential and is often traded and sold in correctional environment, thus increasing risks to the inmate population. When quetiapine or other sedating medications are

prescribed, clinicians get excessive requests for them, with prisoners exaggerating or malingering illness to obtain them. Their availability also alters the social milieu because inmates, especially those with actual mental illness, will be enticed, or even "strongarmed" to obtain sedating medications like quetiapine for distribution. As such, even if some patients may benefit from them, it is safer and better for the prison population when these medications are off formulary and unavailable and alternative medications or treatments are pursued.

145. Another example is ketamine for depression, which is offered in the community, but to my knowledge, is not available through BOP. Transcranial Magnetic Stimulation (TMS) is also a community option for depression treatment, but to my knowledge, TMS is not available through BOP.

146. Thus, although cross-sex hormones and surgeries and items for social transition may be available in the community, it is reasonable that they are not provided in the prison setting. Mental health care for Gender Dysphoria in the prison setting must be adequate and appropriate but should not involve exceptional means that may have long-term negative effect on the prison's vulnerable population. The medical and social transition approach to Gender Dysphoria is exceptional within medicine and mental health care (Amos 2024), because it provides unclear benefits, impedes other proven therapeutic approaches, and calls for changing and harming healthy tissues to treat a mental disorder.

147. The prisoner population necessarily includes vulnerable inmates. Such inmates need added protections to provide them, including those with Gender Dysphoria, the right care, including to guard against over-treatment. For those reasons and the others explained in this declaration, sex-trait modification, such as through cross-sex surgery, in prison settings should not be considered

the standard of care or medically necessary. More conservative and cautious treatments appear much more appropriate.

Self-Injury

148. Self-injurious behavior and threats of self-harm are serious matters within correctional institutions. Correctional psychiatrists and other mental health professionals make difficult decisions to balance risks. Prisoners may have limited regard for their own bodies and may be willing to injure themselves for a constellation of reasons, including sometimes due to a wish to die, but more often as an expression of psychic distress or as a means of avoidance or gain (Carli 2011, Dixon-Gordon 2012). In my experience working in correctional facilities and treating adult and juvenile inmates, including those diagnosed with Gender Dysphoria, inmates frequently use threats of self-harm and suicide to try to obtain concessions from prison officials.

149. Self-harm and threats of self-harm must be met with nuanced responses, yet any response that provides either tangible or psychological rewards, may increase expressions of self-harm. When prisoners' expressions of self-harm or threats of self-harm are rewarded, the institution can be said to "shape up" patterns of thinking and behaving, which can mold chronic, dysfunctional self-harming behaviors and may even end tragically. This can be characterized as an iatrogenic harm. That is, correctional policies, institutional environments, and responses to inmates can and do increase threats of self-harm, suicide, or self-injurious behavior. If prisoners believe that threats of self-harm or actual self-harm will lead to receiving certain items or treatments they prefer, such as hormone therapy, surgeries, or movement to favorable settings, like women's prison, this can lead to more self-harm. In corrections, rewarding self-injury or threats of self-injury tends to increase overall self-harm, both for the individual patient and also within the system. In prisons,

there is always a difficult balance of short- and long-term safety concerns, and each patient must be considered as part of the system.

150. Simple and clear institutional policies, such as no social transitions or no initiation of new hormone treatments, are likely to lead to the lowest level of self-harm and the least overall harm to inmates because when prisoners know the interventions they desire are not available, they are less likely to self-harm to obtain them. In other words, it is reasonable for prison administrators to have outright prohibitions of providing inmates benefits, such as unproven surgeries, special-order items, and housing placements, in response to self-harm or suicide threats to discourage false threats.

151. Malingering is another difficult and common issue in correctional facilities. Gender identity is a declared internal state. But prisoners can easily recite the criteria for Gender Dysphoria to qualify for the special treatments available for those diagnosed with the medical condition. These tangible benefits can include restrictions about who can search you; choice regarding housing and cellmates; more time with therapists, nurses, and medical staff; and other special privileges. Considering the generally powerless position of inmates, it should not be underestimated how psychologically rewarding it can be for some inmates to have power over even minor aspects of the conditions of their confinement.

152. Saying no to patients can seem unkind and unjust. Yet the refusal to provide certain treatments is underpinned by medical ethics, including the prevention of iatrogenic harms from unwarranted, risky, and ineffective treatments. It is, therefore, important that malingering—which can be pronounced in the correctional setting as discussed—is properly addressed without causing harm to the inmate.

153. Finally, medical providers have a duty to protect scarce medical resources and to "apprise their patients of their conditions and the treatment options in language that is accurate, ethically neutral, and in no way misleading" (HHS 2025 at 29). In dealing with the special and vulnerable population of inmates with Gender Dysphoria, medical and mental health providers can serve this population best by straightforward and honest discussion of clinical issues. Neutral policy and a neutral clinical stance that neither affirms nor denies patient claims about themselves appear to represent the most compassionate and medically beneficial approach.

CONCLUSIONS

154. Hormone therapy is unproven and experimental treatment for Gender Dysphoria that generally should not be available to those in the custody of the BOP. Though it is not medically necessary to provide hormone therapy to inmates who are diagnosed with Gender Dysphoria but not currently receiving hormone therapy, inmates currently receiving hormone therapy may be a more complex situation. In most circumstances, it is appropriate, after individual assessment, to discontinue hormone therapy for inmates currently receiving hormone therapy through an appropriate withdrawal process. In a limited set of circumstances, it may be appropriate, after individual assessment, to continue hormone therapy for inmates already being treated with hormones.

155. Cross-sex surgeries are not medically necessary and should not be available in correctional environments.

156. "Social accommodation" is not medically necessary in the correctional setting.

157. It is not medically necessary to house inmates with Gender Dysphoria according to their asserted gender identity.

I verify, under the penalties for perjury the foregoing representations are true.

Executed this 19th day of September, 2025.



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Kristopher E. Kaliebe, M.D.

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The Present State of Housing and Treatment of Transgender Incarcerated Persons

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The care and housing of transgender (TGD) incarcerated persons is a complex concern that is growing because of the increased recognition and diagnosis of gender dysphoria in society. To remain current in this evolving landscape, there have been updates to federal manuals and state guidelines regarding the medical care and housing of the TGD population. Since the publication by Glezer and colleagues in 2013, there has not been a comprehensive overview of current federal and state guidelines, and legal and other considerations on this topic. We provide an update with special consideration given to housing practices, safety, and access to care. A review of the literature shows that the World Professional Association for Transgender Health (WPATH) standards and Prison Rape Elimination Act (PREA) requirements are not uniformly implemented and enforced on a state level. In fact, some states have policies that are in direct conflict with federal requirements. The safety and equitable treatment of both TGD and cisgender populations is an important topic that merits attention. As new challenges emerge, an increase in federal enforcement and consistency is needed to ensure the humane treatment and protection of TGD inmates.

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In 2013, Glezer and colleagues[1] published "Transgendered and Incarcerated: A Review of the Literature, Current Policies and Laws, and Ethics" in The Journal to address a gap in the literature regarding incarcerated TGD individuals. Since then, conceptions of gender identity in psychiatry and the law have evolved substantially, and progress has been made in many areas. For example, in January 2022, the Bureau of Prisons revised its *Transgender Offender Manual*, improving access to gender-affirming care and to housing placement consistent with the individual's gender identity, and requiring prison staff to use inmates' preferred names and pronouns.[2] Correctional facilities continue to struggle with how to manage classification, housing, and treatment. We describe the changes over the past 10 years, as well as the remaining challenges, with a focus on approaches to gender-affirming treatment and housing.

Terms and Definitions

"Transgender" is an umbrella term that is used to describe individuals whose gender identity is different from their external sexual anatomy at birth. In the DSM-IV-TR,[3] the associated diagnosis was "gender identity disorder" (GID).[3] This diagnosis was eliminated in the DSM-5 and replaced with "gender dysphoria."[4] This change focused on the gender identity-related distress that some TGD individuals experience and seek care for, rather than the TGD identity itself. This is an important distinction because, with this change, it is no longer considered pathological to be TGD. Instead, the dysphoria itself may be pathological,

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and appropriate treatment may include not only psychological interventions, but also gender-affirming medical and surgical interventions.

The term "sexual reassignment surgery" has been replaced with "gender affirmation surgery," which is preferred because it focuses on how the treatment brings individuals' external sexual characteristics into alignment with their gender identity, rather than "reassigning" something innate about the individual. It is important to note, however, that being TGD is not dependent upon the individual's physical appearance or medical transition.[5]

Another concept that has become increasingly recognized is "gender nonbinary" or simply "nonbinary." This term is used to describe individuals whose gender identity or expression do not fall within the binary gender identities of male or female. Given that this is a broad term that encompasses many different people with many different conceptions of their gender, nonbinary individuals may or may not consider themselves part of the TGD community. Because most carceral settings operate in a binary system, we will be focusing on TGD individuals, and we will consider nonbinary individuals as TGD for the purposes of this article.

Epidemiology

Although only .5 to .6 percent of the adult population is TGD, TGD people are disproportionately represented in correctional settings.[6–8] TGD individuals often face stigma beginning in childhood because of gender identity-based harassment, and many are rejected by their families. This marginalization often leads to homelessness and lack of employment, putting them at high risk not only for substance use and other mental health disorders, but also for relying on criminal activity such as sex work or selling illicit drugs to meet their basic needs.[9–10] In turn, substantial numbers of TGD inmates enter the correctional system.

In 2013, there were minimal data on this population. In 2014, Reisner and colleagues[9] analyzed data from the National Transgender Discrimination Survey (NTDS), which was a survey distributed to the largest convenience sample of TGD adults in the United States to date. Out of 3,879 TGD women, 19.3 percent reported histories of incarceration, in comparison to less than three percent of the general population. Black and Native American TGD women were more likely to report a history of incarceration than White, non-Hispanic respondents. Among TGD women who were previously incarcerated in either a jail or prison, 47 percent reported victimization, defined as harassment and physical or sexual assaults from other inmates or staff. A quarter reported being denied health care.[9]

Current Standards of Care

The World Professional Association for Transgender Health (WPATH) is a nonprofit organization dedicated to the health of TGD and gender-diverse individuals. The WPATH Standards of Care (SOC) are recognized by some U.S. courts as a benchmark for treating gender dysphoria[11] and are referenced by the National Commission on Correctional Health Care (NCCHC)[12] and the American Psychiatric Association (APA).[13] The guidelines outline best practices in the assessment and treatment of gender incongruence, founded on both a review of the available literature and consensus-based expert opinion. The eighth version of the guidelines (SOC8) was released in 2022.[14]

The new WPATH guidelines de-pathologize gender nonconformity and differentiate it from gender dysphoria. They draw attention to the concept of gender incongruence, a new term in the World Health Organization's International Classification of Diseases and Related Health Problems, 11th Version (ICD-11).[15] Whereas gender dysphoria requires clinically significant distress or impairment in functioning, gender incongruence points to the evolving understanding that diverse gender identities are not inherent states of ill health or dysfunction. SOC8 advances the principle that gender-affirming care (GAC) is essential for the health and wellbeing of all TGD persons, regardless of a diagnosis of gender dysphoria, which is often required by insurance companies to warrant gender-affirming treatments.

The main pillars of treatment for gender incongruence remain gender-affirming hormonal and surgical treatments. Hormone treatments involve the administering of feminizing or masculinizing hormones (estrogen and testosterone), alongside antiandrogen medications in some cases. In addition to "top surgeries" (double mastectomy, breast augmentation) and "bottom surgeries" (phalloplasty, metoidioplasty, and vaginoplasty), SOC8 includes an expanded list of medically necessary procedures including gender-affirming facial surgery, body contouring, and voice therapy or surgery. Some TGD

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persons seek gender-affirming treatments, while some do not and may wish to transition without medical interventions.

The previous requirement of assessment by two medical providers prior to accessing gender-affirming medical or surgical treatments (GAMSTs) was changed to a single medical opinion in SOC8, as was the requirement of an assessment (or two for genital surgery) by a mental health professional. The previous recommendation that a person live in a gender-concordant manner publicly, known as social transition, for a period of 12 months prior to accessing GAMST is also changed; there is greater recognition that such a social transition may not be possible and should not be a barrier to care. This is especially salient in a correctional environment where living as, for example, a TGD woman housed in a male institution may pose safety concerns. The prior requirement of 12 months of hormonal treatment prior to surgical intervention has been reduced to six months and removed altogether for nonbinary persons not pursuing hormonal treatment. The guidelines provide new recommendations for the care of eunuchs, intersex, and nonbinary persons. Nonbinary individuals face greater barriers to accessing care than TGD individuals, and nonjudgmental exploration of treatment options is recommended, with caution against making assumptions about what options might fit each person.

The guidelines recommend TGD individuals who are institutionalized, including in carceral settings, be afforded treatment without delay and that people with gender dysphoria should be provided "medically necessary surgical treatments that contain similar elements provided to persons who reside outside institutions" (Ref. 14, p S106). There are expanded recommendations for gender-affirming practices in institutions, including the use of chosen names and pronouns, the availability of gender-affirming hygienic and grooming supplies, and the assignment of housing based on preference, gender identity, and safety considerations rather than on external genitalia or assigned gender. Nonbinary and other gender-diverse individuals are not easily fit into the dichotomous structure of correctional facilities, so flexibility is recommended when housing these individuals. Finally, TGD persons should not be placed in segregation or isolation solely based on their gender identity; this should only be done to address safety concerns.

Prison Rape Elimination Act

The Prison Rape Elimination Act (PREA)[16] was enacted in 2003 after a congressional inquiry was launched into sexual assault in the correctional system. PREA standards are intended to align practices across local, state, and federal institutions to eliminate sexual violence in prisons. The standards were implemented in 2012 and have jurisdiction over both state and federal correctional facilities, including privately operated facilities.[17] The standards include sections on prevention of sexual violence, responsive planning, training and education, screening for risk of sexual victimization and abusiveness, reporting, official response following report, investigations, discipline, and compliance.[17]

PREA contains 13 provisions specifically addressing TGD inmates, which are outlined in Table 1. There are definitions and requirements pertaining to staff training, prevention and response to abuse, and housing and classification. Regarding staff training, PREA states that no inmate will be physically examined for the "sole purpose of determining the inmate's genital status" (Ref. 17, § 115.15), and training must be provided in conducting respectful cross-gender pat-down searches. Employee training should also include instruction on communicating "effectively" with LGBT inmates, although the act does not describe effective communication or provide examples of such practices. In terms of prevention and response to abuse, staff must consider whether inmates' LGBT status or perceived status affects their risk of victimization or was a motivating factor in their abuse. With respect to housing and classification, there are three recommendations about using information on gender identity to assign a TGD inmate to a particular facility: decisions should be made on a case-by-case basis; decisions should be reassessed twice per year; and the TGD inmate's own views should "be given serious consideration" (Ref 17 §115.42). TGD inmates should be able to shower separately and not be placed into involuntary segregation solely because of their LGBT status.[16]

Finally, LGBT inmates should not be segregated into separate facilities, as this separation can be stigmatizing, lead to a decrease in access to programming and recreation, and in some cases be synonymous with solitary confinement, which causes psychological distress and has been recognized as a form of inhumane punishment.[18–21] PREA does allow an exemption of this statute under a consent decree or

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Table 1 Thirteen Provisions of PREA[16] Related to Transgender Incarcerated Individuals

	Provisions	Description
1	§115.5 General definitions	Gender nonconforming means a person whose appearance or manner does not conform to traditional societal gender expectation.
2		Transgender means a person whose gender identity (i.e., internal sense of feeling male or female) is different from the person's assigned sex at birth.
3	§115.15 Limits to cross-gender searches	The facility shall not search or physically examine a transgender or intersex inmate for the sole purpose of determining the inmate's genital status.
4		The agency shall train security staff in how to conduct cross-gender pat-down searches, and searches of transgender and intersex inmates, in a professional and respectful manner, and in the least intrusive manner possible, consistent with security needs.
5	§115.31 Employee training	The agency shall train all employees who may have contact with inmates on: How to communicate effectively and professionally with inmates, including lesbian, gay, bisexual, transgender, intersex, or gender nonconforming inmates.
6	§115.41 Screening for risk of victimization and abusiveness	The intake screening shall consider, at a minimum, the following criteria to assess inmates for risk of sexual victimization: Whether the inmate is or is perceived to be gay, lesbian, bisexual, transgender, intersex, or gender nonconforming.
7	§115.42 Use of screening information	In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.
8		Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experienced by the inmate.
9		A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration.
10		Transgender and intersex inmates shall be given the opportunity to shower separately from other inmates.
11		The agency shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.
12	§115.43 Protective custody	Inmates at high risk for sexual victimization shall not be placed in involuntary segregated housing unless an assessment of all available alternatives has been made, and a determination has been made that there is no available alternative means of separation from likely abusers.
13		Consider whether the incident or allegation was motivated by race; ethnicity; gender identity; lesbian, gay, bisexual, transgender, or intersex identification, status, or perceived status; or gang affiliation; or was motivated or otherwise caused by other group dynamics at the facility.

settlement agreement. For example, the K6G unit of the LA County Men's Central Jail has been operating since 1985 and described as an affirming and humanizing alternative for LGBT inmates.[22,23]

Malkin and DeJong[24] analyzed states' policies on TGD inmates with attention to each of the PREA provisions addressing TGD inmates. They found that only Indiana contained all 13 of the PREA provisions addressing TGD inmates, and only one-quarter of state policies included most of the provisions. Malkin and DeJong also found that 40 percent of states had policies that were incompatible with the TGD-related PREA provisions. For example, Hawaii and Idaho have blanket policies to house inmates based on their sex assigned at birth; and segregation or "protective custody" based on TGD identity is still commonly used in the District of Columbia, Virginia, and Oregon. Overall, the PREA provision least commonly included was the one preventing the use of segregation based solely on LGBT status.[24]

States not in compliance with PREA regulations must forfeit five percent of federal funding provided to the state correctional department unless the state can provide assurances that it is using the federal funds to work toward compliance. According to the Bureau of Justice, as of 2020, 21 states and the District of Columbia were fully compliant with PREA, and 30 provided assurances of working toward compliance.[25] Only two states (Alaska and Utah) provided neither. At the time of writing, Alaska was planning to provide an assurance, leaving Utah as the only state that continues to refuse the implementation of PREA.

The United States Appeals Courts have ruled differently with respect to inmate claims of Eighth Amendment violations for failures to conform policy to PREA guidelines. For example, in *Williams v.*

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Kincaid,[26] the Fourth Circuit held that gender dysphoria is a protected disability under the Americans with Disabilities Act (ADA) and is different from its original exclusion of gender identity disorder. The diagnosis of gender identity disorder was excluded as qualifying as a disability in 42 U.S.C. § 12211. The court also held that Kesha Williams, a TGD woman imprisoned in Virginia in a men's facility, had been discriminated against and that the prison's blanket policy of housing inmates by genital status was in direct contravention of federal regulations under the Prison Rape Elimination Act that require determination be made on a case-by-case basis. Justice Quattlebaum dissented and argued that gender dysphoria was similar enough to gender identity disorder to be exempt from the ADA. He also argued that Sheriff Kincaid was not grossly negligent, as she demonstrated some degree of care in attempting to balance housing decisions with safety concerns of cis-gendered female inmates and correctional staff. In *Rivera v. Bonner,*[27] the Fifth Circuit held that while PREA was a helpful guideline, it did not establish a constitutional obligation for institutions to conform their policies and training to PREA.

Despite the very small number of TGD inmates who are housed based on their gender identity,[28] it is currently a matter of social controversy. In March 2023, Republican lawmakers introduced the "Preventing Violence Against Female Inmates Act of 2023" in the U.S. Senate and House of Representatives that would prohibit such housing in state and federal correctional institutions.[29] The case of a New Jersey trans woman impregnating two inmates garnered significant media attention and raised important considerations for such housing decisions, including the realities of consensual sexual interactions in such facilities, the difficulties of discerning consent in institutional settings, and the lack of available condoms in U.S. prisons and jails.[30]

Access to Treatment in U.S. Federal Prisons

The U.S. Federal Bureau of Prisons houses approximately 1,200 TGD inmates and has undergone several revisions to its TGD inmate policies following successive presidential administrations.[31] In 2017, the *Transgender Offender Manual* recommended TGD inmates be "hous(ed) by gender identity when appropriate" (Ref. 32, p 6). The manual also recommended that "hormone or other medical treatment may be provided after an individualized assessment" (Ref. 32, p 8). This policy was changed in 2018,[33] using biological sex as the initial determination for housing decisions as well as adding medical necessity for gender-affirming treatments. The manual was revised again in 2022.[2] The provision on the use of biological sex as the initial determinant of inmate placement was removed, as was the terminology of medical necessity. A new subsection was added specifically addressing access to gender-affirming surgery, noting that a case could be referred to the Transgender Executive Council for approval after "one year of clear conduct and compliance with mental health, medical, and programming services" (Ref. 2, p 9) The updated manual also contained a new provision outlining that staff must not deliberately misgender an inmate by using incorrect pronouns.[2]

Despite changes to formal policy, access to care still faces considerable barriers in practice, especially regarding surgical interventions. Cristina Nichole Iglesias was one of the first federal inmates to access gender-affirming surgery after the Federal Bureau of Prisons was ordered in 2022 to secure her surgery following three years of litigation by Ms. Iglesias.[34]

Access to Treatment in U.S. State Prisons

In 2017, Routh and colleagues[35] conducted a detailed review of state statutes and department of corrections (DOC) policies concerning TGD inmates' access to care, analyzing whether there were provisions for counseling, the continuation and initiation of hormone therapy, and sex-reassignment surgery. They found that most states had a policy that specifically considered TGD inmates, and of those that did, the policies generally recognized the diagnosis of gender identity disorder or gender dysphoria. The states that did not have a specific TGD policy recognized the Prison Rape Elimination Act, with its provisions for the protection of TGD prisoners from sexual violence. At the time of writing, 21 states had formally expanded access to care for TGD inmates. Only New Mexico, Tennessee, and Indiana disallowed all gender-affirming medical treatment once a person is incarcerated, down drastically from the 28 states that did so five years previously. Thirty-three states allowed for the continuation of hormone therapy, 28 allowed for the initiation of hormone therapy, and 13 allowed "sex reassignment surgery." The policies of eight states were either unknown or

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not publicly available (Louisiana, Alaska, Florida, Kansas, Kentucky, Mississippi, Montana, and Utah).[35]

This expansion of services is likely in response to the legal success TGD inmates have had in gaining recognition of gender dysphoria as a serious medical concern, establishing grounds for deliberate indifference claims under the Eighth Amendment.[36] The Seventh Circuit ruled that blanket bans on treatment for gender dysphoria are unconstitutional.[37] There is, however, a circuit split on what constitutes deliberate indifference in the care of TGD inmates. The Fourth,[38] Seventh,[37] and Ninth Circuits[11] have ruled in favor of plaintiffs' claims, recognizing the WPATH SOC as the widely accepted guidelines for the treatment of gender dysphoria, and ordered access to care, including surgical treatments in some cases.[11,37,38] In contrast, the First, Fifth, and Eleventh Circuits have ruled in favor of defendants,[39–41] and held that less comprehensive gender-affirming care can negate the high bar for deliberate indifference,[39] that the WPATH SOC do not represent a medical consensus on the treatment for gender identity,[40] and that courts should defer to the safety concerns cited by correctional institutions in their reasons for providing or declining to provide certain elements of gender-affirming care.[41]

The Supreme Court has not directly addressed the matter of what constitutes medically necessary care for TGD inmates. It has denied applications for *certiorari* in the First, Seventh, Ninth, and Eleventh Circuits.

Despite this expansion of services, there have been an unprecedented number of bills introduced by Republican law makers banning aspects of gender-affirming medical care in 2023, including bills banning correctional departments from funding gender-affirming surgery,[42] and bills criminalizing gender-affirming care for youth in Florida, Idaho, North Dakota, and Oklahoma.[43] Practitioners should familiarize themselves with state policies and legislation governing gender affirming care, as it is an area that is rapidly evolving.

Housing and Safety

The 2022 *Transgender Offender Manual*[2] incorporates the thirteen PREA provisions related to TGD inmates. The manual states that housing should be considered on a case-by-case basis with some consideration given to the inmate's own gender identity. TGD inmates must have the opportunity to shower separately from the general population. It also establishes that TGD inmates cannot be placed in dedicated wings based on their gender identity unless established by separate legal action (e.g., consent decree) for safety purposes. If an inmate is transitioning, transfers to facilities concordant with their gender identity are considered upon the condition that the inmate has been compliant with programs, medications, and mental health treatment and is meeting hormone goal levels. These guidelines are consistent with PREA requirements.

As noted in our discussion of PREA implementation, states vary considerably in their implementation of the housing and safety standards, without recognizable patterns. For example, as of 2018 only Indiana contained all 13 provisions.[24] About half of the states contain at least seven; for example, California had seven, New York had eight, and Texas had 11.[24] A quarter of the states had less than four of the provisions.[24] Florida, Indiana, Illinois, and Mississippi contained no accessible data about their policies at the time of publication.[24]

Safety is an important factor in housing decisions, especially because TGD inmates are at considerably higher risk of physical and sexual violence than the general population.[44] Safety should also extend to protecting other inmates from potential violence perpetrated by a TGD individual. For example, there may be concern about the risk of victimization from an inmate assigned male at birth transitioning to female who is housed in a female facility. PREA includes standards that mandate screening to assess TGD inmates' vulnerability to attacks as well as the risk that they themselves will be physically or sexually abusive toward other inmates. It states, "The initial screening shall consider prior acts of sexual abuse, prior convictions for violent offenses, and history of prior institutional violence or sexual abuse, as known to the agency, in assessing inmates for risk of being sexually abusive" (Ref. 16, § 115.41). The 2022 *Manual* includes provisions on initial housing screening and transfer requests protecting "the wellbeing of all inmates" (Ref. 2, p 6), which specifically incorporates the inmate's "criminal and behavioral/disciplinary history" and "likelihood of perpetuating abuse" (Ref. 2, p 6). On a state level, no comprehensive literature search has been published to date about specific protections afforded to cisgender inmates or the incidence of violence against the cisgender population.

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Ongoing Challenges

Safety

The topic of physical and sexual violence perpetuated by the TGD individual against the general population is controversial. It merits consideration, especially in the case of male to female facility transfers. The Eighth Amendment imposes a duty on prison officials to "protect prisoners from violence at the hands of other prisoners" (Ref. 45, p 825). This duty not only applies to protecting the TGD individual, but also the general population against possible violence committed by the TGD person. There are no readily accessible data on the incidence of such violence or the extent to which it is a problem.

An Illinois case demonstrates these safety concerns. Janiah Monroe, a TGD woman, allegedly raped a cisgender woman after being transferred to a female prison despite pretransfer concerns about her risk of violence.[46] Ms. Monroe was transferred from a male to a female facility in 2019 after she successfully sued the Illinois Department of Corrections alleging that she was sexually assaulted while housed in a male facility.[47–49] There was considerable controversy surrounding Ms. Monroe's transfer to female housing; prison officials raised concern about whether she was psychiatrically stable based on her previous attempts at suicide and efforts to castrate herself.[50,51] There was additional concern regarding her history of serious violence; she had been incarcerated since 2005 after shooting two people outside of a barbershop and was later convicted of murder after strangling her cellmate in 2006.[50,51] It should be noted that some of the rape allegations made by the cisgender woman were later retracted.[50] Nonetheless, the case illustrates a potential example of the possible risk of TGD inmates to the safety of others.

Diagnosis and Readiness for Treatment

Although mental health professionals are no longer required to provide letters in support of gender-affirming treatments by WPATH standards, a diagnosis of gender dysphoria is necessary to access gender-affirming medical and surgical treatment (GAMSTs) in the United States. Mental health symptoms that interfere with a person's capacity to consent to treatment, such as cognitive impairment and psychosis, must be prioritized for assessment and treatment prior to proceeding with gender-affirming treatments.[14] Other possible causes of apparent gender incongruence must be excluded. For example, in the presence of a psychotic illness, the evaluator must consider whether the gender incongruence predates or persists outside of an acute episode of psychosis. Mental health symptoms that do not affect the capacity to provide consent, including anxiety, depression, and self-harm, should not be a barrier to initiating gender-affirming treatment. In fact, research suggests that access to GAMST tends to improve such mental health symptoms.[52]

Some conditions, such as mania, severe depression, psychosis, and substance intoxication or withdrawal, may pose challenges to perioperative care. These can include complications arising from missed follow-up appointments, problems with frequent dressing changes, and other aspects of postoperative recovery such as vaginal dilation. In these cases, support should be offered to address these symptoms to reduce the potential negative affects on surgical outcomes. Overall, any delay in accessing gender-affirming treatments must be carefully weighed against the risks of delaying such treatment, including increased distress.[14]

Assessment of Malingering and Risk

There are no published data on the rates of malingering of gender dysphoria in the community or forensic settings. Despite recent regulatory and legal changes, less than one percent of the TGD population are housed according to their gender identity.[28,53–55] Because of the vulnerable nature of the female prison population and the fact that fewer TGD men request transfers to male facilities, consideration has been given primarily to the transfer of TGD women to all female facilities.[56] There has been considerable media attention toward such transfers, and many articles raise the possibility or outright assumption of malingering gender dysphoria to gain access to potential female victims, especially if the TGD woman has not undergone bottom surgery.[57,58]

Henrich[59] conducted a systematic review of assessments of gender dysphoria. He found no consensus, but recommended a structured approach to the evaluation that included an assessment of malingering. In correctional settings, psychiatrists should consider whether the expression of gender dysphoria and gender identity are sincere, and whether there are any ulterior motivations for expressing gender dysphoria. This is especially important for those with a history of sexual or violent offending. A motive to gain

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access to potential victims is a major consideration. Comorbid disorders that affect identity processes, including personality disorders and histories of severe trauma, should be explored to understand their relevance, as should paraphilic disorders, including transvestitism.[60] Other information relevant to the assessment includes a thorough history of gender discordance, noting periods of social transition and collecting collateral information to supplement self-report. It is possible that TGD individuals outwardly express their gender discordance for the first time in institutional settings. Therefore, evaluators should not conclude that an individual is feigning gender dysphoria just because their first clinical presentation is in a correctional setting.

Assessing sexual safety matters of prison transfers is a bidirectional concern. With respect to TGD individuals with a history of sexual offending, there are no specifically validated tools for assessing risk of re-offense. The STATIC-99R, one of the most widely used tools, is recommended only for use in adult males. According to its coding rules, TGD women are only considered "female" after undergoing bottom surgery and having socially transitioned for two years, while TGD men are not considered at all.[61,62] Jumper[63] summarized the state of the literature for the assessment, treatment, and management of TGD individuals who sexually harm, and advocates for treatment that emphasizes strengths as opposed to deficits and works within a framework that considers individuals' exposure to trauma. There is currently no research demonstrating that access to gender-affirming care reduces violence risk or recidivism in sex offenders; however, more research is needed.[64]

Prison Resources

Several factors have exacerbated already existing barriers to treatment and appropriate housing, including limited access to showers and commissary items, and caused interference with facility transfers. In some instances, prison infrastructure dates to the 19th century and building layout and limited funding may prevent the installation of separate showers. Single celling and transfers may likewise be limited by overcrowding. When coupled with staff shortages and physician availability, diagnosing gender dysphoria and other psychiatric conditions in a timely fashion may be challenging. The global supply chain disruption related to the COVID-19 pandemic resulted in national shortages of some items, including gender-affirming items like clothing and toiletries.[65–67] COVID-19 outbreaks and required quarantines disrupted movement in prisons, making it less likely for TGD inmates to be transferred to the most appropriate facilities. Segregating TGD inmates because of concern over communicable diseases may pose a disproportionate psychiatric burden related to TGD inmates' underlying vulnerabilities.

Equity

There are several considerations regarding equity when making housing and treatment decisions. As it pertains to housing, it may be necessary to separate a TGD inmate from the general population either because of a high risk of harm or in response to actual physical or sexual violence. The BOP does not place TGD inmates in separate facilities based on their gender identity unless "such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmate" (Ref. 2, p 6). If housed separately, this environment may be less equipped and underfunded compared with what is provided to the general population. Importantly, the psychological impact of separate housing could be considerable if it resembles extended solitary confinement for an already vulnerable population.

The concept of justice must also be considered in the fair adjudication of resources that are substantially limited within the penal system that has struggled with overcrowding and timely access to medical care in the general population. The TGD population is a small fraction of the general population, and an argument can be made that a disproportionate amount of time and resources are being spent addressing TGD inmates' housing and access to medical and psychiatric services. In some facilities, TGD individuals get their own committees, special assessments, and large amounts of clinical and administrative time.

Finally, equitable treatment requires education on the needs of TGD inmates. This is essential because TGD inmates report stigma and abuse from correctional officers in higher rates compared with the general population.[10,44,64,68] This can be addressed through staff training, which is already a requirement in PREA, though it has been implemented variably at the state level and only 38 percent of states had

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these provisions.[24] Expanding these services is a crucial component of increasing equity of care.

Conclusions

The matter of housing and access to care in the TGD incarcerated population is a complex topic that will continue to evolve alongside the evolving standards of decency in our society. Despite updates in care standards and U.S. prison manuals regarding policies related to TGD inmates, there is a lack of uniformity, and enforcement of best practices varies widely across the United States. The ethics concerns of safety, housing, and equity are important, and proposed solutions continue to be debated. Safety concerns are bidirectional with regard to TGD incarcerated persons and the general population; although we focus on the question of safety of the general population from the TGD individual, the TGD population is at a much higher risk of victimization.[9] Expanding educational services to staff is fundamental to enacting such changes. Ultimately, expanding services and protections of the TGD population may ensure the humane treatment of all incarcerated persons.

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Trends in suicide death risk in transgender people: results from the Amsterdam Cohort of Gender Dysphoria study (1972–2017)

Wiepjes CM, den Heijer M, Bremmer MA, Nota NM, de Blok CJM, Coumou BJG, Steensma TD. Trends in suicide death risk in transgender people: results from the Amsterdam Cohort of Gender Dysphoria study (1972–2017).

Objective: This study explored the overall suicide death rate, the incidence over time, and the stage in transition where suicide deaths were observed in transgender people.
Methods: A chart study, including all 8263 referrals to our clinic since 1972. Information on death occurrence, time, and cause of death was obtained from multiple sources.
Results: Out of 5107 trans women (median age at first visit 28 years, median follow-up time 10 years) and 3156 trans men (median age at first visit 20 years, median follow-up time 5 years), 41 trans women and 8 trans men died by suicide. In trans women, suicide deaths decreased over time, while it did not change in trans men. Of all suicide deaths, 14 people were no longer in treatment, 35 were in treatment in the previous two years. The mean number of suicides in the years 2013–2017 was higher in the trans population compared with the Dutch population.
Conclusions: We observed no increase in suicide death risk over time and even a decrease in suicide death risk in trans women. However, the suicide risk in transgender people is higher than in the general population and seems to occur during every stage of transitioning. It is important to have specific attention for suicide risk in the counseling of this population and in providing suicide prevention programs.

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Key words: gender dysphoria; transgender; suicide

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Significant outcomes

- Suicide death risk in trans people did not increase over time.
- Suicide deaths occurred during every stage of transitioning.
- Suicide death risk is higher in trans people than in the general population.

Limitations

- Psychological comorbidity was not known.
- No data were available for people on the waiting list for their first appointment.

Introduction

Gender dysphoria (GD) refers to the distress related to a marked incongruence between one's assigned gender at birth and the experienced gender (1). Trans people are diverse in the intensity of experienced GD (2), their needs for medical

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transition (3), and the impairment that GD can have on their life. Studies focusing on the wellbeing of trans people show a greater vulnerability for experiencing mental health problems compared with the non-trans (cis) population (4). Most prevalent are affective and anxiety problems (5-7), often accompanied by feelings, thoughts, or behaviours linked to suicidality (8,9).

The prevalence of suicidality in trans people in suicidal ideation, suicidal attempts, and suicide death rates is studied in varying degrees and shows high variability in findings. A systematic review by McNeil et al (9). reported suicidal ideation rates across 17 identified studies, ranging from 37% (10) up to 83% (11). Prevalence rates on suicidal attempts in trans people, which are generally observed to be lower than suicidal ideation, showed to be lower but also with a wide variation in reported rates, ranging from 9.8% (12) up to 44% (13). Since structured prevalence studies on suicide deaths are lacking in the transgender literature, an estimation comes from a limited number of studies reporting on suicide death rates in small study samples. Derived from a systematic review on suicidality in trans people by Marshall et al. (8), suicide death rates varied from 0% (14) to 4.2% in a sample of 24 post-treatment trans people from Sweden (15). Six of these studies only included postsurgical people (14-19), whereas two studies also included trans people who were only using hormones without surgery (20,21). However, studies differentiating the treatment stage during which death by suicide occurred are lacking. In addition, studies differentiating between suicide in trans women and trans men are scarce. While some studies found that trans men have a higher risk of suicide attempts than trans women (22,23), other studies reported no differences in suicide attempts between trans women and trans men (24,25). Only one cohort distinguished suicide death risk in trans women and trans men and found that trans women had an increased risk of suicide death compared with trans men (20,21).

Aims of the study

The aim of the current study is to explore the overall suicide death rate in trans women and trans men in the largest clinical cohort of gender-referred people seen at the Center of Expertise on Gender Dysphoria of the Amsterdam University Medical Centers between 1972 and 2017 the Netherlands (26). In addition, the change in incidence of suicide death rate over time and at what stage in transition (pretreatment, during hormonal treatment and/or surgical phase, or post-treatment) suicide deaths were observed was explored. The relevance of such information is to get a greater understanding of how large the risk is in clinically referred transgender people and whether suicide prevention interventions should focus on specific stages in transition or not.

Material and methods

Study design

A retrospective chart study was performed, including all people who once visited the Center of Expertise on Gender Dysphoria of the Amsterdam UMC, Vrije Universiteit Amsterdam, the Netherlands, between 1972 and 2017. The selection of the study population is described previously (26). A total of 8263 adults, adolescents, and children were included, with a median age at first visit of 25 years (range 4 to 81 years) and a median follow-up time of 7.5 years (range 0.0 to 45.5 years). Information on death occurrence, time, and cause of death was obtained by cross-checking multiple sources: the National Civil Record Registry (21), which contains date of birth and date of death of all inhabitants of the Netherlands, and the hospital registration system, medical, and psychological files for cause of death.

The Medical Ethics Review Committee of the Amsterdam UMC, Vrije Universiteit Amsterdam, reviewed this study and determined that the Medical Research Involving Human Subjects Act (WMO) did not apply to this study. Therefore, and because of the retrospective design, necessity for informed consent was waived.

Treatment

After an initial visit to the endocrinologist (for adults) or child psychiatrist (for children and adolescents), all people were referred to the psychology department for the diagnostic phase. In this phase, people were seen to gain insight into their experienced gender identity, to verify whether they fulfill the diagnosis gender dysphoria, to explore their treatment desires, and to prepare them for possible medical interventions. After this phase, people may start with hormonal treatment. Trans women received treatment with anti-androgens and estrogens. Trans men were treated with testosterone. In adolescents, treatment first started with a period of puberty suppression, followed by estrogens of testosterone around the age of 16 years (27).

Surgical interventions can be offered to people aged 18 years or older. Depending on the desired

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treatment, the surgery is preceded after at least one year of hormonal treatment (genital surgery) or can be offered after the diagnostic phase (e.g., breast removal). After surgery, all people were usually seen every 2 years for medical check-up.

Statistical analyses

Characteristics of the population were shown as median with range due to the non-normal distribution. The total number of people seen at our center and the total number of suicide deaths were counted and were expressed as percentages as well as incidence per 100 000 person years. For each year, the number of people at risk and the number of people who died by suicide were calculated. Cox regression analyses were performed to calculate hazard ratios (HR) with corresponding 95% confidence intervals (95% CI). Date of first visit was used as start date of follow-up. The end date of follow-up was either date of death or date of closing the database (December 31, 2017). Suicide death was analyzed as event. To analyze whether the incidence of suicide deaths changed over time, the year of first visit was added as determinant to the analyses. Analyses were adjusted for age at first visit as age might be related to suicide death risk. Time between date of suicide death and first visit, and between date of suicide death and start of hormonal treatment, if applicable, were calculated. All analyses were performed for the total population and were stratified for trans women and trans men.

All analyses were performed using STATA Statistical software (Statacorp, College Station, TX, USA), version 15.1.

Results

The characteristics of the study population are shown in Table 1. In total, 8263 people attended the gender identity clinic, of which 5107 were trans women (median age at first visit 28 years, range 4 to 81 years) and 3156 were trans men (median age at first visit 20 years, range 4 to 73 years). The median follow-up time was 7.5 years (range 0.0 45.5 years), which was longer in trans women (10.2 years, range 0.0 45.5 years) than in trans men (4.8 years, range 0.0 45.5 years). The total follow-up time was 92 227 person years (64 287 in trans women and 27 940 in trans men).

Table 1. Characteristics of the study population (A) and the people who died by suicide (B)

	Total	Trans women	Trans men
(A)			
Number of people	8263	5107	3156
Age at first visit, year	25 (4–81)	28 (4–81)	20 (4–73)
Follow up time, year	7.5 (0.0–45.5)	10.2 (0.0–45.5)	4.8 (0.0–45.5)
(B)			
Number of suicides	49 (0.6%)	41 (0.8%)	8 (0.3%)
Age at first visit, year	31 (15–59)	31 (15–58)	21 (16–59)
Age at time of suicide, year	41 (18–66)	41 (18–66)	36 (21–60)
Follow up time, year	6.7 (0.6–32.7)	6.7 (0.6–32.7)	6.7 (0.6–23.1)
Time between start	6.4 (0.4–32.5)	6.1 (0.4–32.5)	6.9 (3.7–23.1)
hormones and suicide, year	*n = 42*	*n = 35*	*n = 7*

Data are shown as number or median (range).

Forty-nine people died by suicide: 41 trans women (0.8%) and 8 trans men (0.3%), which is 64 per 100 000 person years in trans women and 29 per 100 000 person years in trans men. The median follow-up time between first visit and suicide death was 6.7 years (range 0.6 to 32.7 years) in trans women and 6.7 years (range 0.6 to 23.1 years) in trans men. Trans women had a higher overall suicide death risk than trans men (per year: HR 2.26, 95% CI 1.06 4.82). Four suicide deaths occurred in individuals who were referred to the clinic before the age of 18 (0.2%), which is a lower risk than in adults (0.7%, $P = 0.010$).

The course of number of people at risk and the number of people who died by suicide over the years is shown in Fig. 1. Overall suicide deaths did not increase over the years: HR per year 0.97 (95% CI 0.94 1.00). In trans women, suicide death rates decreased slightly over time (per year: HR 0.96, 95% CI 0.93 0.99), while it did not change in trans men (per year: HR 1.10, 95% CI 0.97 1.25). Adjustment for age at the first visit did not change these numbers.

As the median follow-up time between first visit and suicide death was 6.7 years, subgroup analyses were performed in those who had their first visit before 2011. This did not change the outcomes: trans women ($n = 3115$) HR 0.94, 95% CI 0.91 0.98; trans men ($n = 1269$) HR 1.02, 95% CI 0.90 1.16).

Of the 49 people who died by suicide, 35 had a face-to-face contact with the endocrinologist or psychologist of the gender identity clinic in the previous two years, while the other 14 people were no longer in active counseling with the clinic. Sixteen of the 35 people who recently had visited the clinic, only came for a medical check-up, as they were postsurgery (vaginoplasty or phalloplasty). Two people were in the surgery trajectory, and 17 were still in the diagnostic or hormonal phase at time of suicide. The transition phases separately for trans women and trans men who died by suicide are shown in Table 2.

The mean number of suicides in the years 2013 2017 was higher in the trans population (40 per 100 000 person years; 43 per 100 000 trans women

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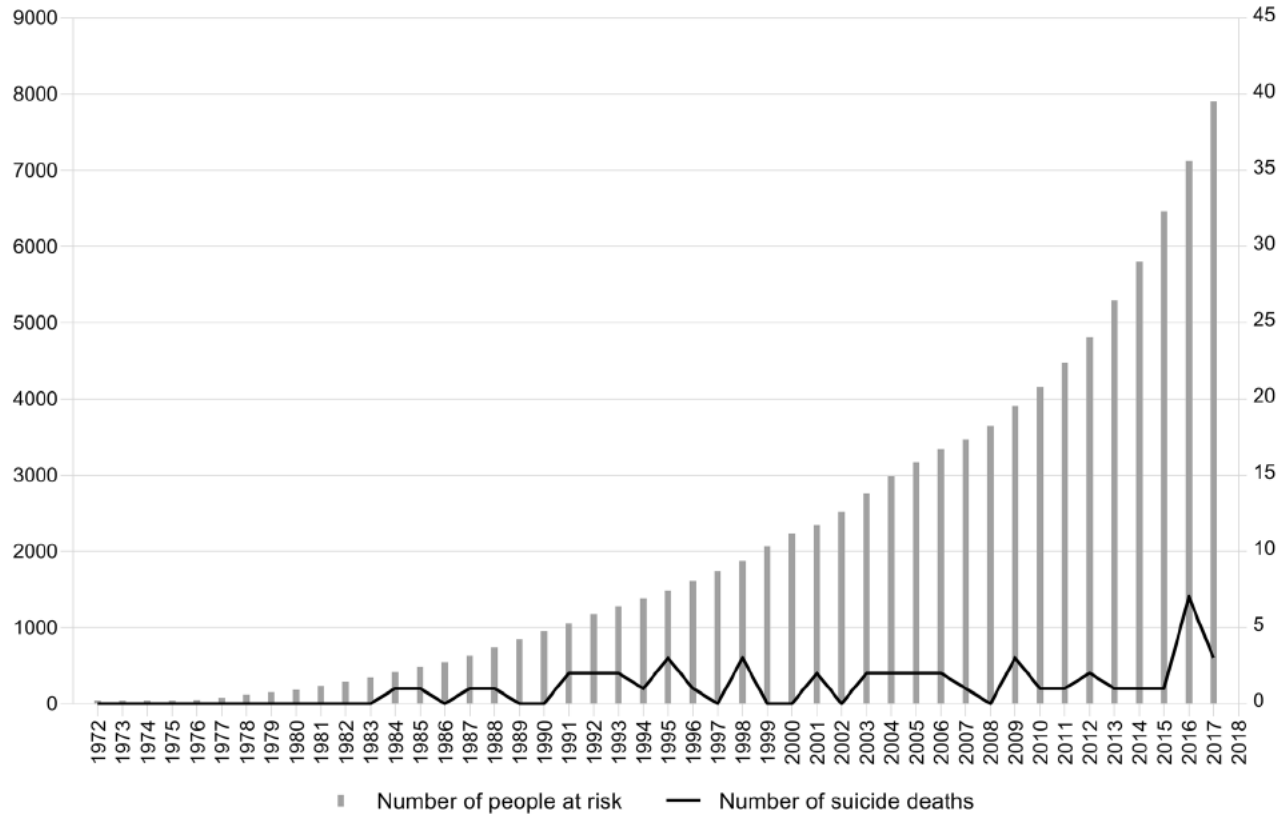

Fig. 1. Number of people at risk (left *y*-axis) and the number of suicides (right *y*-axis), between 1972 and 2017.

Table 2. The occurrence of suicide deaths distinguished for transition stage, and trans women or trans men

	Total (n = 49)	Trans women (n = 41)	Trans men (n = 8)
In active counseling	35	29	6
In diagnostic or hormonal phase	17	16	1
In surgical phase	2	0	2
Only medical follow up care	16	13	3
No active counseling	14	12	2

Data are shown as number. In active counseling is defined as a face to face contact with the endocrinologist or psychologist of the gender identity clinic in the previous two years.

and 34 per 100 000 trans men) compared with the Dutch population in this time frame (11 per 100 000 person years; 15 per 100 00 registered men and 7 per 100 000 registered women) (28).

Discussion

The current study investigated the suicide death risk in the largest clinical cohort of gender-referred individuals to the Center of Expertise on Gender Dysphoria at the Amsterdam UMC, the Netherlands, between 1972 and 2017. Findings from the chart reviews showed us a decrease in suicide death risk over time in trans women and no change in suicide death risk in trans men. Trans women, however, showed a higher suicide death risk than trans men. Between 2013 and 2017, the suicide risk in Dutch referred transgender people (40 per 100 000 person years) showed to be three to four times higher than the general Dutch population (11 per 100 000 person years) (28). Evaluation of transition stage in relation to suicide deaths showed that approximately two-third of the observed suicides occurred in those who were still in active treatment (diagnostic, hormonal, or surgical phase). The incidence of suicide deaths and transition stage was similar in trans women and trans men.

Suicidal behaviour is a complex phenomenon that is a result of many individual (age, male sex assigned at birth, previous suicide attempts, mental health history, substance abuse) as well as more distant environmental factors. A recent literature review clearly demonstrates the specific risk factors for suicide in sexual minority youth, which includes negative social environments, inadequate support within the closest social network, and an absence of lesbian, gay, bisexual, and transgender (LGBT) movements in communities (29). In our cohort, both trans women and trans men show a three- to four-fold elevated

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risk of suicide compared with the population rate in the Netherlands and can therefore be considered a high-risk group. Although the Netherlands is known for its tolerance toward sexual minority groups in comparison to most countries in the world (30), the societal position of trans people is generally less favorable compared with the lesbian, gay, bisexual, and cisgender population. Furthermore, compared with trans men, the societal position of trans women is lower (31,32).

In the Netherlands, between 1972 and 2017 suicide rates showed a fluctuating course. Our finding of a slightly decreasing suicide risk in Dutch trans women may confer some hope. Recent studies showed an increase in societal acceptance toward lesbian, gay, bisexual, and transgender people (31), and indications of an increase in social-economic status over the years (33). Although specific information on trans men and trans women is unavailable, it is conceivable that the improvement of societal position may have effect on the psychological functioning and the prevention of suicidal risk in trans women. The cause of this increase in tolerance seems largely to be the effect of a national and international increase in visibility and attention for trans people in media and society. Another explanation may be that, with the increase in attention and acceptance, the threshold for transgender people to seek treatment or professional help has become lower over the years. This is also reflected by the increase in referrals each year (26). Lastly, with the increase of knowledge in this field and the literature about the vulnerability of the transgender population for suicidal ideation, suicidal attempts, and suicide death rates, it is conceivable to assume that the attention to these risks has increased in clinical counseling and may have its effect on prevention of suicide deaths over the years.

Although the incidence of suicide deaths in trans women decreased over the years, the overall incidence still showed to be higher in trans women compared with trans men. Conflicting results in literature are reported about the risk of suicide attempts between trans women and trans men. Some studies reported that trans men had a higher risk of suicide attempts than trans women (22,23), while in other studies no differences in suicide attempts between trans women and trans men were found (24,25). Only two studies looked at the differences in the risk of death by suicide between trans women and trans men and found that trans women had an increased risk compared with trans men (20,21). However, these two studies were earlier studies performed in our center and therefore include a smaller part of our current study population.

An important finding was that the incidence for observed suicide deaths was almost equally distributed over the different stages of treatment. Although the distribution showed that one-third of the suicides occurred in people who were no longer in active treatment in our center, the other two-third of the people who died by suicide still visited our center in the previous two years. About half of these last two-third people were still in active diagnostic or medical treatment, while the other half completed their transition and only came for a medical check-up. This indicates that vulnerability for suicide occurs similarly in the different stages of transition. Although the literature on suicide risk factors is comprehensive, and particular suicidal risk factors like verbal victimization, physical and sexual violence, and the absence of social support (9,34), may apply for transgender people in all stages of transitioning, it seems clinically highly relevant to understand and explore possible differences in motives and risk factors in the different stages of treatment. Therefore, future research on suicide deaths and suicide risk factors in transgender people should have a greater focus on transition status in relation to these motives and risk factors.

This study is performed in the largest cohort of gender-referred people from the Netherlands, consisting of a large population of both adult and adolescent trans women and trans men at different stages of their transition with a long follow-up time. However, this study has also some limitations. First, this study is a retrospective chart study. Although we used multiple strategies to obtain data about date of death, it is possible that we missed some data. Second, we did not have information about psychological comorbidities or other psychological information, such as social support. Third, we only had information about people who actually visited our gender identity clinic. Information about people on the waiting list for their first appointment was lacking.

To conclude, in our clinic we observed no increase in suicide death risk over time and even a decrease over time in suicide death risk in trans women was found. Since the suicide risk in the transgender population is higher than the general population and seems to occur during every stage of transitioning, it is important that (mental) health practitioners pay attention to this risk and create a safe environment in which these feelings can be discussed at all stages of treatment and counseling. Further research is necessary to investigate the motives behind the suicides, as input in

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the development of adequate suicide prevention programs.

Conflicts of interests

None.

Data availability statement

Author elects to not share data.

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HHS Releases Peer-Reviewed Report Discrediting Pediatric Sex-Rejecting Procedures

WASHINGTON, NOV. 19, 2025 — The U.S. Department of Health and Human Services (HHS) today published *Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices* <https://opa.hhs.gov/gender-dysphoria-report>, its peer-reviewed

<https://opa.hhs.gov/gender-dysphoria-report-peer-reviews> study of the medical dangers posed to children from attempts to change their biological sex.

The report, released through the Office of the Assistant Secretary for Health, finds that the harms from sex-rejecting procedures — including puberty blockers, cross-sex hormones, and surgical operations — are significant, long term, and too often ignored or inadequately tracked. These conclusions confirm President Trump's Make America Healthy Again Commission's findings that unnecessary procedures and long-term health risks such as infertility are the byproduct of the overmedicalization of children.

"The American Medical Association and the American Academy of Pediatrics peddled the lie that chemical and surgical sex-rejecting procedures could be good for children," **said Health and Human Services Secretary Robert F. Kennedy, Jr.** "They betrayed their oath to first do no harm, and their so-called 'gender-affirming care' has inflicted lasting physical and psychological damage on vulnerable young people. That is not medicine — it's malpractice."

"This report marks a turning point for American medicine," said **National Institutes of Health Director Jay Bhattacharya, MD, PhD**. "The evidence in it meticulously documents the risks the profession has imposed on vulnerable children. At the NIH, we are committed to ensuring that science, not ideology, guides America's medical research."

"What are we going to tell the young people who can't have children because the medical profession stole that from them?" said **Assistant Secretary for Health Brian Christine, MD.** "Our report is an urgent wake up call to doctors and parents about the clear dangers of trying to turn girls into boys and vice-versa."

Before submitting its report for peer review, HHS commissioned the most comprehensive study to date of the scientific evidence and clinical practices surrounding the treatment of children and adolescents for "gender dysphoria." The authors were drawn from disciplines and professional backgrounds spanning medicine, bioethics, psychology, and philosophy.

- **Evgenia Abbruzzese**, Society for Evidence Based Gender Medicine

- **Alex Byrne, PhD**, Massachusetts Institute of Technology
- **Farr Curlin, MD**, Duke University
- **Moti Gorin, PhD, MBE**, Colorado State University
- **Kristopher Kaliebe, MD, DFAACAP**, University of South Florida
- **Michael K. Laidlaw, MD**, Michael K. Laidlaw MD, Inc.
- **Kathleen McDeavitt, MD**, Baylor College of Medicine
- **Leor Sapir, PhD**, Manhattan Institute for Policy Research
- **Yuan Zhang, PhD**, Evidence Bridge

HHS invited the American Academy of Pediatrics and the Endocrine Society to contribute their evidence to this report. Both organizations declined to participate.

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PSYCHOSIS IN TRANSGENDER FEMALE

A case of first-onset psychosis and repeated relapses secondary to discontinuation of non-prescription estrogen replacement therapy in a transgendered female

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Abstract

The estrogen hypothesis of psychosis states that estrogens contribute a protective effect against the development of psychotic disorders. Conversely, hypoestrogenic states have been shown to be associated with the occurrence of psychotic disorders in women. We present the case of a 24-year-old transgendered female who experienced a first-onset psychosis and subsequent relapses associated with discontinuation of non-prescription estrogen replacement therapy.

Keywords

Central nervous system, depression, estrogen, hormone replacement therapy, psychosis, transgender

History

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Case report

A 24-year-old Caucasian transgendered female was transferred to our inpatient psychiatric facility from an outside emergency department four days after a suicide attempt by toxic ingestion of lorazepam. Records from the transferring facility indicated that while in the emergency department the patient had reported auditory hallucinations and suicidal ideation, and that her mental status examination had shown thought-blocking and internal preoccupation. The patient required only supportive medical care in the emergency department and her medical evaluation yielded no significant findings. Her outpatient medication regimen of risperidone 0.5 mg at bedtime and fluoxetine 10 mg daily were continued while she was awaiting transfer to an inpatient psychiatric facility.

On initial psychiatric evaluation at our facility, the patient presented as alert but disinterested and evasive. She spoke in a very soft voice and displayed prominent thought-blocking. She was oriented to person and time but not place or situation. She displayed odd mannerisms and frequently scanned the room with her eyes. On several occasions, she seemed to be talking to someone who was not present. She answered ''I don't know'' to most questions and denied any recollection of her suicide attempt. She endorsed vivid visual hallucinations and spent considerable effort during the interview in drawing a gargoyle and a Sphinx-like snake to illustrate these to the treatment team. She signed her picture ''Jane Seymour''. She also reported auditory hallucinations of ''distorted noises''. She was unable to usefully participate in a review of mood symptoms, but her affect appeared moderately depressed. She denied suicidal and homicidal ideations.

Her physical appearance was disheveled and underweight (BMI 17.9). She was noted to have an androgynous body-type with disproportionately long limbs. She reported asthma as her only current medical condition. She reported a surgical history of gender reassignment surgery (GRS) and tracheal shaving two years prior, as well as a history of an appendectomy. Our treatment team initially believed that her report of a history of GRS was delusional in nature due to her degree of feminization in facial features. She was vague in providing a substance abuse history, but did admit to intermittent use of alcohol and daily use of cannabis. She was a high school graduate and was currently unemployed and living with her mother after a recent break-up with her boyfriend with whom she had been previously cohabitating.

Treatment of her psychotic symptoms was initiated by initially increasing her dose of risperidone to 2 mg at bedtime, with upward titration to 4 mg at bedtime over the first 3 days of hospitalization. Fluoxetine was not continued. She initially remained highly psychotic and disorganized, with frequent bizarre behavior (e.g. repeatedly defecating in the shower while fully clothed and stating that she was ''planting a rose garden'' by doing so). She continued to report vivid hallucinations, including hearing the devil auctioning her soul, and a delusion that she was pregnant with his babies. She began reporting suicidal ideation with a plan to drink acid, but did not engage in any self-injurious behavior while hospitalized. She gradually became more cooperative and engaged with the treatment team, but remained overall a poor historian due to psychotic symptoms.

Due to her limited ability to describe her past history, detailed collateral information was obtained from her mother who indicated that the patient had been born male but had felt like a ''girl trapped in a boy's body'' since a young age. She began to

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dress as a female at age 13, and at 16 began hormonal therapy with estradiol (10 mg daily) for gender transition under the treatment of an endocrinologist. She underwent GRS at age 22 and her estradiol dose was decreased from 10 mg to 1 mg daily post-operatively. From age 18 until the present, she had been purchasing her estradiol online without a prescription from pharmacies located in India and Canada; however, her preferred pharmacy had stopped carrying estradiol four months prior to this hospitalization resulting in her abruptly discontinuing hormone therapy. The onset of her psychotic symptoms began within weeks of discontinuing estradiol. Her current hospitalization was her third psychiatric hospitalization in the four months since she had stopped taking estradiol, with similar symptoms during each episode. She had a long history of depression and anxiety prior to the onset of her psychosis, which was related to repeated childhood sexual trauma, but she had never sought treatment.

Under the suspicion that resuming her hormonal therapy may help to reduce her psychotic symptoms, we re-initiated treatment with estradiol 1 mg daily on her 4th day of hospitalization. Sertraline was also added to her treatment regimen for treatment of depression and anxiety. The following day the patient displayed significant improvement in her mood and thought process. She did not display any further bizarre behavior during the remainder of her hospitalization. Her progress continued and by the 7th day of hospitalization, she denied all psychotic symptoms, and her thought processes had become fully coherent, logical and goal directed. Her depression and anxiety symptoms were also markedly improved. Her mother visited her in the hospital and felt that she had returned to her usual self.

She was discharged home on her 9th day of hospitalization with prescriptions for risperidone 4 mg at bedtime, sertraline 100 mg daily and estradiol 1 mg daily. She was provided with psychiatric follow-up and was instructed to resume seeing an endocrinologist for management of her hormone replacement therapy.

Case discussion

Though accurate epidemiological data on the subject are difficult to obtain, the recognition of individuals whose gender identity differs from their biological sex has increased significantly in recent years. Transgenderism was recently reconceptualized as ''gender dysphoria'' in the Diagnostic and Statistical Manual of Mental Disorders, 5th edition [1], with an increased focus on the psychological distress associated with incongruence between one's gender identity and biologic sex, and replacing the pathologic terminology inherent in the previous edition's (DSM-IV TR) [2] diagnosis ''gender identity disorder'' [3,4].

In part due to a recently heightened awareness and acceptance of transgenderism, an increasing number of individuals have sought cross-sex hormone treatment (CHT) to promote the development of secondary sexual characteristics of their desired gender and suppressing those of their biologic sex. CHT is an effective intervention for reducing dysphoria and improving quality of life in these individuals [3]. In transgendered females, the goal of male-to-female CHT is achieving hormone levels of premenopausal women leading to feminization effects such as decreased facial and body hair, female-pattern fat distribution, softened skin and the development of breast tissue [4]. An increasing number of transgendered individuals also subsequently undergo gender reassignment surgery to further enhance the sexual characteristics of their expressed gender.

Many individuals with gender dysphoria have difficulty accessing CHT due to a variety of obstacles, including an inability to find physicians knowledgeable with the treatment and lack of insurance coverage for transgender issues. This has led to some transgendered individuals resulting to the use of non-prescription hormones without appropriate medical monitoring. A study by Rotondi et al. [5] found 25% of transgendered youth in Ontario, Canada undergoing CHT had used non-prescription hormones at some time in their lives. While generally well tolerated, there are significant risks to male-to-female CHT, especially thromboembolism and osteopenia. It is thus important that the dosing and timing of hormone therapy be monitored by laboratory tests and carefully adjusted by a physician to the individual and their goals [3]. This case report illustrates another risk of unmonitored or sporadic use of non-prescription CHT, specifically that of estrogen withdrawal psychosis.

Estrogens have long been hypothesized to play a role in the pathophysiology of schizophrenia and other psychotic disorders in part due to their anti-dopaminergic activity [6,7]. Estrogens are believed to play a neuroprotective role during neural development and throughout the human life cycle, while hypoestrogenic states appear to be associated with the onset of psychotic symptoms [7,8]. Evidence supporting this theory includes the later age of symptom onset and less severe disease course in women with schizophrenia in comparison to men [7,9]. In addition, evidence suggests that women with psychotic illnesses are more likely to experience exacerbations of symptoms during relative hypoestrogenic periods during the menstrual cycle, at menopause and during a variety of other conditions leading to relative deficiencies in estrogen levels (e.g. menarche, post-partum, post-abortion, post-ovariectomy, discontinuation of oral contraceptives, use of clomiphene or leuprolide) [10–12]. These phenomena have been termed estrogen withdrawal associated psychoses (EWAP) by Mahe and Dumain [10].

One of the present authors previously reported a novel case of EWAP in which a post-menopausal female patient experienced recurrent brief psychotic episodes after abrupt discontinuation of non-prescription estradiol acquired from internet pharmacies [13]. Similar to that case report, the present case demonstrates the initial onset of psychotic symptoms and subsequent relapses in a patient experiencing hypoestrogenic states associated with the rapid discontinuation of estradiol obtained without a prescription from the internet. A review of PubMed indicates that this is the second reported case of EWAP associated with CHT in transgendered women. In a similar case, Summers and Onate reported an episode of new-onset psychosis in a 38-year-old transgendered woman, which also resolved with treatment with a combination of an anti-psychotic and estradiol [14]. As in any patient chronically exposed to estrogens, the anti-dopaminergic activity of CHT estrogens causes increased D2 receptor expression and receptor supersensitivity in transgendered women. The abrupt cessation of CHT can thus lead to rebound psychosis in these individuals, which we hypothesize was the cause of our patient's symptoms. Our hypothesis is supported by the history of a clear temporal correlation between the cessation of CHT and the repeated onset of psychotic symptoms, as well as the rapid improvement in her symptoms with the addition of estradiol to her treatment regimen.

In our differential diagnosis, we included several other possible etiologies of our patient's symptoms. Due to her initial thought disorganization and disorientation we considered dementia and delirium, however, she is too young to have a risk of dementia, and there was no evidence of residual cognitive symptoms once her acute psychotic symptoms resolved. No waxing-waning of symptoms or impaired alertness was observed, nor was there a medical condition present to suggest delirium. We also considered substance-induced psychotic disorder; however, we only had evidence of the patient using cannabis, which is unlikely to cause symptoms of this severity, nor for this length of time after cessation of use of the drug. It remains possible that she

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ingested a synthetic drug not detected by laboratory tests (such as synthetic cannabis, salvia or ''bath salts''), but she did not report use of any of these drugs.

Conclusions

This case report adds to the literature supporting the estrogen hypothesis of psychosis and provides another example of estrogen withdrawal associated psychoses phenomena. As the use of male-to-female CHT in transgendered women is likely to continue to increase in the future, physicians should be aware of the risk of the development of psychotic disorders with the rapid discontinuation of CHT estrogens and advise their patients on the need for careful medical supervision of these treatments. Further research into the prevention and treatment of estrogen withdrawal psychosis associated with hormone replacement therapy would be clinically relevant for the future.

Declaration of interest

Drs. Moffitt and Findley have no conflicts of interest to disclose.

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Tapering vs. Cold Turkey: Symptoms vs. Successful Discontinuation of Menopausal Hormone Therapy

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Prior to the late 1990s, standard practice recommended that women be prescribed hormone therapy (HT, estrogen with or without progestin) for both primary and secondary prevention of cardiovascular disease.(1) In 1998 the Heart and Estrogen/ Progestin Replacement Study (HERS)(2) reported an increase in cardiovascular events among women with a history of cardiovascular disease treated with conjugated equine estrogen and medroxyprogesterone acetate. The immediate response was that hormone therapy (HT) was inappropriate for secondary prevention but still retained a role of primary prevention of cardiovascular disease. (3) In 2002, the Women's Health Initiative (WHI) investigators(4) reported an increase in the composite outcome, including breast cancer and cardiovascular events, in women without pre-existing cardiovascular disease randomly assigned to receive conjugated equine estrogen and medroxyprogesterone acetate. At this time, guidelines were revised to recommend against the routine use of HT for reasons other than treatment of menopausal symptoms, and that treatment should continue for the shortest duration possible.(5,6)

When the WHI was stopped, participants abruptly discontinued HT. The investigators surveyed these women about their experience of symptoms after discontinuation of therapy. They found, among women with vasomotor symptoms at baseline, a higher percentage of women assigned to active treatment compared to placebo reported vasomotor symptoms upon discontinuation (55.5% vs. 21.3%).(7) Five percent of the WHI participants elected to restart HT, with women assigned to active treatment more likely to restart than those assigned to placebo (7.6% vs. 2.6%), usually for management of vasomotor symptoms.(7) Many women are able to stop HT without difficulty, but for a significant minority of women discontinuing HT remains a challenge.(8)

For clinicians and patients alike, these results have led to an interest in the most effective method of discontinuing HT. Currently, no evidence-based guidelines exist to help inform best clinical practice in this matter. Experts describe two approaches to HT discontinuation “cold turkey” (abrupt, immediate cessation) vs. tapering either by dose or number of days per week that HT is taken.(9) The duration of these tapers can range from several weeks to several months and no optimal tapering regimen has yet been revealed in existing studies. Prior work looking at the optimal method for discontinuing HT has been inconclusive. A 2003 survey of women in a Northern California staff-based health maintenance organization, found no difference in successful discontinuation based on stopping method (tapering vs. abruptly).(8) Randomized controlled trials examining method of discontinuation showed no difference in remaining off

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HT at 1-year(10) or in recurrence of vasomotor symptoms(11) with “cold turkey” compared to tapering.

In this issue of *Menopause*, Haskell et al. report the results of their survey of a random sample of women veterans, selected from a Veteran's Administration pharmacy data base of 8278 potentially eligible women who had discontinued HT either by stopping abruptly or by tapering. (12) Of the total 836 women veterans who responded to the survey and had discontinued HT participants, 75% stopped cold turkey and 25% stopped by tapering. The authors compare the cold turkey and tapering groups with regards to demographics, patient specific health factors, and recurrence of menopausal symptoms after discontinuation of HT. No details about the tapering methods used by the participants are reported.

Women who tapered, compared to those who quit cold turkey, were younger (62 vs. 63 years), more likely to have used HT for menopausal symptoms (78% vs. 71%), been on HT for 5-12 (42% vs. 39%) or ≥ 12 years (29% vs. 23%) compared to <5 years (28% vs. 38%), and reported using vitamin E (21% vs. 15%) or yoga (6% vs. 2%)) as an alternative treatment for menopause.

They found that tapering was associated with fewer menopausal symptoms after discontinuation ($b=-.58$, $p<.01$), but that women who tapered were more likely to return to using HT (OR: 2.06 (1.20-3.52)). Women who reported more menopausal symptoms also were more likely to return to using HT (OR: 1.19 (1.08-1.31)). In addition to tapering, younger women, those with fewer symptoms prior to HT initiation, reporting excellent, very good, or good (versus fair or poor) health, and not discussing menopause with a health care provider were associated with fewer menopausal symptoms after HT discontinuation, regardless of method. In addition to tapering and reporting more menopausal symptoms, increasing number of years of HT use, reporting excellent, very good, or good health, and discussing HT with are provider were all associated with restarting HT therapy. We do not know if there is an interaction between discontinuation method and return of symptoms that influences restart of HT. The authors also chose to include only variables that were significantly associated with method of discontinuation in their subsequent models examining both symptom return and HT resumption.

Overall, Haskell and colleagues have added to our limited understanding of the differences between women who choose to taper off of HT rather than quit cold turkey. These two groups of women are clearly different. Still unclear is whether it is better, both from a symptom management (Haskell, et. al. suggest tapering) and successful discontinuation perspective (Haskell, et. al. suggest cold turkey), for women to discontinue HT by tapering versus abruptly stopping. Also, for women and clinicians who choose to discontinue HT through tapering, an optimal regimen with regards to duration and dose reduction strategies remains unknown. Future studies are necessary to further our understanding about which women are more prone to restart HT after discontinuing and if there are strategies both they and their physician's can employ to assist in successful stopping. Elucidating these women's motivations for restarting would be helpful in guiding future clinician counseling approaches with regards to HT.

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The Perioperative Care of the Transgender Patient

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Abstract

An estimated 25 million people identify as transgender worldwide, approximately 1 million of whom reside in the United States. The increasing visibility and acceptance of transgender people makes it likely that they will present in general surgical settings; therefore, perioperative health care providers must develop the knowledge and skills requisite for the safe management of

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transgender patients in the perioperative setting. Extant guidelines, such as those published by the World Professional Association for Transgender Health and the University of California San Francisco Center of Excellence for Transgender Health, serve as critical resources to those caring for transgender patients; however, they do not address their unique perioperative needs. It is essential that anesthesia providers develop the knowledge and skills necessary for safely managing transgender patients in the perioperative setting. This review provides an overview of relevant terminology, the imperative for the provision of culturally sensitive care, and guidelines for preoperative, intraoperative, and postoperative management of the transgender patient.

The term “transgender” is used to describe people who identify as gender discordant from the sex they were assigned at birth. An estimated 25 million people identify as transgender worldwide, approximately 1 million of whom reside in the United States.[1–3] The increasing visibility and acceptance of transgender people makes it likely that they will present more frequently in general surgical settings.

TRANSGENDER TERMINOLOGY

Critical to the understanding of what it means to be transgender is recognition that although they are often used interchangeably, gender and sex are distinct. Sex refers to those physical characteristics (eg, hormones, chromosomes, reproductive organs) used to assign people as male, female, or intersex. In contrast, gender is a social construct, rooted in cultural expectations that drive an individual’s outward appearance and behavior. While some cultures celebrate the existence of >2 genders (eg, Indigenous North American “two-spirit” and Samoan “fa’afafine”),[4,5] the conceptualization of gender as binary (a person is either a man or woman) has dominated Western societies. However, this discourse is shifting to an approach that appreciates gender as a continuum,[6] along which a person’s gender may fall anywhere, everywhere, or nowhere.[7] Although some transgender people identify within the dichotomous model of man or woman, the continuum approach frees people to be authentic, both internally (gender identity) and externally (gender expression). This has given rise to an evolving array of terms to describe one’s gender or genders[8,9] (Table 1) and the freedom to express characteristics such as their movement, dress, and mannerisms in ways commonly referred to as masculine, feminine, neither, or both.

GENDER-CONFIRMING THERAPIES (HORMONE THERAPY VERSUS GENDER-CONFIRMING SURGERY)

Transgender individuals may undergo processes to affirm a gender identity different from that assigned at birth, known as “transition.” The extent of this transition is highly variable; some people do not transition at all, some change socially, such as their mannerisms and/or dress, some use techniques such as binding (methods to flatten breast tissue to create a male-appearing chest) or tucking (pushing the testes into the inguinal canal and securing the penis back between the legs with gaff, an undergarment that flattens any bulging), and still others opt for medical and/or surgical interventions.[6,10] The simplified overview presented here is derived from comprehensive standards and guidelines used to support those who wish to transition.[6,11,12]

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Hormone therapy (HT) is generally the first medical intervention for those who wish to align their physical characteristics with their identified gender. For transgender women, exogenous estrogen is used in conjunction with antiandrogens with the goal of developing female secondary sex characteristics (eg, breast development, redistribution of fat, reduction in body hair) and minimizing male characteristics (eg, softening of skin, slowing of scalp alopecia).[11] For transgender men, exogenous testosterone is used to develop male secondary sex characteristics (eg, deepening vocal register, development of facial hair, increased muscle mass).[11,12] Changes to insurance coverage have increased accessibility to HT for some transgender people; for many, insurance remains a barrier. Transgender people may have difficulty finding medical providers who are knowledgeable about their specific health needs, including provision of hormonal therapy. Factors such as lack of access to prescription hormones and the desire to transition more quickly lead some transgender people to alternate sources for hormones, such as the Internet and illicit dealers.[13,14] In addition, some transgender women may inject silicone into their breasts, buttocks, thighs, and face to feminize their appearance. The use of silicone injections is associated with adverse outcomes such as infections, silicone migration, granulomatous disease, pneumonitis, and organ failure.[15–18]

Gender-confirming surgeries are also used to transition; barriers such as lack of insurance and the small number of surgeons with specialty training may render this approach an unobtainable option for many. A variety of surgical approaches is available and should be tailored to the patient.[6] Surgical interventions for transgender women may involve breast augmentation, orchiectomy, vaginoplasty, laryngeal surgery, and/or facial feminization, among others.[19] Transgender men may undergo top surgery (mastectomy and additional reconstructive techniques) and bottom surgery, wherein the female organs are removed and genital reconstruction is achieved through metoidioplasty or phalloplasty, and/or facial masculinization surgery; it is important to remember that many transgender men choose to retain their uterus and ovaries though they undergo transition-related surgeries.[19]

The American Society of Plastic Surgery's annual report showed that in 2016, 1759 transfeminine patients and 1497 transmasculine patients underwent gender confirmation procedures, an increase of 27% and 10%, respectively, compared to 2015.[20] However, getting a true estimate of the number of gender confirmation surgeries is not straightforward because many surgeries may be conducted by other surgical subspecialties (eg, urologists, obstetrician/gynecologists, maxillofacial surgeons). A recent survey of almost 28,000 transgender individuals revealed that among people assigned female at birth, 21% had chest reconstruction, 8% hysterectomy, 1% metoidioplasty, and 1% phalloplasty. Among people assigned male at birth, 10% had undergone vaginoplasty or labiaplasty, 9% orchiectomy, 8% augmentation mammoplasty, and 6% facial surgery.[13]

HEALTH AND WELLNESS

Failure to systematically collect accurate gender data, specifically gender and sex assigned at birth, impairs our understanding of the health of transgender people. Despite calls for collection of these data,[21–23] implementation has been slow in clinical settings and largely absent in large-scale population surveys. This is largely related to limited funding

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opportunities for research and policy initiatives. The resultant implications are extensive and translate to inadequacy of evidence on the clinical care of transgender populations. In attempt to move the care of transgender people forward, leaders in the field rely on the most comprehensive available data. Most recently, the largest study of the experiences of transgender people in the United States revealed staggering disparities related to social determinants of health such as violence, housing instability, access to medical care, and lack of familial and other social support.[13,14]

Although being transgender does not determine a person's health, the experiences of transphobia, enacted and felt stigma, and microaggressions are associated with various adverse health outcomes, such as higher rates of mood disorders, substance use, and elevated risk for human immunodeficiency virus (HIV) and sexually transmitted infections.[24–27] The transgender population has long been stigmatized with the diagnosis of "gender identity disorder" until publication of the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition,[28] which changed the diagnosis to "gender dysphoria." This was a critical step, providing a way to call attention to the distress associated with the incongruence between one's gender identity and sex assigned at birth, rather than classifying it as an illness.[28] While the use of a psychiatric diagnosis is controversial, some suggest that it adds value by supporting access to care for transgender people who may benefit from treatment.[29]

Barriers to health care are multifactorial. Transgender people experience severe economic instability, including 3 times the US unemployment rate and twice the likelihood of living in poverty.[13,14] Encounters in health care settings are marked with insensitivity and other negative experiences including refusal of treatment, harassment, and assault.[13,14,30] Widespread discrimination and mistreatment threaten the health and wellness of transgender people making them one of the most marginalized populations in medicine.[31] Fortunately, the National Institutes of Health's recent designation of transgender people (under the umbrella of sexual and gender minority populations) as a National Disparity Population is now providing the impetus for research on the health of transgender people.

PREOPERATIVE CARE

With increased access to health care offered by the Patient Protection and Affordable Care Act, transgender patients may present more frequently to preoperative clinics for routine surgery. The American Society of Anesthesiologists refers to the preanesthesia evaluation as "the process of clinical assessment that precedes the delivery of anesthesia care for surgery and for nonsurgical procedures," which entails procurement of information from several sources.[32] Goals of this evaluation include optimization of the patient through risk reduction and informed consent.[33] Generally, the provider involved in the preanesthetic evaluation has the knowledge and access to resources to prepare individuals for surgery and anesthesia.

The paucity of evidence-based literature, lack of health care education, and absence of a holistic approach to the health care of transgender patients may translate into health care providers who are unfamiliar and unprepared to manage this unique population.

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Self Identification

Ideally, gender identity data (sex assigned at birth, gender identity, preferred name, and preferred pronouns) are collected on intake forms.[34] The best practice for collection of gender identity, which is to use a 2-step question using gender identity followed by sex assigned at birth,[35] has been found to be both feasible and acceptable to patients (Table 2).[36] Capturing preferred name (versus legal name) and pronoun (Table 3) provides the necessary data for staff to address patients throughout hospitalization. Even when collected appropriately, however, the use of these data is limited by the extent to which they are displayed in the electronic health record. As health care systems develop their electronic health records to support the meaningful display of gender identity data, many are currently forced to develop makeshift strategies, such as including information as free text in existing open fields.

Regardless of the extent to which the electronic medical record provides access to patients' gender identity data, a transgender patient may present to the preanesthetic clinic with legal documents incongruent with their preferred name and/or gender identity. Carefully noting patients' legal photograph identification (eg, driver's license, passport) and insurance card are particularly important. The intricacies involved in ensuring proper documentation for legal and insurance purposes often necessitates conferring with hospital resources, such as legal, patient advocate, and financial departments.

Hormone Therapy

It is important that anesthesia providers are knowledgeable about the hormonal therapies used for medical transition because these treatments may affect perioperative care (Table 4). Leading sources for education regarding transgender HT and clinical practice can be guided by current evidence and expert opinion, using *The Standards of Care for the Health of Transsexual, Transgender and Gender-Nonconforming People*, issued by the World Professional Association for Transgender Health[38] and integrated in the Endocrine Treatment of Transsexual Persons guidelines of The Endocrine Society.[12,39] While helpful, these guidelines on the use and interpretation of laboratory data when transgender people are receiving hormonal therapy are predominantly based on expert opinion and anecdotal experiences.[10] Other concerns include varying dosing regimens, sex-based laboratory reference values, and the safety of short-/long-term use of HT.

Feminizing HT consists of regimens of testosterone blockade combined with estrogens.[39,40] Estrogens are available in different formulations, including oral, transdermal patches, and parenteral. Commonly used androgen blockers include spironolactone, 5 α-reductase inhibitors, such as finasteride, and gonadotropin-releasing hormone agonists such as leuprolide and goserelin (Table 4). HT is continued lifelong unless adverse effects preclude their use. Documented adverse effects of estrogens include a possible increased risk of venous thromboembolism (VTE), changes in lipid profile, vomiting, or migraine headache.[38,41] Risk of VTE with estrogens is related to the formulation prescribed. Orally administered estrogens are more likely to increase the risk due to an altered balance between anticoagulant and procoagulant endogenous factors. In a Dutch study, the incidence of thrombosis was 20 times greater in the first 2 years of estrogen therapy.[42] Risk rises in

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patients who smoke and those on oral estrogen preparations (conjugated estrogens and ethinylestradiol). Some surgeons advocate discontinuance of hormones 2–4 weeks before surgery.[19] Anesthesia providers should be aware that patients who are advised to stop their hormones before surgery may experience emotional and physical effects. Common symptoms include mood swings and hot flashes.[43] If patients stop their hormones for longer periods, this can result in reversal of the feminizing effects.

Masculinizing HT follows the principle of hormone replacement treatment of male hypogonadism by supplementing testosterone to achieve testosterone laboratory values in the normal male range.[39,40] Testosterone is available in different formulations (eg, transdermal gels, patches, parenteral) (Table 4). Testosterone supplementation may have undesirable effects that can be detrimental during the perioperative period; accordingly, testing should focus on identifying these abnormalities in the preoperative period. Despite the assumption that there is an increased perioperative cardiovascular risk in transgender men taking testosterone, to date, there is no conclusive evidence to support this. While there is triglyceride elevation (albeit no alteration in total cholesterol), myocardial infarction rates among transgender men are only one third that of their cisgender male counterparts.[42] Adverse effects such as erythrocytosis, liver dysfunction, lipid level changes, acne, and adverse psychological changes can also occur.[44] If patients stop their hormones for longer periods, this can result in reversal of the masculinizing effects, including loss of muscle mass and resumption of menses.

Due to the fact that complete withdrawal of hormone treatments can have a profound impact on the patient, the surgeon and endocrinologist should collaborate in making a decision on the use of hormones during the month before surgery and reinitiation of HT after surgery.[38,39]

Laboratory Testing

Laboratory testing is an important process in the preparation of the preprocedural patient. However, it is important to note specific issues that are related to the transgender patient population. Particular attention needs to be taken when interpreting values for transgender patients especially those on hormonal therapies. This is often complicated by the various treatment regimes available for transition and the degree of transition completion. Awareness of appropriate reference values is important in identifying values outside normal range, and many laboratory values are calculated utilizing the patient's biologic sex for pharmacological computations. Additionally, laboratory tests should be ordered based on biological sex (eg, prostate specific antigen [PSA] for transgender female, human chorionic gonadotropin [hCG] for transgender male).[39,45] For transgender patients who receive hormones and/or testosterone blockers, alterations in laboratory values may be present that are related to the pharmacology of the replacement therapies. Hormone replacement therapies can influence many hematologic, general chemistry, and special chemistry/endocrine values (Table 5).[45] These changes to laboratory results are highly variable in terms of an increase, decrease, or no change as cited by Goldstein et al.[45] When interpreting values for transgender patients receiving hormones, it is important to consider the physiology behind each test and whether the male or female range is more appropriate. It

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has been suggested that transitioning transgender patients on hormone replacement therapy for >6 months should have their laboratory values compared to that of their cis-counterparts and not their sex assigned at birth[45] However, limited evidence is available to guide the evaluation of laboratory test interpretation in the different stages of transition.

Transgender women have also been shown to experience higher rates of HIV infection,[40] and preoperative laboratory testing and preparation should be conducted accordingly.

Pregnancy Testing

Transgender men may have intact female reproductive organs, internally and/or externally, and clinicians must always consider the possibility of pregnancy in these patients. The American Society of Anesthesiologists recommends screening for pregnancy in all [biologic] women of childbearing age in whom the result would change the course of medical management. On cessation of testosterone, the possibility of becoming pregnant greatly increases if sexual activity involves a biologic, sperm-producing sexual partner. Because of this, it is imperative that all transgender patients with potential for pregnancy have pregnancy testing as part of their preoperative workup.

Privacy

Transgender patients may incite undue curiosity and attention of perioperative staff due to lack of experience with this patient population. A chaperone should be present during physical examinations, and the gender of the chaperone should be decided on by the patient. To minimize invasion of privacy and maintain dignity for transgender patients, it is important to conduct physical examinations when medically indicated; clinicians must avoid delivering suboptimal care stemming from unfounded concerns surrounding privacy issues and fear of offending these patients.

INTRAOPERATIVE CARE

Caring for transgender patients during the intraoperative period requires unique, population-specific considerations involving anatomical, physiological, psychological, and pharmacological aspects. The anesthetic should be planned with careful consideration to all unique findings during the preoperative workup. Perioperative staff should be informed of the patient's preferred pronouns, and these should be maintained throughout the perioperative period.[46] As mentioned previously, privacy is important and efforts should be made to minimize traffic and rotation of staff in the operating room, especially if the surgical procedure involves exposure of the genitalia or chest area.

Venous Thromboembolism

Major perioperative concerns facing transgender patients include VTE such as deep vein thrombosis and pulmonary embolism. These hematological events are related to immobility during surgery for all patients, but the thrombotic effects of transgender HT put this patient population at higher risk. Transgender women are often taking estrogen therapy for testosterone suppression. Rates of VTE in the literature for transgender women on estrogen therapy range from 0% to 6%.[47,48] Protocols on the use of estrogen in transgender women

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should consider additional VTE risk factors such as smoking, hypercoagulable disorders, cancer diagnosis, length of surgery, and duration of immobilization.[47] Because of this, intraoperative VTE prophylaxis in the form of subcutaneous heparin and sequential compression devices are essential.[49]

Drug Interactions

There are no documented drug–drug interactions among estrogen, the various androgen blockers, and testosterone with anesthesia medications. Administration of anesthetic to transgender patients during the intraoperative period should proceed according to standard practice.

Anatomical Considerations

If a transgender patient has undergone gender-confirming surgery involving the urethra, such as vaginoplasty, phalloplasty, or metoidioplasty with urethral lengthening, placement of a urinary catheter may necessitate using a smaller catheter. In some circumstances, a urologist or other practitioner experienced with transgender anatomy may need to be consulted.

Transgender women may have completed a laryngoplasty and/or chondroplasty to alter the voice pitch. Risks of these procedures include vocal cord damage, reduction of tracheal lumen or stenosis, dysphagia,[50] or tracheal perforation. These are important details that directly affect intraoperative airway management and necessitate caution during intubation.[51]

In transgender men who have not undergone genderconfirming surgery, breast binders or chest wraps are commonly used. While literature is lacking, these can potentially pose risks to respiratory function due to their restrictive purpose. Providers must clearly explain to patients that these devices should not be present during the intraoperative and immediate postoperative period. An agreement should be established regarding appropriate time for removal as well as plan for reapplication that satisfies the patient.

Other Considerations

Transgender women experience higher rates of HIV infection.[40] Anesthesia providers need to be vigilant of increased intraoperative risks due to cardiovascular, respiratory, renal, and hepatic compromise. Additionally, antiviral medications are primarily metabolized by the cytochrome P450 enzymes. Sedatives, hypnotics, anxiolytics, and antibiotics may have significant interactions with antiretrovirals; hence, clinicians must assess for potential drug–drug interactions and altered metabolism.[52]

The cardiovascular risks associated with testosterone therapy in cisgender men are not well understood with data showing both increased and decreased risk as compared to a sex hormone–deprived state.[53] However, parenteral testosterone formulations are also associated with a greater incidence of erythropoietin production and hematocrits >48% are linked to higher rates of stroke due to greater blood viscosity.[42,54] Preexisting coronary artery disease and testosterone therapy warrant careful consideration during anesthesia induction, maintenance, and intraoperative monitoring to prevent cardiovascular complications.

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POSTOPERATIVE CARE

The postoperative period also poses a challenging time for transgender patients as they deal with issues of postoperative pain, withdrawal, anxiety, and depression. These are additive to existing concerns over discriminatory health care treatment. Patients should never feel disrespected in the health care setting; unintentional actions that lead to patient distress should be confronted directly and resolution should include a forthright admission that highlights the oversight or offensive event. Awkward or negative interactions with health care providers cause not only psychological discomfort in transgender patients but can also result in experiencing substandard or forced care and loss of the necessary trusting relationship between provider and patient. As previously emphasized, sensitivity training of staff is essential in fostering feelings of respect and trust between the transgender patient and health care provider.

Detailed report and handoff between care providers at different stages are important in the postoperative period when the patient may be unable to accurately confirm medical history and name/pronoun due to residual anesthetic effects.

Postanesthesia Care Unit

The postanesthesia care unit tends to be a busy, high traffic area, accessed by many health care providers, resulting in limited patient privacy. Health care providers should avoid having discussions that can be overheard by neighboring patients and staff who are not involved in the care of the transgender patient. While this is a principle that is applied to all patients, it is of utmost importance to the transgender population because of concerns over discriminatory health care treatment. When a transgender patient has visitors, health care providers must be cognizant of discussion with family and friends that could result in undesired “outing” of the patient.

Room Assignments

Transgender patients should be roomed in accordance with their gender identity. If the medical record is unable to accommodate sex and gender as distinct values, careful communication is necessary to ensure that staff involved in the care of the patient, including support staff, are aware of the intentional discrepancy. If a private room is available, it should be offered as an option because the increased privacy may provide additional comfort and/or safety for the patient. However, offering a private room as the only option should be avoided because it may cause patients to feel isolated instead.[55] It is important to note that including the patient in discussions around room assignment as early as possible will help circumvent issues before they arise.

Psychosocial Issues

Transgender people have been shown to have higher rates of anxiety and depression than the general population.[56] Mental health problems are often exacerbated by surgery and prolonged inpatient hospital stays.[57] When possible, use both pharmacological and nonpharmacological interventions to support the patient’s mental health in the postoperative period. A team approach involving mental health, social work, and spiritual care to address

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all aspects of the patient's discomfort often yields the best results. Community and social work support should also be implemented early in the postoperative period to ease the process of discharge and assist with the transition to recovery at home.

While pain management, as well as physical therapy/rehabilitation and mental health follow-ups are crucial in the subacute phase for the general population, it is of even greater importance for the transgender patients. They will require closer and more attuned follow-up visits with each of these services to address the complex and intertwined needs with a multiprong approach.

Transgender patients may have avoided health care due to fear of stigma and discrimination, leading to health conditions that are not well controlled. Transgender patients living with HIV, for example, are less likely to receive antiretrovirals and to achieve viral suppression.[58,59] This, along with other health conditions, such as higher rates of tobacco and illicit substance use may negatively impact recovery from surgery. To optimize postoperative care of these patients, the appropriate subspecialty services should be consulted early in the process with the goal of immediate and close follow-up in the postoperative period so as to facilitate the patient's recovery.

DISCUSSION

Facilitating easy access and coordination of various subspecialty services, such as endocrinology, anesthesiology, psychotherapy, psychiatry, and social work, ultimately promotes the perioperative care and recovery of the trans-gender patient. However, to achieve this consequential imperative, providers need to be properly educated and vetted in the care of the transgender patient.

Appropriate training for clinicians caring for this population requires both health information education and sensitivity training especially in light of the stigmas and misconceptions associated with the transgender community. Such training needs to begin early in the education of health care providers. For instance, many medical students have inadequate training in lesbian, gay, bisexual, transgender (LGBT) health and particularly in transgender medicine.[60] Residency training provides a time and opportunity for these gaps to be addressed. Program directors should ensure that topics in transgender health care are included in the residency training curriculum, addressing cultural competency and standards of care for HT and gender confirmation surgeries.

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Table 1

Terminology

Term	Definition
Cisgender	People whose gender identity matches their sex assigned at birth
Transgender male (female to male)	A person who was assigned female at birth but identifies as a man or on the masculine spectrum
Transgender female (male to female)	A person who was assigned male at birth but identifies as a woman or on the feminine spectrum
Nonbinary, gender nonconforming, genderqueer	Genders that fall outside the binary conceptualization of gender. A person may identify as both male and female, or as neither or a combination of male and female genders.

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Table 2

Collection of Gender Identity on a Patient Intake Form

1. What is your current gender identity? (check and/or circle all that apply)
   - ☐ Male
   - ☐ Female
   - ☐ Transgender male/transman/FTM
   - ☐ Transgender female/transwoman/MTF
   - ☐ Genderqueer
   - ☐ Additional category (please specify):_____
   - ☐ Decline to answer
2. What sex were you assigned at birth? (check one)
   - ☐ Male
   - ☐ Female
   - ☐ Decline to answer

Adapted from the University of California San Francisco, Center of Excellence for Transgender Health.

Abbreviations: FTM, female to male; MTF, male to female.

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Table 3

Gender Pronouns

Identification	Pronoun
Cis-male	He/him/himself
Cis-female	She/her/herself
Transgender male: female → male	He/him/himself
Transgender female: male → female	She/her/herself
Nonbinary: gender nonconforming	They/them/themself
Gender neutral	Zhe/zhim/zher/zhers/zhimself

Adapted from the Table “Proposed Mapping of Gender ID, Gender Markers, and Pronouns” from the article by Deutsch and Buchholz.[37]

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Table 4

Hormone Therapies for Gender Dysphoria

Male to Female	Female to Male
Androgen suppression	Testosterone
Cyproterone acetate (not available in United States)	Testosterone gel
Medroxyprogesterone acetate (IM)	Testosterone patch
Spironolactone (oral)	Testosterone undecanoate (IM only in United States)
Finasteride (oral)	Testosterone enanthate, cypionate (SQ, IM)
Histrelin (SQ implant)	Testopel (SQ implant)
Progesterone (oral)	
Estrogen	
Estradiol (oral, IM, SQ, transdermal)	

Abbreviations: IM, intramuscular; SQ, subcutaneous.

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Table 5

Published Observational Changes in Laboratory Values for Transgender People on Hormone Therapy Irrespective of Phenotypic Response

	Transwomen	Transmen
Increased	HDL[a]	Hematocrit
	LDL[a]	Hemoglobin
	Total cholesterol[a]	Red cell count
	Triglycerides[a]	ALT
		AST
		Creatinine
		Total cholesterol[a]
		Triglycerides[a]
		HDL[a]
Decreased	Hematocrit	HDL[a]
	Hemoglobin	
	ALT	
	AST	
	Creatinine	
	HDL[a]	
	LDL[a]	
	Total cholesterol[a]	
	Triglycerides[a]	
No change	Total cholesterol[a]	LDL
	Triglycerides[a]	HDL[a]
		Total cholesterol[a]
		Triglycerides[a]

Adapted from Goldstein et al.[46]

Abbreviations: ALT, alanine aminotransferase; AST, aspartate amino-transferase; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

[a]The literature shows contradictory data.

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REVIEW

The effect of cross-sex hormonal treatment on gender dysphoria individuals' mental health: a systematic review

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Abstract: Cross-sex hormonal treatment represents a main aspect of gender dysphoria health care pathway. However, it is still debated whether this intervention translates into a better mental well-being for the individual and which mechanisms may underlie this association. Although sex reassignment surgery has been the subject of extensive investigation, few studies have specifically focused on hormonal treatment in recent years. Here, we systematically review all studies examining the effect of cross-sex hormonal treatment on mental health and well-being in gender dysphoria. Research tends to support the evidence that hormone therapy reduces symptoms of anxiety and dissociation, lowering perceived and social distress and improving quality of life and self-esteem in both male-to-female and female-to-male individuals. Instead, compared to female-to-male individuals, hormone-treated male-to-female individuals seem to benefit more in terms of a reduction in their body uneasiness and personality-related psychopathology and an amelioration of their emotional functioning. Less consistent findings support an association between hormonal treatment and other mental health-related dimensions. In particular, depression, global psychopathology, and psychosocial functioning difficulties appear to reduce only in some studies, while others do not suggest any improvement in these domains. Results from longitudinal studies support more consistently the association between hormonal treatment and improved mental health. On the contrary, a number of cross-sectional studies do not support this evidence. This review provides possible biological explanation vs psychological explanation (direct effect vs indirect effect) for the hormonal treatment-induced better mental well-being. In conclusion, this review indicates that gender dysphoria-related mental distress may benefit from hormonal treatment intervention, suggesting a transient reaction to the nonsatisfaction connected to the incongruent body image rather than a stable psychiatric comorbidity. In this perspective, timely hormonal treatment intervention represents a crucial issue in gender dysphoria individuals' mental health-related outcome.

Keywords: estrogen, testosterone, transsexualism, psychiatry, psychosocial wellbeing

Introduction

A strong and persistent cross-gender identification as well as a persistent discomfort with one's natal sex or a sense of inappropriateness in the gender role of that sex has been considered as a core aspect of nonconforming gender identity since the first inclusion of the condition in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) of the American Psychiatric Association.[1] Until the last DSM revision,[2] the condition has been known as "transsexualism/gender identity disorder".[1,3,4] In 2013, the American Psychiatric Association has significantly revised the condition definition in an attempt to balance between the competing issues of depathologizing nonconforming

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gender identity vs access to care.[2,5] As a consequence, the condition has been renamed "gender dysphoria" in order to imply a diagnostic entity in its own right, not necessarily associated with severe comorbid psychiatric findings, and better characterize the gender incongruence-related experience and discomfort.[2] However, psychiatric comorbidity among individuals with gender dysphoria is still a matter of discussion. Some studies have reported a high prevalence of major psychiatric disorders in gender dysphoria.[6–8] Instead, other research suggests a low level of psychopathology.[9–11] A recent review has concluded that gender dysphoria individuals appear to have a higher risk of psychiatric comorbidity.[12] However, as reported by the authors, many studies were methodologically weak, and sex reassignment procedures appeared to be beneficial in reducing mental distress.[12] Therefore, the lack of consistency between studies about gender dysphoria individuals' psychiatric comorbidity could be partially explained by their design, which usually did not explore the role of the lack of treatment in gender dysphoria individuals' mental distress.

For most gender dysphoria individuals, the subjective experience of persistent cross-gender identification and discomfort with their natal sex may be a stressful situation and cause clinical distress or impairment in important areas of functioning.[9,13,14] Suffering from severe gender incongruence usually leads individuals to pursue hormone treatment and sex reassignment surgery. The purpose of these sex reassignment procedures is to alleviate the individual's distress by reducing the discrepancy between the individuals' biological sex and their experience.[15] Over the last few decades, research has prevalently focused on the effect of sex reassignment surgery on gender dysphoria individuals' mental health. In particular, previous research has suggested that sex reassignment surgery improves gender dysphoria individuals' well-being, increasing their personal and general satisfaction,[16–18] self-confidence with body image,[19–22] and quality of life.[23–26] In contrast, the role of the cross-sex hormonal treatment in the well-being of gender dysphoria individuals has been the subject of relatively little investigation. A 2010 meta-analysis has identified 28 observational studies of the effect of sex reassignment on gender dysphoria individuals' well-being.[27] However, only five studies specifically examined the impact of hormonal treatment and two of them focused on gender-related cognitive aspects, which could be influenced by cross-sex hormones and per se do not inform on hormone-treated individuals' mental health or well-being.[28,29] The remaining three studies addressed the effect of hormonal treatment on gender dysphoria individuals' psychological profile,[30] emotional repercussions,[31] and transformation satisfaction.[32] However, due to its design, the latter one[32] could not infer an association between hormonal treatment and better transformation satisfaction.

Studying the effect of cross-sex hormonal treatment on mental health in gender dysphoria may help to disentangle the burden of psychiatric comorbidity among individuals suffering from this condition. In recent years, a larger body of evidence has accumulated from studies on the specific effect of hormonal treatment on different mental health-related outcome measures. The purpose of this review is to bring together and discuss all available data generated by cross-sectional and longitudinal studies that have investigated the effect of hormone therapy on mental health by carrying out a systematic literature search for all such data.

Materials and methods

Inclusion/exclusion criteria

Inclusion criteria for studies were as follows: 1) studies in gender dysphoria, 2) studies investigating the mid/long-term effects of cross-sex hormonal treatment, and 3) studies measuring mental health-related parameters, including a) depression, b) anxiety, c) personality, d) quality of life, e) dissociative symptoms, f) psychopathology, g) psychosocial/emotional functioning, h) distress, and i) self-esteem. Exclusion criteria were as follows: 1) studies in which cross-sex hormonal treatment was not the intervention of interest (ie, studies including cross-sex hormonal treatment only as a confounder/covariate of no interest) and 2) studies in which the mental health-related outcomes were not directly reported upon.

Search strategy

A final search was undertaken on May 16, 2016. The search terms used were as follows: (gender dysphoria or gender identity disorder or transsexualism) and (hormon* or cross-sex hormonal treatment or hormone therapy) and (psych* or psychiatry or psychopathology or mental health or anxiety or depression). This search was undertaken in Medline, EMBASE, and PsycINFO using the OvidSP platform. All studies published in any language and indexed in the above databases were included. Reference lists from all identified relevant studies, reviews, and conference abstracts were screened for any additional relevant studies.

Data extraction

Demographic and methodological variables and outcome data for studies identified were extracted into a spreadsheet. Primary outcomes of interest were mental health-related parameters. These were compared within hormone-treated

cohorts and/or between hormone-treated and nonhormone-treated control groups.

Risk of bias

Risk of bias and quality assessment of the methodologically heterogeneous group of studies (Table 1) reviewed here required a suitably inclusive and flexible approach. For this purpose, an adapted set of criteria, suggested by the Agency for Healthcare Research and Quality guidance,[33] amended as appropriate for observational studies in humans were used (Table 2). Risk of systematic bias across studies was further identified by assessing all articles for possible confounding factors, such as study population definition, mental health comorbidity, attrition, comparability of subjects, cross-sex hormonal treatment duration, type, and dosage (Table 3).

Results

Study selection

In total, 680 records were identified. All abstracts of the records were screened against the inclusion and exclusion criteria. A final list of 17 studies was identified for systematic analysis in this review. Cumulatively, the included studies investigated different aspects of mental health (Table 1) in response to cross-sex hormonal treatment, using both independent-groups (cross-sectional studies) and repeated measures (longitudinal studies) designs. These include 1) depression, mood states, and self-esteem; 2) anxiety and tension; 3) global and personality-related psychopathology; 4) mental health-related quality of life; 5) dissociative symptoms; 6) psychosocial, interpersonal, and emotional functioning; and 7) social distress, perceived stress,

Table 1 Studies included in the review

Study	Type of study	Target population(s)	Mental health parameters
Bonierbale et al[42]	Cross-sectional study	GID adults with CSHT vs GID adults without CSHT	Personality-related psychopathology
Bouman et al[38]	Cross-sectional study	MtF adults with CSHT vs MtF adults without CSHT	Anxiety, depression, self-esteem, and interpersonal functioning
Colizzi et al[45]	Longitudinal study	GD adults before and after CSHT	Dissociative symptoms
Colizzi et al[37]	Longitudinal study	GID adults before and after CSHT	Anxiety, depression, psychopathological symptoms, and psychosocial functioning
Fisher et al[39]	Cross-sectional study	GD adults with CSHT vs GD adults without CSHT	Body uneasiness and psychopathological symptoms
Gómez-Gil et al[44]	Cross-sectional study	GID adults with CSHT vs GID adults without CSHT	Mental health-related quality of life
Heylens et al[40]	Longitudinal study	GID adults before and after CSHT	Psychopathological symptoms
Colizzi et al[14]	Longitudinal study	GID adults before and after CSHT	Perceived stress
Gorin-Lazard et al[36]	Cross-sectional study	GID adults with CSHT vs GID adults without CSHT	Self-esteem, depression, quality of life, and psychosocial functioning
Gómez-Gil et al[35]	Cross-sectional study	GID adults with CSHT vs GID adults without CSHT	Social distress, anxiety, and depression
Gorin-Lazard et al[43]	Cross-sectional study	GID adults with CSHT vs GID adults without CSHT	Mental health-related quality of life
Gómez-Gil et al[41]	Cross-sectional study	GID adults with CSHT vs GID adults without CSHT	Personality-related psychopathology
Miles et al[29]	1. Longitudinal study 2. Longitudinal study 3. Longitudinal study 4. Cross-sectional study	1. MtF GID adults before and after CSHT 2. MtF GID adults with CSHT and after withdrawal 3. MtF GID adults before and after CSHT 4. MtF GID adults with CSHT vs MtF GID adults without CSHT	Mood states
Newfield et al[24]	Cross-sectional study	FtM adults with CSHT vs FtM adults without CSHT	Mental health-related quality of life
Slabbekoorn et al[31]	Longitudinal study	MtF and FtM adults before and after CSHT	Emotional functioning, affect intensity, anger readiness, nonverbal emotional expressiveness, and mood states
Blanchard et al[34]	Cross-sectional study	MtF adults	Psychological (depression and tension) and social (cohabitation and involvement) adjustment
Leavitt et al[30]	Cross-sectional study	MtF adults with CSHT vs MtF adults without CSHT	Personality-related psychopathology

Abbreviations: CSHT, cross-sex hormonal treatment; FtM, female-to-male; GD, gender dysphoria; GID, gender identity disorder; MtF, male-to-female.

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Table 2 Summary of studies of effect of hormonal treatment on mental health in gender dysphoria

Study	Aim of study	Population receiving CSHT	Age (years), mean ± SD	Sample (N)	Assessment instrument(s)	Type of assessment(s)	Results
Bonierbale et al[42]	Effect of CSHT on personality traits	37 MtF and 15 FtM	Median: 31, range: 18–58 (age at assessment; age information regarded both GID individuals with and without CSHT)	106	MMPI-2	Self-reported	Lower psychopathology in CSHT adults
Bouman et al[38]	Effect of CSHT on anxiety, depression, self-esteem, and interpersonal functioning	38 MtF	MtF: 58.03±5.87 (age at the assessment)	71	HADS, RSE, and IIP-32	Self-reported	Lower anxiety, higher level of self-esteem, less problems with socialization, and interpersonal functioning in CSHT MtF; no effect of CSHT on depression
Colizzi et al[45]	Effect of CSHT on dissociative symptoms	82 MtF and 36 FtM	MtF: 30.41±9.77; FtM: 29.81±6.39 (ages at onset of CSHT and at study recruitment were the same)	118	DES	Self-reported	Lower dissociative symptoms after CSHT with levels lower than that found in general population
Colizzi et al[37]	Effect of CSHT on anxiety, depression, psychopathological symptoms, and functional impairment	78 MtF and 29 FtM	MtF: 29.25±7.27; FtM: 29.08±8.48 (ages at onset of CSHT and at study recruitment were the same)	107	SAS, SDS, SCL-90-R, and SCID-I	Self-reported and clinical interview	Lower anxiety, depression, psychopathological symptoms, and functional impairment after CSHT
Fisher et al[39]	Effect of CSHT on body uneasiness and psychopathological symptoms	42 MtF and 26 FtM	MtF: 33.1±10.25; FtM: 28.7±6.5 (age information regarded both GID individuals with and without CSHT)	125	BUT and SCL-90-R	Self-reported	Lower body uneasiness only in CSHT MtF adults and positive effect of cumulative dose of estradiol on body uneasiness reduction; no effect of CSHT on psychopathological symptoms
Gómez-Gil et al[44]	Effect of CSHT on mental health quality of life	120 GID adults	31.2±9.9 (age at assessment; age information regarded both GID individuals with and without CSHT)	193	WHOQOL-BREF	Self-reported	Higher social and psychological quality of life in CSHT adults
Heylens et al[40]	Effect of CSHT on psychopathological symptoms	46 MtF and 11 FtM	Not mentioned	57	SCL-90-R and psychosocial questionnaire	Self-reported	Lower psychopathological symptoms after CSHT with levels similar to general population; no effect of CSHT on psychosocial parameters
Colizzi et al[14]	Effect of CSHT on perceived stress	45 MtF and 25 FtM	MtF: 29.25±9.87; FtM: 26.78±8.09 (ages at onset of CSHT and at study recruitment were the same)	70	PSS	Self-reported	Lower perceived stress after CSHT with levels similar to normative samples
Gorin-Lazard et al[36]	Effect of CSHT on self-esteem, depression, quality of life, and global functioning	29 MtF and 20 FtM	35.1±10.2	67	SSEI, BDI, SQUALA, and GAF	Self-reported	Higher self-esteem and quality of life and lower depressive symptoms in CSHT adults; no effect of CSHT on global functioning
Gómez-Gil et al[35]	Effect of CSHT and its duration on social distress, anxiety, and depression	84 MtF and 36 FtM	24.6±8.1 (at onset of CSHT); 33.6±9.1 (at study recruitment)	187	SADS and HADS	Self-reported	Lower social distress, anxiety, and depression in CSHT adults; no effect of CSHT duration on these parameters

Gorin-Lazard et al[43]	Effect of CSHT on mental health-related quality of life	25 MtF and 19 FtM	MtF: 39.4±9.8; FtM: 29.9±8.4 (age information regarded both GID individuals with and without CSHT)	61	SF-36	Self-reported	Higher emotional, social, and mental quality of life in CSHT adults, with higher mental health-related quality of life than in non-GID controls
Gómez-Gil et al[41]	Effect of CSHT on personality traits	69 MtF and 10 FtM	MtF: 29.9±9; FtM: 27.6±7.5 (age at assessment; age information regarded both GID individuals with and without CSHT)	163	MMPI-2	Self-reported	Lower psychopathology in CSHT MtF adults; no effect of CSHT in FtM
Miles et al[29]	1. Effect of CSHT on mood states 2. Effect of CSHT withdrawal on mood states 3. Effect of CSHT duration on mood states 4. Effect of CSHT on mood states	1. 27 MtF 2. 27 MtF 3. 20 MtF 4. 74 MtF	1. 37.07±8.68 2. 39.63±9.68 3. 40.30±7.50 4. X	103	POMS	Self-reported	1. Higher confidence and composure in CSHT MtF adults 2. No effect 3. No effect 4. Higher confidence and composure in CSHT MtF adults
Newfield et al[24]	Effect of CSHT and its duration on mental health-related quality of life	248 FtM	FtM: 32.6±10.8 (age at assessment; age information regarded both GID individuals with and without CSHT)	365	SF-36	Self-reported	Higher emotional, social, and mental quality of life in CSHT FtM adults, with CSHT duration associated with higher emotional quality of life
Slabbekoorn et al[31]	Effect of CSHT on emotional functioning, affect intensity, anger readiness, nonverbal emotional expressiveness, and mood states	54 MtF and 47 FtM	MtF: 32.9±10.8; FtM: 25.7±7.5 (ages at onset of CSHT and at study recruitment were the same)	101	ELOMS, AIM, ASQ, ACT, and PAF	Self-reported	Higher positive emotions, affect intensity, anger readiness, and emotional expressiveness in MtF after CSHT; higher aggressive emotions and anger readiness, and lower affect intensity in FtM after CSHT; and no effect of CSHT on mood in FtM adults
Blanchard et al[34]	Effect of CSHT on psychological (depression and tension) and social (cohabitation and involvement) adjustment	34 MtF	27.9±8.8 (age at assessment; age information regarded both GID individuals with and without CSHT)	55	Annual questionnaire and MMPI	Self-reported	No effect of CSHT on psychological and social adjustment
Leavitt et al[30]	Effect of CSHT and its duration on personality traits	22 MtF	26.6±3.6	41	MMPI	Self-reported	Lower psychopathology in CSHT MtF adults with scores tending to approximate the norms for male populations; positive effect of CSHT duration on psychopathology reduction

Note: N, entire sample involved in the study.

Abbreviations: AIM, affect intensity measure; ACT, affective communication test; ASQ, short anger situation questionnaire; BDI, Beck Depression Inventory; BUT, body uneasiness test; CSHT, cross-sex hormonal treatment; DES, Dissociative Experiences Scale; ELOMS, expectancy list of mood and sexual interest; FtM, female-to-male; GAF, Global Assessment of Functioning scale; GID, gender identity disorder; HADS, Hospital Anxiety and Depression Scale; IIP-32, Inventory of Interpersonal Problems-32; MMPI-2, Minnesota Multiphasic Personality Inventory-2; MtF, male-to-female; PAF, premenstrual assessment form; POMS, Profile of Mood States; PSS, Perceived Stress Scale; RSE, Rosenberg Self-Esteem Scale; SADS, Social Anxiety and Distress Scale; SAS, Zung Self-rating Anxiety Scale; SCL-90-R, Symptom Checklist-90-R; SCID-I, Structured Clinical Interview for *Diagnostic and Statistical Manual of Mental Disorders* I; SDS, Zung Self-rating Depression Scale; SSEI, Social Self-Esteem Inventory; SF-36, Short Form (36) Health Survey; SQUALA, Subjective Quality of Life Analysis; WHOQOL-BREF, World Health Organization Quality of Life-shorter version; "X", not mentioned.

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Table 3 Methodological quality of studies of effect of hormonal treatment on mental health in gender dysphoria

Study	Defined study population	CSHT mean duration	CSHT type and dosage	Control
Bonierbale et al[42]	✓ GID formal diagnosis at a gender clinic according to DSM-IV criteria	✓/× 3 months at least for both MtF and FtM	× Not mentioned	✓/× No; comparison with 16 MtF and 38 FtM without CSHT
Bouman et al[38]	✓/× Formal diagnosis at a gender clinic, criteria not mentioned	× Not mentioned	✓/× MtF: estrogens, tablet form or patches (n=21); sometimes in association with cyproterone acetate, spironolactone, or finasteride (n=11); and no information provided for 17 individuals on CSHT dosage, molecule nature, or administration modalities	✓/× No; comparison with 33 MtF adults without CSHT
Colizzi et al[45]	✓ GD formal diagnosis at a gender clinic according to DSM-5 SCID-I criteria	✓ 12 months for both MtF and FtM	✓ MtF: transdermal estradiol gel (1.84±0.49 mg/d) in association with oral cyproterone acetate (100 mg/d) and FtM: IM testosterone (250 mg every 26.31±2.68 days)	✓/× No; normative data from a sample of 1,055 subjects
Colizzi et al[37]	✓ GID formal diagnosis at a gender clinic according to DSM-IV SCID-I criteria	✓ 12 months for both MtF and FtM	✓ MtF: transdermal estradiol gel (1.82±0.53 mg/d) in association with oral cyproterone acetate (100 mg/d) and FtM: IM testosterone (250 mg every 26.24±2.71 days)	× No
Fisher et al[39]	✓ GD formal diagnosis at different gender clinics according to DSM-IV criteria	✓ MtF: 467±323 days and FtM: 1,940±2,595 days	✓/× MtF: estradiol valerate (n=12), transdermal estradiol hemihydrate (n=12), estradiol gel (n=6), and oral cyproterone acetate (n=39) and FtM: IM testosterone enanthate (n=12), IV testosterone undecanoate (n=1), and transdermal testosterone (n=9); no information on four FtM and CSHT dosage	✓/× No; comparison with 57 GD adults without CSHT (24 MtF and 33 FtM)
Gómez-Gil et al[44]	✓ GID formal diagnosis at a gender clinic according to DSM-IV and ICD-10 criteria	× Not mentioned	× Not mentioned	✓/× No; comparison with 73 GID adults without CSHT
Heylens et al[40]	✓ GID formal diagnosis at a gender clinic according to DSM-IV criteria	✓/× 3–6 months for both MtF and FtM	× Not mentioned	× No
Colizzi et al[14]	✓ GID formal diagnosis at a gender clinic according to DSM-IV SCID-I criteria	✓ 12 months for both MtF and FtM	✓ MtF: transdermal estradiol gel (1.77±0.46 mg/d) in association with oral cyproterone acetate (100 mg/d) and FtM: IM testosterone (250 mg every 27.12±2.64 days)	✓/× No; normative data from a sample of 645 subjects
Gorin-Lazard et al[36]	✓ GID formal diagnosis at a gender clinic according to DSM-IV criteria	✓ 12 months at least for both MtF and FtM	✓/× MtF: cyproterone acetate followed by estrogens combined with antiandrogens (luteinizing hormone-releasing hormone analogs) and FtM: synthetic progestagens followed by testosterone (dosage, molecule nature, and administration modalities of CSHT not reported)	✓/× No; comparison with 18 GID adults without CSHT (seven MtF and eleven FtM)

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Comparability of subjects	Statistical analysis	Mental health comorbidity	Attrition	Funding or sponsorship
✓ Sociodemographic characteristics for GID adults with and without CSHT not reported, however, analyses controlled for age, age on onset, and sexual orientation	✓ Mann–Whitney *t*-test, chi-square or Fisher's exact tests, and logistic regression	× Not mentioned	✓/× No available data in 26% of the original cohort (N=143) for different reasons (N=29 patients not eligible for sex reassignment surgery; N=6 with no valid MMPI; N=2 missing data)	✓ Declared
✓ Significant difference in age of referral, coming out, and transitioning; sociodemographic characteristics matched (ethnic group, employment, civil status, and children)	✓ Chi-square, Mann–Whitney *U*-test, and MANCOVA	✓ Psychiatric history was not exclusion criterion, however, clinical characteristics (psychiatric history and self-harm) matched	✓/× No available data in 7.8% of the original cohort (N=77; three did not attend appointment and three FtM excluded from analysis due to small number)	✓ Declared
✓ Pre/postgroups were the same	✓ *t*-test	✓ Unstable psychiatric comorbidity was exclusion criterion	✓ 0 lost at recruitment or follow-up	✓ Declared
✓ Pre/postgroups were the same	✓ McNemar test and *t*-test	✓ Unstable psychiatric comorbidity was exclusion criterion	✓ 0 lost at recruitment or follow-up	✓ Declared
✓ Sociodemographic characteristics for GID adults with and without CSHT not reported, however, analyses controlled for gender, age, gender role, and surgery	✓ ANCOVA and two-step hierarchical linear regression	× Not mentioned (mental retardation was exclusion criterion)	✓/× 55% of original cohort (N=275) were excluded for different reasons (CSHT treatment prior to the study, disorder of sexual development, internalized homophobia, transvestite fetishism, mental retardation, dropout during the assessment, and completed genital reassignment surgery	✓ Declared
✓ Sociodemographic characteristics for GID adults with and without CSHT not reported, however, analyses controlled for gender, age, education, working/student status, partnership status, and family support	✓ Multiple linear regression	× Not mentioned	✓/× No available data in 30% of the original cohort (N=277) for different reasons (N=17 patients refused to participate in the study; N=59 were incomplete answers; and N=8 previous genital surgery)	✓ Declared
✓/× Pre/postgroups were not the same, no mention of possible differences between GID adults completing/not completing follow-up evaluation	✓ Friedman test and Wilcoxon test	✓/× Personality disorder was exclusion criterion	✓/× No available data in 37% of the original cohort (N=90) for different reasons (refused to participate, attended the clinic once, GID NOS, and comorbidity) and 17.5% of the recruited subjects lost at follow-up	✓ Declared
✓ Pre/postgroups were the same	✓ *t*-test	✓ Psychiatric comorbidity was exclusion criterion	✓ 0 lost at recruitment or follow-up	✓ Declared
✓ Significant difference in age and sexual orientation, but corrected	✓ Mann–Whitney *U*-test and multiple linear regression	✓ Psychotic disorder and unstable psychiatric comorbidity (except nonmajor depressive disorder) were exclusion criteria	✓ 0 lost at recruitment	✓ Declared

(*Continued*)

AR-002725

Table 3 (*Continued*)

Study	Defined study population	CSHT mean duration	CSHT type and dosage	Control
Gómez-Gil et al[35]	✓ GID formal diagnosis at a gender clinic according to DSM-IV and ICD-10 criteria	✓ MtF: 11 years and FtM: 4.7 years	✓ MtF: oral estrogens (conjugated estrogens 1.8–2.4 mg/d or estradiol valerate 2–4 mg/d) or transdermal estradiol patches (3 mg twice per week, delivering 100 mg/d), generally in association with oral cyproterone acetate (25–50 mg/d) and FtM: IM testosterone (1,000 mg every 10–14 weeks), or daily transdermal testosterone gel (50 mg/d)	✓/× No; comparison with 67 GID adults without CSHT (29 MtF and 38 FtM)
Gorin-Lazard et al[43]	✓ GID formal diagnosis at a gender clinic according to DSM-IV MINI criteria	✓ 12 months at least for both MtF and FtM	✓/× MtF: antiandrogens along with estrogens and FtM: synthetic progestagens with testosterone (dosage, molecule nature, and administration modalities of CSHT not reported)	✓/× No; comparison with 17 GID adults without CSHT (six MtF and eleven FtM); controls from a normative sample of 3,656 subjects
Gómez-Gil et al[41]	✓ GID formal diagnosis at a gender clinic according to DSM-IV criteria	✓ 12 months at least for both MtF and FtM	× Not mentioned	✓/× No; comparison with 84 GID adults without CSHT (38 MtF and 46 FtM)
Miles et al[29]	✓ GID formal diagnosis at a gender clinic according to DSM-IV criteria	1. ✓/× 3–12 months for both MtF and FtM 2. ✓/× at least 8 weeks of withdrawal after at least 28 months of CSHT for both MtF and FtM 3. ✓/× 6–15 months for both MtF and FtM 4. ×	✓ Conjugated equine estrogens (1.25–7.5 mg/d) or ethinyl estradiol (10–15 μg/d), sometimes in association with cyproterone acetate (50–150 mg/d) or medroxyprogesterone acetate (15 mg/d)	✓/× No 4. Comparison with MtF without CSHT
Newfield et al[24]	× Not mentioned	✓/× <5 years for the majority of FtM (n=203)	× Not mentioned	✓/× No; comparison with 117 FtM adults without CSHT
Slabbekoorn et al[31]	✓/× Formal diagnosis at a gender clinic, criteria not mentioned	✓/× 14 weeks for both MtF and FtM	✓ MtF: oral cyproterone acetate (50 mg/twice a day) in combination with oral ethinyl estradiol (0.05 mg/twice a day, n=32) or 17β-estradiol plasters (0.1 mg/d, n=22); FtM: IM testosterone esters (250 mg/2 weeks, n=42),or oral undecanoate testosterone (200 mg/d, n=5)	× No
Blanchard et al[34]	✓/× Formal diagnosis at a gender clinic, criteria not mentioned	× Not mentioned	× Not mentioned	✓/× No; comparison with 21 MtF adults without CSHT
Leavitt et al[30]	× Not mentioned	✓ 12 months at least	✓/× Oral conjugated estrogens and medroxyprogesterone (cyclically each month in a dose sufficient to inhibit spontaneous erections)	✓/× No; comparison with 19 MtF adults without CSHT

Note: ✓, good quality; ✓/×, fair quality; ×, poor quality.

Abbreviations: ANCOVA, analysis of covariance; ANOVA, analysis of variance; CSHT, cross-sex hormonal treatment; DSM, Diagnostic and Statistical Manual of Mental Disorders; FtM, female to male; GD, gender dysphoria; GID, gender identity disorder; ICD-10, international classification of diseases – 10th revision; IM, intramuscular; IV, intravenous; MANCOVA, multivariate analysis of covariance; MINI, mini-international neuropsychiatric interview; MMPI-2, Minnesota Multiphasic Personality Inventory-2; MtF, male to female; NOS, not otherwise specified; SCID-I, Structured Clinical Interview for DSM I.

AR-002726

Comparability of subjects	Statistical analysis	Mental health comorbidity	Attrition	Funding or sponsorship
✓ Significant difference in age, MtF prevalence, and level of education (without CSHT < CSHT), but these were corrected. Other sociodemographic characteristics matched (living arrangements, sexual orientation, and employment status)	✓ ANOVA/ ANCOVA, chi-square, and Pearson's correlation	× Not mentioned	✓/× No available data in 6.5% of original cohort (N=200)	✓ Declared
✓ Sociodemographic characteristics matched (age for GID adults with and without CSHT and age and sex for GID adults and non-GID controls)	✓ Mann–Whitney test, multiple linear regression, and *t*-test	✓ Psychotic disorder and unstable psychiatric comorbidity (except non major depressive disorder) were exclusion criteria	✓/× No available data in 9% of original cohort (N=67)	✓ Declared
× Not mentioned	✓ *t*-test	× Not mentioned	✓/× No available data in 36% of the original cohort (N=254) for different reasons (N=24 patients failed to meet GID DSM-IV criteria; N=24 patients were administered the MMPI instead of MMPI-2; and N=43 were missing data)	× Not declared
1., 2., and 3. ✓ Pre/postgroups were the same 4. × Significant difference in age, not corrected	✓ MANOVAs and Pearson's correlation	× Not mentioned	✓ 0 lost at recruitment or follow-up	✓ Declared
✓/× Sociodemographic characteristics not reported; analyses were controlled for income and education	✓ ANOVA/ ANCOVA	× Not mentioned	✓/× No available data in 18% of the original cohort (N=446) for different reasons (not from the US, identified as female/no gender information, no information on quality of life or CSHT)	× Not declared
✓ Pre/postgroups were the same	✓ ANOVA and *t*-test	× Not mentioned	✓ 0 lost at recruitment or follow-up	× Not declared
✓ Sociodemographic characteristics for GID adults with and without CSHT not reported, however, analyses controlled for age and social feminization	✓ Multiple regression	✓/× Not mentioned (gender complaint-related psychotic delusion was exclusion criterion)	✓/× No available data in 44% of the original cohort (N=98) for different reasons (N=42 patients excluded because of not expressing – clear – homosexual orientation; N=1 excluded due to Klinefelter's syndrome)	× Not declared
✓ Sociodemographic characteristics matched (age and education)	✓ *t*-test and Pearson's correlation	× Not mentioned	✓ 0 lost at recruitment	× Not declared

AR-002727

and body uneasiness. Key findings are reported in Table 2, and a brief synopsis of them is reported later.

Effect of cross-sex hormonal treatment on depression, mood states, and self-esteem

Depression and its features have been the most extensively investigated mental health-related parameters in gender dysphoria individuals receiving hormonal treatment. The first study to investigate this issue was carried out in 1983.[34] This cross-sectional study assessed male-to-female (MtF) individuals' psychological adjustment depending on their hormonal treatment status. The research did not find any significant difference in terms of depressive symptoms between MtFs with and without hormonal treatment.[34] In a second study, Slabbekoorn et al[31] asked female-to-male (FtM) individuals to keep a mood diary during their testosterone administration. Results indicated no mood changes when assessing depressed mood and other mood-related parameters from baseline to after the fourth testosterone injection.[31] Miles et al[29] used a unique design to disentangle the hormonal treatment contribution to mood in gender dysphoria. Using both independent groups (longitudinal study) and repeated measure (cross-sectional study) designs, this study consistently indicated that hormone-treated MtFs are more composed and confident. Authors also tested for the effect of hormonal treatment withdrawal and duration on mood. Intriguingly, they reported no significant association.[29] In recent years, four more studies have investigated the association between hormonal treatment and depression, using commonly used questionnaires/scales.[35–38] Apart from a study,[38] which reported no significant differences in terms of depression (it only investigated MtFs), the remaining studies reported lower depressive symptoms in gender dysphoria individuals receiving hormonal treatment.[35–37] Two of these studies also assessed self-esteem, reporting higher levels of self-esteem due to the hormonal treatment intervention.[36,38]

Effect of cross-sex hormonal treatment on anxiety and tension

Different from depression, anxiety has been investigated only recently, with three studies addressing this aspect over the last 5 years.[35,37,38] All these three investigations (two cross-sectional studies and one longitudinal one) have consistently reported a reduction in symptoms of anxiety among individuals receiving hormone therapy. A previous research had studied tension as a measure of psychological adjustment, reporting no significant differences between MtFs with and without hormonal treatment.[34]

Effect of cross-sex hormonal treatment on global and personality-related psychopathology

This review has identified three recent studies about the effect of cross-sex hormonal treatment on a global measure of psychopathology.[37,39,40] Intriguingly, all these studies used the same questionnaire. However, while two studies described a significant decrease in global psychopathology occurring after the initiation of hormone therapy,[37,40] a third one did not find any difference between hormone-treated and nonhormone-treated individuals.[39] Interestingly, according to the authors, their negative finding may be attributable to the restricted range and low levels of psychopathology observed in their sample.

Three other studies investigated personality-related psychopathology as a function of cross-sex hormonal treatment, using a similar methodology.[30,41,42] Using a common measure of personality, this body of research has suggested a reduction in personality-related psychopathology among gender dysphoria individuals receiving hormone therapy. However, as one study focused only on MtF individuals[30] and a second study reported hormonal treatment to be beneficial only in MtF and not in FtM individuals,[41] there is still little evidence to suggest a positive effect of cross-sex hormonal treatment on FtM individuals' personality-related psychopathology.[42] Leavitt et al[30] also indicated that the hormone-treated MtF individuals' overall personality-related psychopathology tends to approximate the norms for male populations and negatively correlates with the hormone therapy duration.

Effect of cross-sex hormonal treatment on mental health-related quality of life

The first study to investigate the quality of life among gender dysphoria individuals receiving hormonal treatment was performed in 2006 on a large sample of FtM individuals.[24] With ~250 FtMs receiving cross-sex hormonal treatment, this study sample represents the largest one identified in this systematic review. The research reported higher emotional, social, and mental quality of life in hormone-treated FtM adults, with hormonal treatment duration associated with higher emotional quality of life.[24] Three more recent studies confirmed a better psychosocial and mental quality of life in both MtFs and FtMs receiving hormone therapy.[36,43,44] One study also compared hormone-treated individuals with

a control group, reporting a higher mental health-related quality of life in gender dysphoria individuals.[43]

Effect of cross-sex hormonal treatment on dissociative symptoms

To date, only one study has investigated the prevalence of dissociative symptoms among gender dysphoria individuals receiving cross-sex hormonal treatment.[45] Results of this longitudinal study suggest that suffering from dissociative symptoms may be a common clinical feature in the context of untreated gender dysphoria. Interestingly, this research indicated a significant reduction in gender dysphoria individuals' dissociative symptoms after the beginning of cross-sex hormonal treatment. It is worth reporting that the high prevalence of dissociative symptoms among untreated gender dysphoria individuals was greatly due to the gender-related sense of strangeness. This issue could explain why the dissociative experience was less intense when gender dysphoria individuals received hormone therapy. The unease with the biological sex and the aversion to the corresponding sex-specific body forms belong by definition to the gender dysphoria diagnosis.[2] Therefore, authors argued whether dissociation represents a genuine feature of gender dysphoria rather than a clinically relevant pathological manifestation, highlighting the need for additional/exclusion criteria for a differential diagnosis.[45]

Effect of cross-sex hormonal treatment on psychosocial, interpersonal, and emotional functioning

Psychosocial functioning has been the domain receiving most attention after depression in hormone-treated individuals. Different aspects have been investigated, such as emotional[31] and social components.[34,38] Also two studies have investigated a global measure of psychosocial functioning.[36,37] Impact of hormone therapy on emotional functioning appeared to be different in MtF and FtM individuals, with more generally positive effects in MtF and some undesirable effects in FtM individuals.[31] While Blanchard et al[34] did not find any effect of hormone therapy on social adjustment, a more recent study has identified less problems with socialization and interpersonal functioning in gender dysphoria individuals receiving hormone therapy.[38] Finally, mixed results have emerged from studies investigating global psychosocial functioning, with a study reporting less functional impairment after the beginning of hormone therapy[37] and another one finding no significant differences as a result of hormonal treatment.[36]

Effect of cross-sex hormonal treatment on social distress, perceived stress, and body uneasiness

This review identified three studies specifically analyzing distress intensity among gender dysphoria individuals and how it could be influenced by the hormonal treatment intervention.[14,35,39] These studies used the following three different measures of distress: 1) social distress, ie, avoidance and subjective distress about social interactions; 2) perceived stress, ie, perception of social life experiences as stressful and unpredictable/uncontrollable; and 3) body uneasiness, ie, gender-related distress and discomfort. Using a cross-sectional design, Gómez-Gil et al[35] reported that gender dysphoria individuals who have not received hormonal treatment show higher levels of social distress than those receiving cross-sex hormones. Consistent with these findings,[35] in a second study, hormone-treated gender dysphoria individuals showed lower perceived stress, which overlapped with that found in the normative sample.[14] The last study addressed the impact of hormonal treatment on body-related distress, suggesting a gender-specific effect. In fact, MtF individuals' body uneasiness was lower in the context of cross-sex hormonal treatment, and the reduction correlated negatively with the cumulative dose of estradiol.[39] Instead, FtM subjects did not appear to benefit from the hormone therapy in terms of body uneasiness. Authors themselves commented on it as an unexpected finding, which could be due to the individual's still unsatisfactory comfort with the body at a private/personal level rather than involving a social dimension.[39]

Risk of systematic bias across studies

While generally well designed, results mentioned earlier need to be considered in light of certain limitations. Apart from one study,[39] all the others came from only one clinic and some of them had a relatively small sample size. Most importantly, as no study used a blinded randomized controlled trial design, results could have also different explanations because of the study design(s). Moreover, type and dosage of cross-sex hormonal treatment were often not reported, and when reported, there was poor consistency across studies. The same weakness applied to hormone therapy duration. While differences between analyzed groups were generally taken into account, more than half the studies did not mention/control for psychiatric comorbidity, which could have represented a critical bias in this kind of investigation. Finally, while studies were generally strict on the defined study population (formal diagnosis according to DSM criteria used at the time

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of the study), recruitment/follow-up attrition represented an issue for some of the studies identified in this review.

Discussion

This is the first systematic review of all studies examining the effect of cross-sex hormonal treatment on mental health and psychosocial well-being in gender dysphoria. A previous review has mainly focused on the psychosocial outcome of gender dysphoria individuals receiving sex reassignment surgery.[27] After the publication of that review, the literature has seen an increasing number of studies specifically interested in whether sex hormones induce any improvement in terms of mental health and psychosocial well-being. Overall, this review demonstrates that cross-sex hormonal treatment has definite effects on mental health, generally ameliorating gender dysphoria individuals' well-being at different levels. Taking into account the risks of bias reported earlier, cross-sex hormonal treatment does not seem to affect any of the parameters investigated, except emotional functioning, with a reported higher prevalence of aggressive emotions and lower affect intensity in FtMs receiving hormonal treatment.[31]

More specifically, when treated with hormone therapy, gender dysphoria individuals reported less anxiety,[35,37,38] dissociation,[45] perceived stress,[14] social distress,[35] and higher mental health-related quality of life[24,36,43,44] and self-esteem.[36,38] Also, compared to FtM individuals, MtF individuals seemed to benefit more in terms of body uneasiness,[39] emotional functioning,[31] and personality-related psychopathology.[30,41,42] More mixed results emerged from studies investigating other mental health-related dimensions. In particular, recent studies suggested reduced depressive symptoms in hormone-treated gender dysphoria individuals,[35–37] despite previous evidence of no association between cross-sex hormonal treatment and depression among MtF[34] and FtM individuals.[31] Similarly, global psychopathology appeared to be reduced in two studies,[8,37] while a third one did not detect any change.[39] Finally, while two studies indicated less functional impairment[37] and reduced problems with socialization and interpersonal functioning in gender dysphoria individuals receiving hormone therapy,[38] two other studies did not find any effect of hormone therapy on social adjustment[34] and psychosocial functioning.[36] Negative findings generally came from studies involving a cross-sectional design. On the contrary, the few longitudinal studies identified in this review were consistent in indicating an association between hormonal treatment and better mental health.[14,29,31,37,40,45] Conducting observations of the same subjects over a period of time, longitudinal studies can establish sequences of events and better detect changes in the characteristics of the target population, also due to their higher statistical power.

Some of the studies included in this review offered a comparison of hormone-treated gender dysphoria individuals to normal range values of normative data for a general population. Interestingly, all these studies indicated that after the beginning of the cross-sex hormonal treatment, gender dysphoria individuals express distress levels similar to the general population in several mental health-related dimensions, including perceived stress,[14] dissociative symptoms,[45] personality-related psychopathology,[30] mental health-related quality of life,[43] and global psychopathology.[40] These results are in-line with the majority of the previous studies, indicating that hormone therapy decreases the psychiatric comorbidities often associated with a lack of hormonal treatment.[27]

The finding of a reduced mental distress in the context of hormone-treated gender dysphoria may have several explanations. The question arising is whether cross-sex hormones exert a direct effect on distress levels, implying a biological explanation for their reduction, or rather indirectly elicit a better mental health, implying a psychological mechanism possibly related to the physical changes. Biologically, sex hormones may exert different effects on mental distress. Specifically, estrogens may increase mental distress, making individuals more prone to anxiety and depression.[46] Instead, androgens can reduce mental distress, promoting feelings of euphoria and energy[47] and also eliciting stress and hostility.[48] As a consequence, mental distress should increase in MtF individuals as a consequence of the biological effect of estrogens. Conversely, due to the biological effects of androgens, hormone therapy should induce both positive and negative effects on FtM individuals' mental distress, depending on the mental health parameters evaluated. The only finding in support of a biological mechanism for the observed changes in mental distress is the increase in the prevalence of aggressive emotions among hormone-treated FtM individuals.[31] Nevertheless, studies included in this review found that hormonal treatment has a positive effect on both MtF and FtM individuals' mental health. In addition, this amelioration is more pronounced in MtF individuals, who should be more negatively affected by the cross-sex hormonal treatment intervention according to the biological explanation. In light of all this evidence, this review does not support the hypothesis of a direct effect of hormone therapy on mental well-being in gender dysphoria. Instead, the distress reduction might be an indirect effect of hormone therapy, as already hypothesized by Kuiper

and Cohen-Kettenis.[32] Mental distress may be considered a reaction to the nonsatisfaction arising by the incongruence between the individual's experienced gender and biological sex. Cross-sex hormonal treatment is supposed to mitigate such incongruence, inducing desired physical changes that could eventually be responsible for the individual's better mental state and psychological well-being. In other words, thanks to the body changes obtained, gender dysphoria individuals may experience a reduction in their mental distress. In addition, other psychological explanations support the hypothesis of an indirect effect of hormonal treatment on mental well-being. Due to incongruence between their physical appearance and internal experience, nonhormone-treated gender dysphoria individuals may face major difficulties in managing their gender identity at a social level. Hormonal treatment may reinforce the gender affirmation with a better social recognition. This would explain why in some studies hormonal treatment seems to have a beneficial effect on the social dimension rather than on the private dimension of mental well-being.[39] Finally, as delaying hormonal treatment has been reported to often disappoint gender dysphoria individuals, also increasing their distress,[37,45] we cannot exclude that accessing care and receiving eligibility for hormone therapy may help in reducing distress, representing an acceptance of the individual's needs and requirements. In order to promote the highest standards of health for individuals seeking gender transitioning, the importance of facilitating access to care and reducing barriers across countries and cultures cannot be overemphasized. Several factors have been identified, which can affect gender dysphoria individuals' access to care and eventually lead to a nonsatisfactory outcome, such as stigma, violence, fear of being seen as different, lack of/inadequate access to specialized health care professionals and/or services, and poor access to health care pathway-related information.[49]

Conclusion

This review suggests that gender dysphoria-related mental distress may benefit from hormonal treatment intervention. Even recognizing the suffering of nonhormone-treated gender dysphoria individuals, which represents a possible risk factor for more severe or full-syndromal psychiatric disorders,[12] mental distress in gender dysphoria may be considered as a transient reaction to the nonsatisfaction connected to the incongruent body image and not necessarily a stable psychiatric comorbidity. In this perspective, timely hormonal treatment intervention represents a crucial issue in gender dysphoria individuals' mental health-related outcome.

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Disclosure

The authors report no conflicts of interest in this work.

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PATIENT POPULATIONS PRACTICE TRANSGENDER

Reducing Transgender Surgery Side Effects

BY DEREK BAGLEY | MAY 2021

As with most surgeries, venous thromboembolism is always a potential risk and transgender surgical procedures are no different. A new study published in* The Journal of Clinical Endocrinology & Metabolism *shows no increased clot risk while maintaining hormone therapy during gender affirming surgery.

At a Glance

- Because transgender medicine is still a relatively new field, knowledge gaps persist, leading to heterogeneity in the practice of whether doctors and surgeons advise transgender women to withhold their estrogen therapy before surgery.
- A new study in *The Journal of Clinical Endocrinology & Metabolism* showing no difference in blood clots when estrogen hormone therapy was maintained during gender affirming surgery.
- The news has been positive for patients and physicians alike, since there is now guidance that can help prevent transgender patients from suffering the severe side affects of suspending hormone therapy.

Transgender medicine continues to grow and evolve more and more people are presenting to clinics for hormone therapies and gender affirming surgeries. A 2018 report from the American Society of Plastic

Surgeons found that from 2017 to 2018, gender confirmation surgeries increased from 8,304 to 9,576, and those numbers have continued to rise. But, as with any kind of growth, there has been some pain.

Knowledge gaps persist. For instance, any surgery carries the risk of venous thromboembolism (VTE), but according the authors of a paper recently published in *The Journal of Clinical Endocrinology & Metabolism*, little is known about VTE incidence in a transgender surgical patient, and that gap has led to providers separating into two camps about how to reduce the risk of VTE in these patients. One group advocates for withholding hormone therapy for two to four weeks prior to surgery, while the other group says there is little evidence to support suspending hormones.

So a multidisciplinary team of researchers at the Icahn School of Medicine at Mount Sinai and Center for Transgender Medicine and Surgery in New York wanted to set the record straight, since suddenly stopping hormone therapy in a transgender patient can result in withdrawal symptoms and significant psychological distress. Suddenly stopping estrogen therapy in a transgender woman could be just like stopping estrogen in a cisgender woman severe menopause.

“The discomfort and the distress for our patients in stopping their hormone therapy is not insignificant harm,” says John Henry Pang, MD, assistant professor of Plastic and Reconstructive Surgery, Icahn School of Medicine at Mount Sinai and Center for Transgender Medicine and Surgery and senior author of the JCEM paper. “We really wanted to reassess our practices and better understand what it is we’re really trying to protect our patients from, does this harm actually exist.”

Improving Care and Safety

For this study, Pang and his team evaluated data from 919 transgender patients who underwent gender affirming surgery at Mount Sinai’s Center for Transgender Medicine and Surgery between November 2015 and August 2019 including 407 cases of transgender women who underwent primary vaginoplasty surgery. The researchers found no difference in blood clots when estrogen hormone therapy was maintained during gender affirming surgery. Only one blood clot occurred during the entire period reviewed, in a patient who had stopped her estrogen for the surgery. The authors write that the VTE incidence in their patient cohort was comparable to the VTE incidence seen in patients undergoing benign gynecologic surgeries.

Pang points to how well Mount Sinai as an institution focuses on reducing clots in surgical patients, no matter what procedure they underwent using medications to protect against clots, getting patients out of bed and moving around quicker, modifying already-established risk factors for clots. “We focused our energies on things that we know actually do cause blood clots and modifying those versus focusing on things that may not directly impact the incidence of blood clots in our patient population,” he says.

> **"Precedent gives us a foundation from which we can question existing policies and practices, and then adjust them according to better data and experience as it comes along. And a willingness to question that and to adjust as we learn more is really the bet is really the way that we can provide better care for our patients." – John Henry Pang, MD, assistant professor of Plastic and Reconstructive Surgery, Icahn School of Medicine, Center for Transgender Medicine and Surgery Mount Sinai, New York, N.Y.**

The authors of the study note that there are some limitations, such as its retrospective nature, and the fact that these findings represent one institution, but that just means more large-scale multicenter studies are needed to reproduce the results of this novel study. "I'd say the power of publishing more about the surgeries and publishing more about our work with the community is to make it safer for our patients," Pang says. "Because the more doctors and the more healthcare professionals are talking about how to better provide care and safe care for our patients, the better and safer care becomes. The more you talk about it, the more it becomes a known and safer practice. I think that's the benefit of publishing data."

Questioning Precedents

The first rule of medicine is "Do no harm." If a transgender woman can continue her estrogen therapy throughout her gender-affirming surgery, she shouldn't be made to go through sudden, severe menopause or suffer psychological distress. Pang tells *Endocrine News* that not only have his patients responded positively to the idea the authors of the JCEM paper have even received calls from other providers and medical directors at large healthcare systems throughout the U.S. wanting to talk about the paper's findings and the researchers' experiences. "Now they are rethinking their policies in place," Pang says. "They are with their surgeons now realizing, 'Oh, this policy that we had in place may not be entirely necessary and we can also provide care that is not distressing to our patients.' There is change occurring and that's a very positive thing that we see."

"The Mount Sinai study is a practice-changing advance in care for transgender people undergoing surgery," says Joshua D. Safer, MD, FACP, FACE, executive director of the Center for Transgender Medicine and Surgery at Mount Sinai Health System, professor of Medicine at Icahn School of Medicine at Mount Sinai and co-author of the JCEM paper. "The weeks with sex hormone therapy suspended have been a source of misery for our patients. It is a relief that such an approach is not necessary. The Mount Sinai study also adds to the literature that suggests that the risk of VTE from exogenous estrogens might be less than we've suspected for all women, not just transgender women."

The meaning of “research” is to look again. Pang warns against physicians relying too much on precedent and to continue to ask questions about protocols and guidelines that are in place. Of course, there’s nothing wrong with a physician wanting to err on the side of caution. Until now, most surgical centers have taken a mixed-bag approach on advising their patients whether to stop or continue their hormone therapies prior to surgery.

Pang says he hopes this study can dispel any pervading fear of a harm that may not even exist. “Precedent gives us a foundation from which we can question existing policies and practices, and then adjust them according to better data and experience as it comes along,” he says. “And a willingness to question that and to adjust as we learn more is really the bet is really the way that we can provide better care for our patients.”

— Bagley is the senior editor of Endocrine News*. In the March issue, he wrote about how COVID-19 has made health disparities in obesity treatment more apparent.*

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Patient-Reported Complications and Functional Outcomes of Male-to-Female Sex Reassignment Surgery

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Abstract This study examined preoperative preparations, complications, and physical and functional outcomes of male-to-female sex reassignment surgery (SRS), based on reports by 232 patients, all of whom underwent penile-inversion vaginoplasty and sensate clitoroplasty, performed by one surgeon using a consistent technique. Nearly all patients discontinued hormone therapy before SRS and most reported that doing so created no difficulties. Preoperative electrolysis to remove genital hair, undergone by most patients, was not associated with less serious vaginal hair problems. No patients reported rectal-vaginal fistula or deep-vein thrombosis and reports of other significant surgical complications were uncommon. One third of patients, however, reported urinary stream problems. No single complication was significantly associated with regretting SRS. Satisfaction with most physical and functional outcomes of SRS was high; participants were least satisfied with vaginal lubrication, vaginal touch sensation, and vaginal erotic sensation. Frequency of achieving orgasm after SRS was not significantly associated with most general measures of satisfaction. Later years of surgery, reflecting greater surgeon experience, were not associated with lower prevalence rates for most complications or with better ratings for most physical and functional outcomes of SRS.

Keywords Transsexual · Sex reassignment surgery · Vaginoplasty · Follow-up · Complications

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Introduction

Sex reassignment surgery (SRS) is intended to treat a condition, gender identity disorder or transsexualism, that can only be diagnosed on the basis of patients' self-reports (Cohen-Kettenis & Gooren, 1999). For this reason, patients' reports of satisfaction or regret are now recognized as one of the most meaningful bases for judging the success of SRS (Green & Fleming, 1990; Kuiper & Cohen-Kettenis, 1988). Numerous studies of male-to-female (MtF) transsexuals who have undergone SRS (i.e., vaginoplasty) have attempted to determine whether specific patient characteristics (e.g., age, transsexual typology, coexisting mental health problems) or nonsurgical treatment variables (e.g., amount and adequacy of presurgical psychotherapy, duration of real-life experience in the desired gender role) are associated with greater patient satisfaction following SRS (for reviews, see Green & Fleming, 1990; Lawrence, 2003; Smith, van Goozen, Kuiper, & Cohen-Kettenis, 2005).

Considerably fewer studies have attempted to determine whether specific surgical treatment variables or surgical outcomes are associated with greater patient satisfaction following MtF SRS. Several reports have described the surgical complications of MtF SRS. Table 1 displays the frequency of such complications reported in selected English-language surgical follow-up studies, published over the last 20 years. While information about the nature and prevalence of surgical complications provides some useful guidance to patients and caregivers, the surveillance periods for surgical follow-up are often brief, patients are not uncommonly lost to follow-up, and the relationship between surgical complications and patient satisfaction has rarely been specifically addressed. While it seems reasonable to assume that surgical complications might be associated with reduced patient satisfaction, there is surprisingly little empirical support for

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Table 1 Frequency of complications after MtF SRS in selected studies

Study	*N*	Number of complications reported					
		Rectal-vaginal fistula	Vaginal stenosis	Urethral stenosis	Clitoral necrosis[a]	Vaginal prolapse	Other major complications
McEwen, Ceber, & Daws (1986)	68	1	5	1		2	rectal perforation (4)
Small (1987)	11	0	1	2	—		
Bouman (1988)	55	—	4	6	—		
Stein, Tiefer, & Melman (1990)	14	0	4	1	—	—	
Fang, Chen, & Ma (1992)	9	1	—	—	0	—	
Eldh (1993)	20	1	—	3	1	—	vaginal hair ("some")
Perovic (1993)	25	0	2	—	—	2	
Rubin (1993)	13	2	4	1	6	—	vesical-vaginal fistula (1)
van Noort & Nicolai (1993)	27	3	5	4		7	vaginal hair (2)
Huang (1995)[b]	109	0	4	7	—		vaginal hair (1)
Hage & Karim (1996)	60	—	—	—	0	—	
Eldh, Berg, & Gustafsson (1997)[c]	46	1	4	—	—	4	
Rehman & Melman (1999)	10	—	—	—	2	—	
Perovic, Stanojevic, & Djordjevic (2000)	89	1	6	1	—	0	
Krege, Bex, Lümmen, & Rübben (2001)	66	3	—	7	3	2	necrosis of urethra (1)

Note. All studies used a penile-inversion vaginoplasty technique, with or without scrotal skin flaps or grafts. A dash indicates that the presence or absence of a complication was not reported.

[a]Necrosis of sensate neoclitoris constructed from the glans penis; a blank cell indicates that this clitoroplasty technique was not used.

[b]Patients who underwent SRS from 1978 to 1992 only.

[c]Patients who underwent SRS from 1986 to 1995 only.

this proposition. Pfäfflin and Junge (1992/1998), in their comprehensive review of SRS outcome studies published between 1961 and 1991, could find no consistent evidence that the quality of surgical results affected patient satisfaction. They noted that it was not unusual for patients to be satisfied despite objectively unsatisfactory surgical results or to be dissatisfied despite objectively satisfactory results. A small study by Ross and Need (1989) is sometimes cited in support of the proposition that surgical complications are associated with less satisfactory outcomes of SRS, but this study examined the relationship between complications and clinicians' ratings of patients' mental health, not patients' self-reported satisfaction; moreover, most of the variance in mental health ratings was attributable to complications of breast augmentation, not complications of vaginoplasty.

In addition to describing surgical complications, some surgical follow-up studies have described other physical or functional outcomes of MtF SRS, including neovaginal dimensions, the adequacy of the neovagina for coitus, genital appearance, and patients' ability to achieve orgasm after SRS. Although these factors may plausibly be related to patient satisfaction, only a few studies have formally investigated such associations. Schroder and Carroll (1999), in a study of 17 MtF patients, reported that neovaginal dimensions and vulvar appearance were positively correlated with patients' ratings of the overall success of SRS. Muirhead-Allwood, Royle, and Young (1999a, 1999b) examined 140 patients' subjective ratings on 17 variables representing specific physical and functional outcomes of MtF SRS. Principal component analysis revealed three interpretable factors—erotic sensation, absence of physical problems, and satisfaction with physical dimensions—but only the first two of these were correlated with the highest level of self-reported improvement in quality of life after SRS.

The influence of preoperative regimens on surgical outcomes and patient satisfaction has also received little attention. Many surgeons require patients to discontinue the use of feminizing hormones several weeks before surgery, in an attempt to prevent perioperative deep-vein thrombosis (DVT) and pulmonary embolism (e.g., Eldh, 1993; Hage, 1999; Rehman & Melman, 1999; see also Futterweit, 1998), while other surgeons question the value of this requirement (e.g., Edgerton, 1993) or suggest that it results in unnecessary patient discomfort (e.g., Bowers, 2004a). However, neither the proposed benefits nor the subjective effects of preoperative discontinuation of feminizing hormones have been formally investigated. Some surgeons advise patients to undergo preoperative electrolysis to remove hair from penile and scrotal skin that will be used to line the neovagina, in the belief that this treatment may reduce the likelihood of symptomatic intravaginal hair postoperatively (e.g., Bowers, 2004b). However, the proposed benefit of genital electrolysis in preparation for MtF SRS has not been formally investigated.

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The influence of surgeon experience on postoperative complication rates and patient satisfaction following MtF SRS is also incompletely understood, although there is evidence that the prevalence of some surgical complications declines as experience increases (e.g., Eldh, Berg, & Gustafsson, 1997; Huang, 1995). It is also unclear whether performance of *labiaplasty*, an optional secondary surgical operation that brings the upper ends of the labia together in the midline above the clitoris and better defines the labia minora (see Hage, Goedkoop, Karim, & Kanhai, 2000), contributes to patient satisfaction after SRS.

A follow-up survey of patients who underwent MtF SRS with surgeon Toby Meltzer in Portland, Oregon, between May 1994 and March 2000 (see Lawrence, 2003, 2005) provided an opportunity to examine these questions, based on patients' self-reports.

Method

Participants

Survey participants have been described in detail in previous reports (Lawrence, 2003, 2005). Their mean age at time of SRS was 44 years ($SD = 9$ years; range, 18–70) and they were surveyed a mean of 3 years ($SD = 1$ year; range, 1–7) after SRS.

Preoperative preparation and surgical technique

Patients were instructed to discontinue using feminizing hormones 3 weeks before SRS. Starting in 1997, patients were advised to undergo removal of hair from the penis and scrotum by electrolysis prior to SRS. Meltzer's SRS technique involved creation of a neovagina lined with inverted penile and scrotal skin and construction of a sensate neoclitoris from the glans penis, using a technique similar to that of Fang, Chen, and Ma (1992). No earlier than 3 months after SRS, some patients underwent an optional labiaplasty, using a technique similar to that described by Laub (1997). Some patients also underwent other secondary surgical procedures to improve genital appearance or function, including revision of the urethral meatus (see Karim, Hage, Bouman, & Dekker, 1991) or surgery to widen or deepen the vagina.

Survey method and measures

The survey procedures, including the method by which informed consent was obtained, have been described previously (Lawrence, 2003) and will be summarized only briefly. Postoperative patients were surveyed using a mailed questionnaire, which they completed and returned anonymously. Of 727 eligible patients, 310 (43%) could not be contacted, either due to lack of a current mailing address ($n = 307$) or death ($n = 3$); 185 (25%) were contacted but either declined to participate ($n = 62$), failed to return a questionnaire ($n = 120$), or returned a questionnaire with an ineligible year of surgery ($n = 3$); and 232 (32%) patients, the participant group, returned valid questionnaires.

Many questionnaire items were adapted from a questionnaire developed by Muirhead-Allwood (1998) and others were written by the author. Most questionnaire items relevant to this report have been described previously (Lawrence, 2003, 2005) and will be summarized only briefly.

Participants reported the year in which they had undergone SRS and whether they had undergone any of four additional surgical procedures (*yes* or *no*), all of which were described in lay terms: (a) labiaplasty, (b) revision of the urethral meatus, (c) surgery to widen or deepen the vagina, or (d) other secondary genital surgery, which participants were asked to specify. Participants reported whether they had stopped taking feminizing hormones before surgery (*yes* or *no*) and, if so, how long before surgery they had done so (in days or weeks). Participants who had stopped taking hormones reported whether this had been difficult for them (*yes* or *no*) and what symptoms, if any, they had experienced in connection with stopping. Participants also reported whether they had undergone any electrolysis of their scrotum or other genital areas in preparation for SRS (*yes* or *no*) and, if so, how many hours of electrolysis they had undergone.

Participants reported whether they had experienced any of 10 physical complications of SRS (*yes* or *no*), all of which were described in lay terms (see Lawrence, 2003): rectal-vaginal fistula, vaginal prolapse, vaginal stenosis at all times, vaginal stenosis during sexual arousal only, misdirected urinary stream, urethral stenosis, clitoral necrosis, genital pain, DVT, and "other (specify)." They also reported their experience concerning 19 physical and functional outcomes of SRS, all rated on 11-point Likert scales from 0 (*very poor*, *major problem*, etc.) to 10 (*excellent*, *no problem*, etc.) and all described in lay terms (see Lawrence, 2003). These outcomes included: vaginal depth, vaginal width, vaginal lubrication, vaginal discharge, vaginal hair growth, sensation to touch at the vaginal opening, sensation to touch deep in the vagina, vaginal pain with penetration, vaginal itching, vaginal prolapse, vaginal erotic sensation, clitoral touch sensation, clitoral erotic sensation, clitoral pain, clitoral itching, discharge from around the clitoris, hair on or around the clitoris, urine leakage with cough or strain, and postoperative bladder infections. Participants reported their ability to achieve orgasm with masturbation after SRS on a 5-point scale from *never* to *almost always*, with the additional option of *don't know or not applicable*.

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Finally, participants completed four measures of their overall satisfaction with SRS. They reported whether they regretted having undergone SRS (*yes*, *sometimes*, or *no*); their overall happiness with sexual functioning after SRS result and their overall happiness with their SRS result, both on an 11-point Likert scale from 0 (*very unhappy*) to 10 (*very happy*); and how much they felt their quality of life had worsened or improved as a result of SRS, on a 21-point Likert scale from -10 (*most worsening possible*) to 10 (*most improvement possible*).

Hypotheses

Although the principal aims of the study were descriptive, several hypotheses of potential clinical relevance were formulated and examined:

1. Participants who had undergone preoperative electrolysis to remove genital hair would report less severe intravaginal hair problems than those who had undergone no electrolysis; moreover, a greater number of hours of genital electrolysis would be associated with better ratings concerning intravaginal hair problems.
2. Participants who had undergone labiaplasty would report higher ratings of overall satisfaction than those who had not.
3. Surgical complications would be associated with lower ratings of overall satisfaction.
4. Higher ratings of specific physical and functional outcomes of SRS would be associated with higher ratings of overall satisfaction.
5. More frequent ability to achieve orgasm after SRS would be associated with higher ratings of overall satisfaction.
6. Later years of surgery, reflecting greater surgeon experience, would be associated with higher ratings of overall satisfaction, fewer reported complications, higher ratings for specific physical and functional outcomes of SRS, and more frequent ability to achieve orgasm after SRS.

An alpha level of .05 was used for all statistical tests. Because the intent of the study was primarily exploratory, alpha levels were not adjusted for multiple comparisons.

Results

Overall satisfaction

No participants consistently regretted having undergone SRS and only 15 (6%) participants reported that they were sometimes regretful. Participants' mean rating for overall happiness with their genital sexual function after SRS was 7.8 ($SD = 2.4$; range, 0–10) and their mean rating for overall happiness with their SRS result was 8.7 ($SD = 1.6$; range, 0–10). Participants' mean rating of improvement in their quality of life with SRS was 7.9 ($SD = 2.6$; range, -2–10). Year of surgery, treated as a continuous variable, was not significantly associated with sometimes regretting SRS, based on logistic regression, $\chi^2(1, N = 229) = .03$, *ns*. Year of surgery was significantly associated with overall happiness with SRS result, $r(230) = .14$, $p = .03$,[1] but not with overall happiness with genital sexual function, $r(224) = .08$, *ns*, or with improvement in quality of life with SRS, $r(225) = .11$, $p = .09$.

Effects of discontinuing feminizing hormones

A total of 214 (92%) participants stopped taking feminizing hormones before SRS and 18 (8%) participants did not. Mean duration of abstinence among those who discontinued hormones was 22 days ($SD = 9$ days; range, 3–60). Among participants who discontinued hormones, 74 (35%) reported that this had been difficult. The most common symptoms reported by participants who stopped taking hormones were hot flashes (43 participants, 20% of those who stopped), mood swings or irritability (42 participants, 20% of those who stopped), and increases in facial or body hair growth (12 participants, 6% of those who stopped). No participants, including those who continued to use hormones, reported perioperative DVT.

Preoperative genital electrolysis and postoperative vaginal hair problems

A total of 172 (74%) participants reported that they had undergone preoperative electrolysis for genital hair removal. Among those who had undergone genital electrolysis, the mean number of hours reported was 21 ($SD = 30$; range, 0.4–300). There was no significant difference in mean rating for vaginal hair problems between participants who had or had not undergone genital electrolysis, 8.1 versus 7.8, $t(229) < 1$, *ns*. There was also no significant correlation between participants' ratings of vaginal hair problems and the number of hours of genital electrolysis they reported, $r(213) = .00$. Some participants reported many more hours of genital electrolysis than expected, raising the possibility that they had misinterpreted the question. Consequently, correlations between ratings of vaginal hair problems and number of hours of genital electrolysis were recomputed after excluding participants who reported more than 20, 30, 40, or 50 hours of electrolysis; in no cases were significant correlations found. Among the 17 participants reporting the most serious vaginal hair problems (those giving Likert scale ratings

[1] Based on Spearman rank-order correlation (i.e., with year of surgery treated as an ordinal variable), Lawrence (2003) reported that year of surgery was not significantly associated with happiness with SRS result, $r_s(230) = .09$, $p = .15$.

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of 0, 1, or 2), 10 participants had undergone some genital electrolysis, with a mean duration of 34 h ($SD = 33$ h; range, 2–100). Year of surgery in the 17 participants reporting the most serious vaginal hair problems ranged from 1994 to 2000.

Additional genital surgical procedures undergone

Most participants had undergone at least one additional genital surgical procedure following vaginoplasty. Sixty-two (27%) participants had undergone both labiaplasty and a revision of the urethral meatus, 117 (50%) participants had undergone labiaplasty but not revision of the urethral meatus, 4 (2%) participants had undergone revision of the urethral meatus but not labiaplasty, and 49 (21%) participants had undergone neither procedure. Five (2%) participants had undergone an additional procedure to deepen or widen the neovagina. Eleven (5%) participants had undergone some other additional genital surgical procedure, including three instances of removal of excess periurethral erectile tissue; two instances each of revision of the clitoris, the labia, and the vaginal introitus; one instance of liposuction of the mons area; and one unspecified procedure.

There were no significant associations between having undergone any additional genital surgical procedure and sometimes regretting SRS, based on Fisher's exact tests. Participants who had undergone labiaplasty displayed a nonsignificant trend toward reporting greater improvement in quality of life with SRS than those who had not, 8.1 versus 7.4, $t(225) = 1.75$, $p = .08$. However, having undergone labiaplasty was not significantly associated with greater overall happiness with genital sexual function or greater overall happiness with SRS result. There were no significant associations between having undergone any other additional surgical procedure and greater overall happiness with genital sexual function, overall happiness with SRS result, or overall improvement in quality of life with SRS.

Postoperative complications

No participants reported having experienced rectal-vaginal fistula or DVT. No participants reported having experienced

Table 2 Complications of SRS and overall measures of satisfaction

Complication	*n*	%	Regret SRS sometimes		Happiness with sexual function		Happiness with SRS result		Improvement in QOL[a]	
			n	%[b]	*M*	*SD*	*M*	*SD*	*M*	*SD*
Vaginal stenosis at all times										
Present	19	8	3	16	5.9***	3.2	6.8****	3.1	7.2	2.9
Absent	212	92	12	6	8.0	2.2	8.9	1.3	8.0	2.6
Vaginal stenosis during arousal										
Presnt	15	6	1	7	8.3	1.5	8.1	2.2	8.3	2.7
Absent	216	94	14	6	7.8	2.4	8.8	1.6	7.9	2.6
Misdirected urinary stream										
Present	77	33	6	8	7.7	2.2	8.7	1.5	8.0	2.5
Absent	154	67	9	6	7.9	2.4	8.8	1.7	7.9	2.7
Urethral stenosis										
Present	9	4	1	11	7.7	2.2	8.2	1.3	8.9	1.4
Absent	222	96	14	6	7.8	2.3	8.8	1.7	7.9	1.7
Clitoral necrosis										
Present	8	3	2	25	5.0***	3.5	6.8***	1.9	8.0	2.3
Absent	223	97	13	6	7.9	2.2	8.8	1.6	8.0	2.6
Pain in vagina or genitals										
Present	20	9	3	15	6.0***	3.2	7.1****	2.9	6.6*	3.0
Absent	211	91	12	6	8.0	2.2	8.9	1.4	8.0	2.5
Other complications[c]										
Present	27	12	3	11	6.5**	3.3	7.9**	2.7	7.7	2.6
Absent	204	88	12	6	8.0	2.1	8.8	1.4	7.9	2.6

Note. Happiness with sexual function and with SRS result represent 0–10 Likert scale ratings. Improvement in QOL represents -10 to $+10$ Likert scale ratings. Higher numbers indicate better outcomes. No p values for Regret are significant by Fisher' exact test, $N = 231$. p values for other measures of satisfaction are by t-test, Ns = 225–232. All p values are two-tailed.

*$p < .05$, **$p < .01$, ***$p < .001$, ****$p < .0001$, all versus the complication-absent condition.

[a]Quality of life.

[b]Of those reporting a complication or its absence.

[c]Includes infections, bleeding, poor healing, other tissue loss or necrosis, urinary incontinence, and numbness.

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vaginal prolapse as a complication, but 4 participants reported problematic vaginal prolapse in the section of the questionnaire addressing physical and functional outcomes; the reason for this discrepancy is unclear. The frequency of other surgical complications is summarized in Table 2. Most complications were uncommon and 109 (47%) participants reported no complications of any kind.

Associations between the presence or absence of complications and overall measures of satisfaction after SRS are also summarized in Table 2. There were no significant associations between any complication and sometimes regretting SRS. Vaginal stenosis at all times, clitoral necrosis, genital pain, and "other" complications were significantly associated with lower ratings of happiness with overall genital sexual function and overall happiness with SRS result. Genital pain was significantly associated with lower ratings of improvement in quality of life with SRS. Vaginal stenosis with sexual arousal only, misdirected urinary stream, and urethral stenosis showed no significant associations with any overall measure of satisfaction.

Associations between reported complications and year of surgery, treated as a continuous variable, were examined using logistic regression analysis. Only one association was statistically significant: Vaginal stenosis during sexual arousal only was more likely to have been associated with an earlier year of surgery, $\chi^2(1, N = 230) = 9.8, p = .002$.

Satisfaction with specific physical and functional outcomes

Participants' ratings of satisfaction with specific physical and functional outcomes of SRS are summarized in Table 3. Participants' satisfaction was generally high for all measures except vaginal lubrication, touch sensation deep in the vagina, and erotic sensation in the vagina.

Associations between satisfaction with specific physical and functional outcomes of SRS and overall measures of satisfaction are also summarized in Table 3. All measures of satisfaction with genital touch sensation and genital erotic sensation were significantly correlated with overall happiness with sexual function, overall happiness with SRS result, and improvement in quality of life with SRS. Satisfaction with erotic sensation in the clitoris and vagina and with touch sensation at the vaginal introitus were also significantly associated with absence of regret.

Specific outcome measures addressing vaginal dimensions (satisfaction with vaginal depth, satisfaction with

Table 3 Physical and functional outcomes of SRS and overall measures of satisfaction

			Associations with measures of satisfaction			
Physical or functional outcome	*M*	*SD*	Absence of regret, χ^2	Happiness with sexual function, *r*	Happiness with SRS result, *r*	Improvement in QOL[a], *r*
Vaginal depth	7.5	2.1	2.6	.37****	.45****	.18**
Vaginal width	7.4	2.3	9.0**	.38****	.51****	.20**
Vaginal lubrication	4.4	2.8	7.8**	.30****	.37****	.25***
Vaginal discharge	9.2	2.0	1.8	.00	.02	.03
Vaginal hair	8.0	2.9	9.1**	.14*	.13	.14*
Touch sensation at vaginal introitus	7.8	2.3	4.1*	.47****	.31****	.25***
Touch sensation deep in vagina	6.6	2.9	1.0	.42****	.26****	.19**
Pain with vaginal penetration	7.1	2.4	3.1	.39****	.42****	.22***
Vaginal itching	9.1	1.9	0.3	.08	.16*	.04
Vaginal prolapse	9.8	1.3	2.2	.07	.09	.00
Erotic sensation in vagina	6.5	3.2	9.2**	.61****	.36****	.18**
Touch sensation in clitoris	8.6	2.1	2.5	.56****	.35****	.13*
Erotic sensation in clitoris	7.8	2.7	21.2****	.63****	.38****	.15*
Pain in or around clitoris	9.3	1.9	8.7**	.26****	.27****	.11
Itching in or around clitoris	9.4	1.6	2.3	.04	.07	.10
Discharge from around clitoris	9.6	1.5	0.5	.02	.05	.03
Hair on or around clitoris	8.3	2.8	3.5	.11	.12	.15*
Urine leakage with strain or cough	9.1	2.1	3.1	.33****	.29****	.07
Bladder infections	8.5	2.5	0.1	.25***	.17**	− .07

Note. Physical and functional outcomes represent 0–10 Likert scale ratings; higher numbers represent better outcomes. Associations with absence of regret are by logistic regression, $df = 1$, $Ns = 228–231$. Associations with other measures of satisfaction are by Pearson correlation, $Ns = 222–232$. All *p* values are two-tailed.

$^{*}p < .05$, $^{**}p < .01$, $^{***}p < .001$, $^{****}p < .0001$.

[a]Quality of life.

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vaginal width, and absence of vaginal pain with penetration) were significantly correlated with overall happiness with genital sexual function, overall happiness with SRS result, and improvement in quality of life with SRS. Satisfaction with vaginal width was associated with absence of regret. Satisfaction with vaginal lubrication, which may be conceptually related to both genital sensation and vaginal dimension issues, was significantly associated with all four overall outcome measures.

Among other potentially problematic physical and functional outcomes of SRS, vaginal hair and clitoral pain were especially notable: For both items, lower satisfaction ratings were significantly associated with regretting SRS sometimes and with lower ratings on two other overall outcome measures. Lower satisfaction ratings on two urinary problems, urine leakage with cough or strain and bladder infections, were associated with lower ratings on overall happiness with genital sexual function and overall happiness with SRS result. For the remaining six physical and functional outcome categories, nearly all associations were nonsignificant.

Only two associations between specific physical and functional outcomes of SRS and year of surgery were statistically significant: Later years of surgery were significantly associated with higher ratings of happiness with vaginal depth, $r(230) = .26$, $p = .0001$, and vaginal width, $r(230) = .14$, $p = .03$.

Frequency of achieving orgasm after SRS

Frequency of achieving orgasm with masturbation after SRS and its relationship to overall measures of satisfaction are summarized in Table 4. Frequency of achieving orgasm was not significantly associated with sometimes regretting SRS, based on a Fisher-Freeman-Halton test, $p = .064$. Frequency of achieving orgasm was significantly associated with overall happiness with sexual function, $F(5, 220) = 17.0$, $p < .0001$, but not with overall happiness with SRS result, $F(5, 227) = 1.9$, $p = .097$, or improvement in quality of life with SRS, $F(5, 222) = .83$, *ns*. Post-hoc analyses using Tukey-Kramer HSD tests demonstrated that individuals who were "never" able to achieve orgasm were significantly less happy with their sexual function than persons in other categories and that persons who were "rarely" able to achieve orgasm were significantly less happy than those who were able to achieve orgasm "almost always."

With "don't know/not applicable" responses omitted, frequency of achieving orgasm, treated as an ordinal variable, was significantly correlated with overall happiness with sexual function, $r_s(213) = .45$, $p < .0001$, but not with overall happiness with SRS result, $r_s(217) = .13$, $p = .06$, or with improvement in quality of life with SRS, $r_s(212) = .04$, $p = .52$. Frequency of achieving orgasm was significantly but negatively correlated with year of surgery, $r_s(215) = -.15$, $p = .03$.

Discussion

The goals of this study were: (a) to describe the complications and physical and functional outcomes of MtF SRS reported by a large group of patients who had undergone SRS using a consistent surgical technique and (b) to examine how these outcomes, along with preoperative preparations, additional genital surgery undergone, and surgeon experience, were related to patient satisfaction. The study's descriptive data concerning surgical outcomes represent the experiences of the largest group ($N = 232$) of MtF patients of one surgeon published to date. Moreover, these data represent outcomes of a surgical technique that has become the de facto international standard, combining penile inversion vaginoplasty, widely regarded as the preferred technique for MtF SRS (Giraldo, Mora, Solano, Gonzáles, & Smith-Fernández, 2002; Hage, 1999; Karim, Hage, & Mulder, 1996), with glans-derived sensate clitoroplasty, described as the "state of the art in neoclitoroplasty" (Hage & Karim, 1996, p. 624) and "the best choice for neoclitoroplasty, and the 'gold standard' against which other procedures are compared" (Giraldo et al., 2002, p. 1308). Consequently, the study's descriptive data may be of interest to clinicians and MtF transsexual patients who want to calibrate their expectations concerning the outcomes of contemporary MtF SRS technique.

Nearly all participants complied with instructions to stop taking hormones before SRS and most reported that stopping was not difficult. The most common side-effects after stopping hormones were hot flashes and mood changes. Clinicians may wish to inform their MtF SRS patients about these common side-effects.

Vaginal hair was a significant complaint for a small percentage of participants. It was hypothesized that participants who had undergone preoperative electrolysis of genital hair would report less severe intravaginal hair problems and that more hours of electrolysis would be associated with better self-reported outcomes for intravaginal hair, but no significant effects were found. These results suggest that, when hair-bearing genital skin is used to line the neovagina in MtF SRS, preoperative genital electrolysis does not demonstrably reduce complaints of postoperative vaginal hair problems. In natal women with vaginal agenesis who undergo vaginoplasty using full-thickness grafts or flaps of hair-bearing skin, vaginal hair follicles sometimes eventually disappear or at least cannot be detected on biopsy (Pierce, Klabunde, O'Connor, & Long, 1956; Whitacre & Alden, 1951). This has been reported to occur as early as a few months after surgery (Whitacre & Alden, 1951). Some surgeons (e.g., Eldh, 1993; Huang, 1995; Small, 1987; van Noort &

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Nicolai, 1993) have proposed that a similar process occurs when hair-bearing skin is used intravaginally in MtF SRS, implying that vaginal hair eventually becomes a minimal or nonexistent problem. However, this opinion is not universal (Edgerton, 1993, 1995; Hage, 1995). A few participants in this study reported significant vaginal hair problems as long as six years after vaginoplasty, suggesting that passage of time does not reliably eliminate these complaints.

Most participants had undergone labiaplasty following their initial SRS operation and over one quarter had undergone a revision of the urethral meatus. It was hypothesized that participants who had undergone labiaplasty would report greater overall satisfaction than those who had not, but no significant association was found.

Reports of significant surgical complications were uncommon and there were no reports of recto-vaginal fistula or DVT, two of the most serious complications. A misdirected urinary stream, usually considered to be a minor complication, was reported by 33% of participants, higher than in the small study published by Blanchard, Legault, and Lindsay (1987). Vaginal stenosis with sexual arousal, reported by 6% of participants, may have been related to incompletely resected periurethral erectile tissue, as described by Karim, Hage, Bouman, and Dekker (1991). Later years of surgery, reflecting greater surgeon experience, were associated with significantly fewer instances of this complication but not with significantly fewer instances of other complications. It is especially notable that misdirected urinary stream, the complication most commonly reported, did not become significantly less frequent in later years. These observations suggest that, while greater surgeon experience may be associated with more satisfactory removal of periurethral erectile tissue and less likelihood of vaginal stenosis during sexual arousal, urinary stream problems may continue to occur frequently.

It was hypothesized that participants who experienced complications would report lower overall satisfaction than those who did not, but significant differences were found only for vaginal stenosis at all times, clitoral necrosis, genital pain, and "other" complications. It is notable that no individual complications were significantly associated with regretting SRS, although a previous report (Lawrence, 2003) found that the presence of multiple complications was significantly associated with an increased likelihood of regret. Genital pain was reported by 9% of participants and was the only complication that was significantly associated with less improvement in quality of life with SRS. Although some reports of genital pain complications may have reflected pain with vaginal penetration, several participants who reported genital pain reported little problem with pain during vaginal penetration, based on favorable Likert scale ratings.

It may seem surprising that most reported surgical complications were not associated with lower overall satisfaction or with less improvement in quality of life with SRS. These findings are, however, consistent with the observation by Pfäfflin and Junge (1992/1998) that patients who undergo SRS often report being satisfied despite surgical outcomes that are objectively unsatisfactory. Possibly some participants in the current study reported complications that they did not regard as especially serious or consequential. In a study by Schroder (1995), 17 MtF transsexuals who had undergone SRS reported a total of 15 postsurgical complications, including 7 instances of vaginal stenosis, but only 3 individuals rated their complications as "serious." Moreover, MtF transsexuals who experience surgical complications may nevertheless feel that the benefits of SRS significantly outweigh any negative consequences of these complications. Schroder and Carroll (1999) noted that their MtF transsexual informants rated "absence of the genitals you wanted to be rid of" (p. 139) as the most important physical outcome of SRS. This result is invariably achieved in MtF SRS, even when surgical complications occur.

On average, participants expressed high levels of satisfaction with nearly all of the specific physical and functional outcomes of SRS. The outcomes with which they were least satisfied were vaginal erotic sensation, touch sensation deep in the vagina, and vaginal lubrication. Some participants may have had unrealistic expectations concerning vaginal

Table 4 Frequency of achieving orgasm after SRS and overall measures of satisfaction

Frequency of achieving orgasm with masturbation	*n*	%	Regret SRS sometimes		Happiness with sexual function		Happiness with SRS result		Improvement in QOL[a]	
			n	%[b]	*M*	*SD*	*M*	*SD*	*M*	*SD*
Almost always	82	36	2	2	8.8	1.5	9.0	1.4	8.0	2.4
More than half the time	27	12	1	4	8.2	1.4	8.9	1.0	8.4	1.7
Less than half the time	33	15	1	3	8.2	1.8	8.7	1.6	8.4	2.0
Rarely	34	15	5	15	7.4	2.3	8.7	1.4	7.4	3.2
Never	40	18	5	13	5.2	3.1	8.1	2.5	7.7	2.9
Don't know/not applicable	10	4	1	10	8.4	1.8	9.2	1.3	8.0	2.9
p for group differences				.064		<.0001		.097		*ns*

Note. The *p* value for Regret is by Fisher-Freeman-Halton test; *p* values for other measures of satisfaction are by ANOVA, *Ns* = 220–227.

[a] Quality of life.

[b] Of those giving this answer.

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sensation. Kinsey, Pomeroy, Martin, and Gebhard (1953) observed that most natal women reported very little touch sensation or erotic sensation deep in the vagina. MtF transsexuals are sometimes surprised to learn that their vaginas are capable of lubrication. Vaginal lubrication is caused by transudation of fluid into the vaginal lumen due to pelvic vascular engorgement, a process that occurs in both natal (Levin, 1991, 2002) and surgically created vaginas (Masters & Johnson, 1961). Many natal women with vaginal agenesis who undergo skin graft vaginoplasties report achieving lubrication adequate for coitus (Allesandrescu, Peltecu, Buhimschi, & Buhimschi, 1996) and Muirhead-Allwood et al. (1999a) reported that a significant minority of their MtF SRS patients also experienced satisfactory vaginal lubrication. Physiologically, many or most MtF transsexual patients should be able to experience vaginal lubrication following vaginoplasty, if they are able to achieve high levels of sexual arousal and pelvic vasocongestion. Dissatisfaction with vaginal lubrication after MtF SRS may in part reflect difficulty in achieving high levels of sexual arousal.

It was hypothesized that higher ratings of specific physical and functional outcomes of SRS would be associated with higher overall satisfaction and significant associations were observed for most outcomes, especially those related to genital sensation and vaginal dimensions. Problems with clitoral pain, vaginal hair, stress incontinence, and bladder infections were also associated with lower overall satisfaction. These results confirm the observation by Muirhead-Allwood et al. (1999a, 1999b) that satisfaction with genital sensation is significantly associated with improvement in quality of life with SRS. However, in contrast to their findings, this study found that satisfaction with vaginal dimensions was also significantly associated with improvement in quality of life. These differing results may partly reflect different methodologies: Muirhead-Allwood et al. (1999a, 1999b) performed principle component analysis and used a dichotomous measure of improvement in quality of life with SRS, whereas this study examined specific outcomes individually and used a continuous measure of improvement in quality of life. The differing results may also partly reflect differing surgical technique: 14% of participants in the survey by Muirhead-Allwood et al. (1999a, 1999b) had undergone only "cosmetic surgery," without vaginoplasty. MtF transsexuals often express concern about achieving adequate vaginal depth following SRS and less frequently express concern about vaginal width; in this study, however, vaginal width was significantly associated with absence of regret, while vaginal depth was not. This is consistent with the observation by Perovic (1993) that even patients with vaginas as short as 9 cm were satisfied after SRS, if their vaginas were wide enough.

It was hypothesized that more frequent ability to achieve orgasm after SRS would be associated with higher overall satisfaction, but this was observed only for happiness with sexual function. Although MtF transsexual patients often express concern about their ability to achieve orgasm after SRS, it appears that this may bear little relationship to postoperative regret or to self-rated improvement in quality of life following SRS.

It was hypothesized that later years of surgery, reflecting greater surgeon experience, would be associated with higher overall satisfaction, fewer reported complications, higher ratings of specific physical and functional outcomes of SRS, and more frequent ability to achieve orgasm after SRS. In most instances, however, significant associations were not found. Later years of surgery were significantly associated with greater overall happiness with SRS result but not with other general measures of satisfaction. Later years of surgery were significantly associated with fewer instances of vaginal stenosis during sexual arousal and with greater satisfaction with vaginal depth and width, but not with fewer complications of other kinds or with superior outcomes in other physical or functional categories.

Year of surgery was significantly but negatively associated with ability to achieve orgasm with masturbation after SRS, which might seem counterintuitive. Although this finding could reflect minor variations in surgical technique over time (e.g., more complete removal of sexually sensitive periurethral erectile tissue), it might also reflect patients' increasing familiarity over time with their surgically modified genitals, resulting in the ability to more reliably achieve orgasm through self-stimulation.

Limitations, generalizability, and suggestions for further research

Only 32% of eligible persons returned valid questionnaires, raising the possibility that these participants may not have constituted a representative sample of Meltzer's MtF SRS patients during the 6-year study period. An earlier report (Lawrence, 2003) addressed this issue by comparing participants who underwent SRS in partial year 2000, for whom the response rate was 79%, with participants who underwent SRS from partial year 1994 through 1999, for whom the overall response rate was only 29%, on 24 demographic, personality, treatment, and outcome measures. No significant differences between these groups of participants were found for any of the measures examined (for details, see Lawrence, 2003, p. 310). Because participants from partial year 2000 comprised 79% of the group of patients who underwent SRS in that partial year, they probably constituted a fairly representative sample of that patient group. The most parsimonious explanation of the many observed similarities between these participants and participants from earlier years is that both groups probably constituted fairly representative samples of a postsurgical population that remained reasonably consistent with regard to many demographic,

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personality, treatment, and outcome characteristics over the 6-year study period. Assuming that this explanation is correct, biases related to the survey's low response rate were probably small. Because the cost of SRS with Meltzer was higher than with many other surgeons who perform MtF SRS, participants may not have constituted a representative sample of post-SRS MtF transsexuals in the United States.

Although the survey questionnaire described the complications of SRS in both lay and professional terms, complications reported by patients may not correspond exactly to what surgically trained persons would regard as complications. Consequently, comparison of the prevalence of self-reported complications in this study with the prevalence of complications in studies in which assessments were conducted by surgically trained personnel (e.g., those in Table 1) should be undertaken cautiously, if at all.

One of the unexpected findings of this study was the prevalence of genital pain complaints following SRS. Experienced by 9% of participants, genital pain was the second-most-common complication reported and was the only complication significantly associated with less improvement in quality of life after SRS. Although some reports of genital pain may have occurred primarily in the context of vaginal penetration, this appears not to have been true in at least a substantial minority of cases. Pain with vaginal penetration is a recognized phenomenon following MtF SRS (Blanchard et al., 1987; Krege, Bex, Lümmen, & Rübben, 2001; Stein, Tiefer, & Melman, 1990; van Noort & Nicolai, 1993), but other types of genital pain have rarely been described or discussed. Further study of the prevalence, nature, and consequences of post-SRS genital pain might better inform prospective patients and their caregivers about this potential complication and might contribute to reducing its prevalence.

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Treatment of Symptoms of the Menopause: An Endocrine Society Clinical Practice Guideline

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Objective: The objective of this document is to generate a practice guideline for the management and treatment of symptoms of the menopause.

Participants: The Treatment of Symptoms of the Menopause Task Force included six experts, a methodologist, and a medical writer, all appointed by The Endocrine Society.

Evidence: The Task Force developed this evidenced-based guideline using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence. The Task Force commissioned three systematic reviews of published data and considered several other existing meta-analyses and trials.

Consensus Process: Multiple e-mail communications, conference calls, and one face-to-face meeting determined consensus. Committees of The Endocrine Society, representatives from endorsing societies, and members of The Endocrine Society reviewed and commented on the drafts of the guidelines. The Australasian Menopause Society, the British Menopause Society, European Menopause and Andropause Society, the European Society of Endocrinology, and the International Menopause Society (co-sponsors of the guideline) reviewed and commented on the draft.

Conclusions: Menopausal hormone therapy (MHT) is the most effective treatment for vasomotor symptoms and other symptoms of the climacteric. Benefits may exceed risks for the majority of symptomatic postmenopausal women who are under age 60 or under 10 years since the onset of menopause. Health care professionals should individualize therapy based on clinical factors and patient preference. They should screen women before initiating MHT for cardiovascular and breast cancer risk and recommend the most appropriate therapy depending on risk/benefit considerations. Current evidence does not justify the use of MHT to prevent coronary heart disease, breast cancer, or dementia. Other options are available for those with vasomotor symptoms who prefer not to use MHT or who have contraindications because these patients should not use MHT. Low-dose vaginal estrogen and ospemifene provide effective therapy for the genitourinary syndrome of menopause, and vaginal moisturizers and lubricants are available for those not choosing hormonal therapy. All postmenopausal women should embrace appropriate lifestyle measures. (*J Clin Endocrinol Metab* 100: 3975–4011, 2015)

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Abbreviations: BZA, bazedoxifene; CEE, conjugated equine estrogens; CHD, coronary heart disease; CI, confidence interval; CVD, cardiovascular disease; DVT, deep vein thrombosis; EPT, estrogen plus progestogen therapy; ET, estrogen therapy; GSM, genitourinary syndrome of menopause; HR, hazard ratio; MetS, metabolic syndrome; MHT, menopausal hormone therapy; MI, myocardial infarction; MPA, medroxyprogesterone acetate; OTC, over the counter; PE, pulmonary embolism; POI, primary ovarian insufficiency; QOL, quality of life; RCT, randomized controlled trial; SERM, selective estrogen receptor modulator; SSRI, selective serotonin reuptake inhibitor; SNRI, serotonin-norepinephrine reuptake inhibitor; VMS, vasomotor symptoms; VTE, venous thromboembolism; VVA, vulvovaginal atrophy.

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Summary of Recommendations

1.0 Diagnosis and symptoms of menopause

1.1 We suggest diagnosing menopause based on the clinical criteria of the menstrual cycle. (2|⊕⊕◯◯)

1.2 If establishing a diagnosis of menopause is necessary for patient management in women having undergone a hysterectomy without bilateral oophorectomy or presenting with a menstrual history that is inadequate to ascertain menopausal status, we suggest making a presumptive diagnosis of menopause based on the presence of vasomotor symptoms (VMS) and, when indicated, laboratory testing that includes replicate measures of FSH and serum estradiol. (2|⊕⊕◯◯)

2.0 Health considerations for all menopausal women

2.1 When women present during the menopausal transition, we suggest using this opportunity to address bone health, smoking cessation, alcohol use, cardiovascular risk assessment and management, and cancer screening and prevention. (Ungraded best practice statement)

3.0 Hormone therapy for menopausal symptom relief

3.1 Estrogen and progestogen therapy

3.1a For menopausal women < 60 years of age or < 10 years past menopause with bothersome VMS (with or without additional climacteric symptoms) who do not have contraindications or excess cardiovascular or breast cancer risks and are willing to take menopausal hormone therapy (MHT), we suggest initiating estrogen therapy (ET) for those without a uterus and estrogen plus progestogen therapy (EPT) for those with a uterus. (2|⊕⊕◯◯)

Cardiovascular risk

3.1b For women < age 60 or < 10 years past menopause onset considering MHT for menopausal symptom relief, we suggest evaluating the baseline risk of cardiovascular disease (CVD) and taking this risk into consideration when advising for or against MHT and when selecting type, dose, and route of administration. (2|⊕⊕◯◯)

3.1c For women at high risk of CVD, we suggest initiating nonhormonal therapies to alleviate bothersome VMS (with or without climacteric symptoms) over MHT. (2|⊕⊕◯◯)

3.1d For women with moderate risk of CVD, we suggest transdermal estradiol as first-line treatment, alone for women without a uterus or combined with micronized progesterone (or another progestogen that does not adversely modify metabolic parameters) for women with a uterus, because these preparations have less untoward effect on blood pressure, triglycerides, and carbohydrate metabolism. (2|⊕⊕◯◯)

Venous thromboembolic events

3.1e For women at increased risk of venous thromboembolism (VTE) who request MHT, we recommend a nonoral route of ET at the lowest effective dose, if not contraindicated (1|⊕⊕◯◯); for women with a uterus, we recommend a progestogen (for example, progesterone and dydrogestone) that is neutral on coagulation parameters. (1|⊕⊕⊕◯)

Breast cancer

3.1f For women considering MHT for menopausal symptom relief, we suggest evaluating the baseline risk of breast cancer and taking this risk into consideration when advising for or against MHT and when selecting type, dose, and route of administration. (2|⊕⊕◯◯)

3.1g For women at high or intermediate risk of breast cancer considering MHT for menopausal symptom relief, we suggest nonhormonal therapies over MHT to alleviate bothersome VMS. (2|⊕⊕◯◯)

Tailoring MHT

3.1h We suggest a shared decision-making approach to decide about the choice of formulation, starting dose, the route of administration of MHT, and how to tailor MHT to each woman's individual situation, risks, and treatment goals. (Ungraded best practice statement)

Custom-compounded hormones

3.1i We recommend using MHT preparations approved by the US Food and Drug Administration (FDA) and comparable regulating bodies outside the United States and recommend against the use of custom-compounded hormones. (Ungraded best practice statement)

3.2 Conjugated equine estrogens with bazedoxifene

3.2 For symptomatic postmenopausal women with a uterus and without contraindications, we suggest the combination of conjugated equine estrogens (CEE)/bazedoxifene (BZA) (where available) as an option for relief of VMS and prevention of bone loss. (2|⊕⊕⊕◯)

3.3 Tibolone

3.3a For women with bothersome VMS and climacteric symptoms and without contraindications, we suggest tibolone (in countries where available) as an alternative to MHT. (2|⊕⊕◯◯)

3.3b We recommend against adding tibolone to other forms of MHT. (1|⊕⊕◯◯)

3.3c We recommend against using tibolone in women with a history of breast cancer. (1|⊕⊕◯◯)

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3.4 Clinical management of patients taking hormone therapies

Monitoring during therapy

3.4a For women with persistent unscheduled bleeding while taking MHT, we recommend evaluation to rule out pelvic pathology, most importantly, endometrial hyperplasia and cancer. (1|⊕⊕⊕◯)

3.4b We recommend informing women about the possible increased risk of breast cancer during and after discontinuing EPT and emphasizing the importance of adhering to age-appropriate breast cancer screening. (1|⊕⊕⊕◯)

3.4c We suggest that the decision to continue MHT be revisited at least annually, targeting the shortest total duration of MHT consistent with the treatment goals and evolving risk assessment of the individual woman. (Ungraded best practice statement)

3.4d For young women with primary ovarian insufficiency (POI), premature or early menopause, without contraindications, we suggest taking MHT until the time of anticipated natural menopause, when the advisability of continuing MHT can be reassessed. (2|⊕⊕◯◯)

Stopping considerations

3.4e For women preparing to discontinue MHT, we suggest a shared decision-making approach to elicit individual preference about adopting a gradual taper vs abrupt discontinuation. (2|⊕⊕◯◯)

4.0 Nonhormonal therapies for VMS

4.0 For postmenopausal women with mild or less bothersome hot flashes, we suggest a series of steps that do not involve medication, such as turning down the thermostat, dressing in layers, avoiding alcohol and spicy foods, and reducing obesity and stress. (2|⊕⊕◯◯)

4.1 Nonhormonal prescription therapies for VMS

4.1a For women seeking pharmacological management for moderate to severe VMS for whom MHT is contraindicated, or who choose not to take MHT, we recommend selective serotonin reuptake inhibitors (SSRIs)/serotonin-norepinephrine reuptake inhibitors (SNRIs) or gabapentin or pregabalin (if there are no contraindications). (1|⊕⊕⊕◯)

4.1b For those women seeking relief of moderate to severe VMS who are not responding to or tolerating the nonhormonal prescription therapies, SSRIs/SNRIs or gabapentin or pregabalin, we suggest a trial of clonidine (if there are no contraindications). (2|⊕⊕◯◯)

4.2 Over-the-counter and alternative nonhormonal therapies for VMS

4.2 For women seeking relief of VMS with over-the-counter (OTC) or complementary medicine therapies, we suggest counseling regarding the lack of consistent evidence for benefit for botanicals, black cohosh, omega-3-fatty acids, red clover, vitamin E, and mind/body alternatives including anxiety control, acupuncture, paced breathing, and hypnosis. (2|⊕⊕◯◯)

5.0 Treatment of genitourinary syndrome of menopause

5.1 Vaginal moisturizers and lubricants

5.1a For postmenopausal women with symptoms of vulvovaginal atrophy (VVA), we suggest a trial of vaginal moisturizers to be used at least twice weekly. (2|⊕⊕◯◯)

5.1b For women who do not produce sufficient vaginal secretions for comfortable sexual activity, we suggest vaginal lubricants. (2|⊕⊕◯◯)

5.2 Vaginal estrogen therapies

5.2a For women without a history of hormone- (estrogen) dependent cancers who are seeking relief from symptoms of genitourinary syndrome of menopause (GSM) (including VVA) that persist despite using vaginal lubricants and moisturizers, we recommend low-dose vaginal ET. (1|⊕⊕⊕◯)

Practice statement

5.2b In women with a history of breast or endometrial cancer, who present with symptomatic GSM (including VVA), that does not respond to nonhormonal therapies, we suggest a shared decision-making approach that includes the treating oncologist to discuss using low-dose vaginal ET. (Ungraded best practice statement)

5.2c For women taking raloxifene, without a history of hormone- (estrogen) dependent cancers, who develop symptoms of GSM (including VVA) that do not respond to nonhormonal therapies, we suggest adding low-dose vaginal ET. (2|⊕⊕◯◯)

5.2d For women using low-dose vaginal ET, we suggest against adding a progestogen (ie, no need for adding progestogen to prevent endometrial hyperplasia). (2|⊕◯◯◯)

5.2e For women using vaginal ET who report postmenopausal bleeding or spotting, we recommend prompt evaluation for endometrial pathology. (1|⊕⊕◯◯)

5.3 Ospemifene

5.3a For treatment of moderate to severe dyspareunia associated with vaginal atrophy in postmenopausal women without contraindications, we suggest a trial of ospemifene. (2|⊕⊕⊕◯)

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5.3b For women with a history of breast cancer presenting with dyspareunia, we recommend against ospemifene. (1|⊕◯◯◯)

Method of Development of Evidence-based Clinical Practice Guidelines

The Clinical Guidelines Subcommittee (CGS) of The Endocrine Society deemed management of menopause a priority area in need of a practice guideline and appointed a Task Force to formulate evidence-based recommendations. The Task Force followed the approach recommended by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) group, an international group with expertise in development and implementation of evidence-based guidelines (1). A detailed description of the grading scheme has been published elsewhere (2). The Task Force used the best available research evidence to develop the recommendations. The Task Force commissioned three systematic reviews of the literature to inform its key recommendations. The Task Force used consistent language and graphical descriptions of both the strength of a recommendation and the quality of evidence using the recommendations of the GRADE system. In terms of the strength of the recommendation, strong recommendations use the phrase "we recommend" or "we recommend against" and the number 1, and weak recommendations use the phrase "we suggest" or "we suggest against" and the number 2. Cross-filled circles indicate the quality of the evidence, such that ⊕◯◯◯ denotes very low quality evidence; ⊕⊕◯◯, low quality; ⊕⊕⊕◯, moderate quality; and ⊕⊕⊕⊕, high quality. The Task Force has confidence that persons who receive care according to the strong recommendations will derive, on average, more good than harm. Weak recommendations require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action. Linked to each recommendation is a description of the evidence and the values the panelists considered when making the recommendation. In some instances, there are remarks, a section in which panelists offer technical suggestions for testing conditions, dosing, and monitoring. These technical comments reflect the best available evidence applied to a typical person being treated. Often this evidence comes from the unsystematic observations of the panelists and their values and preferences; therefore, these remarks should be considered suggestions. In this guideline, the Task Force made several statements to emphasize the importance of shared decision making, general preventive care measures, and basic principles of women's health. These were labeled as ungraded best practice statements. Direct evidence for these statements was either unavailable or not systematically appraised and was considered out of the scope of this guideline. The intention of these statements is to draw attention and remind providers of these principles, and these statements should not be considered as graded recommendations (3).

The 2013 Appraisal of Guidelines for Research and Evaluation II (AGREEII) criteria (23 items) were satisfied, with three exceptions. Item 5 stipulates that the views and preferences of the target population (patients, public, etc) have been sought. The Task Force did not conduct specific polling/outreach to the public in anticipation of this guideline. Item 14 states that a procedure for updating the guideline is provided. This process has not been formalized. Item 20 suggests that the potential resource implications of applying the recommendations have been considered. The Task Force did not include cost analysis of risk assessment tools or prescription drug therapies.

The Endocrine Society maintains a rigorous conflict-of-interest review process for the development of clinical practice guidelines. All Task Force members must declare any potential conflicts of interest, which are reviewed before the members are approved to serve on the Task Force and periodically during the development of the guideline. The conflict-of-interest forms are vetted by the CGS before the members are approved by the Society's Council to participate on the guideline Task Force. Participants in the guideline development must include a majority of individuals without conflict of interest in the matter under study. Participants with conflicts of interest may participate in the development of the guideline, but they must have disclosed all conflicts. The CGS and the Task Force have reviewed all disclosures for this guideline and resolved or managed all identified conflicts of interest.

Conflicts of interest are defined by remuneration in any amount from the commercial interest(s) in the form of grants; research support; consulting fees; salary; ownership interest (eg, stocks, stock options, or ownership interest excluding diversified mutual funds); honoraria or other payments for participation in speakers' bureaus, advisory boards, or boards of directors; or other financial benefits. Completed forms are available through the Endocrine Society office.

Funding for this guideline was derived solely from the Endocrine Society, and thus the Task Force received no funding or remuneration from commercial or other entities.

Commissioned systematic reviews

The Task Force formulated three questions for systematic reviews to provide evidence supporting this guideline. The first compared the effect of oral vs transdermal es-

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trogens on the risk of venous and arterial thrombotic events. Low-quality evidence derived from 15 observational studies suggested that, compared with transdermal MHT, oral MHT was associated with increased risk of VTE, deep vein thrombosis (DVT), and possibly stroke, but not myocardial infarction (MI) (4). The second question evaluated the effect of MHT on mortality. Data from 43 randomized controlled trials (RCTs) demonstrated no association between all-cause mortality, regardless of hormone type, the presence of pre-existing heart disease, or length of follow-up (5). Meta-analysis of 2 RCTs in which MHT was started at a *mean* age less than 60 and 3 RCTs in which MHT was started less than10 years after menopause suggested possible reduction of mortality with MHT. The third question compared the effect of MHT with natural progesterone vs synthetic progestins on breast cancer risk. Low-quality evidence from two observational studies suggested that natural progesterone may be associated with a reduced risk for breast cancer compared with synthetic progestins, but data were insufficient to draw a firm conclusion.

Introduction and background

VMS, hot flashes, and night sweats, are the hallmarks of menopause, although not all women experience these symptoms. Other climacteric symptoms include sleep disturbance (6, 7), arthralgia (7–9), and vaginal dryness and dyspareunia (7, 10, 11). It is less clear whether anxiety, irritability, depression, palpitations, skin dryness, loss of libido, and fatigue can be attributed to menopause (7, 9, 12). Symptoms frequently start in the years before the final menstrual period and can last, with unpredictable duration, from a few years to more than 13 years (13–16).

ET has long been recognized as the most effective treatment for the relief of bothersome vasomotor and vaginal symptoms associated with menopause. However, prescriptions for MHT declined considerably after the 2002 publication of the Women's Health Initiative (WHI) RCT. This study determined that for postmenopausal women (average age, 63 y), oral CEE alone after hysterectomy (17), or coupled with daily medroxyprogesterone acetate (MPA) in women with a uterus (18), was associated with risks disproportionate to preventive benefits (17, 18). During ensuing years, a consensus arose that most healthy symptomatic women, without contraindications and closer to the time of menopause (<10 y after menopause onset or age <60 y), were appropriate candidates for MHT for symptom relief (19, 20). Post hoc WHI analyses and observational data suggest that benefits exceed risks in most of these women. At this juncture, women in the United States and some other countries have a broader range of therapeutic choices than ever before, including: MHT dose, type, and route of administration; new selective estrogen receptor modulators (SERMs) as solo or combination therapies; and expanded choices of nonhormonal prescription medications. In this guideline, we emphasize safety in identifying which late perimenopausal and recently postmenopausal women are candidates for various therapeutic agents. Considerations include the risks and benefits of each available therapy, the expected duration of treatment, the intensity of monitoring during therapy, and most importantly, individualizing the course of therapy to reflect the specific characteristics of the patient who is making decisions regarding symptom management.

This guideline covers the full spectrum of therapies for relief of the most common and bothersome menopausal symptoms (Figure 1). (The detailed management of early menopause transition, primary ovarian insufficiency, and prevention of osteoporosis and fracture are considered beyond the current scope.) Choice of therapy is ideally based on available evidence regarding safety and efficacy and is generally a shared decision including both patient and provider. The treatment selected should be tailored to the individual patient and will vary according to each woman's symptom severity, age, medical profile, personal preference, and estimated benefit/risk ratio. The impact of severe menopausal symptoms on quality of life (QOL) can be substantial, and there are instances in which a woman with a history of coronary heart disease (CHD) or breast cancer, for example, will choose to accept a degree of risk that might otherwise be considered to outweigh the benefits of MHT. An accepted philosophy is that a fully informed patient should be empowered to make a decision that best balances individual QOL benefits against potential health risks (21).

1.0 Diagnosis and symptoms of menopause

1.1 We suggest diagnosing menopause based on the clinical criteria of the menstrual cycle. (2|⊕⊕◯◯)

1.2 If establishing a diagnosis of menopause is necessary for patient management in women having undergone a hysterectomy without bilateral oophorectomy or presenting with a menstrual history that is inadequate to ascertain menopausal status, we suggest making a presumptive diagnosis of menopause based on the presence of VMS and, when indicated, laboratory testing that includes replicate measures of FSH and serum estradiol. (2|⊕⊕◯◯)

Technical remark

Table 1 summarizes other etiologies of secondary amenorrhea to be considered in the differential diagnosis.

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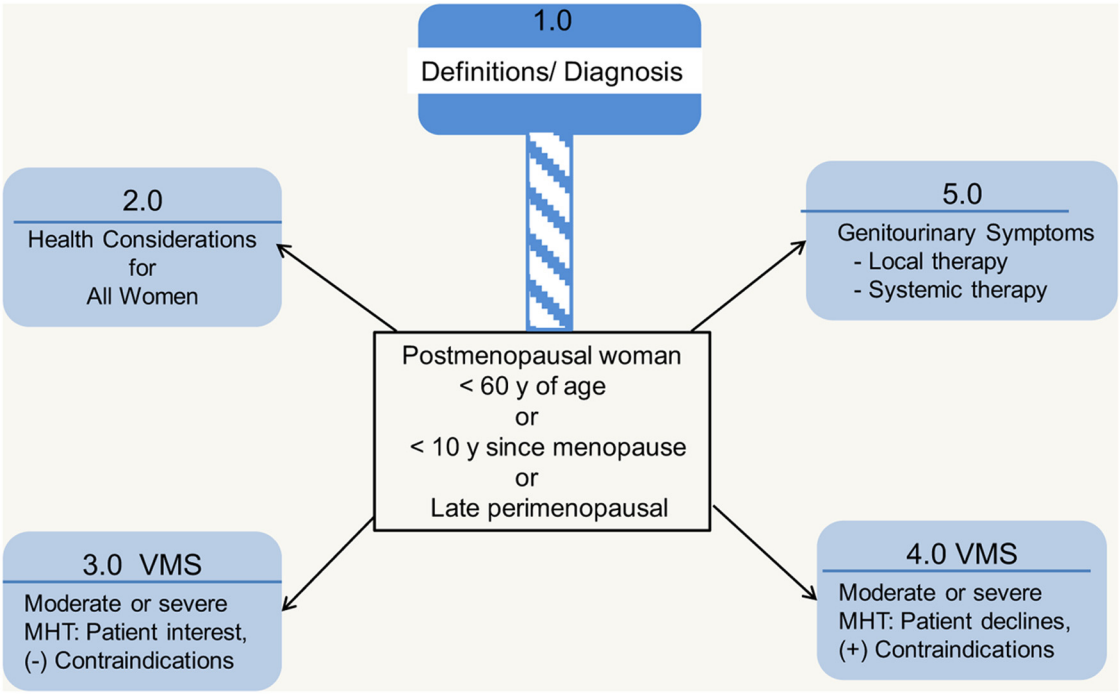

Figure 1. Approach to menopause guideline. Numbers correspond to section of text addressing selected clinical issue.

Diagnosis

Table 1 lists definitions of the clinical spectrum of menopause. In a woman with an intact uterus, menopause is a clinical diagnosis based upon cessation of menses for at least 12 months. Sex steroids, gonadotropins, inhibin B, or anti-Mullerian hormone measurements do not further inform the diagnosis, do not indicate precisely when the final menstrual period will occur, and will not influence management unless a woman is seeking fertility. In women having undergone a hysterectomy but not bilateral oophorectomy, elevated FSH levels and estradiol concentrations < 20 pg/mL on several occasions support but do not

Table 1. Definitions of Spectrum of Menopause

Menopause	Clinical status after the final menstrual period, diagnosed retrospectively after cessation of menses for 12 mo in a previously cycling woman and reflecting complete or nearly complete permanent cessation of ovarian function and fertility.
Spontaneous menopause	Cessation of menses that occurs at an average age of 51 y in the absence of surgery or medication (316–318).
Menopausal transition (or perimenopause)	An interval preceding the menopause characterized by variations in menstrual cycle length and bleeding pattern, mood shifts, vasomotor, and vaginal symptoms and with rising FSH levels and falling anti-Mullerian hormone and inhibin B levels, which starts during the late reproductive stage and progresses during the menopause transition (15, 319).
Climacteric	The phase in the aging of women marking the transition from the reproductive phase to the nonreproductive state. This phase incorporates the perimenopause by extending for a longer variable period before and after the perimenopause.
Climacteric syndrome	When the climacteric is associated with symptomatology.
Menopause after hysterectomy without oophorectomy	Spontaneous cessation of ovarian function without the clinical signal of cessation of menses.
Induced menopause	Cessation of ovarian function induced by chemotherapy, radiotherapy, or bilateral oophorectomy.
Early menopause	Cessation of ovarian function occurring between ages 40 and 45 in the absence of other etiologies for secondary amenorrhea (pregnancy, hyperprolactinemia, and thyroid disorders).
POI	Loss of ovarian function before the age of 40 y with waxing and waning course and potential resumption of menses, conception, and pregnancy (320). The prevalence of POI is approximately 1% (321) and is differentiated into idiopathic, autoimmune (associated with polyglandular autoimmune syndromes), metabolic disorders, and genetic abnormalities (including fragile X premutation).

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confirm the diagnosis. A distinction between the late perimenopause transition, marked by episodes of > 60 days of amenorrhea and increasing severity of VMS (15), and early postmenopause cannot be made on the sole basis of hormone measurements. With radiotherapy- or chemotherapy-induced menopause, it is important to recognize that ovarian function may resume after 12 months of amenorrhea (22), depending on the age of the woman and the dose and duration of treatment (22). For POI, persistent FSH elevation in women < age 40 provides a tentative diagnosis (Table 1).

Signs and symptoms

Vasomotor symptoms

Prevalence. Hot flashes (also called hot flushes) occur in approximately 75% of postmenopausal women in the United States (23). In the Study of Women Across the Nation (SWAN), after controlling for age, education, health, and economic strain, researchers found that US Caucasian women report more psychosomatic symptoms, African American and Hispanic women report more VMS, and Asian women report more somatic complaints (16, 24). Notably, across countries and ethnic backgrounds, the percentage of women reporting hot flashes varies (25–27). In a cross-sectional study of premenopausal women (mean age, 48 y), one-third reported "ever" experiencing hot flashes (28). A comparison between VMS experienced during the premenopause vs the postmenopause may be informative when counseling a postmenopausal woman regarding symptom relief, although to our knowledge, the presence and frequency of premenopausal hot flashes have not been studied as being predictive of response to therapy in the postmenopause. Persistence of hot flashes may also vary depending upon when in the menopausal transition VMS were first noted. In SWAN, earlier onset of VMS was associated with longer postmenopausal duration (16).

Clinical manifestations. Hot flashes typically begin as the sudden sensation of heat centered on the upper chest and face. When moderate or severe, the hot flash rapidly becomes generalized, lasts from 2 to 4 minutes, and can be associated with profuse perspiration, palpitations, or anxiety. Triggers include spicy food or alcohol. At night, vasomotor instability manifests as hot flashes or night sweats, which may represent different physiological mechanisms. The differential diagnosis includes several entities distinguishable by clinical features (Table 2). New-onset VMS in older (age, ≥ 65 y) postmenopausal women may be associated with, but not necessarily causally related to, increased risk of major CHD and all-cause mortality (29).

Table 2. Conditions That May Cause or Mimic Vasomotor Events and That Can Be Distinguished From Menopausal Symptoms by History, Examination, and Investigations, as Indicated

Hormone excess
Thyroid hormone excess
Carcinoid syndrome (flushing without sweating)
Pheochromocytoma (hypertension, flushing, and profuse sweating)
Dietary factors
Alcohol
Spicy food
Food additives (eg, monosodium glutamate, sulfites)
Pharmaceuticals
Chronic opioid use
Opiate withdrawal
SSRIs (may cause sweats)
Nicotinic acid (intense warmth, itching lasting up to 30 min)
Calcium channel blockers
Medications that block estrogen action or biosynthesis
Chronic infection (increased body temperature)
Other medical conditions
Postgastric surgery dumping syndrome
Mastocytosis and mast cell disorders (usually with gastrointestinal symptoms)
Some cancers: medullary carcinoma of the thyroid, pancreatic islet-cell tumors, renal cell carcinoma, lymphoma
Anxiety disorders

Association with sleep. In polysomnography studies, nocturnal hot flashes are more common during the first 4 hours of sleep, whereas subsequent rapid eye movement sleep suppresses hot flashes, arousals, and awakenings (30). A recent study that induced estrogen deficiency in healthy premenopausal women with a GnRH agonist directly demonstrated that hot flashes are associated with three factors: 1) an increase in episodes of waking after sleep-onset; 2) a decrease in perceived sleep efficiency; and 3) a statistically significant correlation between nocturnal VMS and sleep disruption (31). Although these data are informative, it has not been substantiated whether they apply in naturally postmenopausal women with continuously high gonadotropins. An important contributing factor is aging, which likely is also involved in sleep disturbances in menopausal women.

Mechanisms. VMS appear to involve the central nervous system (32) because: 1) hot flashes occur simultaneously with, but are not caused by, LH pulses (33, 34); and 2) research has shown an association with the neuroregulators kisspeptin, neurokinin B, and dynorphin (35). Alterations of thermoregulatory systems are mechanistically involved because women with hot flashes exhibit a narrowing of the thermoregulatory-neutral zone (32). Whereas premenopausal women initiate mechanisms to dissipate heat when the core body temperature increases

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by 0.4°C, this happens with much lower increases in temperature in menopausal women (36). Core body temperature is usually still within the normal range at the onset of the flash, but inappropriate peripheral vasodilatation with increased digital and cutaneous blood flow and perspiration results in rapid heat loss and a fall in core body temperature (32). Shivering may occur to restore the core temperature (36).

Genitourinary syndrome of menopause

This new term "genitourinary syndrome of menopause" (GSM) combines the conditions of VVA and urinary tract dysfunction (Table 3) (37). VVA most often presents in the late postmenopausal stage, when VMS may have abated (15). When VVA is severe, women may have discomfort wearing tight-fitting clothing or while sitting or exercising. Sexual activity is not required for patients to experience vaginal or genital discomfort. Urinary symptoms— dysuria, urinary frequency, and recurrent urinary tract infections—increase in severity with time since menopause.

Other signs and symptoms

The menopausal decline of estradiol increases bone resorption and contributes to fractures (38).

Possible related signs and symptoms

Research has suggested (but not proven) a direct relationship between menopause and mood changes, mild depressive symptoms, anxiety, irritability, arthralgias, loss of libido, palpitations, skin dryness, fatigue, and reduction in QOL (38, 39). As opposed to the conclusions in the 2005 National Institutes of Health State of the Science consensus regarding the uncertain relationship between mood and menopause, more recent longitudinal studies now support an association of the menopause transition with depressed mood, major depressive episodes, and anxiety.

Table 3. Genitourinary Syndrome of Menopause

Symptoms
Vulvar pain, burning, or itching
Vaginal dryness
Vaginal discharge
Dyspareunia
Spotting or bleeding after intercourse
Dysuria, urinary frequency, urgency
Recurrent urinary tract infections
Signs, external genitalia
Decreased labial size
Loss of vulvar fat pads
Vulvar fissures
Receded or phimotic clitoris
Prominent urethra with mucosal eversion or prolapse
Signs, vagina
Introital narrowing
Loss of elasticity with constriction
Thin vaginal epithelial lining
Loss of mature squamous epithelium
Pale or erythematous appearance
Petechiae, ulcerations, or tears
Alkaline pH (>5.5)
Infection (yellow or greenish discharge)

Derived from D. J. Portman et al: Genitourinary syndrome of menopause: new terminology for vulvovaginal atrophy from the International Society for the Study of Women's Sexual Health and the North American Menopause Society. *Menopause*. 2014;21:1063–1068 (37), with permission.

2.0 Health considerations for all menopausal women

2.1 When women present during the menopausal transition, we suggest using this opportunity to address bone health, smoking cessation, alcohol use, cardiovascular risk assessment and management, and cancer screening and prevention. (Ungraded best practice statement)

Evidence

The menopause transition, a portal to the second half of life, is a critical window to reassess lifestyle, recognize ongoing and potential health concerns, and encourage a proactive approach to future well-being, regardless of menopausal symptoms. To decrease morbidity and mortality from CVD and cancer and maintain QOL, optimizing diet and exercise to maintain healthy weight are important measures, as are counseling regarding alcohol use and smoking cessation and identifying and treating hypertension, glucose intolerance, and dyslipidemias (40, 41).

Adequate intake of calcium and vitamin D, along with limiting alcohol consumption will minimize bone loss and reduce the risk of falls and fractures (42). For postmenopausal women < 65 years of age and at high risk of osteoporosis, dual-energy x-ray absorptiometry assessment of bone mineral density contributes to risk assessment. ET for the relief of menopausal symptoms prevents bone loss and reduces fracture risk (43). Women without VMS and at significant risk of osteoporosis can discuss the merits of ET for bone preservation. Recent guidelines address bone-specific therapies (43).

3.0 Hormone therapy for menopausal symptom relief

3.1 Estrogen and progestogen therapy

3.1a For menopausal women < 60 years of age or < 10 years past menopause with bothersome VMS (with or without additional climacteric symptoms) who do not have contraindications or excess cardiovascular or breast cancer risks and are willing to take MHT, we suggest initiating ET for those without a uterus and EPT for those with a uterus. (2⊕⊕○○)

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Evidence

In postmenopausal women, ET improves menopause-associated (climacteric) symptoms (eg, VMS, genitourinary symptoms, sleep disturbance, menopause-associated anxiety and depressive symptoms, and arthralgias). ET also reduces menopause-related bone loss, lowers the risk of fragility fractures in older women, and reduces the incidence of self-reported diabetes. In addition, combined EPT reduced the risk of colorectal cancer and, in cumulative follow-up of the WHI, endometrial cancer (38, 44).

MHT is not appropriate for all symptomatic menopausal women (Figure 2). There are no commonly recognized lists of absolute or relative contraindications to MHT as published in professional society guidelines. And whereas US product labeling (regulated by the FDA) does include contraindications to MHT (Table 4), caution is also advised for women with certain additional medical conditions (Table 4). Risk/benefit assessment is the most important consideration, and QOL may be an important issue in a decision to recommend MHT. Women with conditions precluding MHT (Table 4) who are unwilling to take MHT, or at substantial risk for breast cancer or CVD, can consider nonhormonal options for symptom relief (*Section 4.0*).

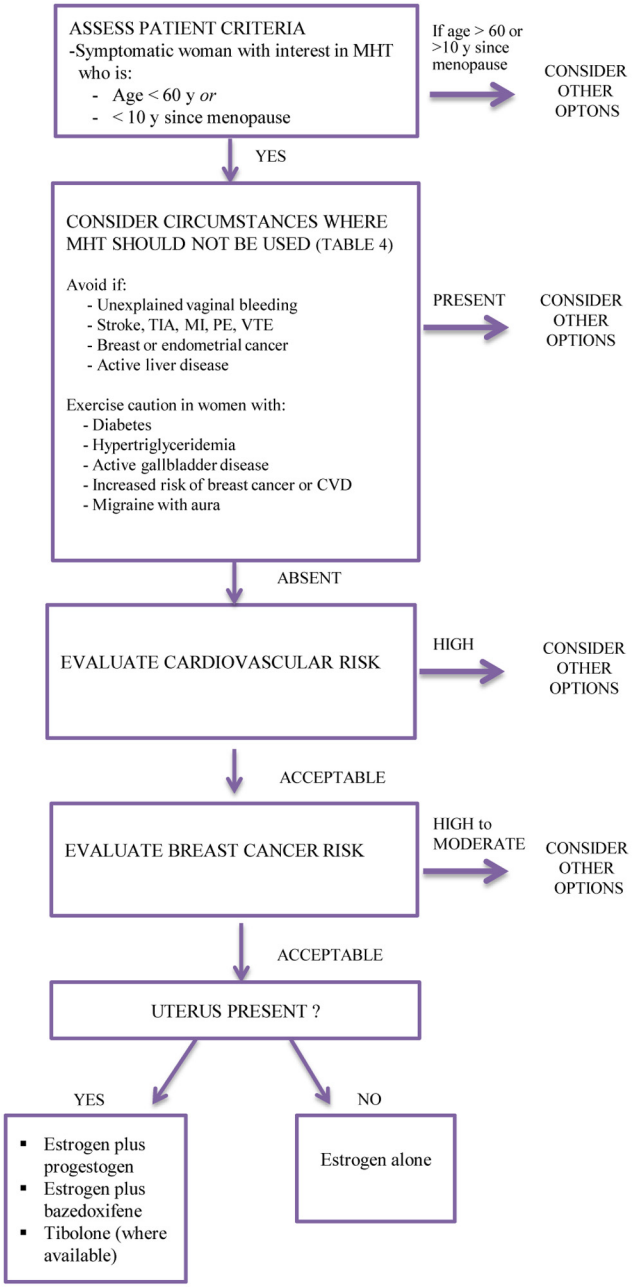

Figure 2. Approach to the patient with VMS contemplating MHT. TIA, transient ischemic attack.

Risks and benefit overview

Healthcare providers and patients should choose MHT based on individual risks and benefits utilizing a shared

Table 4. Specific Cautions to Use of Systemic MHT or SERMs[a,b] for Treatment of Menopausal Symptoms

In general, ET should not be used in women with any of the following conditions:
Undiagnosed abnormal genital bleeding
Known, suspected, or history of cancer of the breast
Known or suspected estrogen-dependent neoplasia including endometrial cancer
Active DVT, pulmonary embolism, or history of these conditions
Active arterial thromboembolic disease (for example, stroke, MI) or a history of these conditions
Known anaphylactic reaction or angioedema in response to any ingredient in the medication[c]
Known liver impairment or disease
Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders[c]
Known or suspected pregnancy
Caution should also be exercised in women with:
Gallbladder disease (oral ET)
Hypertriglyceridemia (>400 mg/d) (oral ET)
Diabetes
Hypoparathyroidism (risk of hypocalcemia)
Benign meningioma
Intermediate or high risk of breast cancer
High risk of heart disease
Migraine with aura (oral ET)
Other conditions[d]

[a] Also apply to conjugated estrogens/BZA, ospemifene, and tibolone therapies.

[b] Advice not to use estrogens in the specific conditions listed is based on FDA recommendations and package labeling in the United States. The advice to exercise caution is based on a review of the literature (including package labeling) and not dictums generally included in various Menopause Society guidelines. Because these guidelines are meant to be used internationally, it should be noted that these considerations may vary from country to country.

[c] Specific to CEE ± combination with BZA.

[d] Estrogen therapy may cause an exacerbation of asthma, diabetes mellitus, epilepsy, migraine, porphyria, systemic lupus erythematosus, and hepatic hemangiomas and should be used with caution in women with these conditions.

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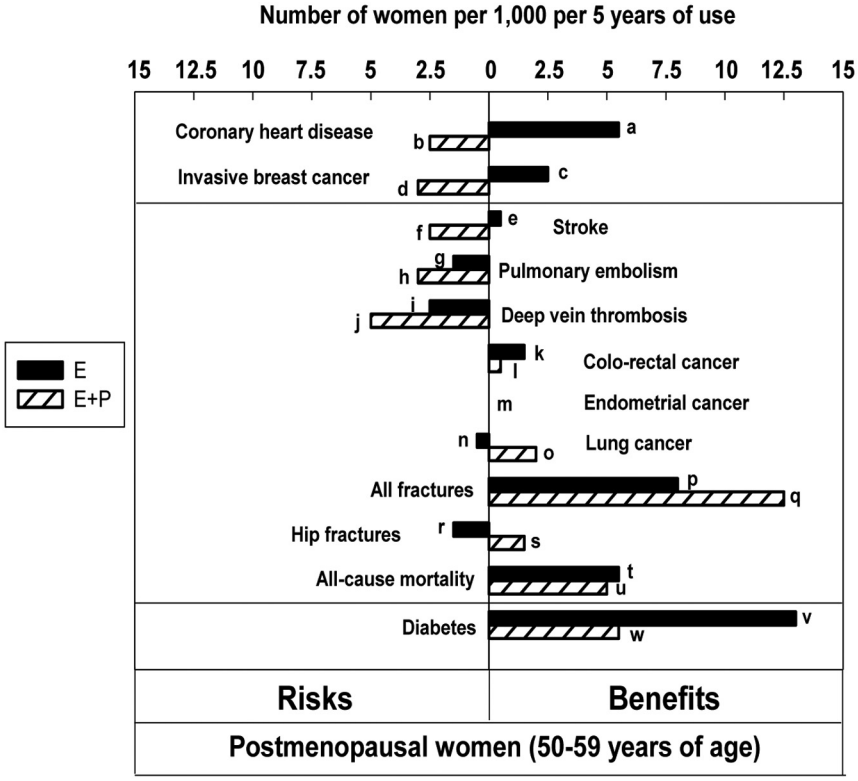

Figure 3. Updated summary of the effects of orally administered CEE alone or combined with MPA in women ages 50–59 years during intervention phase of WHI. One set of analyses examined the risks and benefits of these agents in women ages 50–59 years. This figure plots these data, which are expressed here as excess risks and benefits per 1000 women using MHT for 5 years. Because women deciding to use MHT are more likely to continue this for a period of years rather than 1 year, this figure is constructed according to that assumption. WHI studies were not powered for age-related subset analyses, and none of the data presented in the figure are statistically significant. Nonetheless, this figure represents the best estimates that are available at the present time and are likely more reliable than similar estimates based on observational studies as reported previously in The Endocrine Society Scientific Statement (38). The HR (95% CI) values for the bars in the figure are listed here with reference to the alphabetical designations shown next to the bars: a, HR, 0.60 (0.35–1.04); b, HR, 1.34 (0.82–2.19); c, HR, 0.82 (0.50–1.34); d, HR, 1.21 (0.81–1.80); e, HR, 0.99 (0.53–1.85); f, HR, 1.51 (0.81–2.82); g, HR, 1.53 (0.63–3.75); h, HR, 2.05 (0.89–4.71); i, HR, 1.66 (0.76–3.67); j, HR, 3.01 (1.36–6.66); k, HR, 0.71 (0.30–1.67); l, HR, 0.79 (0.29–2.18); m, HR, 1.00 (ns-ns); n, HR, 1.12 (0.45–2.75); o, HR, 0.62 (0.30–1.29); p, HR, 0.90 (0.72–1.11); q, HR, 0.82 (0.68–1.00); r, HR, 5.01 (0.59–42.9); s, HR, 0.17 (0.02–1.45); t, HR, 0.70 (0.46–1.09); u, HR, 0.67 (0.43–1.04); v, HR, 0.83 (0.67–1.04); and w, HR, 0.85 (0.66–1.09). [RJ Santen, et al: Competency in menopause management: whither goest the internist? *J Womens Health (Larchmt)*. 2014;23(4): 281–285, courtesy of Mary Ann Liebert, Inc].

decision-making approach. Current recommendations suggest that the initiation of MHT should generally be limited to women < 60 years of age or < 10 years after menopause onset. Accordingly, data are needed to estimate risks and benefits in this specific population. No adequately powered RCTs with clinical outcomes have been specifically conducted with younger, symptomatic women, however, and data for women < 50 years old are limited. The best available evidence comes from subgroup analyses of WHI data, which provide information specifically in women 50 to 59 years of age or < 10 years since menopause onset. Because of the number of women participants ages 50 to 59 (5520 in the combined therapy arm and 3313 in the estrogen-alone arm), and the low event rate for MI and stroke in this age group, such data provide trends but few statistically significant differences. Findings from observational studies, case reports, and clinical expertise, both from the United States and other countries, provide additional sources of evidence regarding younger postmenopausal women.

Estimations of risks and benefits previously published in The Endocrine Society's 2010 Scientific Statement utilized both observational and RCT data. However, updated outcomes from the WHI are now available. Accordingly, the updated reanalysis of the WHI (44) is considered by many to provide the best available data on risks and benefits in women ages 50 to 59, but not in those younger than age 50. The 2010 Statement expresses attributable (excess) benefits and risks as the number of affected women/1000 users/5 years of therapy, assuming that most women initiating MHT will consider therapy for 5 years. Maintaining this format, the risks and benefits (as reported in the WHI and reflecting the specific oral therapies studied) are presented in Figure 3 and are not repeated in the text of this guideline. These data, representing the effects of CEE with or without MPA, cannot be extrapolated to other MHT regimens. However, in the absence of RCTs with other specific agents, they provide the most conservative estimates. Notably, the baseline risk of most adverse events is lower in younger vs older women and results in lower attributable risk although relative risks may be similar among various age groups. The converse is also true for benefits, such as fracture reduction.

Benefits of MHT

Vasomotor symptoms

ET is the most effective treatment for VMS and improving QOL in symptomatic women (38). In a dose-dependent manner, MHT reduces hot flash frequency by approximately 75% and severity by 87%, compared with 50% with placebo (38, 45, 46).

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Genitourinary syndrome of menopause

Systemic estrogen administration effectively treats VVA and improves symptoms of overactive bladder and recurrent urinary tract infections (47, 48). With lower doses of systemic MHT, vaginal symptoms may persist and local therapy may be needed (*Section 5*).

Sleep disruption

Large placebo-controlled trials reported significantly fewer sleep disturbances with MHT use (44), but additional data are required for definitive conclusions.

Anxiety and depressive symptoms

Anxiety symptoms increase during the menopause transition and are associated with an increased likelihood of a major depressive disorder (49). ET may improve mild-to-moderate depressive symptoms during or shortly after the menopause transition, whereas antidepressant therapy remains appropriate treatment for major depression (50, 51).

Arthralgia

Joint pain or stiffness and general aches or pains were improved in women receiving EPT (38, 44, 52). Joint pain increased slightly after discontinuation of treatment (44).

Potential preventive benefits of menopausal hormone therapy

Although studies have suggested certain preventive benefits, the U.S. Preventive Services Task Force (53) and many expert groups (40, 54–56) recommend against MHT for primary or secondary disease prevention, whereas other experts disagree (57).

Bone loss and fracture. RCTs, observational studies, and meta-analyses consistently report reduction in bone loss with ET (38). The updated WHI analysis reports a significant reduction in vertebral fractures and a borderline significant reduction for all fractures with EPT in women ages 50 to 59 years (Figure 3); this effect was greater than with ET (44). Benefit may also be dose-related (38).

Type 2 diabetes. RCTs (58–60) and large observational studies (61, 62) reported that MHT reduced the prevalence of self-reported diabetes by 14 to 19% (44), an effect that did not persist after therapy was discontinued (44).

Colorectal cancer. In clinical trials, EPT was associated with a nonsignificant lower incidence of colorectal cancer in women ages 50 to 59 (44). Cancers that did occur in women receiving EPT, however, were diagnosed at a more advanced stage when all age groups were considered (64). The reduction in cancer during active therapy did not persist after discontinuation (44).

Endometrial cancer. During 13 years of cumulative follow-up of the WHI, combined CEE and MPA was associated with a 35% reduction in endometrial cancer in women ages 50 to 59 years (hazard ratio [HR], 0.65; 95% confidence interval [CI], 0.37–1.12) (44). This finding may be unique to the specific type, dose, and regimen utilized.

Risks of MHT

Endometrial cancer

Unopposed ET increases the risk of endometrial hyperplasia and cancer (38, 65, 66), whereas concurrent progestogen therapy (Table 5) for at least 12 days per month reduces this risk (18, 44, 67) and is recommended for all women with a uterus. Continuous combined CEE and MPA was associated with a reduced risk of endometrial cancer over 13 years of cumulative follow-up (44). After 6 to 10 years, sequential regimens may be associated with a 2-fold increased risk of endometrial cancer, particularly in thin women (38). Micronized progesterone and dydrogesterone, in combination with estrogen, have been associated with an approximate 2-fold increase in endometrial cancer when continued beyond 5 years in a large observational study (68). In contrast, one RCT comparing micronized progesterone with MPA (3 y) (69), a second RCT comparing micronized progesterone with chlormadinone acetate (18 mo) (70), and a third trial of single-tablet formulation of cyclical estradiol-dydrogesterone (2 y) (71) each demonstrated endometrial safety. The difference in outcome may reflect enhanced patient compliance with progestogen therapies when formulated in combination. Limited information is available about the safety of long cycle intermittent use of progestogens, but concern has been raised about increased risk of endometrial cancer (72, 73).

The levonorgestrel intrauterine device (not approved for a postmenopausal indication in the United States, but widely used in other countries and, increasingly, off-label in United States) appears effective at minimizing hyperplasia and endometrial cancer risk, especially in obese women (74–76).

Breast cancer

Estrogen therapy. Most, but not all, observational studies report an increased breast cancer risk with oral or transdermal estradiol when initiated in recently menopausal women (77–79). This increase occurs as a function of duration of ET (38, 80–82) with a linear trend in the largest study (83). Insufficient numbers of patients may confound

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Table 5. Commonly Prescribed Hormone Therapies

Preparation	Doses	Comments
Systemic estrogen therapies[a]		
Oral estrogen tablets		
Micronized E2	0.5, 1.0, 2.0 mg/d	
Estradiol valerate[b]	1.5 mg/d	
CEE	0.3, 0.45, 0.625 mg/d	Higher doses available Preparation used in WHI
Transdermal estrogens		
Estradiol patch	0.025 to 0.1 mg once or twice weekly depending on preparation	Corresponds to 0.5 to 2.0 mg estradiol tablets Diffusion can be different from one patch to another
	0.014 mg/wk	Preserved bone in women >60 y old
Estradiol percutaneous gel	0.25–1.5 mg qd	Corresponds to 0.5 to 2.0 mg estradiol tablets Can be transferred to persons and pets by skin contact
Estradiol transdermal spray	1.5 mg qd	Estradiol via spray Can be transferred to persons and pets by skin contact
Vaginal ring		
Estradiol acetate	0.05–0.10 mg/d	Systemic levels of estradiol provide relief of VMS; 90-d duration/ring
Progestogen therapies		
Oral progestin tablets		
Medroxyprogesterone acetate	2.5, 5, 10 mg/d	Utilized in WHI
Norethindrone	0.35 mg/d	
Neta	5.0 mg/d	
Megestrol acetate	20, 40 mg/d	
Dydrogesterone[b]	10 mg/d	
Chlormadinone acetate[b]	5, 10 mg/d	
Medrogestone[b]	5 mg/d	
Nomegestrol acetate[b]	3.75, 5 mg/d	
Promegestone[b]	0.125, 0.25, 0.5 mg/d	
Oral progesterone capsule		
Micronized progesterone	100, 200 mg/d	In peanut oil; avoid if peanut allergy. May cause drowsiness and should be taken at bedtime
Intrauterine system progestin[c]		
LNorg	20 μg released/d	IUD for 5-y use
	6 μg/d	IUD for 3-y use
Vaginal gel progesterone[c]	4%, 8%	45- or 90-mg applicator
Combination hormone therapies		
Oral		
CEE + MPA	0.3–0.625 mg/1.5–5 mg/d	Cyclic or continuous
E2 + Neta	0.5–1 mg/0.1–0.5 mg/d	Continuous
E2 + drospirenone	0.5–1 mg/0.25–1 mg/d	Continuous
E2 + norgestimate	1 mg/0.09 mg/d	Cycle 3 d E alone, 3 d E + progesterone
E2 + dydrogesterone[b]	1–2 mg/5–10 mg/d	Cyclic and continuous
E2 + cyproterone acetate[b]	2 mg/1 mg/d	Continuous
E2 + MPA[b]	1–2 mg/2–10 mg/d	Continuous
CEE + BZA[d]	0.45 mg/20 mg/d	Continuous
Transdermal		
E2 + Neta	50 μg/0.14–0.25 mg/patch	Twice weekly
E2 + LNorg	45 μg/0.015 mg/patch	Once weekly

Abbreviations: IUD, intrauterine device; E, estrogen; E2, 17-β estradiol; LNorg, levonorgestrel; Neta, norethindrone acetate or norethisterone acetate; qd, once daily.

[a] Not all preparations and doses are available in all countries.

[b] Only available outside the United States.

[c] Not approved in the United States for endometrial protection when administered with postmenopausal estrogen.

[d] Approved indications in the United States include treatment of moderate to severe VMS associated with menopause and prevention of postmenopausal osteoporosis. In the European Union, the indications state: treatment of estrogen deficiency symptoms in postmenopausal women with a uterus (with at least 12 mo since the last menses) for whom treatment with progestin-containing therapy is not appropriate. The experience treating women older than 65 years is limited.

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the interpretation of these data on ET alone (ie, type II statistical error). It is possible that in observational studies mammographic surveillance differed between users and nonusers of MHT. The finding of increased risk in recently menopausal women is controversial, however. In women in the WHI ages 50 to 59 or < 10 years after menopause onset, CEE did not increase risk (44, 84). The statistically significant 21% reduction of invasive breast cancer in the 13-year cumulative follow-up of all women in the estrogen-alone arm of the WHI was of similar magnitude in each age group (44), but some analyses have suggested less reduction or an increase in risk among women starting ET close to menopause (77, 85).

The presence or absence of obesity confounds the interpretation of existing data. The aromatase enzyme, which increases with obesity, results in enhanced endogenous estrogen production, which may minimize the additional effects of exogenous ET. The insulin resistance associated with obesity also confounds the relationship between obesity and breast cancer risk (86). Therefore, increased breast cancer risk with ET in non-US studies might reflect differing levels of obesity between US and European populations. CEE and estradiol may also have differential effects as suggested by in vitro (87) and primate (88) studies. In summary, the risk of breast cancer from estrogen alone, taken for 5 years, appears to be small.

Combined EPT. Studies examining the effects of combined therapy report a consistent increase in breast cancer risk (38, 89, 90). It should be noted that the original WHI study did not report any increase overall in women who had not previously used MHT (hormone naive), but data on this issue are not available for women ages 50 to 59 or < 10 years postmenopausal (18, 91), and there are no reported follow-up data for the hormone-naive women. In women ages 50 to 59 in the WHI, the excess risk of invasive breast cancer during the intervention phase persisted 7 years after the cessation of EPT, with 4.5 excess cases/1000 over 5 years (HR, 1.34; 95% CI, 1.03–1.75) (44). Studies have reported similar findings with most other estrogen/progestogen combinations (38, 89, 92). However, observational data suggest that progesterone or dydrogesterone (5, 89) may be associated with a lower risk, but further studies are required to confirm this. Observational studies also report a greater risk when EPT is started close to menopause (79, 85, 93) and with continuous rather than with cyclic regimens (78, 82, 94).

Lung cancer

In the 50- to 59-year age group in the WHI study, the incidence of lung cancer was not significantly increased or decreased in either treatment arm (44).

Ovarian cancer

In the 50- to 59-year age group of the WHI, the HR of ovarian cancer with EPT was 0.30 (two vs six cases; 95% CI, 0.06–1.47), with 1.5 fewer cases/1000 per 5 years of treatment (44). No data have been reported for ET. A controversial meta-analysis of 52 observational studies (95–97) showed an increase of 0.52 cases/1000 in women starting MHT (no difference in risk between ET and EPT) at age 50 and continuing therapy for 5 years. Risk persisted 5 years after stopping MHT, with 0.37 cases/1000 in the same women when ages 55 to 59 (95). Of note, the overall risk of ovarian cancer with EPT in the WHI (HR, 1.41), although not statistically significant, was comparable to findings in the meta-analysis, as was the rate in the cumulative follow-up (HR, 1.24). Based on current data, adequately powered RCTs are needed to fully ascertain ovarian cancer risk in symptomatic, recently postmenopausal women.

Coronary heart disease

Estrogen therapy. The age at initiation of ET influences risk. In the WHI, there was a trend toward a reduction in CHD and total MI in women aged 50 to 59 years at trial enrollment (44). Composite outcomes, including revascularization (98) and coronary artery calcium scores (99), were lower with ET than with placebo.

Observational studies of ET suggest the potential for CHD benefit in some women, although a number of biases might have contributed to those conclusions (100). In summary, ET does not increase CHD risk in women starting therapy at ages < 60 years and may possibly reduce this risk.

Although observational studies suggest that a dermal route of ET may carry a lower risk of MI (101, 102), a meta-analysis reported no significant difference in CHD outcomes between oral and transdermal MHT (4). No associations with estrogen dose were reported (101, 102).

Combined EPT. Age at initiation of EPT does not appear to influence the relative risk of CHD, based on the most recent WHI data (44) and a meta-analysis (4). In women in the WHI aged 50 to 59, there was a trend toward excess risk of CHD, but no increased risk was apparent in women < 10 years since menopause onset (44). These findings and those of several recent studies have been controversial. A randomized osteoporosis trial that did not have CHD as a predefined primary endpoint reported that 10 years of MHT treatment in women < 50 years old at study onset was associated with the reduction of a composite safety endpoint (death, hospital admission for MI, or heart failure) (103). This study has been criticized for its composite index and nonblinded nature. A primary pre-

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vention RCT of recently (< 3 y) postmenopausal women ages 42 to 58 failed to detect a difference in progression of atherosclerosis (as assessed by carotid intima-medial thickness and coronary artery calcium determinations) after 4 years of therapy (104) but may have been underpowered to detect significant differences (ie, type II error). In summary, EPT does not appear to be associated with an increased risk of CHD among women close to the onset of menopause, and if any risk elevation is present in women younger than 60 years, its magnitude is small. A definitive conclusion regarding CHD risk requires an appropriately powered RCT.

Stroke

Researchers reported a nonsignificant trend toward an increase in stroke risk with EPT in women ages 50 to 59 in the WHI (44) but did not report an adverse effect with ET. When examined by years since menopause, ET increased stroke risk in women < 10 years since menopause (6.5 women/1000 over 5 y) (44). The differences between these two groups might reflect the difficulty in establishing time of menopause in women with a hysterectomy.

No RCTs have evaluated stroke risk according to estrogen type, dose, or route of administration. Some observational studies suggest that transdermal estradiol in doses ≤ 50 μg may confer a lower risk compared with higher dose transdermal or oral therapies (4, 105). Other studies are conflicting regarding effects of estrogen type (102, 106) and dose (101, 105, 107). In summary, MHT may confer a small risk of stroke.

Venous thromboembolic events

Estrogen therapy. RCTs demonstrate that oral ET increases VTE risk in women ages 50 to 59 (44). These data are supported by observational studies (106, 108, 109). Risk declined after discontinuing therapy (44). Observational studies (108–112) and meta-analyses (4, 113) suggest that transdermal ET does not increase VTE risk, even in women with thrombophilia or obesity (114–117). In an observational study, oral CEE was associated with a 2-fold increase in VTE compared with oral estradiol (106).

Combined EPT. The WHI trial found an association between EPT and both DVT and pulmonary embolism (PE) in women ages 50 to 59 (44). Risks resolved when therapy was discontinued. Observational studies suggest that formulations containing MPA and normethytestosterone derivatives appear to be associated with greater risk than other progestogens (108, 109, 111). A recent meta-analysis comparing ET and EPT did not report any statistically significant differences in risk (4).

Gallbladder disease

No data are available specifically for women ages 50 to 59; conclusions regarding gallbladder disease rely on overall findings of the WHI. ET resulted in 29 excess cases/1000 women over 5 years (44). This risk did not persist after discontinuation (44, 118). With EPT, the excess risk was 23 women/1000 (44), similar to another trial (119). Risk persisted at least 5 years after cessation of EPT (44, 120). Observational studies report increased risk with oral, but not transdermal, estradiol (121, 122) and increased dose and duration (120, 123).

Incontinence

Stress urinary incontinence, urge urinary incontinence, and mixed urinary incontinence increase in women taking oral ET and EPT (124, 125). An increased risk may persist after discontinuation (44).

Uncertain benefits of hormone therapy

Mortality

A meta-analysis of RCTs demonstrated no significant effect on all-cause mortality with MHT use, but these data included women < and > 60 years of age (5). A recent Cochrane collaboration review reported a 30% relative risk reduction (HR, 0.70; 95% CI, 0.52–0.95) of all-cause mortality in women starting MHT < 10 years since menopause (or < age 60) (127). Comparison of the ET and EPT groups in the WHI suggested a stronger trend by age group among those on ET, with a statistically significant trend by age in the ET trial but not in the EPT trial (44). Observational studies (128–130) reported a reduction in mortality with MHT, as did one small RCT with composite endpoints (103). This is consistent with meta-analyses that reported a 30–40% mortality reduction (131, 132). In summary, further data are required for definitive conclusions about mortality in younger women.

Dementia

Observational studies suggest a possible benefit of MHT if started in younger women closer to menopause (133), as opposed to the detrimental effects reported in clinical trials when MHT is initiated in women > 65 years old (134). Some studies of postmenopausal women treated with estradiol reported an improvement in verbal memory and executive function (135–138), whereas other studies did not associate CEE therapy with cognitive improvement (139, 140). Definitive conclusions about MHT in women < age 60, therefore, are lacking.

Individual baseline risk assessment and therapeutic decisions

Evaluating risk facilitates individual counseling and decisions regarding MHT for symptom relief (Figure 2).

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However, no clinical trial evidence is available to support the practice of incorporating risk assessment instruments for quantifying cardiovascular (CHD, stroke, and VTE) and breast cancer risks among women considering MHT. Nevertheless, we feel that risk assessment instruments are useful to facilitate decision-making regarding MHT.

Cardiovascular risk

3.1b For women < age 60 or < 10 years past menopause onset considering MHT for menopausal symptom relief, we suggest evaluating the baseline risk of CVD and taking this risk into consideration when advising for or against MHT and when selecting type, dose, and route of administration. (2|⊕⊕◯◯)

3.1c For women at high risk of CVD, we suggest initiating nonhormonal therapies to alleviate bothersome VMS (with or without climacteric symptoms) over MHT. (2|⊕⊕◯◯)

Technical remarks

High risk includes known MI, cerebrovascular disease, and peripheral arterial disease, abdominal aortic aneurysm, diabetes mellitus, chronic kidney disease, and 10-year CVD risk > 10% (40).

3.1d For women with moderate risk of CVD, we suggest transdermal estradiol as first-line treatment, alone for women without a uterus or combined with micronized progesterone (or another progestogen that does not adversely modify metabolic parameters) for women with a uterus because these preparations have less untoward effect on blood pressure, triglycerides, and carbohydrate metabolism. (2|⊕⊕◯◯)

Evidence

Cardiovascular risk

Results showing fewer excess CHD and stroke events when MHT was initiated in younger rather than older study participants in the WHI (141) provide the foundation for the widely accepted consensus that MHT should be initiated primarily in younger women (age < 60 y) close in time (< 10 y) to menopause onset, when women likely have less baseline atherosclerosis (19, 20). The population prevalence of obesity, hypertension, dyslipidemia, and diabetes continues to increase. Accordingly, baseline CVD risk evaluation is important in women considering MHT. As reviewed in recent statements, CHD and stroke are associated with a wide range of risk factors, many unique to women (40, 41). Notably, a prior history of CHD conveys the highest risk of subsequent MI and stroke (142). We feel that methods to integrate these factors to categorize individual risk as minimal, moderate, and high are useful and can be accomplished qualitatively by clinical judgment or quantitatively by risk assessment tools.

Country- and population-specific CVD risk calculators are available to quantify individual risk per local guidelines (143). However, specific cutoffs for the safe use of MHT have not been formally validated, and practice differs from country to country.

The Menopause Decision-Support Algorithm (63) starts with calculating the American College of Cardiology (ACC)/American Heart Association (AHA) 10-year CVD risk (144), then stratifies by years since menopause to suggest appropriateness of MHT (Table 6) (63). For a woman at intermediate risk, family history, coronary artery calcium score, C-reactive protein, and ankle-brachial index can further stratify risk (144); inflammatory markers and lipid ratios predict treatment-related CHD events (145).

Metabolic syndrome. The metabolic syndrome (MetS) is associated with higher risk of cardiovascular events and breast and colon cancers (146). In a nested case-control study in the WHI, women with MetS at baseline were twice as likely to have CHD events while taking oral MHT as with placebo (147). In contrast, women without MetS had no increase in CHD risk on MHT. Transdermal estradiol with micronized progesterone might have less deleterious metabolic effects than oral therapies, but there are no RCTs that have evaluated the safety of these preparations in women with MetS.

Diabetes. Diabetes is considered by the AHA to be a CHD risk equivalent (40), which would suggest that women with diabetes should not take MHT. However, clinical trial evidence of CVD outcomes associated with MHT in women with diabetes is mostly lacking. Some diabetic women were included in RCTs (Heart and Estrogen/Progestin Replacement Study [19%]; WHI [4.4–7.7%]), but these trials were not powered to assess differences in CVD

Table 6. Evaluating CVD Risk in Women Contemplating MHT

	Years Since Menopause Onset	
10-y CVD Risk	**<5 y**	**6 to 10 y**
Low (<5%)	MHT ok	MHT ok
Moderate (5–10%)	MHT ok (choose transdermal)	MHT ok (choose transdermal)
High (>10%)[a]	Avoid MHT	Avoid MHT

CVD risk calculated by ACC/AHA Cardiovascular Risk Calculator (144). Methods to calculate risk and risk stratification vary among countries. Derived from J. E. Manson: Current recommendations: what is the clinician to do? *Fertil Steril.* 2014;101:916–921 (63), with permission. © Elsevier Inc.

[a] High risk includes known MI, stroke, peripheral artery disease, etc.

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outcomes. A few short-term RCTs have evaluated glucose control in diabetic women taking a variety of MHT preparations and showed either no effect or improved control (148). The evidence at this time is inadequate to make firm recommendations. An individualized approach to treating menopausal symptoms could be considered, with a low threshold to recommend nonhormonal therapies, particularly in women with concurrent CVD. However, some diabetic women, after careful evaluation of cardiovascular risk, may be candidates for MHT, preferably transdermal estrogen and micronized progesterone or another less metabolically active progestogen.

Venous thromboembolic events

3.1e For women at increased risk of VTE who request MHT, we recommend a nonoral route of ET at the lowest effective dose, if not contraindicated (1|⊕⊕◯◯); for women with a uterus, we recommend a progestogen (for example, progesterone and dydrogestone) that is neutral on coagulation parameters. (1|⊕⊕⊕◯)

Evidence

Obesity, age, and thrombophilia are associated with increased risk of VTE. An approximately 2-fold increased risk of VTE (both DVT and PE) with oral MHT is similar among women at low, intermediate, or high risk (149, 150). Accordingly, the attributable risk of MHT will be higher in those at high or intermediate baseline risk.

A prior history of VTE confers the highest risk. If the patient has a known inherited coagulation defect, such as Factor V Leiden, oral ET or EPT should be avoided because research has shown a high risk of VTE recurrence (114). A history of VTE due to pregnancy, oral contraceptives, unknown etiology, or blood clotting disorders poses a contraindication to any ET, whereas VTE due to past immobility, surgery, or bone fracture would be a contraindication to oral but not necessarily transdermal MHT (151). In some countries, a history of any VTE is a contraindication to oral but not low-dose transdermal ET.

Breast cancer

3.1f For women considering MHT for menopausal symptom relief, we suggest evaluating the baseline risk of breast cancer and taking this risk into consideration when advising for or against MHT and when selecting type, dose, and route of administration. (2|⊕⊕◯◯)

3.1g For women at high or intermediate risk of breast cancer considering MHT for menopausal symptom relief, we suggest nonhormonal therapies over MHT to alleviate bothersome VMS. (2|⊕⊕◯◯)

Technical remarks

High or intermediate risk includes calculated level of risk that would qualify for risk-reducing medications.

Evidence

There are no established clear criteria for recommending (or avoiding) MHT based on a woman's risk of breast cancer. Nonsignificant trends from the WHI suggest that the relative risk of breast cancer in association with MHT remains stable or increases in the 5-year Gail model breast risk categories of < 1.25 vs ≥ 1.75. On this basis, the excess or attributable risk should increase in women at higher categories of risk (90, 152). As another consideration, it seems prudent not to recommend MHT for women whose risk meets the criteria for breast cancer prevention with SERMs or aromatase inhibitors. The U.S. Preventive Services 2013 Task Force recommends that women with a 5-year risk of $\geq 3\%$ should be considered for preventive therapy with tamoxifen or raloxifene (126), whereas the American Society of Clinical Oncology guidelines suggest discussing such therapy in women with a risk of $\geq 1.67\%$ (153), consistent with enrollment criteria of breast cancer prevention trials. Prevention recommendations differ outside the United States. Another consideration is to take into account the data suggesting that breast cancer risk is associated with combined estrogen/progestogen use, but less so, if at all, with CEE alone.

We suggest one potential algorithm for MHT counseling, extrapolated from breast cancer prevention trial enrollment criteria (Table 7); however, it is not validated in clinical trials or widely utilized. This algorithm requires the assessment of breast cancer risk, which can be accomplished by qualitative methods or preferably with readily available quantitative risk assessment tools. The National Cancer Institute Breast Cancer Risk Assessment Tool pro-

Table 7. Breast Cancer Risk Cutoffs for Counseling Before Recommending MHT[a]

Risk Category[a]	5-y NCI or IBIS Breast Cancer Risk Assessment, %	Suggested Approach
Low	<1.67	MHT ok
Intermediate	1.67–5	Caution[b]
High	>5	Avoid

Abbreviations: IBIS, International Breast Intervention Study; NCI, National Cancer Institute.

[a] Categories here are newly defined for these guidelines and based on recommendations published for use of antiestrogens for breast cancer prevention (126, 153, 322, 323). The assumption is that candidates for breast cancer prevention with antiestrogens should not be candidates for initiating MHT. Method to calculate risk varies among countries.

[b] Caution indicates need for detailed counseling regarding anticipated benefits and risks of MHT with strong consideration of nonhormonal therapies for symptom relief, and possible consideration of chemopreventive strategies for women who meet suggested criteria.

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vides a standardized online risk calculator for 5-year risk of invasive breast cancer (154). The International Breast Intervention Study calculator predicts 10-year and lifetime risk (155, 156). For women with strong family histories of breast cancer, several other methods are available (155). Although these provide useful predictive information, all are limited by only moderate discriminatory accuracy (155). Mammographic breast density, when added to these methods, may emerge as an important objective risk for women contemplating MHT (157–159).

Although a history of breast cancer is considered by most to be a contraindication to MHT, the severity of menopausal symptoms, the compromise in QOL experienced by breast cancer survivors, and limitations of nonhormonal therapies for relief of VMS present a persistent clinical challenge. As recently summarized, it is not possible from currently available studies to draw firm conclusions regarding the risks of MHT in this population (38), but adding estrogen seems counterintuitive when current breast cancer therapies interrupt or decrease estrogen levels. Future studies taking into account estrogen receptor status, time since diagnosis and therapy, mastectomy status, and risks for breast cancer recurrence might better inform decision-making.

Tailoring menopausal hormone therapy

3.1h We suggest a shared decision-making approach to decide about the choice of formulation, starting dose, the route of administration of MHT, and how to tailor MHT to each woman's individual situation, risks, and treatment goals. (Ungraded best practice statement)

Clinicians prescribe estrogen alone for women without a uterus. Starting dosages are generally lower than those in the WHI (Table 5), and the overarching principle is to use the lowest effective dose with upward titration based on clinical response. Clinicians usually do not measure estradiol levels to monitor therapy except when symptoms do not improve with escalating doses, particularly after changing the mode of administration from oral to transdermal. For younger women with surgical menopause or those with POI who are accustomed to higher baseline endogenous estradiol levels, clinicians often prescribe higher starting doses of ET (eg, transdermal estradiol, 100 μg), and then slowly lower the dose as tolerated. When women with premature menopause approach the age of natural menopause, the reassessment and tapering of MHT dose seems reasonable.

Estrogen preparations

Oral estrogens. Estradiol tablets or conjugated estrogens (synthetic or equine) are convenient, are studied most extensively, and alleviate climacteric symptoms in a dose-dependent fashion. CEE, derived from pregnant mares' urine and used for decades, contain more than 200 compounds with varying estrogenic potency (160). Oral micronized estradiol and other oral estrogen preparations may result in up to 5-fold higher levels of circulating estrone and 10- to 20-fold higher estrone sulfate than transdermally administered estradiol at comparable or even higher doses. The biological effects of these estrone and estrone-sulfate increments are unknown (161–163).

Cutaneous and transdermal estradiol. Cutaneous and transdermal estradiol, administered via percutaneous gels, sprays, emulsions, or transdermal patches, have a similar efficacy as oral ET in reducing climacteric symptoms and are easily tailored to the individual (164, 165). The primary advantage of transdermal ET is to alleviate the first-pass hepatic metabolic effect (166) of oral estrogens resulting in a procoagulant effect and increases in SHBG, thyroid-binding globulin, cortisol-binding globulin (167, 168), triglycerides, and markers of inflammation such as C-reactive protein (167, 169).

Transdermal therapies, at low doses, are preferable for women with a VTE risk, as evidenced by a recent meta-analysis commissioned for these guidelines (4), and they may also be preferable in patients with hypertension, hypertriglyceridemia, obesity, MetS, diabetes, or a history of gallbladder disease. Clinicians should keep in mind that there are no existing head-to-head RCTs with clinical outcomes that compare transdermal with oral therapies.

Vaginal delivery of systemic estrogens. Estradiol acetate vaginal rings, delivering 50 or 100 μg of estradiol daily (Table 5), provide consistent systemic estradiol levels for 3 months per ring insertion. They are indicated for treatment of moderate to severe VMS and VVA due to menopause (170, 171). High-dose vaginal creams containing estradiol or CEE (ie, 1–2 g) also result in systemic estrogen levels. Concomitant progestogen is needed with these preparations to abrogate endometrial stimulation. We discuss low-dose vaginal ETs for the specific treatment of GSM in *Section 5.0*.

Progestogen administration

In women with a uterus, a progestogen must be added to prevent endometrial hyperplasia and cancer. The various formulations (Table 5) are administered in two regimens. The combined sequential regimen includes estrogen for 20 to 25 days and a progestogen for 12 to 15 days each month. This approach is preferred for recently menopausal woman who are prone to breakthrough bleeding during the first year or two of therapy. The combined continuous regimen utilizes both an estrogen and pro-

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gestogen daily on a continuous basis. Clinicians can administer progestogen orally, transdermally by patch, vaginally, or by intrauterine administration (172). The levonorgestrel intrauterine device minimizes systemic progestogen absorption, but increased blood levels do occur, and one observational study reported higher breast cancer incidence (173).

Progestogen alone. For those who do not tolerate ET, progestogens can relieve VMS. In RCTs, oral synthetic progestogens (Table 5) (174, 175) and micronized progesterone (176) were effective. Clinical outcome trials are lacking in women with breast cancer; thus, progestogen therapy is best avoided, except under limited circumstances in these patients, because the effect on recurrence is unclear (80).

Custom-compounded hormones

3.1i We recommend using MHT preparations approved by the FDA and comparable regulating bodies outside the United States and recommend against the use of custom-compounded hormones. (Ungraded best practice statement)

Evidence

A number of FDA-approved hormonal therapies are "biochemically identical" to endogenous estradiol and progesterone and are preferred to custom-compounded options. Custom-compounded hormone therapies have become increasingly popular but are not recommended because the manufacturing process lacks FDA oversight (177). Clinical trials documenting the efficacy and safety of compounded progesterone for endometrial protection are lacking. Proponents of custom-compounded hormone therapies often advise measuring salivary hormone levels to monitor therapy. However, scientific evidence is lacking to justify salivary measurements due to inter- and intra-assay variability, variable salivary flow rates dependent upon hydration, food intake, and other factors, and the inability to predict the pharmacokinetics of a custom-compounded hormone dose in a manner that would allow for valid salivary sampling.

3.2 Conjugated equine estrogens with bazedoxifene

3.2 For symptomatic postmenopausal women with a uterus and without contraindications, we suggest the combination of CEE/BZA (where available) as an option for relief of VMS and prevention of bone loss. (2|⊕⊕⊕◯)

Evidence

The combination of CEE with the SERM/BZA (available in the United States and licensed in the European Union) relieves VMS and vaginal atrophy and reduces bone resorption in women with a uterus; it provides an alternative to progestogen therapy for women averse to vaginal bleeding, breast tenderness, or altered mood. A series of RCTs up to 2 years in duration evaluated effects of CEE/BZA (0.45 mg/20 mg, the approved dose) compared with MHT (CEE 0.45 mg/MPA 1.5 mg) (178–180).

Benefits

Vasomotor symptoms. The number and severity of moderate-to-severe VMS were significantly decreased at 12 weeks; hot flash frequency was reduced by 74% compared with 51% for placebo, and hot flash severity was reduced up to 54%. Hot flash reduction was sustained at 12 months ($P < .05$) (181).

Bone loss. Bone loss at the lumbar spine and hip was prevented in postmenopausal women at risk for osteoporosis (182), as reflected by reduction of serum bone turnover markers and enhancement of bone mineral density vs placebo (180, 181). At 12 months, CEE/BZA was less effective at the lumbar spine than CEE/MPA (180). Fracture data are lacking.

Vaginal effects. Treating postmenopausal women ages 40 to 65 with VVA at baseline (183) improved vaginal maturation at 12 weeks (181). Women reported a lower incidence of dyspareunia.

Quality of life. Secondary endpoints included improvements in sleep, health-related QOL, and improved treatment satisfaction (184, 185). In RCTs, both CEE/BZA and CEE/MPA improved sleep disturbance and time to fall asleep (185).

Safety considerations

Breast. The incidence of breast pain and tenderness was similar for CEE/BZA and placebo (185–187) and was less than with CEE/MPA. After 1 year of therapy with CEE/BZA, mammographic breast density was not appreciably different than with placebo, whereas it increased with CEE/MPA (184). In trials up to 2 years, the rates of breast cancer (reported as adverse events, not clinical outcomes) were not sufficient to assess risk or benefit (186, 187).

Endometrium. Cumulative amenorrhea rates for CEE/BZA were comparable with placebo and greater than for CEE/MPA (188). At 2 years, the incidence of neither endometrial hyperplasia nor endometrial cancer was increased (180, 189).

Potential risks

Adverse events. Although an osteoporosis trial found a 2-fold risk of VTE with BZA 20-mg therapy alone (190),

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there was no additive effect on VTE when BZA was combined with CEE, although adequately powered studies are necessary (181). In trials of up to 2 years in women ages 40 to 65, rates of cardiovascular events, cancers (breast, endometrial, ovarian), and mortality were similar to placebo (191), but studies were underpowered to draw firm conclusions regarding these endpoints.

3.3 Tibolone

3.3a For women with bothersome VMS and climacteric symptoms and without contraindications, we suggest tibolone (in countries where available) as an alternative to MHT. (2|⊕⊕◯◯)

3.3b We recommend against adding tibolone to other forms of MHT. (1|⊕⊕◯◯)

3.3c We recommend against using tibolone in women with a history of breast cancer. (1|⊕⊕◯◯)

Evidence

Tibolone belongs to the group of normethyltestosterone progestogen derivatives and has metabolites that exhibit estrogenic, progestogenic, and androgenic effects (192). This agent (193) is available in many countries outside of the United States at doses of 1.25–2.5 mg/d.

Benefits

Menopausal symptoms. Tibolone alleviates VMS with equivalent or lesser potency than conventional MHT. Tibolone also improves sleep, mood, and urogenital atrophy and may improve libido (194–197).

Bone loss and fracture. Tibolone prevents postmenopausal bone loss and osteoporotic fractures in women with osteoporosis (198, 199), but is not approved for this purpose because of the increased risk of stroke in older women with osteoporosis initiating therapy at ages ≥ 60 years (199).

Possible risks

Endometrium. There is no endometrial thickening (197) or increase in myoma with tibolone (200). A Cochrane analysis concluded that there was no clear evidence of endometrial cancer with tibolone therapy (seven RCTs, n = 8152; odds ratio, 1.98; 95% CI, 0.73–5.32) (194).

Thrombosis and CVD. In an observational study (110), tibolone did not increase the risk of thrombosis. In an RCT of older women with osteoporosis, tibolone increased stroke (199).

Breast and colon cancers. The incidence of breast tenderness is low (around 3%), (201, 202), and neither mammographic density nor invasive breast cancer was increased; however, the risk of colon cancer was decreased (199, 201). An RCT of women with a history of breast cancer, after a median follow-up of 3.1 years, reported a higher rate of breast cancer recurrence with tibolone (HR, 1.40; 95% CI, 1.14–1.70) (203). The study reported the greatest increase for women taking an aromatase inhibitor (HR, 2.42; 95% CI, 1.01–5.79).

3.4 Clinical management of patients taking hormone therapies

Monitoring during therapy

3.4a For women with persistent unscheduled bleeding while taking MHT, we recommend evaluation to rule out pelvic pathology, most importantly, endometrial hyperplasia and cancer. (1|⊕⊕⊕◯)

3.4b We recommend informing women about the possible increased risk of breast cancer during and after discontinuing EPT and emphasizing the importance of adhering to age-appropriate breast cancer screening. (1|⊕⊕⊕◯)

Technical remarks

Regular clinical follow-up, initially, within 1 to 3 months after starting MHT, and then every 6 to 12 months, depending upon the individual (and health care system), allows for monitoring efficacy and side effects (abdominal/pelvic pain, mastalgia, metrorrhagia, weight gain, mood changes, blood pressure), and if necessary, making treatment adjustments (Table 8).

Duration of therapy

3.4c We suggest that the decision to continue MHT be revisited at least annually, targeting the shortest total duration of MHT consistent with the treatment goals and evolving risk assessment of the individual woman. (Ungraded best practice statement)

Technical remarks

Most published recommendations suggest using MHT for the shortest duration possible, but strong evidence is lacking to support this recommendation. Current proposed limits on duration of therapy are informed by large intervention trials (5 to 7 y) with extended follow-up for 13 years (44). Regarding duration of use, these data suggest that risk rates for breast cancer and CVD increase with age and time since menopause, although the risks with ET appear to be less than with EPT. Ovarian cancer risk may also increase relative to duration of MHT (95). We conclude, and guidelines from other societies concur, that clinicians and patients should reassess MHT continuation yearly and discuss the risks (and individual benefits) beyond 5 years (55, 56). Patients likely to consider

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Table 8. Clinical Caveats During Treatment With MHT

Symptom/Condition When MHT Started	Approach to Resolution
Persistent, intolerable VMS	Switch mode of administration or adjust dose of estrogen and/or progestogen.
Hot flashes that persist after treatment adjustment	Consider another etiology of flashes (Table 2). Ensure absorption: if transdermal, consider serum estradiol determination.
Bleeding: approach depends on time since menopause, MHT regimen, duration of therapy, duration and character of bleeding	Sequential regimen may be more appropriate for recently menopausal (<2 y), because unscheduled bleeding with continuous combined MHT can be problematic. Persistent irregular bleeding (>6 mo) should be evaluated for endometrial pathology; if obese, diabetic, or having family history for endometrial cancer, evaluate sooner. Atrophic endometrium in women more remote from menopause may respond to increased estrogen dose if otherwise appropriate.
Breast tenderness	Usually responds to a reduction in estrogen dose or change in progestogen preparation. CEE/BZA may improve symptoms. Changing to tibolone may be helpful in women who develop mastalgia on conventional MHT.
Baseline TG level >200 mg/dL	Review family history and seek contributing factors. Transdermal ET is preferred. If oral estrogen is selected, monitor serum TG levels 2 wk after starting therapy.
Hypothyroid on thyroid replacement	Monitor TSH 6 to 12 wk after starting oral MHT; T_4 dose may need to be increased (209).

Abbreviation: TG, triglycerides.

continuing therapy include those who fail an attempt to stop EPT, who are at high risk for fracture, or for whom alternative therapies are not appropriate.

3.4d For young women with POI, premature, or early menopause, without contraindications, we suggest taking MHT until the time of anticipated natural menopause, when the advisability of continuing MHT can be reassessed. (2⊕⊕◯◯)

Stopping considerations

3.4e For women preparing to discontinue MHT, we suggest a shared decision-making approach to elicit individual preference about adopting a gradual taper vs abrupt discontinuation. (2⊕⊕◯◯)

Evidence

A number of studies have compared methods (ie, taper protocols vs abrupt cessation) to facilitate the discontinuation of MHT (204–207) and have detected no differences. Therefore, the approach to discontinuation is an individual choice. Anecdotally, some women find that a very low dose of ET maintains adequate symptom relief and well-being and prefer that to complete discontinuation.

Menopausal symptoms and joint pain can recur when MHT is discontinued (44). Depending on the severity of the symptoms, women may elect to restart MHT, perhaps at a lower dose, or seek relief with nonhormonal therapies. Accelerated bone loss was reported after the discontinuation of MHT, whereas in contrast, bone density is stable for some years after discontinuing bisphosphonate therapy. Bisphosphonates, however, remain in bone indefinitely, and most expert groups do not recommend initiating bisphosphonate therapy for osteoporosis prevention in women aged 50 to 59. Adverse effects such as osteonecrosis of the jaw and atypical femur fractures, while rare, increase with the duration of therapy. Furthermore, as opposed to reports from observational studies (208), in the long-term follow-up of the WHI, hip fracture rates did not increase during 5 to 7 years of observation after MHT was discontinued (44). Breast cancer risk after 5 years of EPT in the WHI persisted 7 years after discontinuation. A large meta-analysis of observational studies found a persistent risk of ovarian cancer up to a decade after discontinuing MHT (95). Urinary incontinence persisted after oral MHT was discontinued; however, the percentage of affected women was approximately one-third less than during active treatment (44). MHT discontinuation may result in symptoms of VVA (*Section 5.0*), and when oral therapy is discontinued, glucose, cholesterol, triglycerides, calcium, and TSH (209) levels may change.

4.0 Nonhormonal therapies for VMS

4.0 For postmenopausal women with mild or less bothersome hot flashes, we suggest a series of steps that do not involve medication, such as turning down the thermostat, dressing in layers, avoiding alcohol and spicy foods, and reducing obesity and stress. (2⊕⊕◯◯)

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Evidence

As hot flashes result from alterations of the thermoregulatory neutral zone, shedding layers of clothing, using fans, keeping the bedroom cool (30), avoiding alcohol and spicy foods, and reducing stress may be effective. Being overweight or obese is a risk factor for VMS (26, 210, 211), and weight loss may reduce hot flash frequency (212, 214).

4.1 Nonhormonal prescription therapies for VMS

4.1a For women seeking pharmacological management for moderate to severe VMS for whom MHT is contraindicated, or who choose not to take MHT, we recommend SSRIs/SNRIs or gabapentin or pregabalin (if there are no contraindications). (1|⊕⊕⊕◯)

Evidence

The interpretation of hot flash efficacy studies requires an appreciation of an important confounding factor. There is a strong, consistently reported placebo effect, which averages 30% (range, 4–57%; Figure 4) and occurs more often in women with high anxiety and stress scores (215–220). Clinical trials of paroxetine, venlafaxine, desvenlafaxine, citalopram, and escitalopram demonstrate statistically significant efficacy with a reduction of frequency of hot flashes ranging from 25 to 69% (Figure 4). The composite score of hot flash frequency and severity is reduced by 27–61%. Other agents such as sertraline and fluoxetine are associated with non-statistically significant trends toward the reduction of hot flashes and inconsistent results (221–223).

Meta-analyses and a Cochrane review concluded that SSRIs and SNRIs exert mild-to-moderate effects to reduce hot flashes in women with a history of breast cancer (217, 224–227). Each of these agents appears to have similar efficacy in breast cancer survivors as in healthy menopausal women, although studies are small (213, 217, 228–234). Caution is advised in the use of paroxetine in patients taking tamoxifen because paroxetine markedly interferes with the metabolism of tamoxifen to its metabolite, endoxifen (221, 222, 224, 235–237).

The only FDA-approved agent in this class is low-dose paroxetine mesylate, but others have been used off-label in the United States. No direct trials are available to determine the relative efficacy of one over another. We describe suggested daily doses, efficacy, side effects, and contraindications in Figure 4. In general, the evidence suggests that these agents are effective and well tolerated.

Gabapentin

Four RCTs confirmed moderate efficacy in relieving hot flashes (238–241). On the basis of clinical experience, women whose hot flashes occur primarily at night respond well to a single bedtime dose. Individual dose requirements vary widely, as determined by empiric dose escalation, and range from 300 to 1200 mg. Gabapentin effects as a sedative and a reducer of vasomotor instability work well together when used at bedtime because sedating side effects dissipate by morning. However, when used during the day, gabapentin may result in a level of lethargy that is not tolerable.

Pregabalin

In one 6-week RCT, pregabalin (75–150 mg twice daily) decreased mean hot flash scores by 65 and 71%, compared with 50% by placebo (242), and was reasonably well tolerated.

Choice of SSRI/SNRI vs gabapentin/pregabalin

A randomized, crossover, multicenter trial that compared recommended doses of venlafaxine vs gabapentin, 300 mg three times a day (243), reported that both agents reduced hot flash scores by 66%, but two-thirds of patients preferred venlafaxine over gabapentin. The quality of this comparative evidence is low due to imprecision.

Relative efficacy of nonhormonal prescription therapies vs estrogens

A limited number of head-to-head RCTs have compared varying estrogen doses, preparations, and routes of administration with nonhormonal agents (213, 240, 244). None of the RCTs established statistically significant superiority of one treatment regimen over another. However, when these and other published data are taken into account (213, 217, 236, 245), the limited evidence available suggests that standard-dose MHT is more effective than nonhormonal agents.

4.1b For those women seeking relief of moderate to severe VMS who are not responding to or tolerating the nonhormonal prescription therapies SSRIs/SNRIs or gabapentin or pregabalin, we suggest a trial of clonidine (if there are no contraindications). (2|⊕⊕◯◯)

Evidence

Clonidine

Several RCTs demonstrated that this α-2-adrenergic receptor agonist reduced hot flashes, but less effectively than the SSRI/SNRIs, gabapentin, and pregabalin, and with more side effects (Figure 4) (217, 236). Clonidine transdermal patches are preferred over tablets because of more stable blood levels.

4.2 OTC and alternative nonhormonal therapies for VMS

4.2 For women seeking relief of VMS with OTC or complementary medicine therapies, we suggest counseling re-

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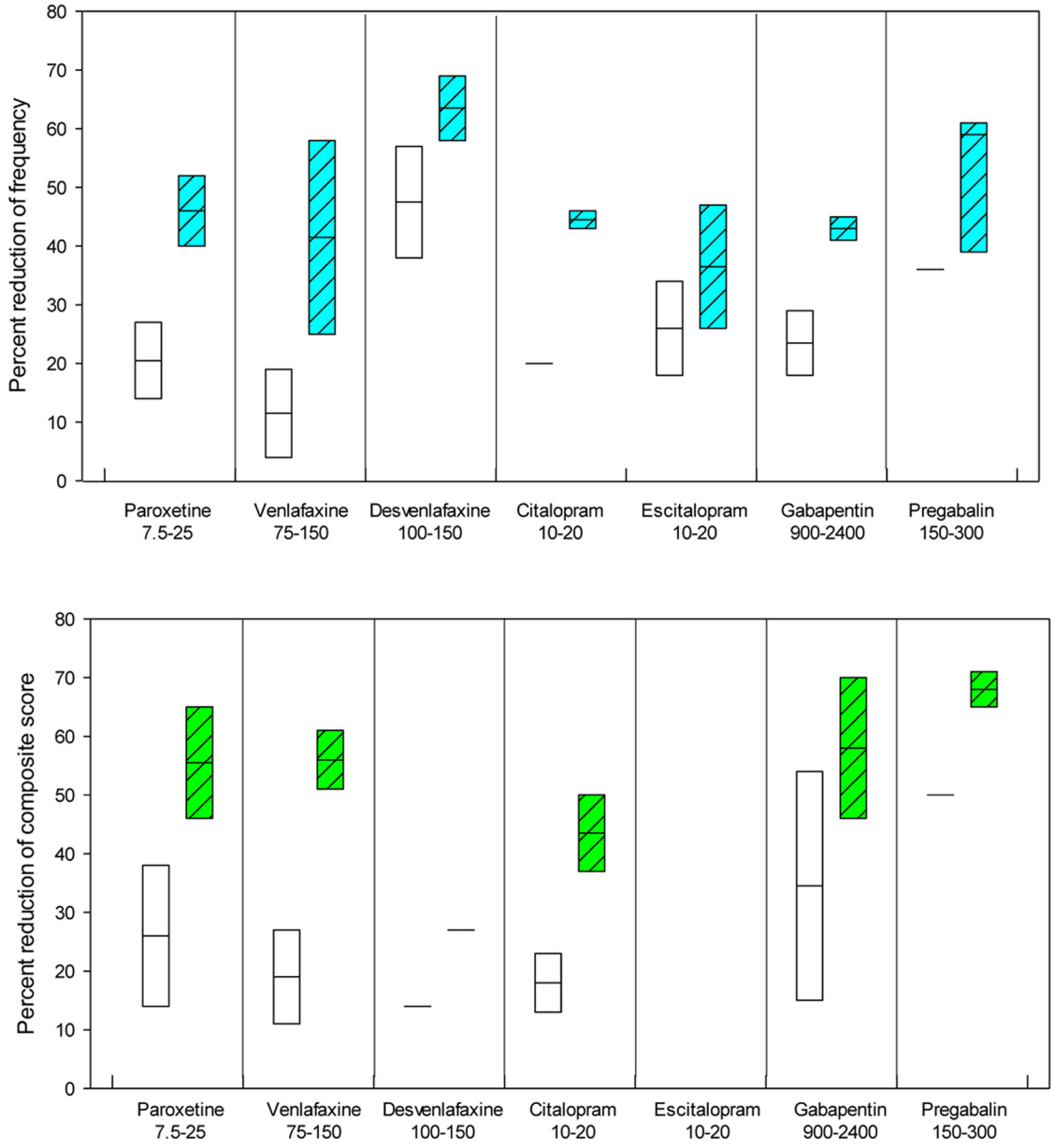

Figure 4. Hot flash frequency and composite score with nonhormonal prescription therapies for relief of VMS. Upper panel, Effect on frequency of VMS; lower panel, effect on composite score (severity times frequency; best representation of effect); open bars, placebo; colored bars, therapies; length of bars, ranges in studies; horizontal bar, means. All of these agents are generally well tolerated (226). Hypersensitivity or prior adverse drug reactions to each of these agents represent contraindications. For the SSRI/SNRIs, prior neuroleptic syndrome, serotonin syndrome, and concurrent use of monoamine oxidase inhibitors are also contraindications. SSRI/SNRIs should be used with caution in patients with bipolar disease, uncontrolled seizures, hepatic or renal insufficiency, uncontrolled hyponatremia, concurrent use of other SSRI/SNRIs, or poorly controlled hypertension. These agents uncommonly induce suicidal thoughts within the first few months of treatment. Preliminary evidence suggests a possible increase in risk of bone fracture. Gabapentin and pregabalin may increase suicidal thoughts and behaviors, cause drowsiness or dizziness, and impair balance and coordination. Pregabalin may impair memory and concentration. Clonidine is contraindicated in patients with low blood pressure and may cause lightheadedness, hypotension, headache, and constipation; sudden cessation of treatment can be associated with significant increments in blood pressure (63).

garding the lack of consistent evidence for benefit for botanicals, black cohosh, omega-3 fatty acids, red clover, vitamin E, and mind/body alternatives including anxiety control, acupuncture, paced breathing, and hypnosis. (2⊕⊕◯◯)

Evidence

Clinical trials with these agents have reported inconsistent efficacy over placebo, but individual patients may experience benefit (Table 9). The MSFLASH trial showed that omega-3 fatty acids do not improve VMS (246). In a randomized trial of 187 symptomatic menopausal women, clinical hypnosis was associated with a 74.2% reduction in hot flashes compared with a 17.1% reduction in women randomized to structured attention control ($P < .001$) (247). The phytoestrogens are nonsteroidal compounds that have both estrogenic and anti-

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Table 9. Alternative Therapies for Treatment of VMS

Agents	Comments	Refs.
Agents with inconsistent reports of benefit		
Genistein	Purified isoflavone ±Estrogenically active Breast safety not established	324–336
Daidzein	Purified isoflavone ±Estrogenically active Breast safety not established	324–336
S-equol	Metabolite of daidzein	337
Nonpurified isoflavones	Breast safety not established	338
Flaxseed		225, 236, 328, 339–341
Red clover	Breast safety not established	225, 236, 328, 339–341
High-dose extracted or synthesized phytoestrogen		225, 236, 328, 339–341
Dietary soy	Agreement about breast safety	248
Vitamin E	10% benefit in some studies	217, 342, 343
Reports with predominantly no benefit		
Black cohosh	Some short-term trials report benefit, most report no benefit Breast safety not established Reports of liver toxicity	225, 344–352
Omega-3 fatty acids	No benefit in MSFLASH trial	246
Acupuncture	Not effective when compared to "sham acupuncture" controls	353–356
Exercise	Exercise with sweating may increase hot flashes	357
Other complementary approaches	Ginseng, dong quai, wild yam, progesterone creams, traditional Chinese herbs, reflexology, magnetic devices	225, 332
Agents requiring further study		
Stellate ganglion block	Need further RCTs to establish lack of complications	358
Guided relaxation	Stress management, deep breathing, paced respiration, guided imagery, mindfulness training	217, 225, 247, 359–365
Hypnosis	Recent studies suggest efficacy	247
Cognitive behavior modification	Recent studies suggest efficacy with trained practitioners	366, 367

estrogenic properties. Caution is advised because some of these agents, when consumed as supplements, can exert estrogenic effects, a concern in breast cancer survivors although dietary soy appears to have no adverse effects on breast cancer prognosis (248).

5.0 Treatment of genitourinary syndrome of menopause

5.1 Vaginal moisturizers and lubricants

5.1a For postmenopausal women with symptoms of VVA, we suggest a trial of vaginal moisturizers to be used at least twice weekly. (2|⊕⊕◯◯)

Evidence

Vaginal moisturizers (eg, polycarbophil-based moisturizer, hyaluronic acid-based preparations, and a pectin-based preparation), when used regularly (at least twice weekly), may provide an effective nonhormonal approach to alleviating symptoms of vaginal atrophy. However, studies have been small, mostly open-labeled, and limited to 12 weeks (249–257). Although helpful, these approaches are not likely as effective as vaginal ET. Vaginal moisturizers have not been shown to reduce urinary tract symptoms or asymptomatic bacteriuria. Use of a vaginal moisturizer may not eliminate the need for a vaginal lubricant during intercourse.

5.1b For women who do not produce sufficient vaginal secretions for comfortable sexual activity, we suggest vaginal lubricants. (2|⊕⊕◯◯)

Evidence

Vaginal lubricants are used to enhance the sexual experience in women with symptoms of VVA by alleviating vaginal dryness and preventing dyspareunia (258). Lubricants do not treat the underlying problem and only briefly alleviate symptoms. Several OTC options are available. Because data do not demonstrate the superiority of one to another, women can experiment with these products. Olive oil is also effective (259). Petroleum jelly has been associated with an increased rate of bacterial vaginosis (260).

5.2 Vaginal estrogen therapies

5.2a For women without a history of hormone- (estrogen) dependent cancers who are seeking relief from symptoms of GSM (including VVA) that persist despite using

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vaginal lubricants and moisturizers, we recommend low-dose vaginal ET. (1|⊕⊕⊕○)

Evidence

A 2006 Cochrane meta-analysis of vaginal estrogens (261) compared 19 efficacy trials and found that all products effectively alleviated symptoms, but study differences limited comparisons among agents. As a guiding principle, we recommend using the lowest effective dose.

RCTs of low-dose vaginal estrogen products (262–267) report rapid improvement of vaginal symptoms (vaginal dryness or dyspareunia) and urinary symptoms (dysuria and urge incontinence) within 2 to 3 weeks. Objective improvements continue at 12 weeks and are maintained to 1 year. Limited evidence suggests that vaginal ET may prevent recurrent urinary tract infections (268, 269) and overactive bladder (270, 271). No clear proof exists that vaginal ET prevents or improves pelvic prolapse (272), but it may be advantageous preoperatively (273). Adverse effects include potential transfer to partner via penile or oral absorption and, with vaginal creams, residue on undergarments.

Vaginal estrogens

Vaginal estrogen preparations have been categorized as: 1) low, 2) intermediate, and 3) systemic doses (274) (Table 10). By using the lowest effective doses, systemic absorption is minimized. During the initiation of therapy, vaginal atrophy may enhance systemic absorption, although not all studies demonstrate this effect (267, 275). When vaginal epithelium is restored (after several weeks of ET), systemic absorption may decrease (276, 277).

Low-dose therapies

Low-dose vaginal ring. Low-dose vaginal rings result in estradiol levels that remain within the normal postmenopausal range; however, bone resorption and lipid levels decrease, suggesting possible systemic effects (278, 279). Insertion and removal at 3-month intervals may be difficult, the ring can be sensed during intercourse, and it can be expelled, particularly in women who have undergone a hysterectomy (265).

Vaginal estradiol tablets. The 10-μg tablet provides standard twice weekly dosing, relieves vaginal symptoms by 8 weeks, and is effective for at least 52 weeks (263, 275, 280, 281). Therapy is initiated with daily administration for 2 weeks, and then twice weekly thereafter. Vaginal placement of the tablet may provide less introital benefit than creams.

Promestriene (estradiol diether). This is a low-dose estrogen used outside the United States. Evidence is limited to studies of poor quality and very few RCTs (282).

Intermediate-dose vaginal estrogen

The 25-μg estradiol tablets increase plasma estradiol from 3.1 ± 0.83 to 19.8 ± 6.1 pg/mL by 7 days (283). An RCT of CEE vaginal cream ≥ 0.3 mg applied daily or twice weekly reported an improvement in VVA by 12 weeks that was sustained for 52 weeks without reports of endometrial effects (266). Intermediate-dose estradiol and CEE creams provide flexibility of dosing, allow treatment from the introitus to the vaginal apex, and provide the emollient effect of vehicle. Some systemic absorption exists (284, 285).

Table 10. Classification of Government-Approved Vaginal Estrogens

Type	Dose	Serum Estradiol Level
Low dose		<20 pg/mL
Silastic estradiol vaginal ring	7.5 μg	
Estradiol vaginal tablet	10 μg	
Promestriene (estradiol diether) ovule[a]	10 mg	
Estriol ovule[a]	0.5 mg	
Estriol + progesterone + *Lactobacillus Doderleini* ovule[a]	0.2 mg + 2 mg + 341 mg	
Promestriene cream[a]	3 mg	
Estriol cream[a]	0.015–0.03 mg	
Intermediate dose		>20 pg/mL
CEE vaginal cream >0.3-mg dose		5–50 pg/mL
Estradiol vaginal tablet 25 μg[b]		Some >20 pg/mL
High dose (systemic)		35–200 pg/mL
Estradiol vaginal ring	50 and 100 μg	
Vaginal estradiol	>0.5 mg	
Vaginal CEE	>0.5 mg[c]	

[a] Not approved or recommended in United States.

[b] No longer available in United States.

[c] Predominantly estrone sulfate; LH suppression reflects systemic absorption.

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Systemic-dose vaginal estrogen

CEE 0.625- to 2.5-mg vaginal cream, administered daily, results in systemic effects as evidenced by LH and FSH suppression (285). No RCT data are available regarding the FDA-approved dosing of estradiol 2- to 4-g vaginal cream, administered daily for 1 to 2 weeks, followed by a maintenance dosage of 1 g, one to three times a week.

Other hormonal agents

Estriol vaginal preparations (gels and suppositories) are manufactured and government regulated in a number of countries outside the United States. Estriol is considered a low-affinity estrogen and, despite increased plasma concentration after repeated vaginal administration, is not considered to have substantial systemic effects (286, 287).

Adverse events

Because serum estradiol levels during therapy usually fall within the normal postmenopausal range, the risk profile with low-dose vaginal ET is expected to be lower than with systemic ET (288). However, long-term endometrial safety data are lacking, and 1 year is the maximum duration of RCTs of vaginal ET (261). Side effects include vulvovaginal candidiasis (289, 290) and, with higher dosing and systemic absorption, vaginal bleeding and breast pain (289). Increased CVD or VTE risk has not been reported (261). This may reflect an actual neutral effect due to the absence of a first-pass hepatic effect by vaginal estrogens, or that studies of women at high CVD or VTE risk are lacking (281). Available evidence does not support the boxed warning on low-dose vaginal estrogen regarding an increased risk of CHD, stroke, VTE, dementia, and breast cancer, and efforts to modify the labeling of these products are in progress (288).

Practice statement

5.2b In women with a history of breast or endometrial cancer, who present with symptomatic GSM (including VVA), that does not respond to nonhormonal therapies, we suggest a shared decision-making approach that includes the treating oncologist to discuss using low-dose vaginal ET. (Ungraded best practice statement)

Evidence

Breast cancer

Whether small increases in circulating estrogens from low-dose vaginal estrogen can stimulate the growth of residual breast cancer cells (280, 291–293) remains an unanswered question. However, for women taking aromatase inhibitors, the effectiveness of which depends upon blocking up to 95% of estrogen synthesis and reducing circulating estradiol levels to < 1 pg/mL (250), caution is raised because minimal amounts of estrogen can be absorbed with low-dose vaginal ET. In a cohort case-control study of 13 479 breast cancer survivors taking adjuvant tamoxifen or aromatase inhibitor therapy for at least 1 year, after 3.5 years of concurrent administration of the low-dose estrogen ring or 10-μg vaginal tablet, breast cancer recurrence did not increase (relative risk, 0.78; 95% CI, 0.48–1.25) (294). These data are insufficient, however, to conclude safety and to recommend this approach.

Endometrial cancer

The effect of low-dose vaginal ET on endometrial cancer recurrence is unknown. The only RCT attempting to evaluate the effect of systemic ET on recurrence rate and survival in women after surgery for stage I or II endometrial cancer was closed prematurely without complete enrollment (295). In the absence of RCT findings to guide practice recommendations, the decision to use ET remains controversial and involves assessing the severity of postmenopausal symptoms and tumor characteristics (296, 297).

5.2c For women taking raloxifene, without a history of hormone- (estrogen) dependent cancers, who develop symptoms of GSM (including VVA) that do not respond to nonhormonal therapies, we suggest adding low-dose vaginal ET. (2⊕⊕◯◯)

Evidence

Raloxifene has neutral vaginal effects (298–300). In two clinical trials, vaginal, but not oral (301) ET, was safely used to treat vaginal symptoms in women taking raloxifene without untoward endometrial effects (302, 303).

5.2d For women using low-dose vaginal ET, we suggest against adding a progestogen (ie, no need for adding progestogen to prevent endometrial hyperplasia). (2⊕◯◯◯)

5.2e For women using vaginal ET who report postmenopausal bleeding or spotting, we recommend prompt evaluation for endometrial pathology. (1⊕⊕◯◯)

Evidence

Bleeding or spotting in a woman using only vaginal estrogens is uncommon in the absence of endometrial pathology. The 2006 Cochrane review of 19 studies found no significant difference among vaginal creams, tablets, or rings in terms of endometrial thickness or hyperplasia or in the proportion of women with adverse events (261). Recent 1-year-long studies of vaginal CEE cream and low-dose vaginal estradiol tablets revealed no cases of endometrial hyperplasia or cancer as determined by endometrial biopsy (263, 266, 304). Vaginal administration of

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estradiol tablets, when placed in the upper third of the vagina, may result in a uterine first-pass effect resulting in a higher degree of uterine stimulation (305–309). It is unknown whether endometrial proliferation, hyperplasia, or cancer can occur after long-duration treatment (> 1 y) or in women with risk factors (late menopause, higher body mass index, higher dosing). For women at higher risk of endometrial cancer, surveillance using transvaginal ultrasound, followed by endometrial biopsy if endometrial thickening is present, may be prudent. Intermittent (possibly annual) progestogen withdrawal may be considered to assess endometrial status (261, 280).

5.3 Ospemifene

5.3a For treatment of moderate to severe dyspareunia associated with vaginal atrophy in postmenopausal women without contraindications, we suggest a trial of ospemifene. (2|⊕⊕⊕◯)

5.3b For women with a history of breast cancer presenting with dyspareunia, we recommend against ospemifene. (1|⊕◯◯◯)

Evidence

Benefits

Not all women are comfortable using vaginal ET, and women may prefer an oral medication specifically indicated for dyspareunia.

Vaginal symptoms and sexual function. Two 12-week RCTs of ospemifene reported improvements in pH and vaginal maturation index, severity of dyspareunia (310, 311), and standardized measures of sexual function (including desire, arousal, orgasm, and satisfaction) (312). Two year-long studies (313, 314) demonstrated sustained vaginal benefits.

Risks

Vasomotor symptoms. The most common adverse effect was VMS (7.2% of women taking ospemifene compared with 2% taking placebo) (314).

Cardiovascular. Ospemifene involves risk of VTE (315) and is contraindicated in women at risk for venous or arterial thrombosis or stroke. In safety studies, incidence rates for thromboembolic stroke, hemorrhagic stroke, and DVT were 0.72, 1.45, and 1.45/1000, respectively, in women receiving ospemifene 60 mg vs 1.04, 0, and 1.04/1000, respectively, in women assigned to placebo (310).

Endometrium. No cases of endometrial carcinoma have been reported. Studies reported endometrial thickening of ≥ 5 mm at a rate of 60.1/1000 women per year of therapy with ospemifene vs 21.2/1000 women per year of therapy with placebo. The incidence of proliferative endometrium (weakly plus active plus disordered) was 86.1/1000 women with ospemifene vs 13.3/1000 with placebo (315). The incidence of uterine polyps was 5.9 cases/1000 women with ospemifene vs 1.8/1000 women with placebo (315).

Breast. Data on breast density or breast cancer risk are lacking. Estrogen-dependent neoplasia is a contraindication.

Future research

There are numerous gaps in our knowledge regarding menopause symptoms. Some of these include a lack of the most basic understanding of what causes hot flashes, questions regarding the potential link between VMS and CVD in older vs younger postmenopausal women, and a poor understanding of the relationships between menopause and sleep and hormonal transitions and mood, which have significant social and economic implications. Given the uncertainties regarding the precise neuroendocrine events that cause VMS, developing specific targeted therapies is challenging. Establishing appropriate animal models and expanding recent research involving the neuroregulators kisspeptin, neurokinin B, and dynorphin may help develop new effective treatments (35).

Management of the transition to menopause remains uncharted territory. The SWAN and the Melbourne Women's Midlife Health Project provide extensive epidemiological, physiological, and descriptive data characterizing reproductive changes that occur during the transition to menopause. However, clinical management decisions are often based on the extrapolation of observational data collected from studies conducted in younger, reproductive age women. RCTs of frequently prescribed therapies, such as oral contraceptives, MHT, and measures to control mood, with clinical outcomes relevant to women of relatively advanced age are sorely needed to confidently advise patients regarding the safest and most effective therapies to use during this transition.

Managing the loss of ovarian function in premenopausal women due to surgery, the range of disorders manifesting as POI, or the sequelae of treatment for breast cancer and other malignancies remains challenging. This is due to a dearth of quality data assessing the long-term risks and benefits of MHT or other options for symptom relief and prevention of chronic diseases in these groups. Fertility issues can be managed with modern assisted reproductive technology, but we fall short on adequately managing estrogen deficiency. Pressing questions remain

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regarding optimal treatment preparation, dosing and regimens, and the merits of long-term MHT, even in women without menopausal symptoms. International registries and clinical trials are overdue to address the long-reaching implications of these important issues.

The most persistent question for naturally postmenopausal women is how to balance menopausal symptom relief with the prevention of chronic diseases of aging such as CHD, osteoporotic fractures, and dementia. ET has long been hypothesized to meet this goal, although conclusive evidence remains elusive, and questions persist regarding the interaction between EPT and these outcomes, as well as breast cancer. Observational data suggesting differences in VTE risk and other CVD outcomes continue to accumulate, suggesting a significant need for adequately powered clinical trials comparing the safety and efficacy of oral with transdermal therapies in younger, recently postmenopausal women.

Finally, new SERM therapies (alone and partnered with estrogens) are promising, but larger, longer trials are needed to fully characterize the benefit/risk profiles of these new treatments and inform the clinician as to which patients stand to benefit the most from their use.

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Timing of testosterone discontinuation and assisted reproductive technology outcomes in transgender patients: a cohort study

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Objective: To determine if there is an association between the timing of testosterone discontinuation and assisted reproductive technology (ART) outcomes.
Design: Retrospectivse cohort study.
Setting: Single academic center.
Patient(s): We included consecutive transgender patients seeking fertility preservation between October 2019 and April 2021. Patients who identified as transgender on androgens for >1 month on presentation were included.
Intervention(s): None.
Main outcome measure(s): A linear regression model was used to evaluate the effect of testosterone discontinuation duration on the number of mature oocytes retrieved.
Result(s): Eighteen patients (mean age 27.7 [SD 5.2] years, mean body mass index 27.3 [SD 4.6] kg/m^2, mean antimüllerian hormone 27.2 [SD 11.8], median antral follicle count 20 [interquartile range (IQR) 14–32]) were included in the analysis. No patient underwent transition-related surgery (eg, oophorectomy, hysterectomy). None of the patients were previously pregnant. Mean time o,n testosterone was 44 (SD 29.6) months. The median time off testosterone until the start of ovarian stimulation was 7.7 weeks (IQR 4.3–20.7). All patients underwent oocyte cryopreservation except one who had embryo cryopreservation. The median total number of oocytes was 11 (IQR 7–14). The median number of mature oocytes was 7.5 (IQR 5–12) oocytes. The univariate regression model evaluating the duration of time off testosterone before ART demonstrated no significant association with the outcome of mature oocytes (regression coefficient, 0.19; 95% confidence interval, −0.13 to 0.50).
Conclusion: In a retrospective analysis of transgender patients recently on testosterone undergoing ART, no association was detected between the timing of testosterone cessation and the number of mature oocytes. (Fertil Steril Rep® 2023;4:55–60. ©2023 by American Society for Reproductive Medicine.)
Key Words: ART, IVF, transgender

The transgender population has been marginalized and understudied in medicine (1–3). Nearly half of the transgender patients reported a desire to have children. Of the transgender patients with ovaries, 37% would consider freezing oocyte if that option were available (4). However, a considerable proportion of transgender patients decline to proceed with fertility preservation because of the need for testosterone discontinuation (5).

There are variable reported durations in the literature on when to discontinue testosterone before starting the fertility preservation cycle. Presently, no guidelines specify the duration or necessity of testosterone discontinuation. Therefore, counseling transgender patients who have already started testosterone therapy is challenging. In a series of 16 transgender men reporting a mean testosterone discontinuation time of 4.5 months, most patients resumed menses before starting assisted reproductive technology (ART). A matched retrospective cohort study reported that transgender

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patients with a history of testosterone therapy were able to have cycle outcomes similar to that of cisgender women (6). Several observational studies have described oocyte cryopreservation among transgender men before initiation or after discontinuation of androgen therapy (6–11).

The literature includes reports that transgender men demonstrate similar oocyte retrieval outcomes to cisgender women (6); however, there are no reports examining whether the timing of testosterone cessation impacts fertility preservation outcomes. Therefore, we aimed to evaluate whether the timing of testosterone cessation was associated with ART outcomes in transgender men presenting to a high-volume fertility center.

MATERIALS AND METHODS

This study is a retrospective cohort study of consecutive transgender men seeking fertility preservation at a single, high-volume academic fertility clinic between October 2019 and April 2021. The institutional research ethics board approval was obtained. Transgender male patients taking androgens for at least one month were included in the study. Transgender patients who did not start hormone replacement therapy or stopped hormone replacement therapy for more than one year were excluded. Patients were followed until the completion of their ART cycle. The primary analysis evaluated the association existing between the duration of testosterone cessation and the number of mature oocytes retrieved in transgender men.

All patients who had initiated testosterone therapy stopped before their fertility preservation cycle started. The standard recommendation at this clinic was the discontinuation of testosterone at least four weeks before ovarian stimulation; however, some patients voluntarily stopped testosterone earlier. Resumption of menses was not required before starting the cycle. Gonadotropin dosing was determined by the treating physician based on patient factors such as age, weight, and ovarian reserve. Transvaginal ultrasound and bloodwork monitoring were initiated to monitor the ovarian response. A gonadotropin releasing hormone (GnRH) antagonist was started between day 7 and 9 of the stimulation cycle once the patient met one of the following two criteria: serum estradiol (E2) concentration greater than 2,000 pmol/L or a follicle measuring $\geq$ 14 mm. A daily subcutaneous injection of a GnRH antagonist (0.25 mg) was administered by the patient subcutaneously to prevent an endogenous surge in luteinizing hormone (LH) concentration. Monitoring of the ovarian response continued until three or more follicles were visualized by transvaginal ultrasound with a mean diameter of $\geq$ 17 mm. Ovulation was subsequently triggered with a subcutaneous injection of human chorionic gonadotropin or GnRH agonist, depending on the managing in vitro fertility physician. If a GnRH agonist trigger was chosen 12 hours after their trigger medication, the patient returned to the clinic for blood work, including LH and progesterone levels. This was a routine blood test to confirm that an endogenous LH surge had occurred. Transvaginal ultrasound-guided oocyte retrieval was performed approximately 36 hours after the administration of the initial trigger.

Statistical Analysis

Continuous variables were examined for normality using normality probability plots and the Shapiro-Wilk test (12). Normally distributed variables were reported as mean with standard deviation. Non-normally distributed variables were reported as median with interquartile range (IQR).

The primary outcome of this study was the association between testosterone discontinuation duration (weeks) and the number of mature oocytes. Other covariates evaluated as secondary outcomes included: patient age, antimüllerian hormone (AMH), antral follicle count (AFC), and duration on testosterone (weeks). All covariates were continuous variables. These models were also run for the outcome of the total number of oocytes. The total dataset was >99% complete; no missing data for covariates or outcomes were used in the regression analyses. All patients completed the follow-up necessary to obtain outcome data for their respective ART cycles. Statistical analysis was performed using R statistical software (version 4.1.2) (13).

RESULTS

A total of 18 transgender men were included. The mean age at cycle start was 27.7 (SD, 5.2; IQR, 24–30) years. None of the patients were previously pregnant. None of the patients who pursued treatment had undergone transition-related surgery (eg, oophorectomy or hysterectomy). The mean AMH was 27.2 (SD, 11.8) pmol/L. One patient had an AMH level of 7.1 pmol/L. The median AFC was 20 (IQR, 14–32). All patients had previously been on testosterone treatment and had stopped before their fertility preservation cycle. Mean time on testosterone therapy was 44 (SD, 29.6) months. The median time off testosterone until the start of ovarian stimulation was 7.7 (IQR, 4.3–20.7) weeks. There were no complications secondary to the fertility preservation cycle, including no thromboembolic events. Table 1 details the remaining demographics of included patients.

The median number of mature oocytes was 7.5 (IQR, 5–12; Table 2). The median number of total oocytes was 11 (IQR, 7–14). One patient cryopreserved seven embryos. For this patient, 14 oocytes were retrieved: 12 were fertilized through conventional in vitro fertility using donor sperm. Of these, seven progressed to the embryo stage. A total of seven embryos were cryopreserved: five were cryopreserved on day five, and two were cryopreserved on day 6. The remainder of the patients underwent oocyte cryopreservation. The median total number of cryopreserved oocytes was 7.5 (IQR, 5–12).

There was no significant association between testosterone discontinuation duration and number of mature oocytes (regression coefficient 0.19, 95% confidence interval (CI), 0.13 to 0.50, P=.226). AMH (P=.039) and AFC (P=.001) were associated with the number of mature oocytes. There was no statistical significance demonstrated between age and the number of mature oocytes (P=.059) and between age and the total number of oocytes (P=.058). There was no association detected between the duration on testosterone

TABLE 1

Characteristics of patients

Characteristic	Value*
Age (y)	27.7 (5.2)
BMI (kg/m^2) (n = 16)	27.3 (4.6)
Smoking, n (%)	
Never	13 (72.2)
Present	4 (22.2)
Past	1 (5.6)
AMH (pmol/L)	27.2 (11.8)
AFC	20 (14 to 32)
Partner sex (n = 17)	
Female, n (%)	11 (64.7)
Male, n (%)	1 (5.9)
No partner, n (%)	5 (29.4)
Time on testosterone therapy (w)	191 (129)
Time off testosterone therapy before IVF (w)	7.7 (4.3 to 20.7)
Resumed bleeding before stimulation, n (%)	10 (55.6)
Estradiol at trigger (pmol/L)	4695 (3135 to 6430)
Progesterone at trigger (nmol/L)	2.7 (1.5)
Luteal phase priming	
None, n (%)	15 (83.3)
Estrace, n (%)	1 (5.6)
OCP, n (%)	2 (11.1)
Recombinant FSH dose (IU)	210.4 (52.6)
Total gonadotropin dose per patient (IU)	2284 (858)
FSH only protocol, n (%)	13 (72.2)
FSH + LH protocol, n (%)	5 (27.8)
Days of stimulation, n (%)	10.6 (1.5)
Trigger	
hCG, n (%)	14 (77.8)
GnRH Agonist, n (%)	4 (22.2)
Endometrial lining at time of trigger (mm)	9.1 (3.3)

All variables have complete data unless otherwise specified.
AFC antral follicle count; AMH antimüllerian hormone; BMI body mass index; FSH follicle-stimulating hormone; hCG human chorionic gonadotropin; IVF in-vitro fertilization; LH luteinizing home; OCP oral contraceptive pill; PCOS polycystic ovarian syndrome.
* Continuous variables reported as mean (SD) or median (interquartile range).

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TABLE 2

In vitro fertilization outcomes

Outcome	Value*
Follicles over 11 mm at time of trigger	15.8 (6.2)
Follicles 16–22 mm at time of trigger	8 (6 to 10)
Total oocytes	11 (7 to 14)
Mature oocytes	7.5 (5 to 12)

* Continuous variables reported as mean (SD) or median (interquartile range).

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and number of mature oocytes (P=.339). The remaining regression outcomes are reported in Table 3. Figure 1 plots the testosterone discontinuation duration and mature oocyte count with 95% CI bands.

DISCUSSION

Our study is among the largest cohort of transgender patients previously on testosterone therapy undergoing fertility preservation. Our analyses did not detect an association between testosterone discontinuation time and the number of oocytes obtained, as well as the number of mature oocytes. These results have important implications for transgender men who wish to undergo ART but are concerned about the potential undesirable effects of stopping testosterone therapy (14) or are concerned about the effects of testosterone on fertility outcomes (15).

Studies have reported that approximately 0.6% of the population in the United States (16) and 0.24% of the population in Canada (17) identifies as transgender. Approximately 47% of transgender persons wish to have a child that is genetically related to them (18). Notably, 37% of transgender men with ovaries reported considering freezing oocytes if that option were available (4). Unfortunately, in addition to fertility preservation being a costly, time-consuming, and invasive process (19–21), the effects of testosterone cessation can be psychologically stressful (14). A study found that even although 76% of transgender men and women had considered fertility preservation before transition, only 3% of transgender men had completed this process (22). The resumption of pelvic bleeding is one of the causes of distress for this patient population (14). A study of 41 transgender men examined the timing of resumption of pelvic bleeding after testosterone cessation: 8% of patients had resumption at <1 month after testosterone cessation; 24% had resumption at 1 month after cessation; 28% after 2 months; 16% after three months; 4% after 4–6 months (23). Twenty percent had no pelvic bleeding before pregnancy (23). The patients in our study were on testosterone for varying durations ranging from one month to eight years. Univariate analyses showed no association between the duration of testosterone before the cycle started and oocyte yield. Because patients who discontinued testosterone for only one month did not have inferior results to those who stopped for more than one month, discontinuing testosterone for one month may be a reasonable compromise to reduce the discomfort associated with the return of menses without compromising good oocyte yield. Future studies are needed to evaluate even shorter periods of testosterone discontinuation. A recent case report by Gale and colleagues reported a 20-year-old transgender man on testosterone treatment for 18 months who chose to continue treatment throughout the fertility preservation cycle (18). The patient had a robust outcome with 22 mature oocytes.

In our study, most patients were on testosterone hormone therapy for more than 12 months, with no negative result on the baseline ovarian reserve given a mean AMH of 27.2 pmol/L. Most patients had normal baseline E2 and follicle-stimulating hormone levels, with average to above-average ovarian reserve results for a given age. Several case reports and case series have reported similar normal ovarian reserve parameters and ovarian responses (6–11, 24). In the present study, the average total dose of gonadotropins used was 2284 IU, and the median number of total oocytes was 11 (mature oocytes 7.5). Leung and colleagues matched

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TABLE 3

Simple unadjusted regression analyses for mature oocytes and total oocytes

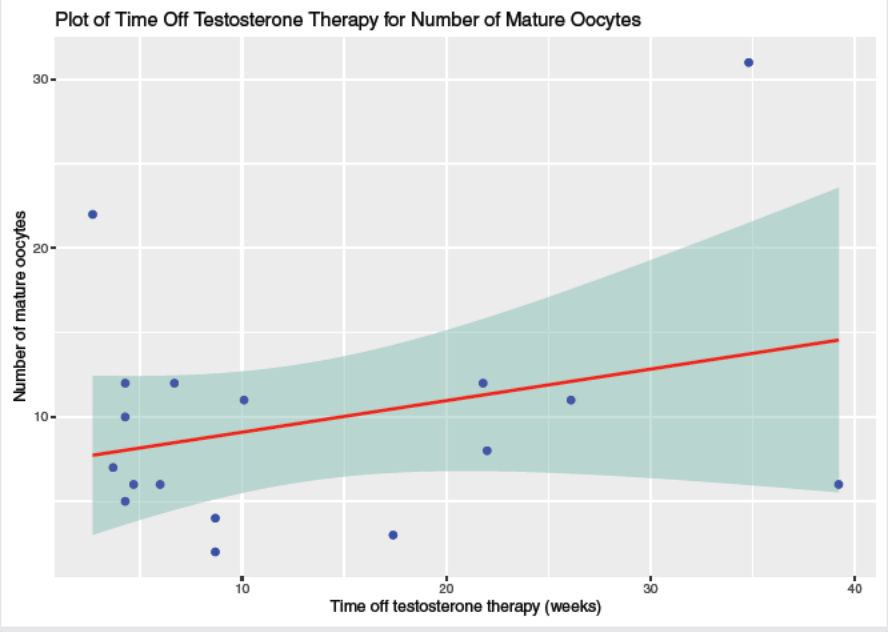
Outcome	Covariates	Regression coefficient (95% CI)	*P* value
Mature oocytes	Age	−0.62 (−1.26 to −0.03)	.059
	AMH	0.29 (0.02 to 0.57)	.039
	AFC	0.43 (0.20 to 0.67)	.001
	Duration on testosterone	−0.01 (−0.04 to 0.02)	.339
	Testosterone discontinuation duration	0.19 (−0.13 to 0.50)	.226
Total oocytes	Age	−0.74 (−1.51 to −0.03)	.058
	AMH	0.34 (0.003 to 0.68)	.048
	AFC	0.58 (0.33 to 0.83)	.0002
	Duration on testosterone	−0.01 (−0.05 to 0.02)	.434
	Testosterone discontinuation duration	0.24 (−0.13 to 0.62)	.188

AFC antral follicle count; AMH antimüllerian; CI confidence interval.

Albar. Stopping testosterone for IVF cycles. Fertil Steril Rep 2023.

cisgender and transgender patients across several variables, including age and AMH, with transgender patients receiving significantly higher doses of gonadotropins (4155 vs. 2707, *P*=.002) (6). The mean number of oocytes retrieved per patient was 18.6, of which 77% were mature oocytes (6). Notably, the mean number of gonadotropins used in cisgender patients (2707 IU) was similar to the amount of gonadotropins used in our study in transgender patients (2284 IU). Leung and colleagues explained that the higher doses used are because of the mindset that this is a "one-shot deal" because of the intent of maximizing oocyte yield given the transition-related and financial costs of performing a cycle. Accordingly, higher gonadotropin doses may be needed in transgender patients to obtain a similar number of oocytes as in cisgender patients. Another larger study showed a similar number of retrieved oocytes compared with our results (25). Law and colleagues performed a population-based cohort study of 221,221 treatment cycles in cisgender patients (25): in the 18–29-year-old group, 36.1% had 4–9 oocytes retrieved, 28.5% had 10–14 oocytes

FIGURE 1



Plot of testosterone discontinuation duration vs. mature oocytes with 95% confidence interval band, demonstrating no association

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retrieved, and 15.7% had 15–19 oocytes retrieved. This right-skewed distribution, with the majority (64.6%) of patients having between 4–14 oocytes retrieved, is similar to the right-skewed distribution in our study of transgender patients, whereby 72.2% had between 4–14 oocytes retrieved. Future studies evaluating ART outcomes between transgender and cisgender patients may consider differences in populations, gonadotropin dosage, or other cycle factors should differences in oocyte yield be demonstrated. Should future studies support higher gonadotropin dosages explaining this discrepancy, higher doses of gonadotropins may be considered to maximize the success of a single cycle.

Part of the lack of consensus on the timing of testosterone cessation may be secondary to an incomplete understanding of the effects of androgen therapy on the ovarian environment. A study by Caanen and colleagues reported a reduction in AMH levels (median 3.5 to 0.3 μg/L, $P<.0001$) in 22 female-to-male transgender patients with a mean age of 22.4 years (24). The investigators conclude that androgens are important in regulating AMH (26). Leung and colleagues performed a matched cohort study and found that after being matched on age, BMI, and AMH, transgender men showed a similar number of oocytes compared with cisgender women (6). These patients discontinued testosterone for a mean of 4 months (6). The transgender patients had a mean AMH of 24.3 (SD 13.6) pmol/L and a mean age of 28.3 (SD 6.7) (6). In our study, the mean AMH was 27.3 pmol/L, but the median total oocytes count was 11, and the median mature oocytes count was 7.5. As the transgender population remains to be investigated in large studies, several hypotheses can explain these results: transgender patients may inherently have lower oocyte yield, the effect of using testosterone before the cycle may reduce the number of retrieved oocytes, ART cycles may require optimization (eg, higher gonadotropin dosage), or there is no true difference, and the observed difference is secondary to selection bias.

Our study had several strengths. Our center is one that aims to reduce the period of testosterone discontinuation and the start of stimulation to 4 weeks. This period is shorter than other discontinuation periods (27), and accordingly permits evaluating patients with both short and long discontinuation periods. In addition, our primary analysis attempted to evaluate whether a relationship exists between testosterone discontinuation duration and oocyte yield. This analysis is the first step toward ultimately identifying a minimum evidence-based threshold for when to discontinue testosterone in this population. Nevertheless, our study contains limitations. First, our sample size is low, so the lack of association in our primary outcome may be based on an unpowered sample. Unfortunately, there always remains a probability of an outcome being negative because of insufficient statistical power. With limited knowledge of the true effect size in transgender patients, determining the statistical power of analysis is difficult. We aimed to minimize the effect of our low sample size by only evaluating a single covariate in the model. Future studies, including patients from several centers, must validate our findings with higher statistical power. Second, our study was retrospective, which increases the risk of selection bias. Third, there was clinical heterogeneity, such as differences in trigger (human chorionic gonadotropin vs. lupron), which may have differences in effect on oocyte maturity. Fourth, pregnancy success rates were not assessed in this study, so the pragmatic question of the effect of testosterone discontinuation on oocyte quality remains to be completely evaluated. Finally, the transgender population is a diverse population, likely requiring larger studies to capture the diversity of patients interested in pursuing ART. Larger studies would increase the clinical generalizability of our results and allow for subgroup analyses that may predict differences in ART outcomes.

CONCLUSIONS

In a sample of 18 transgender patients undergoing fertility preservation, there was no association between testosterone discontinuation duration and ART, including the number of mature oocytes. Transmale patients who have already started hormone therapy and who are interested in minimizing their time off of testosterone may, therefore, still consider fertility preservation. Larger studies are needed to confirm these findings.

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BMJ INVESTIGATION

Dispute arises over World Professional Association for Transgender Health's involvement in WHO's trans health guideline

WHO says that it adheres to standard protocol for its transgender health guideline, but the process has been criticised for lacking transparency and an association with WPATH—an organisation under fire for meddling with its own guideline development. **Jennifer Block** reports

Jennifer Block *freelance journalist*

When the World Health Organization (WHO) announced the roster last December for its first guideline panel "on the health of trans and gender diverse people," it seemed heavily weighted towards the "gender affirming" approach, which promotes patient led access to hormonal and surgical treatments.[1 2] The endeavour quickly became mired in controversy, including a mass letter to WHO from more than 100 clinicians. Signatories charged that most of the panel's 21 members favoured the affirming approach, reporting affiliations with organisations including Global Action for Trans Equality (GATE) and the World Professional Association for Transgender Health (WPATH). There was also concern over the degree to which the panel's recommendations would be evidence based.

WHO seemed to address some of those criticisms: it published an FAQ document in January, postponed a February meeting to interpret evidence and issue recommendations, and in June announced that it was adding six new members.[2 3]

That same month, however, documents emerged showing that two members of WHO's guideline committee, in their capacity as executives of WPATH, had attempted to interfere with an independent evidence review commissioned by that organisation for its 2022 guidelines—and that the US government appeared to have influenced WPATH's guidelines. Despite these revelations, the two members remain on WHO's committee.

Based on rights or evidence?

A WHO guideline begins with a multidisciplinary panel charged with generating the research synthesis questions in need of answers, explains Paul Garner, professor emeritus at the Liverpool School of Tropical Medicine, UK, who has worked for 30 years in evidence based guideline development with Cochrane and WHO. Those questions determine which evidence reviews it chooses to commission, which will then inform the recommendations. "So, if a guideline development group lacks ideological diversity, it's likely to bias the recommendations," says Garner.

This was the chief concern raised in a January letter signed by more than 100 clinicians from 17 countries. WHO's guideline group "does not reflect the breadth of professional perspectives," it read. "A panel tasked with developing this guideline requires the expertise of members who have experience with patients who have transitioned as well as patients who have detransitioned."

There were also concerns about WHO's stated goal[2] of providing guidance on "interventions aimed at increasing access and utilization" of health services, among them "provision of gender affirming care, including hormones," without first demonstrating strong evidence that those interventions are beneficial.

Letters to WHO from the Society for Evidence Based Gender Medicine (SEGM), which has itself commissioned several forthcoming relevant systematic reviews,[4-7] and the Clinical Advisory Network on Sex and Gender (CAN-SG), a network of mainly UK and Irish clinicians, raised the question of whether WHO would be evaluating the benefits and harms of hormonal treatments for gender incongruence—or if instead it "has taken a policy position on this without critically appraising the evidence," as a letter from CAN-SG put it.[8]

Although WHO began work on the guideline in 2022, its public statements have been light on detail about its scope and process. The agency initially announced that it would follow standard WHO guideline development protocol, but the lack of specifics on a highly contentious topic drew heightened scrutiny. It wasn't until January this year that it clarified that the guideline would apply only to adults.

WHO extended the deadline for public feedback but maintained that it was focused on provision of health services and advocating the legal recognition of self-identified gender.[9] "The guideline will reflect the principles of human rights, gender equality, universality and equity," it wrote in January, but it provided no details or references regarding the "evidence synthesis" that it said was initiated in 2023.[10]

Hannah Ryan, a specialty registrar in clinical pharmacology at the Royal Liverpool University Hospital, is a Cochrane author with experience in guideline development and a member of CAN-SG. Ryan understood from WHO's statement that it saw the expanded provision of gender treatments as a matter of human rights, rendering the evidence base secondary. "While we welcome the commitment to upholding human rights," she tells *The BMJ*, "liberalised access to healthcare interventions that

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might in fact have harmful effects is not actually in support of anyone's human rights."

SEGM wrote an 11 page letter in February calling for a more transparent process to ensure that "proper evidence reviews have been commissioned to address key questions." After the June revelations regarding WPATH's executives, both SEGM and CAN-SG wrote to express ongoing concerns that, as SEGM put it, the "strong overlap" between the WHO guideline group and WPATH "will have direct negative implications for the credibility of WHO's own process." WHO didn't respond directly to either group.

Reviews "completed and submitted" but not approved

WPATH's updated Standards of Care Version 8 (SOC8) guidelines—widely cited in support of gender affirming medical interventions for all ages—were published in late 2022 and were promoted as having "followed the most rigorous protocol in the world . . . a long and painstaking scientific review process."[11] In June this year, however, documents from two US lawsuits over the provision of treatment for gender dysphoria showed that WPATH had attempted to institute an "approval process" over manuscripts emanating from the independent systematic reviews it commissioned.[12]

The SOC8 update began in 2018, when WPATH commissioned systematic reviews from a team at Johns Hopkins University, Baltimore. Over the next few years that team "completed and submitted a number of reviews to the WPATH SOC8 Chairs and Chapters," said a March 2023 email exclusively obtained by *The BMJ* through a public records request. But the process didn't go smoothly, and just two manuscripts were published: one on the impact of hormones on mental health and another on prolactin levels in trans women taking oestrogen.[13 14] "We had hoped to publish more of those reviews but for a few reasons have not done so," wrote Karen Robinson, Johns Hopkins research lead, in the email.

In a separate exchange three years earlier with Christine Chang, a director at the US Agency for Healthcare Research and Quality, Robinson had referred to submitting "reports of reviews (dozens!)" to WPATH, but she added that "we have been having issues with this sponsor trying to restrict our ability to publish."

Johns Hopkins is one of nine centres contracted with the Agency for Healthcare Research and Quality to conduct systematic reviews on a wide variety of topics, and the agency was considering having one done on treating gender dysphoria in children and adolescents. Exactly how many systematic review manuscripts Johns Hopkins drafted remains unknown, and neither Robinson nor anyone from the university responded to *The BMJ*'s email requests for comment.

Robinson emailed Chang about problems with WPATH just days after receiving a letter from several members of its executive committee outlining new "policy and procedures," which instructed the Hopkins team to submit manuscripts to WPATH for an approval process that involved a vote by the SOC8 chair and co-chairs, as well as WPATH's board. Only then would the Johns Hopkins researchers be given a "green light to be published."

WPATH sent an update to Robinson and all SOC8 coauthors in October 2020 stating, "It is paramount that any publication based on the WPATH SOC8 data is thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense."

The approval process was to be overseen by the organisation's president elect at the time, Walter Bouman, a specialist in trans health at the University of Nottingham, UK. Gail Knudson, a physician at the University of British Columbia and former WPATH president, had also signed the letters to Robinson. Bouman and Knudson were appointed to WHO's guideline development group for transgender health and remain members. Neither responded to *The BMJ*'s request for comment.

Documents turned over to the courts also reveal that, as the SOC8 guidelines were nearing publication in summer 2022, WPATH was under external pressure from high up in the US Department of Health and Human Services to make a last minute change.[15] Specifically, Rachel Levine, assistant secretary for health, asked authors to remove minimum age recommendations[16] for gender related hormones and surgeries. Bouman met with Levine and staff in late July. At first, WPATH declined to remove the age minimums because this would subvert its "consensus based" methodology, offering instead to downgrade those recommendations into weaker "suggestions." But when the American Academy of Pediatrics threatened to denounce SOC8 if this change wasn't made, WPATH removed the ages entirely.[17]

Earlier that year Levine had referred to WPATH on National Public Radio as setting the "evidence based standard of care for the evaluation and treatment of trans individuals." The health agency and the academy declined to comment when approached by *The BMJ*.

The presence of WPATH executives on WHO's guideline development group is especially troubling to watchdogs such as Zhenya Abbruzzese, cofounder of SEGM. "If WHO continues to ignore the evidence that two of its guideline development group members led a recent effort to suppress evidence related to treatments in this area," she says, "it may harm WHO's reputation in other areas of medicine, where its clinical guidance is sorely needed."

WHO responds

When *The BMJ* began querying WHO in July the organisation defended the makeup of its guideline group as well as its process. It was "aware of allegations and media reports regarding WPATH" but "does not comment on legal issues involving external organisations." WHO conducts "careful reviews on conflicts of interest," it said, and "GDG [guideline development group] members act in their own expert capacity." Regarding evidence reviews for hormonal treatments, WHO said only that "members participate in consensus based decision making that uses internationally recognised methods to appraise relevant bodies of evidence."

In late August it provided more detail, telling *The BMJ* that "systematic reviews have been commissioned" to evaluate the risks and benefits of hormone treatment for gender incongruence in adults. This left the critics scratching their heads as to why this hadn't been made explicit, particularly given all the calls for more transparency. "Multiple inquiries from the concerned clinicians and researchers worldwide have been met with silence," says Abbruzzese.

WHO subsequently provided a list of nine systematic reviews and other research protocols to *The BMJ*. Seven are registered with the Prospero database and one with the Open Science Framework. WHO said that it couldn't locate a public link for the final commission, titled "Systematic reviews on the burden and health impact of stigma/discrimination and violence against trans and gender diverse people."[18-25] The registration details indicate that reviews were started as early as January 2023 and that some commenced months

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earlier than their public registration in July 2024. None appear to have been completed or published yet.

Of those nine reviews, one will evaluate hormonal treatment specifically. Ryan and Abbruzzese take issue with the lack of attention to harms. Ryan says, "They plan to look for adverse events including misuse of hormones, suicidal behaviours, and mortality, but don't specify that they will examine the evidence for adverse effects attributable to hormone treatment, reproductive health, regret, or detransition." Abbruzzese adds, "There is nothing in the protocol about evaluating any of the potential harms such as cardiovascular and metabolic disease, osteoporosis, and hormone sensitive malignancies. This is highly unusual given the known risks of these medications."

Ryan also expresses concern that the systematic reviews "fail to examine the impacts" of legal recognition of self-identified gender—which WHO has defined as a health measure—"on any group other than trans and gender diverse people." Abbruzzese concurs, saying that "research must examine the potential harm on females who will lose the safety of single sex spaces to potentially fully genitally intact and testosterone empowered biological males. The impact on women's safety and values and preferences must be a key part of the research."

A positive recommendation by WHO has widespread health policy implications, says Garner. Once one of these has been made for a specific drug, for example, it's likely to be submitted for inclusion on WHO's essential medicines list. Garner says that a recommendation in a technical guideline tends to carry weight with WHO's Expert Committee that evaluates essential medicine applications, and it's "likely" to be approved. "Once it goes on the essential medicines list, that obliges governments to supply the drug," he says.

Gordon Guyatt, distinguished professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University in Ontario, isn't bothered by this. "I think most people would say that adults thinking of transitioning should be allowed to make the decision, and the medical care to help them transition should be made available to them," he says. While there may be only low quality evidence of benefit, adds Guyatt, "it seems to me a very value and preference sensitive decision."

Juan Franco, a family physician and editor of *BMJ Evidence-Based Medicine*, agrees, as long as "the guideline clearly clarifies that patients have an understanding that the evidence is uncertain, and safeguards are in place to follow up and monitor for adverse events."

"An untenable position"

Robinson of Johns Hopkins pushed back on WPATH's demands, apparently many times. She wrote to WPATH, "We have the right to publish and any [Johns Hopkins University] publications arising out of the work conducted as part of this contract are not subject to approval by WPATH nor subject to any policy of WPATH. I feel like I have made these statements several times in email and phone conversations, beginning when the contract was being negotiated in 2018."

The hesitation among some WPATH SOC8 authors was that independent appraisals of the evidence would undermine legal efforts to protect affirming interventions from legislative restriction in minors. In a form that appears to have been part of WPATH's SOC8 publication process and is now legal evidence, a chapter author wrote, "Our concerns, echoed by the social justice lawyers we spoke with, is that evidence based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits." Several WPATH SOC8 authors were serving as expert witnesses in lawsuits brought by the American Civil Liberties Union and other plaintiffs. Another commented that any language in the guidelines undermining medical necessity—such as "insufficient evidence" or "limited data"—would empower the people calling treatments experimental and arguing for limiting them to clinical trials.

In August 2020 Robinson conveyed to Chang at the Agency for Healthcare Research and Quality that "we found little to no evidence about children and adolescents." WHO came to a similar conclusion this year, calling the evidence "limited and variable."[3] Laura Edwards-Leeper, who cowrote the chapter on adolescents, explains to *The BMJ*, "We were told by WPATH leadership that Johns Hopkins couldn't do a review for the child or adolescent chapters because there weren't enough studies to review, so we just needed to write the guidelines based on expert consensus, essentially." The chapter on adolescents says that the "emerging evidence base indicates a general improvement in the lives of transgender adolescents" who receive medical treatment, but it doesn't cite a systematic review.

Carl Heneghan, director of the University of Oxford's Centre for Evidence-Based Medicine, says, "There's no such thing as 'not enough evidence to do a systematic review,' because what you do is set out a question and try to find all the available evidence." If a review finds only low certainty evidence, he says, the recommendation should be to "pursue treatment in the context of a research study addressing the uncertainties"—otherwise, patients will continue to have limited evidence to inform their decisions.

Franco of *BMJ Evidence-Based Medicine* says, "I think we all agree that we need more evidence in children. And we need to help the parents of children with diverse identities understand the need for research and how it will be helpful for them."

After the dispute between Johns Hopkins and WPATH just one review was published,[13] and it contains the wording WPATH demanded in its email to Robinson—language implying editorial independence: "The authors of this manuscript are responsible for its content. Statements in the manuscript do not necessarily reflect the official views of or imply endorsement by WPATH." Led by Kellan Baker, who received a PhD from Johns Hopkins in 2021, it found the strength of the evidence "low" in determining the effect of hormonal treatment on anxiety, depression, and quality of life, but it nevertheless concluded that such treatment "promotes the health and wellbeing of transgender people." Baker didn't respond to a request for comment.

WPATH stood by its guidelines, commenting that "WPATH could not and did not prohibit the [Johns Hopkins] evidence based review team from publishing." Others have come to WPATH's defence, among them Robinson's colleague Ian Saldanha, associate director of the Johns Hopkins Evidence-Based Practice Center. He cowrote a recently filed "friend of the court" brief that calls the SOC8 development process "rigorous" and "methodologically sound" and states, "While in theory it might be ideal for every aspect of a clinical practice guideline to be directly supported by a systematic review, in practice this is extraordinarily rare if not impossible."[26]

Heneghan says that a guideline written without a systematic review "invalidates the guideline as far as I'm concerned," as without a rigorous appraisal of the evidence "it comes down to opinion and dogma."

Mary Butler, co-director of the University of Minnesota's Evidence-Based Practice Center, signed the legal brief—which was sent to her by attorneys fully drafted—but tells *The BMJ* that she

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wasn't familiar with the reported interference in WPATH's guideline development. She believed that the brief's intent was to promote "the ability of evidence based processes to support healthcare."

Guyatt says, "All guidelines should be based on systematic reviews of the relevant evidence." Furthermore, he says, "well conducted science that benefits the general community" should be available to all, so "it's mysterious why Johns Hopkins didn't publish" all the reviews it conducted, and it's "problematic" that WPATH would "attempt to block publication."

"Best practice would be to publish," Franco concurs. Even if the reviews were disseminated on preprint servers, says Heneghan, "there are no excuses in this modern era for not making your data or your particular systematic review available."

Competing interests: I have read and understood the BMJ Group policy on declaration of interests and have no relevant interests to declare.

Provenance: Commissioned; externally peer reviewed.

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Hierarchy of evidence: a framework for ranking evidence evaluating healthcare interventions

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Summary

• A number of hierarchies of evidence have been developed to enable different research methods to be ranked according to the validity of their findings. However, most have focused on evaluation of the effectiveness of interventions. When the evaluation of healthcare addresses its appropriateness or feasibility, then existing hierarchies are inadequate.

• This paper reports the development of a hierarchy for ranking of evidence evaluating healthcare interventions. The aims of this hierarchy are twofold. Firstly, it is to provide a means by which the evidence from a range of methodologically different types of research can be graded. Secondly, it is to provide a logical framework that can be used during the development of systematic review protocols to help determine the study designs which can contribute valid evidence when the evaluation extends beyond effectiveness.

• The proposed hierarchy was developed based on a review of literature, investigation of existing hierarchies and examination of the strengths and limitations of different research methods.

• The proposed hierarchy of evidence focuses on three dimensions of the evaluation: effectiveness, appropriateness and feasibility. Research that can contribute valid evidence to each is suggested. To address the varying strengths of different research designs, four levels of evidence are proposed: excellent, good, fair and poor.

• The strength of the proposed hierarchy is that it acknowledges the valid contribution of evidence generated by a range of different types of research. However, hierarchies only provide a guide to the strength of the available evidence and other issues such as the quality of research also have an important influence.

Keywords: evidence, hierarchy, levels of evidence, research.

Introduction

The past two decades have seen a growing emphasis on basing healthcare decisions on the best available evidence. This evidence encompasses all facets of healthcare, and

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includes decisions related to the care of an individual, an organization or at the policy level. Attention has also focused on the quality of the scientific basis of healthcare and, with this, recognition that not all evidence is equal in terms of its validity.

To aid the interpretation and evaluation of research findings, hierarchies of evidence have been developed which rank research according to its validity. The major focus of these hierarchies has been effectiveness and, as a result, the randomized controlled trial (RCT) has been commonly viewed as providing the highest level of evidence. While many valid approaches to research exist, they are often ranked at a level lower than the RCT although each approach provides its own unique perspective.

To address this, a hierarchy for ranking research evaluating healthcare interventions was developed. This hierarchy differs from existing models in that it recognizes the contribution of evidence generated by a range of research methodologies.

Grading the evidence

It has long been recognized that not all research designs are equal in terms of the risk of error and bias in their results. When seeking answers to specific questions, some research methods provide better evidence than that provided by other methods. That is, the validity of the results of research varies as a consequence of the different methods used. For example when evaluating the effectiveness of an intervention, the RCT is considered to provide the most reliable evidence (Muir Gray, 1997; Mulrow & Oxman, 1997; Sackett *et al*., 1997). It is considered the most reliable evidence because the processes used during the conduct of an RCT minimize the risk of confounding factors influencing the results. As a result of this, the findings generated by RCTs are likely to be closer to the true effect than the findings generated by other research methods.

This confidence in the findings of research has important implications for those developing practice guidelines and clinical recommendations, or implementing the results of research in their area of practice. The aim during this development and implementation is to use the best available evidence. The problem that arises from this situation is how to determine the best evidence. To address this, hierarchies of evidence have been developed to allow research-based recommendations to be graded. These hierarchies or levels are used to grade primary studies according to their design, and so reflect the degree to which different study designs are susceptible to bias [National Health Service (NHS) Centre for Reviews and Dissemination, 1996]. Ranking research designs according to their internal validity not only grades the strength of the evidence, but also indicates the confidence the end-user can have in the findings.

Hierarchies of evidence

Hierarchies of evidence were first popularized by the Canadian Task Force on the Periodic Health Examination in the late 1979, and since that time many different hierarchies have been developed and used (Canadian Task Force on the Periodic Health Examination, 1979; Sackett, 1986; Woolf *et al*., 1990; Cook *et al*., 1992, 1995; Guyatt *et al*., 1995; Wilson *et al*., 1995). Until recently, these focused on effectiveness, and for this reason the RCT was most commonly listed as providing the highest level of evidence.

These hierarchies have used a range of different approaches to grading research. For example, one hierarchy for clinical recommendations used levels A1 through to C2 (Guyatt *et al*., 1995). Level A1 represented RCTs with no heterogeneity and a confidence interval (CI) all on one side of the threshold number needed to treat (NNT). Level C2 at the other end of this scale was assigned to observational studies with a CI overlapping the threshold NNT. NNT is the number of patients who have to be treated to prevent one event occurring (see Information Point in Vol. 10, no. 6, p. 783). Another hierarchy used a scale of level I through to level IV [National Health and Medical Research Council (NHMRC), 1995]. Level I was assigned to evidence obtained from a systematic review of all relevant randomized controlled trials, while level IV comprised opinions of respected authorities, descriptive studies, or reports from expert committees. The Cochrane Collaboration ranks the validity of studies on a scale of A to C, with A indicating that the study met all quality criteria (Mulrow & Oxman, 1997). One hierarchy that was used during the development of clinical guidelines used an alpha-numerical approach to rank both evidence and recommendations (Meltzer *et al*., 1998; Sackett, 1986). The highest ranking in this hierarchy was 'Grade A Recommendations supported by Level I evidence' (Cook *et al*., 1992).

With the increasing popularity of systematic reviews, these are starting to replace the RCT as the best source of evidence (NHMRC, 1995). More recently, one hierarchy listed N of 1 randomized trials as the highest level of evidence (Guyatt *et al*., 2000). N of 1 randomized trials use a single patient who is randomly allocated to the treatment and comparison interventions. Hierarchies have

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now been developed to address a range of other areas, including prevention, diagnosis, prognosis, harm and economic analysis (Carruthers *et al*., 1993; Ball *et al*., 1998; Meltzer *et al*., 1998).

Ultimately, these hierarchies aim to provide a simple way to communicate a complex array of evidence generated by a variety of research methods. From the perspective of healthcare decision-makers, they provide a measure of the trust that can be placed in the recommendations, or alert the user when caution is required. However, the exact format and order of rank for research designs within these hierarchies have not been determined and existing systems have used a range of different approaches.

Determining best evidence

A limitation of current hierarchies is that most focus solely on effectiveness. Effectiveness is concerned with whether an intervention works as intended. While this is obviously vital, the scope of any evaluation should be broader. For example, it is also important to know whether the intervention is appropriate for its recipient. From this perspective, the evidence on appropriateness concerns the psychosocial aspects of the intervention and so would address questions related to its impact on a person, its acceptability, and whether it would be used by the consumer. A third dimension of evidence relates to its feasibility, and so involves issues concerning the impact it would have on an organization or provider, and the resources required to ensure its successful implementation. Feasibility encompasses the broader environmental issues related to implementation, cost and practice change.

Evidence on effectiveness, appropriateness and feasibility provides a sounder base for evaluating healthcare interventions, in that it acknowledges the many factors that can have an impact on success. This highlights the range of dimensions that evidence should address before healthcare interventions can be adequately appraised. It also means that, no matter how effective an intervention is, if it cannot be adequately implemented, or is unacceptable to the consumer, its value is questionable. The risk with available hierarchies is that, because of their single focus on effectiveness, research methods that generate valid information on the appropriateness or feasibility of an intervention may be seen to produce lower level evidence.

In response to these limitations of existing frameworks, a new hierarchy of evidence was developed that acknowledges the legitimate contribution of a range of research methodologies for evaluating healthcare interventions (see Fig. 1). This approach addresses the multidimensional nature of evidence and accepts that valid evidence can be generated by a range of different types of research. It does not attempt to diminish the value of RCTs, or the importance of determining effectiveness; rather, it accepts that RCTs answer only some of the questions. Importantly, this framework acknowledges the contribution of interpretive and observational research.

From a slightly different perspective, the hierarchy was also developed to serve as a framework during the production of systematic review protocols. In this context, the aim of the hierarchy was to help formulate review questions and to assist in determining what research could provide valid evidence when questions extended beyond the effectiveness of an intervention.

	Effectiveness	Appropriateness	Feasibility
Excellent	• Systematic review • Multi-centre studies	• Systematic review • Multi-centre studies	• Systematic review • Multi-centre studies
Good	• RCT • Observational studies	• RCT • Observational studies • Interpretive studies	• RCT • Observational studies • Interpretive studies
Fair	• Uncontrolled trials with dramatic results • Before and after studies • Non-randomized controlled trials	• Descriptive studies • Focus groups	• Descriptive studies • Action research • Before and after studies • Focus groups
Poor	• Descriptive studies • Case studies • Expert opinion • Studies of poor methodological quality	• Expert opinion • Case studies • Studies of poor methodological quality	• Expert opinion • Case studies • Studies of poor methodological quality

Figure 1 Hierarchy of evidence: ranking of research evidence evaluating health care interventions.

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EFFECTIVENESS

Effectiveness has been the most common concern of systematic reviews and clinical guidelines. Effectiveness relates to whether the intervention achieves the intended outcomes and so is concerned with issues such as:

- Does the intervention work?
- What are the benefits and harm?
- Who will benefit from its use?

It can be argued that multicentre RCTs provide the best evidence for the effectiveness of an intervention because the results have been generated from a range of different populations, settings and circumstances (see Fig. 1). The findings from systematic reviews are generated in a similar manner, and so also provide rigorous evidence (Mulrow, 1987; Cook *et al*., 1998). As a result, the robustness and generalizability of evidence from both these approaches are better than what is generated by other research designs. This means that for the evaluation of effectiveness, the best evidence would be that produced by either of these approaches.

However, this is not the only source of good-quality evidence. A well-conducted single-centre RCT also produces results that are at low risk of error or bias, and so provides valid evidence on the effectiveness of an intervention. However, this evidence is ranked at a lower level because the findings are based on a single population. This means that factors unique to the study site, such as skill mix, available resources, staffing levels or expertise, may have an impact on the findings of the RCT.

For observational studies, such as case control or cohort studies, their place within the hierarchy of research designs is less clear and they have often been viewed as being at greater risk of systematic error than RCTs (Chalmers *et al*., 1983; Colditz *et al*., 1989; Miller *et al*., 1989). The concern with these studies is that they can distort the treatment effects, making them appear smaller or larger than they really are (Mulrow & Oxman, 1997). Recently, however, comparisons of the results of observational studies and RCTs evaluating the same intervention have questioned this claim (Benson & Hartz, 2000; Concato *et al*., 2000), and suggest that the findings of observational studies are similar to those produced by RCTs.

There are important differences between the RCT and observational study relating to their internal and external validity. Internal validity in this context is a measure of how easily differences in outcomes between comparison groups can be attributed to the intervention (Elwood, 1998). External validity refers to the way in which the results of a study can be generalized to the wider population (Elwood, 1998). The RCT minimizes the risks posed by confounding variables through processes such as randomization and strict inclusion criteria and, as a result, the RCT has high internal validity. However, because of these very processes, only a narrow spectrum of patients may qualify for inclusion in the study. This means that the external validity is low and so the generalizability of the findings of the RCT may be limited. Conversely, observational studies observe what is happening in practice and thus have a lower internal validity as a result of potential differences between comparison groups. As a result it is harder to attribute the differences in the outcome to the intervention. However, this lack of control means that observational studies are more firmly based in the real world, in that the comparison groups more closely reflect clinical practice. Therefore, it can be argued that observational studies have a higher external validity than RCTs. To put it more simply, gains in the internal validity of the RCT are achieved at the expense of external validity, while the high external validity of the observational study is achieved at the expense of internal validity.

In some situations, observational studies may be more suitable than the RCT, such as when measuring infrequent adverse outcomes, evaluating interventions designed to prevent rare events or those evaluating long-term outcomes (Black, 1996). Legal or ethical issues may also prevent the conduct of RCTs. Observational studies may also be the only option where clinicians or patients are unwilling to accept randomization as the mechanism for assignment of treatment (Horwitz *et al*., 1990). For some treatments, a sustained effort is required from the recipient and so their evaluation may require a different approach from the RCT (Brewin & Bradley, 1989). Additionally, these studies cost less than RCTs and allow evaluation of a broader range of participants (Feinstein, 1989). Finally, situations in which the results of RCTs contradict consistent findings from observational studies serve to highlight the need for caution (Guyatt *et al*., 2000).

From this perspective, it can be argued that both the RCT and observational study can contribute valid evidence related to the effectiveness of an intervention and therefore should have a role in any evaluation. The important difference between methods is that the RCT solely evaluates the intervention, while the observational study measures the intervention in clinical practice. When differences in results exist, they cannot be assumed to be solely due to the presence or lack of randomization (McKee *et al*., 1999). Factors such as differences in study populations, characteristics of the intervention or patient preferences may be responsible for the difference in

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findings (McKee *et al*., 1999). However, these approaches can provide complementary evidence, and end-users must be aware that both methods have their strengths and weaknesses (McKee *et al*., 1999).

In addition to the studies already discussed, evidence is also produced by other methods such as non-randomized controlled trials, un-controlled trials, and studies with historical controls; however, their results are at greater risk of error (Dawson-Saunders & Trapp, 1994). With quasi-experimental designs, such as the non-randomized controlled trial, it is more difficult to show that any difference in outcome is the result of the intervention rather than differences between groups (Elwood, 1998). These non-randomized studies differ from observational studies because the allocation to comparison groups is made by the researcher rather than healthcare workers who are independent of the study. As a result of these factors, the risk of error or bias is high.

Uncontrolled trials may also be used to evaluate an intervention, but the lack of any comparison group makes interpretation of findings difficult. The exception to this is studies with dramatic results, for example, the administration of oxygen to a hypoxic person or adrenaline to a person in shock. However, for most situations, the evidence generated by uncontrolled trials should be regarded with suspicion, and must also be ranked at a lower level than the findings of RCTs or observational studies.

Finally, evidence about the effectiveness of an intervention may be generated through descriptive studies, expert opinion, case studies or poorly conducted studies. This evidence is at the greatest risk of error and is inadequate for evaluating the effectiveness of an intervention. As a result these methods are ranked as the lowest level of evidence.

APPROPRIATENESS

Appropriateness, in this context, addresses the impact of the intervention from the perspective of its recipient. It also relates to the impact of illness to enable this information to be integrated into healthcare management and to assist in the prioritization of care. Appropriateness is concerned more with the psychosocial aspects of care than with the physiological and, with regard to the intervention, is reflected in questions such as:

- What is the experience of the consumer?
- What health issues are important to the consumer?
- Does the consumer view the outcomes as beneficial?

The range of research methods that can contribute valid evidence on the appropriateness of an intervention is broader than that addressing effectiveness (see Fig. 1). Firstly, as with effectiveness, results generated by multicentre studies and systematic reviews represent the best evidence on the appropriateness of an intervention. However, the systematic review and multicentre study need not be limited to RCTs, but would focus on all methods that can reasonably be used to evaluate the intervention from the perspective of appropriateness. Recommendations based on these sources of evidence would be at least risk of error.

Good evidence can also be generated by a range of other research methods. As with effectiveness, a well-conducted single-centre RCT or observational study can provide valid evidence about the appropriateness of an intervention through a focus on psychosocial outcome measures. As previously stated, while experimental and observational studies evaluate the intervention from different perspectives, the evidence is complementary.

Interpretive studies can also contribute valid evidence, in that they represent the consumer's perspective on the treatment, illness or other such phenomenon, and thus help capture the subjective human experience that is often excluded from experimental research. This interpretive inquiry helps healthcare workers gain an understanding of everyday situations and experiences (Van Manen, 1990; Van der Zalm, 2000). While this information differs considerably from that generated by experimental or observational research, it contributes to our understanding of the impact of healthcare and is no less valid than that produced by other methods.

Evidence on appropriateness can also be generated by descriptive studies such as surveys, questionnaires and case studies. These contribute descriptive data related to interventions, their use and consumer responses. In addition to this, focus groups have emerged as a method for gathering information on the feelings and opinions of small groups of people, and so can aid in the evaluation of healthcare programmes (Beaudin & Pelletier, 1996; Robinson, 1999). This information offers another perspective on appropriateness and is valid evidence. However, its strength is less than that of the evidence produced by experimental, observational or interpretive research. Finally, evidence can also be generated by expert opinion or poor quality studies; however, this is at the greatest risk of error and as a result is ranked as the lowest level of evidence.

FEASIBILITY

Feasibility addresses the broader environment in which the intervention is situated and involves determining whether the intervention can and should be implemented. This focus acknowledges that the process of intentional

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change in large organizations is very complex. In this context, feasibility is reflected in questions such as:

- What resources are required for the intervention to be successfully implemented?
- Will it be accepted and used by healthcare workers?
- How should it be implemented?
- What are the economic implications of using the intervention?

A broad range of research methods can reasonably be used to evaluate feasibility, and while each has a different focus, all offer important evidence (see Fig. 1). Once again, results generated by multicentre studies and systematic reviews can be considered the best evidence for evaluating the feasibility of an intervention. These reviews and studies need not be limited to synthesizing the findings of RCTs, but may focus on all methods that can reasonably be used to evaluate the intervention from the perspective of feasibility.

A well-conducted single-centre RCT can provide good evidence on the feasibility of an intervention. From this perspective, the RCT would be likely to focus on organization, utilization or implementation outcome measures or on activities that support the intervention, such as education programmes. Both observational and interpretive studies can generate valid evidence and would focus on issues related to implementation, acceptance, long-term benefits, or the impact of the organizational culture on implementation.

Other methods can also provide useful evidence on feasibility. For example, action research is able to explore the relationships between attitudes and specific aspects of care, to identify barriers to practice change, and to systematically develop knowledge related to practice (Meyer, 2000). As a result of this, action research can contribute legitimate evidence on which to influence and shape clinical practice. As with appropriateness, focus groups can also gather valid information from small groups of people (Basche, 1987; Beaudin & Pelletier, 1996), and so assist in evaluating healthcare programmes (Robinson, 1999). From the perspective of feasibility, this information would relate to such things as implementation, identifying barriers or determining what support is required. Descriptive studies can also provide information related to the feasibility of an intervention. However, the evidence generated by these methods would be ranked at a lower level than that produced from experimental, observational and interpretive research.

Finally, as with both effectiveness and appropriateness, evidence can be based on expert opinion, case studies or poor-quality research. However, this evidence is at the greatest risk of error and so is ranked at the lowest level of hierarchy.

Levels of evidence

The primary purpose of developing this hierarchy was to provide an indication of the validity and trustworthiness of different types of research. This process assists in the selection of the best evidence to guide clinical practice. However, each level proposed in this hierarchy differs from others, as described below.

- *Excellent:* This level of evidence provides the strongest scientific base for clinical practice. As this evidence is at the least risk of error, it is optimal for the development of practice guidelines and clinical recommendations.
- *Good:* This level of evidence also provides a sound basis for clinical practice and is at low risk of error. However, as it may have been generated by single studies, it also highlights areas where replication of research is needed.
- *Fair:* As this level of evidence will be at varying degrees of risk of error, it does not provide a strong evidence-base for clinical practice. However, these studies represent initial exploration of interventions and so assist in prioritizing the research agenda. The rationale for this is that while the evidence is at greater risk of error than the previous levels, it allows identification of potentially beneficial interventions that require additional investigation and evaluation.
- *Poor:* This level of evidence provides a poor basis for clinical practice and is at serious risk of error or bias. Additionally, while this evidence can help in determining research priorities, because there is a greater risk that it may be wrong, and therefore misleading, it is ranked below other forms of evidence.

Value of this approach

The benefit of this approach for grading evidence evaluating interventions is that it moves beyond having a single focus on RCTs. This broader focus is important because an RCT is unlikely to be able to answer all the questions needed for a complete evaluation. From this perspective, it acknowledges that, when evaluating an intervention, a variety of research methods can contribute valid evidence. This hierarchy also recognizes the greater strength of evidence when it has been generated from multiple populations, settings and circumstances. For this reason, evidence generated by properly conducted systematic reviews or multicentre studies should be considered the strongest evidence.

This approach to ranking evidence also legitimizes the perspective of the consumer of the intervention and so recognizes the pivotal role this should have in healthcare decisions. It also acknowledges the importance of the

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psychosocial impact of interventions and that consumers' priorities on important health needs may differ from those of the providers of care. While the views of the consumer have long been part of the rhetoric, to date they have fitted poorly within the evidence-based framework. Through the use of this hierarchy, evidence addressing this aspect of the evaluation of an intervention can be ranked at a more appropriate level.

While an intervention may be effective, it must also be feasible to implement. This relates to such things as cost, healthcare workers' acceptance and the resources which will be required to support the intervention. This hierarchy recognizes that evidence addressing the feasibility of an intervention is as important as that addressing effectiveness. A broader approach to the ranking of evidence will provide a more robust scientific base for healthcare, in that it moves beyond the single focus of effectiveness that has dominated the evidence-based healthcare movement since its inception.

The gold standard

In the context of this hierarchy it can be argued that there are two interpretations of the label 'gold standard'. The common use of this term refers to the optimal research design to answer a question. Over the past decade, this label has most commonly been applied to RCTs evaluating the effectiveness of interventions. However, for research questions addressing issues other than effectiveness, different methods will be needed. The optimal research method will be determined by the type of question, and it is the method that produces the most valid evidence that should become the standard to which others are compared.

Secondly, the use of this hierarchical structure for grading evidence provides another interpretation of what is meant by the gold standard. The concept of gold standard could move beyond research design and refer to evidence addressing all three dimensions of the evaluation of an intervention. That is, evidence demonstrates that the intervention works, can be implemented and fulfils the needs of its consumers. Only when all these dimensions have been subjected to investigation can an intervention be fully appraised and the evidence considered to be of a gold standard.

Cautionary note

It must be acknowledged that the use of any hierarchy is, at best, a guide rather than a set of inflexible rules. A hierarchy provides the end-user of research with a framework to judge the strength of available evidence. Other issues, such as what outcome measures were used and the populations studied, also exert a major influence on the usability of the evidence. While I have used this hierarchy to provide a logical framework for a review, it has not been subject to any formal evaluation and so caution is needed. Finally, and most importantly, hierarchies cannot be used to rank evidence without some consideration of the quality of research. Regardless of the research method, if the processes used during the study were poor, then the findings must be regarded with suspicion.

Conclusion

The proposed hierarchy of evidence provides a tool by which research addressing the many dimensions of an intervention can be ranked at an appropriate level. This approach takes the emphasis away from the RCT, to one that accepts that different research designs may be required for different clinical questions. The focus on effectiveness, appropriateness and feasibility provides a broader base for evaluating healthcare, and one that better fits the perspective of clinical practice.

This hierarchical approach recognizes the greater strength of evidence generated by systematic reviews and multicentre studies because the findings have been derived from multiple populations, settings and circumstances. In all three dimensions of the evaluation of an intervention, these sources provide the most valid and reliable evidence. Importantly, this hierarchy acknowledges that a range of research methods can contribute valid evidence.

The hierarchy provides a guide that helps the determine best evidence; however, factors such as research quality will also exert an influence on the value of the available evidence. Finally, for an intervention to be fully evaluated, evidence on its effectiveness, appropriateness and feasibility will be required.

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Gender Dysphoria: Definition and Evolution Through the Years

3

Lin Fraser

3.1 Definition

3.1.1 Gender Dysphoria

The dictionary defines gender as the state of being male or female (typically used with reference to social and cultural differences rather than biological ones) [1] and dysphoria as the state of unease or generalized dissatisfaction with life, the opposite of euphoria [2]. The term dysphoria is from the Greek word *dysphoros* meaning "hard to bear" [3].

Below are two medical definitions of gender dysphoria, both from the World Professional Association for Transgender Health (WPATH) Standards of Care (SOC), the first from the earliest (1979) [4] version, Standards of Care, The hormonal and surgical sex reassignment of gender dysphoric persons, and the second from the current and seventh version (2011) [5] Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People. Both documents and their intervening versions are written and distributed by WPATH, formerly known as the Harry Benjamin International Gender Dysphoria Association (HBIGDA).

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3.1.2 1st SOC (1979)

Gender dysphoria herein refers to that psychological state whereby a person demonstrates dissatisfaction with their sex of birth and their sex role, as socially defined, which applies to that sex, and who requests hormonal and surgical sex reassignment. Gender dysphoria, herein, does not refer to cases of infant sex reassignment or reannouncement nor does it refer to those persons who, although dissatisfied with their genetically and socially defined sex status (i.e., transvestites and transgenderists), usually do not request sex reassignment. Gender dysphoria, therefore, is the primary working diagnosis applied to any and all persons requesting surgical and hormonal sex reassignment [6].

3.1.3 SOC 7 (2011)

Gender dysphoria – Distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics) [7].

These two definitions, separated by 32 years between the first and the seventh guidelines, reflect the overarching change in the evolution of the professional approach to gender dysphoria.

Using the SOC as a mirror of the evolution, the original professional approach was a medicalized one, and these guidelines of care described

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the medical management of gender dysphoria and presumed a full transition from one sex to another (the sex-change model).

The title, as noted above, of the 1st SOC was "Standards of Care, The hormonal and surgical sex reassignment of gender dysphoric persons."

In the most recent SOC, the medical part of the definition (about requesting sex reassignment) has been intentionally omitted. The current professional approach has been to broaden the focus of transgender health [8], with an emphasis on health and not only on treatment. Individuals with gender dysphoria requesting medical care receive individualized health care, which may or may not include hormonal and/or sex reassignment. These SOC include other aspects of health care, for example, reproductive health, voice and communication therapy, lifelong preventive and primary care, and care in institutional environments [9]. Psychological care has been included from the beginning.

Thus, the title of the 7th SOC is "The Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People," unlike the early ones that specifically mention sex reassignment.

Another major change from the original SOC, consistent with the above change from treatment to health, is a shift in gender paradigms.

Initially, a binary system of gender (man, woman, boy, girl) was the predominant paradigm. Now, the view is that gender falls on a spectrum and multiple gender identities and expressions are possible.

In addition, although not clear from these definitions, professional consensus has moved away from seeing gender dysphoria as a disorder and now sees it as part of an overall pattern of gender diversity [10].

The approach for providers in providing health care more broadly has, as its basis, an underlying emphasis and recognition of human rights. Health care is a human right. And trans rights are part of human rights.

The evolution of the name and approach is due to an interplay of several factors such as advancing knowledge and better clinical treatments, the aforementioned changing gender paradigms, input and participation from trans people themselves including human rights and the right to self-define, the rise of the Internet, more global participation, and evolving shifts in how transgender people are seen by the culture. Expansion of knowledge beyond Western approaches is also part of the evolution. These changes have accelerated in recent years and are exponential rather than linear.

Other names used frequently in the literature include "*gender identity disorder* [11], the formal diagnosis set forth by the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Rev. (DSM IV-TR) (American Psychiatric Association 1987) which is characterized by a strong and persistent cross-gender identification and a persistent discomfort with one's sex or sense of inappropriateness in the gender role of that sex, causing clinically significant distress or impairment in social, occupational, or other important areas of functioning)", "*transsexualism* (transsexual: an adjective (often applied by the medical profession) to describe individuals who seek to change or who have changed their primary and/or secondary sex characteristics through feminizing or masculinizing medical interventions (hormones and/or surgery) typically accompanied by a permanent change in gender role) [12]", and "*transgender* (an adjective to describe a diverse group of individuals who cross or transcend culturally defined categories of gender). The gender identity of transgender people differs to varying degrees from the sex they were assigned at birth [12]".

Although gender dysphoria, an essentially neutral label, is the term most commonly used in the current medical literature, that neutrality was not always so. Until recently, the value-laden gender identity disorder, which by definition implied a "disordered condition," was the most commonly used term. Although the name gender dysphoria has come full circle, approaches to care have evolved.

These names cannot be separated from the evolution of professional understanding.

3.2 Evolution and SOC

This chapter describes the evolution of the name and professional approaches to the condition start-

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ing with the 1st international symposium on gender identity, in London, in 1969, and the beginnings of HBIGDA, in 1979, followed by the seven versions of the SOC that document the evolution of the nomenclature and the prevailing approaches to care, and then ends with the 23rd 2014 WPATH Symposium, Transgender Health from Global Perspectives, held in Bangkok, Thailand.

3.2.1 WPATH and SOC

WPATH (formerly HBIGDA) writes and disseminates the SOC.

It is the oldest and only international multidisciplinary professional organization devoted solely to the health of trans people with the mission to promote evidence-based care, education, research, advocacy, public policy, and respect in transsexual and transgender health.

Hence, the organization is in a good position to publish guidelines that reflect the state of the art and science and evolution of care.

The SOC document the evolution of the nomenclature and prevailing medical standards and are based on the best available science and expert professional consensus.

Revisions to the 1979 Standards of Care (1980, 1981, 1990, 1998, 2001, 2011) have occurred concurrent with the advancement of knowledge.

Other classification systems naming this phenomenon are the Diagnostic and Statistical Manual of Mental Disorders (DSM) put out by the American Psychiatric Association (APA) and the International Classifications of Diseases (ICD) put out by the World Health organization (WHO). These manuals have also evolved, often along parallel lines to the SOC. Although the last publication of ICD, ICD-10, was in 1990 [13], ICD-11 has a planned publication in 2017. As both the DSM and ICD have contributed to and reflect evolving notions of health care, their nomenclature will also be described.

WPATH has worked with APA and the WHO during the period of writing of SOC7 (the SOC7 process) and beyond. WPATH has had formal consensus processes advising the workgroups for APA and the WHO regarding the nomenclature for both DSM 5 and ICD-11.

This chapter will not describe the terminology and health care of children.

By necessity, broad-brush strokes will be used to provide an overview of the evolution.

Information on the background and beginnings of approaches is followed by briefer descriptions of middle periods where the interplay of factors brings us to the dramatic shifts in recent years.

Some things have not changed such as the complexity of the condition, ethical concerns, the interdisciplinary nature of the field, and the need for social understanding and education.

Major changes include the growing number of people involved in the field including more transgender people themselves. The addition of transsexual, transgender, and gender-nonconforming people joining with providers in the evolution of approaches has had a major impact. Mainstream growing acceptance is also a factor.

3.3 Pre-SOC to 1979

3.3.1 1950s and 1960s

The possibility of medical treatment for gender dysphoria entered the popular imagination in the early 1950s when Christine Jorgensen, an American GI, had a sex-change operation in 1951 in Denmark and then returned to the United States. Although not the first to have a "sex change," Dr. Harry Benjamin, an early pioneer in the field [14], remarked that Jorgensen's "sex conversion" and the worldwide publicity it created was perhaps the most important milestone in the history of transsexualism. Her surgeon Christian Hamburger in his 1953 report [14] urged the medical and legal professions to help the plight "of these unfortunate people for whom psychotherapy proved useless."

The aforementioned Benjamin, a NY endocrinologist, saw many patients and wrote the first article about the condition in 1953 [15] in the no longer existing International Journal of Sexology.

In 1966 [16], he published his magnum opus, *The Transsexual Phenomenon*. In it, he interpreted transsexualism as a form of psychic intersexuality, the intensity of which varies. He suggested that the condition was due to complex factors,

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most likely had more than one causation, and was primarily a neuroendocrine disorder. He argued that since there was no cure, it was in the best interest of both transsexuals and greater society to alleviate this intense suffering of transsexuals by sex reassignment, in selected cases [17].

Also in 1966, the Gender Clinic, championed by renowned medical psychologist Dr. John Money, opened at Johns Hopkins. The clinic lasted until 1979 when it was forced to close by pressure from psychiatry, asserting that it was treating a mental disorder by doing surgery [18].

Hopkins served as a model for gender clinics scattered throughout the United States.

The oldest and largest gender identity clinic in the world began operations in the mid 1960s and is still in operation located in Hammersmith in London and is sometimes known as Charing Cross Gender Identity Clinic [19].

Don Laub, M.D., Chief of Plastic Surgery at Stanford and also founder of Interplast, which was the forerunner of medical humanitarian ventures worldwide, founded another gender clinic, known as "the Stanford Program." Laub led medical teams on humanitarian surgical trips to the developing world and at the same time developed new surgical techniques for sex-reassignment surgery. Eventually, he moved to private practice but was never forced to close. Laub was instrumental in the foundation of the organization that was later to become WPATH, serving as President from 1981 to 1983 [20].

Psychiatrist and lawyer Richard Green and medical psychologist John Money (eds) published a multidisciplinary volume *Transsexualism and Sex Reassignment* in 1969, which, along with instructions on hormonal and genital sex reassignment, included sections on social and clinical aspects of transsexualism. Topics included such as psychological aspects, somatic aspects, treatment aspects, and medicolegal aspects, are themes that continue to be major topics today.

The editors dedicated the volume to Harry Benjamin, M.D., the pioneer of transsexual research, stating: His compassion and courage in treatment of the transsexual patient opened a new frontier in the knowledge of human nature [21].

Hence, foundational themes and key points from the earliest years included the following:

Gender dysphoria cannot be cured via psychotherapy.

A medical necessity for surgical sex reassignment exists in some cases.

The field is interdisciplinary.

Compassion and courage are foundational.

3.3.2 1970s

Early pioneers and early conferences

Prior to the 1st SOC, a small group of interdisciplinary professionals supported by wealthy transsexual Reed Erickson via his foundation, the Erickson Educational Foundation, assembled at six conferences in Europe and the United States to discuss the new medical condition known then as either gender disorientation, transsexualism, or gender dysphoria, starting in July 1969 with the 1st International Symposium on Gender identity: Aims, Functions, Clinical Problems of a Gender Identity Unit, London. These international symposia continue to this day, with the 23rd just held in February 2014 in Bangkok, Thailand. The next will be held in Amsterdam, the Netherlands, in 2016.

The people involved were pioneers and highly respected in their fields.

Some of the concerns of the early conferences are equally compelling today.

In the opening address of the first conference in 1969, Professor C. J. Dewhurst from Queen Charlotte's Hospital, London, states, "I actually regard this to be one of the most difficult conditions I have ever come across in clinical medicine. If we consider the condition as an anomaly that would be cured by getting the patient to accept their true anatomic sex, can we say that is ever possible?" To paraphrase Dr. Dewhurst, "What do we know of its origin? Under what circumstances does it arise? If we medically intervene, what are criteria and at what age? What is their legal sex? Can they marry?" [22].

The cover of the brochure states the following: *In addition to the medical and research aspects of the problem, there is urgent need for greater*

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academic and professional understanding and for education, the latter of which could be said to be the most pressing need today.

At the 1971 2nd International Gender Identity Symposium in Denmark, there was a recognition that *this is an interdisciplinary, complex condition and area of human rights*. The brochure stated that the field calls attention on the problem of gender identity and "gender disorientation, not only as a psychiatric entity but also as an area of specialized medical study and treatment and social understanding" [23].

The 1973 3rd Symposium on Gender Identity in Dubrovnik included families along with surgery and etiology as topics of discussion [24].

The 4th conference on Gender Identity in Palo Alto in 1975 was the first to use the Harry Benjamin name in the title. It also focused on the interdisciplinary exchange of scientific information and how to achieve greater acceptance. In a first-person recollection, Roy Mackenzie stated that the "first step was to make it professionally respectable to even study such material" [25].

At the 1977 5th International Gender Dysphoria Symposium in Norfolk, VA, a founding committee for an interdisciplinary international organization named after Harry Benjamin, the Harry Benjamin International Gender Dysphoria Association (HBIGDA), was founded and charged with developing Standards of Care guidelines based on knowledge and ethics at that time. Paul Walker, Ph.D., a protégé of John Money, was named as chair [26].

3.3.2.1 Literature

Aside from the literature coming from the above pioneers, most of the literature was psychodynamic and pathologizing, positing dysfunctional family, mostly mother–child dynamics, as the cause of the condition and recommended reparative psychotherapy and psychoanalysis. Examples of literature in that vein include Stoller's [27]) *Perversion* among other books [28–30] and a series of articles by psychoanalysts Ovesey and Person [31, 32] and Person and Ovesey [33, 34, 35].

Other psychological treatments were behavioral, for example, Rekers and Lovaas [36], designed to extinguish cross-sex gender expressions and reinforce gender normative behaviors.

3.3.3 Nomenclature Pre-1st SOC

SOC – The SOC did not exist.
DSM 1 (1952) – There was no nomenclature for the condition.
DSM II (1968) – (Parent) sexual deviations; (diagnosis) transvestism.
ICD-6 (1948) and ICD-7 (1955) – There was no nomenclature for the condition.
ICD-8 (1965) – (Parent) sexual deviations; (diagnosis) transvestism.
ICD-9 (1975) – (Parent) sexual deviation; (diagnosis) transvestism and transsexualism.

3.3.4 Summary

This period marked the beginning of gender clinics, the first surgeries, and the beginning of psychopathologization as a sexual deviation in the nomenclature. The paradigm was clearly binary.

The two strands of literature and approaches still continue today, but one (reparative) is now considered unethical and is not part of mainstream care. The early specialized conferences draw surprising parallels to today.

3.4 1979–1981

SOC v1. 1979 Standards of Care
The hormonal and surgical sex reassignment of gender dysphoric persons
SOC v2. 1980 Standards of Care
The hormonal and surgical sex reassignment of gender dysphoric persons
SOC v3. 1981 Standards of Care
The hormonal and surgical sex reassignment of gender dysphoric persons

The 1st 3 SOC had the same name. The healthcare approach for all was comprised of the triadic sequence, the three required steps to medically transition from one sex to another. These three included living in the preferred gender for 1 year termed the life test, hormonal, and finally genital sex reassignment. The first SOC used the name gender dysphoria.

The paradigm about gender was binary.

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HBIGDA was incorporated, and the first Standards of Care were approved by the membership of the fledgling society in 1979 at the seventh conference in San Diego. From the beginning, it was made up of interdisciplinary international providers, most from Western Europe and North America, primarily from the United States. Much of the hard science came out of Europe.

One purpose of having guidelines was to gain respectability. The purpose of the new organization and the SOC was to gain academic acceptance among professional peers, to provide a place for professionals to share knowledge, to move the field forward, and to protect trans people from disreputable surgeons.

The term gender dysphoria was adopted as a descriptive and accurate label [37]. Dysphoria was about the subjective distress of the mind/body mismatch. Later, the word was extolled as being value-free compared to other labels that included the designation disorder.

The first Standards were only eight pages long, and although contributed to via professional consensus, they were actually written by Psychologist Paul Walker from the University of Texas at Galveston. Dr. Walker was the first President of HBIGDA, who later started a private practice in San Francisco, before his untimely death in 1991.

These first SOC covered such items as definitions, principles, description of the triadic sequence, and recognition of the interdisciplinary nature of the field. Strict eligibility requirements for medical treatments, including two evaluations by mental health professionals for surgery and one for hormones, were also described. Psychotherapy was compulsory.

Meanwhile, providers were excoriated on multiple fronts.

McHugh [18], pointing to studies showing that operated patients were no better off than they had been before treatment, shut down the Hopkins gender clinic in 2006. He neglected, however, to take into account that most were subjectively happy about their surgeries and few had regrets [38].

Also in 1979 radical feminist Janice Raymond, in her book *The Transsexual Empire*, proposed that male-to-female transsexuals transitioned as a way to invade female space. She also accused providers of creating a medical treatment "empire" as a means to make money [39].

The term gender identity disorder (GID) as a subset of psychosexual disorders was first introduced in DSM III (1980) [40] (for children), which initiated the language of disorder. GID would become the language for adults in DSM II-R (1987) [41]. The term suggested that one was at core disordered, this supposition becoming the basis of future protests from trans people and professionals alike. The mental disorder designation became the default position. Although no concrete evidence existed for a psychological or a physical basis for the condition, DSM III suggested that a predisposing factor was a disturbed parent–child relationship [40] consistent with Stoller [42]. One also wonders if the stigma of cross-gender behavior may have played a role in the decision regarding this placement in the nomenclature [43].

3.4.1 Nomenclature

SOC 1979, 1980, 1981 – Gender dysphoria.

DSM III (1980) – (Parent) psychosexual disorders, (diagnosis) transsexualism. Gender identity of childhood was introduced.

ICD-9 (1975) – (Parent) sexual deviations, (diagnosis) transvestism and transsexualism.

3.4.2 Summary

Today's preferred term gender dysphoria was used in the first SOC whereas the term gender identity disorder was first used elsewhere, in DSM III.

3.5 1981–1990

SOC v4 (1990) Standards of Care – The hormonal and surgical sex reassignment of gender dysphoric persons

SOC v4 had the same name as the first three versions; the health-care approach concerned medical transition from one sex to another, the triadic sequence, and used the name gender dysphoria.

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The paradigm about gender was binary and the condition was still considered primarily a mental disorder.

During this period, competing theories abounded, suggesting how little was actually known.

Blanchard developed a new typology based on sexual orientation. In his view, there were two types of male to female transsexuals, one early onset and attracted only to men and the other a later onset type recognizable by a sexual orientation directed toward an inner image of oneself as a woman, which Blanchard labeled autogynephilia [44]. This eroticism of identity has created much dissension particularly among the trans community and remains a point of contention even today.

Also in 1987 Green published the influential *Sissy Boy Syndrome and the Development of Homosexuality*, which continues to have influence although the title remains controversial. In a study still cited, Green found that most children with GID grow up to be gay, not trans, and that one cannot predict adult outcomes based on childhood behavior [45]. Although this chapter is not about children, a big question regarding children has to do with who will benefit from early medical transitions and who will not? How do we predict outcomes?

Another example, presented at the HBIGDA 1989 conference in Cleveland and in his writings, Leslie Lothstein, a psychoanalytic clinician, described the etiology and treatment of FTM transsexualism. He posited that FTMs suffered from severe impaired object relations and borderline psychopathology requiring long term psychodynamic psychotherapy rather than medical intervention [46, 47].

3.5.1 Nomenclature

The SOC were still using the term gender dysphoria while others started or continued using the term GID.

DSM III-R (1987) – (Parent) disorders usually first evident in infancy, childhood, or adolescence; (diagnosis) transsexualism, gender identity disorder of adolescence and adulthood – nontranssexual type.

ICD-10 (1990) – (Parent) gender identity disorders; (diagnosis) transsexualism, dual-role transvestism, other gender identity disorders, gender identity disorder, unspecified. This ICD is still in use. ICD-11 will not be out until 2017 [48].

3.6 1991–1998

SOC Version 5 (1998) – The Standards of Care for Gender Identity Disorders

The 1998 SOC, to be consistent with DSM III, for the first time called the condition GID, rather than gender dysphoria.

Nevertheless, despite the shift in terminology, a beginning of change in approach was evident.

Although the triadic sequence was prioritized, the standards suggested that other approaches (described in the psychotherapy section) might be helpful for some people in adapting to the condition. For the first time, psychotherapy, although highly recommended, was not a prerequisite for treatment.

As a precursor to the current emphasis on human rights, the SOC stated that although GID was still considered a mental disorder, a disorder designation was not a license for stigma.

SOC v5 stated that the overarching treatment goal was "lasting personal comfort with the gendered self in order to maximize overall psychological well-being and self-fulfillment" [49]. This goal remains in place today.

Although difficult to break down how things changed exactly, a pattern emerged via an interplay of forces. The issue of labeling the condition a disorder was becoming more controversial. The literature marked a shift away from the binary into a spectrum paradigm. Biological differences were also noted. Moreover, the community started to have a larger voice.

For example, in 1994, Gil Herdt's 614-page series of articles entitled "Third Sex Third Gender, Beyond Sexual Dimorphism in Culture and History, Recognizing Global Diversity Outside the Binary" was published, describing many variations on the trans spectrum. On the biological side [50, 51], reported differences in

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the size of brain structures among homosexual and heterosexual men and transsexual women, in the part of the brain that regulates circadian rhythm, with the nuclei of the transsexual women being the largest [51].

3.6.1 Community

The community was beginning to have more authority among themselves and providers began to listen. The role and importance of the trans community started to grow. People started defining themselves.

The term transgender came from the community and this increasingly vocal community started to reject medical models.

For example, transgender activist and writer Dallas Denny, at a recent conference on transgender history (2014), described the impact of Holly Boswell's article (1991) "The Transgender Alternative" where she described the term transgender as a middle ground between transsexual and transvestite [52]. According to Denny, "The impact of "The Transgender Alternative" was immediate and dramatic. By 1994, the term transgender had become the consensual umbrella term for all of us. That does not mean everyone liked it. Essentialist transsexuals in particular felt they had little in common with crossdressers and transgenderists." As an aside, these differences continue to this day, hence the inclusive and respectful use of language in current terminology such as the title of SOC7. Regarding the community's relationship to the provider community, Denny noted, "It's a community in which we look to professionals for help, but not for direction. It's a community that rejects medical models of transsexualism and cross-dressing and the harmful labels that accompany them. And it's a community that has demolished all-or-nothing binary notions of gender and embraced our diversity and wholeness" [53].

Press for Change, an influential activist group (and one of the many to come), was founded in the United Kingdom in 1992. According to its welcome page on the website, Press for Change has been a key lobbying and legal support organization for trans people in the United Kingdom since its formation (http://www.pfc.org.uk) [54].

Bornstein [55] in her iconic book *Gender Outlaw* continued the theme of describing the trans perspective from outside the gender binary.

Google Search was initiated in 1997. The impact of the Internet on the rise of the trans community cannot be overestimated. Originally isolated, members were able to communicate and discuss common concerns and issues, including discussions about nomenclature. Members of the community questioned the terms used and, more tellingly, posed the question, who decides on the name of this condition? Who gives providers this right?

3.6.2 Nomenclature

SOC 5 (1998) – Gender identity disorder
DSM IV (1994) – (Parent) sexual and gender identity disorders, (diagnosis) gender identity disorder in adolescents or adults
ICD-10 (1990) – No change

3.6.3 Summary

This period was the beginning of change toward a more varied approach, marking the use of the term transgender as an umbrella term and the rise of a more vocal trans community.

3.7 1999–2001

Version 6 (2001) – The Standards of Care for Gender Identity Disorders

The SOC continued to use the name gender identity disorder.

3.7.1 Evolution and Literature

The SOC v6 offered more flexibility and more individualized treatment. Given that there was no name change and for other factors that remain unclear, an increasingly unhappy client population did not recognize these changes.

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The popularized term transgender was mentioned in this SOC, not as a formal diagnosis but as a term that does not connote psychopathology [56] indicating recognition for providers to shift away from stigmatizing language and the binary paradigm.

3.7.2 Community

An example of the growing voice of the trans community was the 1999 *Reclaiming Genders* by legal scholar and Professor Stephen Whittle BCE who was later to become the first transgender President of WPATH [57].

The increasing vocal community became more critical to providers, using the common complaint that they were required to "jump through hoops" to receive medically necessary services. A growing tension developed between providers and service end users.

Trans academics groups began to form. Movies such as Boys Don't Cry (1999) and Southern Comfort (2001) portrayed trans people as recipients of horrific treatment: murder by his peers in the former when his identity as a trans man was discovered and murder by neglect from medical professionals in the second, who refused to provide treatment to a trans man with ovarian cancer [58, 59]. These sympathetic portrayals began to bear witness to trans people's plight in the popular imagination.

3.7.3 Nomenclature

SOC – No change
DSM – No change
ICD – No change

3.7.4 Summary

This period was marked by continued flexibility in the SOC, more support in the popular imagination, and continued growth of the community without change in the nomenclature.

3.8 2001–2011

3.8.1 SOC7 (2011)

Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People

This 10-year period marks a major shift in the approach to health care in the SOC and among providers in general, summarized by a change from a focus on treatment to one of overall health and individualized care. In SOC7, the name has been quite consciously changed back to gender dysphoria and the condition is no longer considered a disorder.

The paradigm shifted from a binary to a spectrum.

The rate of evolution moved from linear to exponential concurrent with the continued massive growth of the Internet.

The exponential rate of change can be seen in the following chronology, which is marked by more of an emphasis on human rights. Other concrete examples include the newly named WPATH and the vastly different seventh version of the Standards of Care.

The literature began normalizing the condition with books such as the award winning and compassionate 2004 *Transgender Emergence* by Arlene Lev and the 2004 autobiographical *Becoming a Visible Man* by trans man Jamison Green, who later became WPATH President in 2014 [60, 61]. Although some literature remained focused on disorder such as Bailey's 2003 *Man who would be Queen*, supportive of Blanchard's typology emphasizing the sexual nature of the condition [62], the book was met by a tremendous outcry from the community and other professionals. Although discussion of the latter theory is outside the scope of this chapter, the degree of dissent highlights the power of the voices demanding normalcy as well as the growing power of the transgender movement.

In 2006, the Harry Benjamin International Gender Dysphoria Association's (HBIGDA) name was changed to the World Professional Association for Transgender Health (WPATH). This change was a major milestone reflecting broader changes

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in the field. For example, the inclusive and umbrella term transgender in the title marks an emphasis on multiple trans identities and gender diversity, accentuating the change from a binary to a spectrum paradigm. The term health, as in SOC7, underscores that the field now emphasizes health rather than treatment.

Moreover, while the Standards were being developed, the field was growing internationally.

For example, a group of experts in human rights met in Indonesia and wrote the Yogyakarta Principles (2007) on the Application of International Human Rights Law in relation to Sexual Orientation and Gender Identity [63]. Although not legally binding, these set of principles were and are intended to apply international human rights law to Sexual Orientation and Gender Identity.

In 2007, Dr. Gail Knudson, current WPATH President-Elect, founded the Canadian Professional Association for Transgender Health (CPATH), modeled after WPATH, but at the national level.

At the 2009 WPATH Oslo Conference, then President Dr. Walter Bockting announced that WPATH's primary goal would be to broaden the focus of transgender health [64].

In 2009, the Council of Europe Commissioner for Human Rights recommended that anything related to gender identity should not be classified as a mental disorder in ICD-11 [65].

In 2010, the WPATH Board of Directors issued a press release and policy statement depathologizing gender variance worldwide. This statement, now known now colloquially as the "depath statement" says the following: "The WPATH Board of Directors strongly urges the depsychopathologisation of gender variance worldwide. The expression of gender characteristics, including identities that are not stereotypically associated with one's assigned sex at birth is a common and culturally diverse human phenomenon, which should not be judged as inherently pathological or negative" [66].

This statement was shortly followed by the Identity Recognition Statement (2010), emphasizing the human right to self-define. The statement reads as follows: "No person should have to undergo surgery or accept sterilization as a condition of identity recognition. If a sex marker is required on an identity document, that marker could recognize the person's lived gender, regardless of reproductive capacity. The WPATH Board of Directors urges governments and other authoritative bodies to move to eliminate requirements for identity recognition that require surgical procedures" [67].

Consistent with self-definition, medical clinics with an informed consent model such as Fenway Health in Boston and Callen–Lorde Community Health Center in NYC flourished.

Major changes in SOC7 paralleled and underscored these changes in the field.

For example, the names used in the title are inclusive and respectful of names used by trans people themselves and include transsexual, transgender, and gender-nonconforming people rather than using the term gender identity disorder.

The title is about health, not treatment. The document is evidence based, has multiple authors, and is 115 pages long with 265 references compared to the 1st SOC, for example, that was only 8 pages long, had no references, with input from a small group of professionals, and was written by basically one author. Psychotherapy is no longer a requirement and the new SOC are compatible with informed consent models.

Finally, the 2011 SOC recognize its Western-centric nature and supports global adaptations. It calls for more partnerships outside of Western Europe and North America.

3.8.2 Community

Prior to writing SOC7, the WPATH leadership called upon an international advisory committee comprised of carefully selected leaders from the trans community. One of these, Christine Burns, commented on the improved SOC and implicit improved provider and service end user relationship with the following:

If I had to sum it up then it would be that whereas previous versions of the SOC were always perceived to be about the things that a trans person must do to satisfy clinicians, this version is much more clearly about every aspect

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of what clinicians ought to do in order to properly serve their clients. That is a truly radical reversal… one that serves both parties very well [68].

3.8.3 Nomenclature

SOC – Name returns to gender dysphoria.
DSM 5 workgroup is in the process of changing to gender dysphoria.
ICD-11 workgroup is in the process of selecting a name.

3.9 Post SOC7

Since 2011, a tipping point has occurred in trans health and the rate of change is clearly exponential and not linear.

SOC7 has been met with almost universal acclaim. It has been translated into eight languages, with more to come. As a living document, updates will be introduced as knowledge advances. Support for the development of companion documents for resource-poor nations exists. PAHO has developed such a document, the Blueprint for the Provision of Care for Trans Persons and Their Communities in Latin America and the Caribbean PAHO under the leadership of Rafael Mazin, M.D. [69].

Exchange of knowledge has moved from Western to global. The goal of WPATH President Lin Fraser, during this period, has been global expansion and educational exchange. WPATH 2014, the 23rd International Symposium, was held for the first time outside of Western Europe and North America. The conference, entitled Transgender Health from Global Perspectives, convened in Bangkok, Thailand, and was attended by people from 34 countries and 6 continents. Plenaries were held on the following topics, indicating new directions in the field: new research regarding transsexual brain differences; surgical centers outside the West; ICD-11 where diagnostic placement will no longer be in mental health, furthering depathologization models; uterine transplants; and reproductive and hormonal possibilities. Trans thought leaders were invited and convened a special session series on "Trans People in Asia and the Pacific."

More partnerships are developing between professionals and providers.

WPATH convened an international gathering of global thought leaders in San Francisco February 2013 to continue its ICD Consensus Process to advise the WHO on ICD-11 and invited trans activists to be part of the process. The PAHO Blueprint was a joint professional/activist process. More trans people are also professionals, who bring added richness and depth to the conversation.

The field is growing at a rapid rate and the demand for education and training is following suit. WPATH has founded a Global Educational Initiative (GEI) to address this huge need to educate providers, policy makers, and other interested parties worldwide. GEI is designed to educate from both a human rights and standard medical education models. The hope is that education will be multimodal, both face2face and via the Internet, and in collaboration with global partners.

3.9.1 Nomenclature

SOC – No change.
DSM 5 2013 – Gender dysphoria.
ICD-11 – The name is undecided but it will not include the term disorder and will not be placed in the mental disorders section.

3.9.2 Summary

This period can be summarized by the exponential growth of the field, perhaps best described by the designation "transgender beyond disorder."

Conclusion

Finally, although the field has enjoyed remarkable growth, rapid change, and new knowledge, as providers, we might still listen to the wise words of the early pioneers. We can listen to Hamburger in his 1953 report, urging the medical and legal profession to help, to the

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brochure at the 1969 first conference calling for the *Need for better understanding, and urgent need for education*, to heeding the topics on the program of 1971 2nd International Gender Identity Symposium in Denmark, *recognizing that this is an interdisciplinary, complex condition and area of human rights*.

The foundational themes, such as compassion and courage are as relevant today as they were 60 years ago.

The subject matter in Green and Money's 1969 epistle and the early conferences echo the plenary topics at the recent Bangkok symposium.

The call for education is as much a crying need today as it was then and needs to be responded via medical education and human rights work.

As from the beginning, much needs to be done, and as interdisciplinary health-care providers partnered with others, we have much to do. The clarion call today is for training and education as we move from transgender beyond disorder to all facets of transgender health.

We could do worse than follow in the footsteps of our forebears.

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Randomized controlled trials are the ‘gold standard’ of research — but a difficult fit for trans care



By Theresa Gaffney[1] Sept. 15, 2023



Adobe

In order to provide gender-affirming care, clinicians must sometimes jump through unusual hoops.

In Australia, for example, the government won’t subsidize testosterone treatment for a trans man without a peculiar bureaucratic maneuver; a doctor must say the patient has a testicular disorder. The disorder: Trans men, being trans, are born without testes.

Clinician and researcher Brendan Nolan has advocated for a billing code that would allow government subsidization of testosterone directly for the purpose of gender-affirming care. “And we were told we needed a randomized controlled trial before they would even consider that,” he told STAT.

Politicians in the United States and other critics of gender-affirming care have similarly pushed for more highly-valued research like randomized controlled trials (RCTs) to justify the treatments. As the name suggests, these studies randomly assign participants to either a group that receives the treatment being tested or a control group that doesn’t, and they are considered the gold standard of medical research. But clinicians and researchers say it’s

time to rethink the insistence on RCTs, which they say are impractical and almost impossible to perform ethically when looking at the benefits of gender-affirming care like hormones and puberty blockers.

Nolan, a University of Melbourne researcher, actually devised a way to conduct what he describes as a "world-first" randomized trial of gender-affirming hormones. The results of the small study[3], published last week, showed that testosterone therapy had significant mental health benefits for trans masculine adults. But the difficulty of carrying out the research — Nolan readily acknowledges the study has limitations due to ethical and practical considerations — shows just how challenging these studies are.

"[I] have to commend the team for figuring out the one ethical way to conduct an RCT of gender-affirming care," Ayden Scheim, an assistant professor of epidemiology at Drexel University's Dornsife School of Public Health, wrote in an email to STAT. "Not that the naysayers won't just move the goalposts."

The people calling for RCTs in order to provide gender-affirming care "are simply not serious," he added. "Not serious in terms of their understanding of basic principles of epidemiology and public health research."

The practical and ethical limitations of RCTs

Efforts to limit or ban gender-affirming care often hinge on the argument that the existing evidence — made up mainly of observational studies — is insufficient. In U.S. federal court cases[4] where judges are considering bans on gender-affirming care for youth, controversial medical leaders with financial ties[5] to anti-trans institutions have called such care "experimental" and said they believe there's insufficient evidence to treat youth.

But there are countless medical treatments that haven't been tested with "high quality[6]" evidence like RCTs — for reasons such as difficulty enrolling patients, the cost or time it would take to perform such a study, or ethical considerations. In such cases, observational data can be good enough, when there are multiple studies involving many patients in many places that produce consistent results.

Surgeries — with a few exceptions — are usually developed without randomized trials, as it's clearly difficult to convince people in a control group that they've had a major surgery when they haven't.

While some psychotherapies, including cognitive behavioral therapy, have been tested in RCTs, it can be hard for researchers studying mental health treatments to meet the design requirements of RCTs for a range of reasons; in studies measuring the efficacy[8] of psychotherapies, for example, patients and therapists may already be familiar with different approaches, and are therefore less likely to be blind to the type of treatment being studied.

"There are many treatments that had already been in use for many decades before we decided as a field that RCTs are the gold standard, and we didn't decide that we were going to stop providing all the treatments until we conducted them all as RCTs," Scheim said.

When concerns do arise about widely used treatments in other areas of medicine, experts don't typically suggest withholding those treatments. For example, a small 2010 trial suggested that giving supplemental testosterone to cis men with low levels of the hormone could heighten the risk of heart attacks. A much larger follow-up study[9] this year allayed those concerns — but in the meantime, physicians had continued prescribing the medication as needed without legislative interference.

In a paper[10] published earlier this year in the International Journal of Transgender Health, researchers wrote that RCTs are "methodologically inappropriate" for research focused on the mental health benefits of gender-

affirming care for youth, noting many logistical barriers. Hormone treatments, for example, lead to visible physical changes, making it impossible to blindly sort patients into treatment and control groups. The impossibility of hiding who is and isn't receiving treatment could lead patients assigned to the control group to opt out of research for fear of not receiving hormones, as well as potentially bias any self-reported results.

Such concerns arose in a 2001 study[13] in which researchers attempted an RCT looking at the effects of puberty blockers and growth hormones in cisgender, adopted children who both experienced precocious puberty and were predicted to have a short final height. The team was forced to switch to an observational study because parents of children in the control group refused to participate, wanting to ensure their kids received treatment.

Many of the calls for more research[7] on gender-affirming care particularly focus on the importance of more evidence on puberty blockers. But the 2001 study "really underscores this unfair bias," said Diana Tordoff, an epidemiologist currently working on the national PRIDE Study at Stanford University School of Medicine and a co-author of the IJTH paper. "We don't expect cisgender youth to have to undergo this [an RCT]. … But it is being argued that this is expected for gender-affirming care."

Observational studies are the "bread and butter" of epidemiology, Tordoff said. She and co-author Florence Ashley, a bioethicist and law professor at the University of Alberta, believe that a system of overlapping observational studies can provide the needed rigorous evidence to prove the efficacy and safety of care like hormones and puberty blockers.

And there are already quite a number[14] of[15] observational[16] studies finding mental health benefits of gender-affirming care for both trans youth and adults. The existence of this evidence raises another important ethical concern for RCTs.

The principle of clinical equipoise holds that, when starting a trial, researchers must be uncertain about whether the control group or the treatment group is most likely to benefit. If they can make an assumption, there is an obligation to provide all patients with the best care. At this point, there is so much observational evidence on the benefits[18] of gender-affirming care that most researchers won't withhold treatment in order to have a control group, especially for longer-term studies.

These types of issues are common for researchers in any field considering RCTs. But critics tend to hold transgender health to higher standards than other, similar areas of medicine, experts say.

"Maybe the larger question is, would anything be enough?" said Zack Marshall, an associate professor of community health sciences at the University of Calgary's Cumming School of Medicine. "For certain audiences, governments, leaders, it doesn't matter what the research says. It's almost irrelevant."

In pursuit of bigger questions

Still, some researchers haven't given up on reaching the gold standard. Nolan and his team managed to run a small, short-term randomized trial comparing the effects of immediate testosterone therapy to waiting three months on gender dysphoria, depression, and suicidality. They believe it is the first randomized trial of gender-affirming care that included a control group that received no treatment.

Withholding treatment for three months was ethical because that's the average wait time for patients to be seen at their clinic, the researchers said.

Nolan said he sees the benefits of hormones “every single day” in his clinic, and launched the study because “there’s obviously a lot of very disappointing things that are being said and a lot of attacks that are actually not based on any evidence.”

The trial of 64 transgender and gender-diverse adults found decreased gender dysphoria, depression, and suicidality in the group treated with testosterone. Notably, half of suicidal patients in the treated group (11 people) reported these feelings resolved during the study compared with just one (5%) in the control group. The results were first presented[19] at the Endocrine Society meeting in June and were published this month in JAMA Network Open[3].

The trial had important shortcomings. It was not a blinded study, so participants knew whether they were receiving treatment or not. Nolan said it wouldn’t have been ethical to give somebody a placebo, though he recognizes this is a limitation to the study. Still, they found that setting a specific, short time period for withholding treatment helped to reduce the chances that participants in the control group would drop out of the study due to too long of a wait.

There are other issues that researchers would like to dedicate their time to, such as questions about personalizing gender-affirming care to fit the physical changes individual trans people want to see.

“There’s a lot of stuff that can be done, like comparative effectiveness studies and all sorts of RCT-based studies, around producing the exact physiological changes that people want,” said Ashley.

But for now, some researchers feel that they’re stuck playing defense as the basic value of gender-affirming care continues to be questioned.

“Those clinics in many states across the country are literally fighting for their survival because of these attacks,” Scheim said. “They’re not well positioned to be able to do research that would be really helpful, but isn’t as urgent as just keeping the doors open.”

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1/3 FREE STORIES

The UK is the latest country to ban puberty blockers for trans kids. Why is Europe restricting them?



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By Gabriela Galvin

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Several countries have restricted the use of puberty blockers, citing insufficient evidence on their benefits for gender-questioning youth and potential long-term effects.

The United Kingdom has banned puberty blockers for children and adolescents under age 18, making it the latest country in Western Europe to limit access to the treatment for transgender and gender-questioning youth.

The rule extends a temporary ban issued earlier this year on the sale and supply of puberty blockers, which delay the physical changes associated with puberty, such as the growth of breasts, testicles, and body hair, and a deeper voice.

Typically used for children with **precocious puberty** – when puberty starts around age 7 or younger for girls, and age 8 or younger for boys – puberty blockers can also be offered to children on the cusp of normal puberty, with the goal of giving young people time to consider their gender identity.

Later, adolescents may go on hormones like oestrogen or testosterone to develop in their chosen gender, or opt for more invasive procedures like surgeries when they are older.

The UK decision means gender-questioning adolescents will no longer be able to receive puberty blockers from their doctors. But the UK isn't the only country to roll back access in recent years.

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UK was named unhappiest country for children in 2024. Are youth in the rest of Europe any happier?

A handful of European countries – such as Sweden, Denmark, and France – have also moved to limit their use to research settings or in exceptional circumstances, amid intense medical debate over how to care for the growing number of children who identify with a gender other than their biological sex.

“We've shifted into a direction saying if we're going to stop normal puberty in certain young people, then we need to do it with our eyes open [and] collect the data very carefully,” Dr Ashley Grossman, emeritus professor of endocrinology at the University of Oxford, told Euronews Health.

“There may be some children who are going to improve, who feel this is absolutely the right thing to do, and others for whom it's inappropriate,” he said.

What has changed?

It’s an apparent reversal from the so-called “Dutch protocol,” which for years was hailed as the gold standard for medical care for transgender children.

In the 1990s, clinics in the Netherlands began offering puberty blockers and hormonal treatments to children and teenagers, who previously had to wait until adulthood to seek gender-affirming medical care.

In a long-term study **published in 2014**, Dutch researchers reported that access to these treatments had improved patients’ mental health and curbed their gender dysphoria, which is when someone experiences distress because their gender identity does not match their biological sex at birth.

EU countries clash with WHO over trans rights and access to healthcare

This care enabled them to “develop into well-functioning young adults,” researchers said.

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But in recent years, clinicians and researchers in the Netherlands and elsewhere have argued that those findings may not apply to today's gender-questioning youth, and that the early studies didn't track how the patients fared long enough into adulthood.

In 2015, for example, Finnish researchers found that patients who were biologically female at birth were **"markedly overrepresented"** at two clinics specialising in gender identity, differing from studies done elsewhere and meaning the Dutch patients may have had different backgrounds and needs than the Finnish patients.

Further, 62 per cent of the Finnish patients began questioning their gender identity around age 12 or later, and many experienced gender dysphoria alongside other psychological issues and "considerable challenges" in their development overall.

Today, the medical debate is being driven by the "increase in the numbers of people who are presenting [to gender clinics], the change in the type of people presenting, and social changes," as well as the "demand for some data and evidence" on puberty blockers, according to Dr Joe Brierley, a critical care doctor in the UK and head of ethics at the European Academy of Paediatrics.

"But it's kind of hard, because at the same time as wanting data, no one's funding research," Brierley told Euronews Health.

In 2020, the UK government commissioned Dr Hilary Cass, the former president of the Royal College of Paediatrics and Child Health, to assess the evidence on gender-affirming medical care for young people and provide recommendations.

Sweden's parliament makes it easier for young people to change gender

The landmark **Cass Review** was published earlier this year and concluded that the evidence on how puberty blockers affect children's gender dysphoria and mental health is weak, and that it's still unclear how the drugs affect their cognitive and psychosexual development in the long term.

How European countries approach puberty blockers

Countries like Denmark and Finland are now prioritising counselling and supportive services over medical interventions for young people with gender dysphoria.

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In Denmark, the number of referrals to the country's sole adolescent gender clinic more than tripled between 2016 and 2022 – from 97 to 352 – but patients have become less likely to be offered hormone treatments.

That share fell from 67 per cent in 2016 to 10 per cent in 2022, according to the Copenhagen area's health agency.

In Finland, hormonal treatments can be given to adolescents if it is clear that their identity as another gender is of a "permanent nature and causes severe dysphoria".

In 2022, the Swedish authorities said the risks likely outweigh the benefits of puberty blockers, but said that the treatment can be offered in "exceptional" cases to adolescents with gender dysphoria.

France takes a similar approach. The French medical academy says puberty blockers are available at any age with parental consent, but encourages "the greatest reserve" in their use given the potential long-term side effects, which may include osteoporosis or fertility issues.

Georgia passes Russian-style anti-LGBTQ+ law ahead of crucial election

Meanwhile, in Norway, puberty blockers are limited to clinical trials, and in Spain and the Netherlands, they are available through specialist care.

The debate over how to care for these children is also ongoing in Belgium and Italy.

Yet while a handful of countries have limited the use of puberty blockers while calling for more research on them, other parts of Europe are moving to restrict gender-affirming medical care overall as part of a broader pushback against LGBTQ rights.

In Georgia, for example, the parliament passed a ban on all trans-specific healthcare in a bid to preserve “family values” this year.

“Different countries in Europe are in massively different places here,” Brierley said.

Going forward

Grossman said the debate over puberty blockers and other medical care for gender-questioning youth should be less politicised and instead focus on scientific inquiry into how safe the drugs are, how well they work for kids with gender dysphoria, and any potential long-term effects.

“There's been a lot of people riding on one train or another saying this is clearly, absolutely essential for these children, [or] we should never use it at all,” Grossman said.

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“You've got to have the evidence”.

Nearly 40% of European workers are at higher risk of poor mental health, according to new survey

In the meantime, Brierley said medical care for gender-questioning children should be more holistic, with better collaboration between pediatricians, specialists, and mental health professionals.

That could be especially important for children and teenagers who have already started puberty blockers or other gender-affirming treatments in countries where access has been rolled back, he said.

“There’s a bit of a gap… This has now been restricted, but nothing's really been put in its place just yet,” Brierley said.

“The child has to be treated as a person, with all of their issues looked at and considered”.

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ORIGINAL ARTICLE

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Cross-sex hormone therapy in transgender persons affects total body weight, body fat and lean body mass: a meta-analysis

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Summary

Weight gain and body fat increase the risk of cardiometabolic disease. Cross-sex hormone therapy in transgender persons leads to changes in body weight and body composition, but it is unclear to what extent. We performed a meta-analysis to investigate the changes in body weight, body fat and lean body mass during cross-sex hormone therapy in transgender persons. We searched the PubMed database for eligible studies until November 2015. Ten studies reporting changes in body weight, body fat or lean mass in hormone naive transgender persons were included, examining 171 male-to-female and 354 female-to-male transgender people. Pooled effect estimates in the male-to-female group were +1.8 kg (95% CI: 0.2;3.4) for body weight, +3.0 kg (2.0;3.9) for body fat and −2.4 kg (−2.8; −2.1) for lean body mass. In the female-to-male group, body weight changed with +1.7 kg (0.7;2.7), body fat with −2.6 kg (−3.9; −1.4) and lean body mass with +3.9 kg (3.2;4.5). Cross-sex hormone therapy increases body weight in both sexes. In the male-to-female group, a gain in body fat and a decline in lean body mass are observed, while the opposite effects are seen in the female-to-male group. Possibly, these changes increase the risk of cardiometabolic disease in the male-to-female group.

KEYWORDS
body composition, body weight, cross-sex hormone therapy, sex steroids, transgender

1. | INTRODUCTION

Part of the gender affirming therapy of trans persons is treatment with cross-sex hormones which aims to induce the secondary sex characteristics of the desired sex. Male-to-female trans persons (MtFs) receive anti-androgens and oestrogen therapy to induce feminisation, and female-to-male trans persons (FtMs) receive androgen therapy to obtain masculinisation. Most studies performed on the safety of this therapy found lower or similar cardiovascular morbidity in FtMs compared to control women, while multiple studies in MtFs observed more cardiovascular morbidity in comparison with biological men (Asscheman et al., 2011; Gooren, Wierckx, & Giltay, 2014). Possibly lifestyle factors or ethinyl oestradiol use resulting in thrombogenic haemostatic alterations may have contributed to the increased incidence of cardiovascular disease observed in MtFs in these studies.

Another possible explanation is that changes in body weight and body composition during cross-sex hormone therapy (CSHT) play a role in this increased cardiovascular risk in MtFs in comparison with biological men. Current studies suggest that CSHT increases body weight in both MtFs and FtMs (Deutsch, Bhakri, & Kubicek, 2015; Mueller et al., 2011; Pelusi et al., 2014). Opposite effects for MtFs and FtMs are seen in body composition (Lee et al., 2013; Mueller et al., 2011; Pelusi et al., 2014; Uhernik, Erceg, & Milanovic, 2012). MtFs show an increase in body fat and a decrease in lean body mass, while a decrease in body fat and an increase in lean body mass are observed in FtMs (Deutsch et al., 2015; Giltay et al., 1998; Gooren et al., 2014; Pelusi et al., 2014; Van Caenegem et al., 2015). It is well established that weight gain and body fat are associated with unfavourable cardiovascular risk factors such as dyslipidaemia (Lee et al., 2013; Pelt, Evans, Schechtman, Ehsani, & Kohrt, 2002) and an increased risk

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of developing type 2 diabetes and hypertension (De Mutsert, Sun, Willett, Hu, & van Dam, 2014; Shimazu et al., 2009; Uhernik et al., 2012). Furthermore, obesity, weight gain and high body fat are associated with an increased overall risk of mortality (De Mutsert et al., 2014; Heitmann, Erikson, Ellsinger, Mikkelsen, & Larsson, 2000; Hu et al., 2004; Kuk et al., 2006; Shimazu et al., 2009). An increase in lean body mass on the other hand has been associated with lower mortality (Navaneethan, Kirwam, Arrigain, & Schold, 2014).

Studies examining the effects of hormone therapy in hypogonadal men and women found similar effects of oestrogen and testosterone therapy on body composition compared to CSHT. Additionally, those studies showed that type and duration of hormone treatment influence the magnitude of changes in body composition. In post-menopausal women, larger effects on body fat and lean body mass were seen in women using oral oestrogens in comparison with transdermal oestrogens (O'Sullivan, Crampton, Freund, & Ho, 2010). In elderly men, lean body mass increased more in the group using testosterone injections in comparison with oral administration forms and a larger increase was seen in the first six months of treatment in comparison with a longer follow-up period (Neto et al., 2015). Studies in trans persons examining the effects of CSHT on body weight and body composition used various treatment protocols. So far, the potential differential effects of these treatment protocols on body weight and body composition are unknown.

The aim of this study was to investigate the effects of CSHT on total body weight, body fat and lean body mass by performing a meta-analysis. Additionally, we evaluated the effects of different treatment types and varying duration of hormone treatment.

2. | METHODS

2.1 | Data sources and search method

A systematic search of the PubMed database was performed until 23rd of November 2015 using the following Mesh terms, entry terms and related key words:

(("Transgendered Persons"[Mesh] OR "Transsexualism"[Mesh]) OR (transgend*[tiab] OR transsex*[tiab] OR transex*[tiab] OR trans-gend*[tiab] OR trans-sex*[tiab])) AND (("Body Composition"[Mesh] OR "Body Mass Index"[Mesh] OR "Body Weight"[Mesh] OR "Adipose Tissue"[Mesh]) OR (body composition*[tiab] OR body weight*[tiab] OR adipose tissue*[tiab] OR fat tissue*[tiab] OR body fat[tiab] OR body mass[tiab] OR fat mass[tiab] OR lean mass[tiab] OR lean body mass[tiab] OR fat free mass[tiab] OR BMI[tiab])).

The search was performed in collaboration with a medical librarian.

2.2 | Study selection

All titles and abstracts were screened by MK to select them for further analysis. We included published prospective and retrospective studies in all languages that studied CSHT in transgender individuals and reported data on body weight and/or body composition. Studies describing patients with a history of cross-sex hormone use were excluded to rule out influence of earlier hormone treatment on body weight and body composition. We checked for duplicate studies based on overlapping authorship, study description and number of patients.

2.3 | Main outcome measures and data extraction

Main outcome measures were total body weight (kilograms [kg]), total body fat (kg) and total lean body mass (kg). Data extraction included numbers of MtFs and FtMs, study design, age, type of therapy and dosage, therapy duration and outcome measures. Means and standard deviations of pre- and post-measurements or absolute or relative change scores with associated *p*-values or confidence intervals were extracted. If studies published unclear results, authors were contacted to obtain the correct data. After examination of our own data (Klaver, Dekker, Megens, & den Heijer, 2015), which showed an equal change in both patients with low or high body weight, body fat and lean body mass, we chose to present the results expressed as absolute changes. Results on body fat are presented as relative changes as well.

2.4 | Statistical analysis

Treatment effects for body weight, body fat and lean body mass were calculated for each study by extraction or calculation of change scores and standard errors. Change scores were calculated as the difference in means between pre- and post-measurements. Standard errors, important to calculate the effect size, were never reported and had to be computed from other reported data such as the standard deviation of the change score or the *p*-value. A detailed description of these methods can be found in Appendix A. The analyses of pooled data to calculate the effect sizes were performed with a random-effects model and only included studies performed after 12 months of therapy.

2.5 | Publication bias and heterogeneity

To test for evidence of publication bias, we examined a Begg's funnel plot (Egger, Smith, Schneider, & Minder, 1997). In addition, we performed a Begg's rank correlation test (Begg & Mazumdar, 1994) and the Egger's test (Egger et al., 1997). Heterogeneity was assessed for each outcome in MtFs and FtMs. The Cochran's Q statistic, associated *p*-value and I^2 were provided by RevMan 5.3, where I^2 represents the percentage of the variability in effect estimates that is due to heterogeneity rather than change.

2.6 | Meta-regression

A random-effects meta-regression was performed in Stata version 13.1 (StataCorp LP) to assess the associations between type and duration of treatment and changes in body weight, body fat and lean body mass. Duration of treatment was classified as ≤6, 12 or 24 months of treatment. In MtFs, four types of treatment were examined: cyproterone acetate either in combination with 17ß-oestradiol valerate (orally), a 17ß-oestradiol patch or ethinyl oestradiol (orally) and goserelin

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acetate (gonadotropin-releasing hormone analogue (GnRH)) in combination with 17β-oestradiol valerate (intramuscularly). In FtMs, the following types of treatment were analysed: Nebido®, Sustanon®, Testoviron® and Androgel®. In the analyses on type of treatment, only studies with a 12-month follow-up were included. If studies described a group of patients using different types of medication, but did not provide any insight in possible differences between the therapy groups in the result section, they were excluded from meta-regression analysis on type of treatment. Data are expressed as changes in kilograms against the reference group.

2.7 | Sensitivity analysis

We conducted sensitivity analyses to assess the impact of individual studies on the overall estimate of outcome measures. In these analyses, summary estimates were repeatedly computed, omitting a single study in each cycle, to evaluate its effect on the summary estimate. Another sensitivity analysis was performed to assess whether the use of imputed correlation coefficients, used to calculate the standard errors, influenced the overall result of the analysis.

This meta-analysis only contains published data, so no separate ethics committee approval was needed.

3. | RESULTS

3.1 | Selected studies

The initial PubMed search yielded 79 articles. All titles and abstracts were explored to determine whether the predefined data could be extracted, which resulted in 17 selected articles. Five studies were excluded because of the use of duplicate patients in articles with different topics (Elbers, Asscheman, Seidell, & Gooren, 1999; Elbers, Asscheman, Seidell, Megens, & Gooren, 1997a; Elbers et al., 1997b, 2003; Mueller, Kiesewetter, Binder, Beckmann, & Dittrich, 2007). One study was excluded (Quirós et al., 2015) because they described patients which had a history of cross-sex hormone use, and another study was excluded because they provided insufficient information (Haraldsen, Haug, Falch, Egeland, & Opjordsmoen, 2007). This resulted in ten studies of which seven studies examined the effects on main outcome measures after 12 months of therapy. In MtF, three studies were used in body weight and body fat analyses and two studies were included for lean body mass analyses. In FtMs, all analyses included five studies. The year of publication ranged from 1998 to 2015.

3.2 | Participant and treatment characteristics

A total of 171 MtFs and 354 FtMs participated in the included studies. Table 1 shows information on each included study. The mean age of the included patients was 32.8 ± 3.6 years for MtFs and 30.1 ± 4.2 years for FtMs.

Types of CSHT used by MtFs were cyproterone acetate or spironolactone in combination with 17β-oestradiol (valerate), a 17β-oestradiol patch or ethinyl oestradiol (Deutsch et al., 2015; Giltay et al., 1998; Wierckx et al., 2014). In one study, MtFs used goserelin acetate (GnRH analogue) in combination with 17β-oestradiol valerate (Mueller et al., 2011). FtMs used testosterone undecanoate (Nebido®) (Cupisti et al., 2010; Giltay, Toorians, Sarabdjitsingh, de Vries, & Gooren, 2004; Mueller et al., 2010; Pelusi et al., 2014; Van Caenegem et al., 2015; Wierckx et al., 2014), Sustanon® (Giltay et al., 1998, 2004), testosterone cypionate (Deutsch et al., 2015), Testoviron® (Berra et al., 2006; Pelusi et al., 2014), testosterone gel (Deutsch et al., 2015; Pelusi et al., 2014) or a testosterone patch (Deutsch et al., 2015). The dosages and administration routes used in each study are described in Table 1. Treatment duration varied from 3–4 to 24 months.

3.3 | Changes in body weight, body fat and lean body mass

Three studies in MtFs (N = 155) and five studies in FtMs (N = 211) were available for the analyses of effects of CSHT on total body weight. Most studies in MtFs showed an increase in total body weight, ranging from 0 to 3.7 kg. The pooled estimate of total body weight change was +1.8 kg (95% confidence interval [CI] 0.2;3.4). Studies in FtMs showed effects ranging from 0 to 3.5 kg, with a pooled estimate effect of +1.7 kg (95% CI 0.7;2.7) (Figs 1a and 2a).

The same three studies in MtFs (N = 155) and five studies in FtMs (N = 181) were included for the analyses of the effects of CSHT on total body fat. All studies in MtFs showed an increase in body fat ranging from 2.1 to 4.6 kg, with a pooled estimate effect of +3.0 kg (95% CI 2.0;3.9). This equals an increase in body fat of 25% (95% CI 12.7;39.9). In FtMs, studies showed changes in body fat ranging from a decrease of −0.2 kg to a decrease in body fat of −4.8 kg. The pooled estimate effect was −2.6 kg (95% CI −3.9; −1.4). This corresponds to a decrease in body fat of −10.5% (95% CI −1.1; −24.2) (Figs 1b and 2b).

Two studies in MtFs (N = 137) and five studies in FtMs (N = 181) were used for the analyses of the effects of CSHT on lean body mass. In MtFs, the effects on lean body mass ranged from −2.4 to −3.1 kg. The pooled estimate effect was −2.4 kg (95% CI −2.8; −2.1). Studies in FtMs showed increases in lean body mass ranging from 1.8 to 5.3 kg, with a pooled estimate effect of +3.9 kg (95% CI 3.2;4.5) (Figs 1c and 2c).

3.4 | Publication bias and heterogeneity

Examination of funnel plots showed considerable symmetry, suggesting there was no publication bias. Additional testing with a Begg's rank correlation and an Egger's test, respectively, showed no publication bias in MtFs for body weight (p = .45, p = .44), body fat (p = .81, p = .93) and lean body mass (p = .50, p = .73). Also in FtMs, no publication bias was found in body weight (p = .83, p = .95), body fat (p = .47, p = .76) and lean body mass (p = .84, p = .60), although this does not rule out any kind of bias.

Substantial heterogeneity was present in analyses in FtMs of body weight (X^2 = 54.3, p < .00001, I^2 = 89%), body fat (X^2 = 26.1, p = .0002, I^2 = 77%) and lean body mass (X^2 = 17.2, p = .009,

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TABLE 1 Data description of all studies included in this meta-analysis

Study	Population	Age (years)	Study design	Medication	Duration of treatment	Body composition measurement
Deutsch et al. (2015)	16 MtFs	29 ± 9.4	Prospective	Spironolactone 100 mg/day[a] + *N* = 14 E2 4 mg/day (SL) *N* = 1 E2 patch 100 mcg/day (TD) *N* = 1 E2 valerate 20 mg/2 weeks (IM)	6 months	–
	31 FtMs	29 ± 6.9		*N* = 28 Testosterone cypionate 50 mg/week (SC)[b] *N* = 2 Testosterone gel 1% 5 mg/day (TD) *N* = 1 Testosterone patch 4 mg/day (TD)		
Van Caenegem et al. (2015)	23 FtMs	27 ± 9	Prospective	TU 1000 mg/12 weeks (IM)*	12 months	DEXA
Wierckx et al. (2014)	53 MtFs	30.3 ± 4.0	Prospective	*N* = 40 CPA 50 mg/day + E2 valerate 4 mg/day (PO) *N* = 13 CPA 50 mg/day + E2 patch 100 mcg/24 h (TD)	12 months	DEXA
	53 FtMs	24.6 ± 2.8		TU 1000 mg/12 weeks (IM)*		
Pelusi et al. (2014)	45 FtMs	29.5 ± 1.1	Prospective	*N* = 15 Testoviron 100 mg/10 days (IM) *N* = 15 Testosterone gel 50 mg/day (TD) *N* = 15 TU 1000 mg/12 weeks (IM)*	54 weeks 30 weeks	DEXA
Mueller et al. (2011)	84 MtFs	36.3 ± 11.3	Prospective	Goserelin acetate 3.8 mg/4 weeks (SC) + E2 valerate 10 mg/10 days (IM)	12 months 24 months	DEXA
Mueller et al. (2010)	45 FtMs	30.4 ± 9.1	Prospective	TU 1000 mg/12 weeks (IM)	12 months 24 months	DEXA
Cupisti et al. (2010)	45 FtMs	29.9 ± 1.1	Prospective	TU 1000 mg/12 weeks (IM)	12 months	–
Berra et al. (2006)	16 FtMs	30.4 ± 5.4	Prospective	Testoviron 100 mg/10 days (IM)	6 months	BIA
Giltay et al. (2004)	81 FtMs	36.7 (21–61)	Retrospective	*N* = 61 Sustanon 250 mg/2 weeks (IM) *N* = 20 TU 240 mg/day (PO)	3–4 months	–
Giltay et al. (1998)	18 MtFs	27.0 (18–37)	Prospective	CPA 100 mg/day + Ethinyl oestradiol 100 mcg/day (PO)	12 months	BIA
	15 FtMs	23.0 (16–33)		Sustanon 250 mg/2 wkn (IM)		

E2, 17-ß oestradiol; CPA, cyproterone acetate; DEXA, dual-energy X-ray absorptiometry; BIA, bioimpedance analyser; TU, testosterone undecanoate (* with a single extra dose after 6 weeks of therapy); SL, sublingual, TD, transdermal; IM, intramuscular; PO, per os; Testoviron, testosterone enanthate; Sustanon, testosterone propionate 30 mg, -phenylpropionate 60 mg, -isocaproate 60 mg, -decanoate 100 mg.

[a]66% of the patients increased to 200 mg/day at 3 months.

[b]10 participants were increased to 70 mg/week after 3 months.

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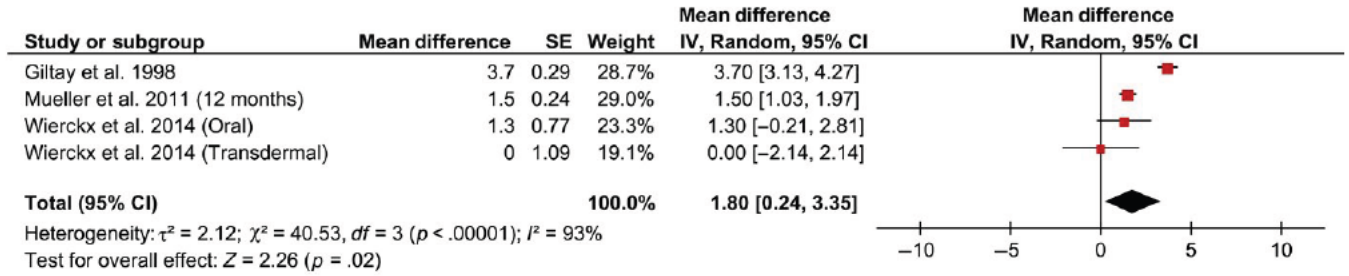
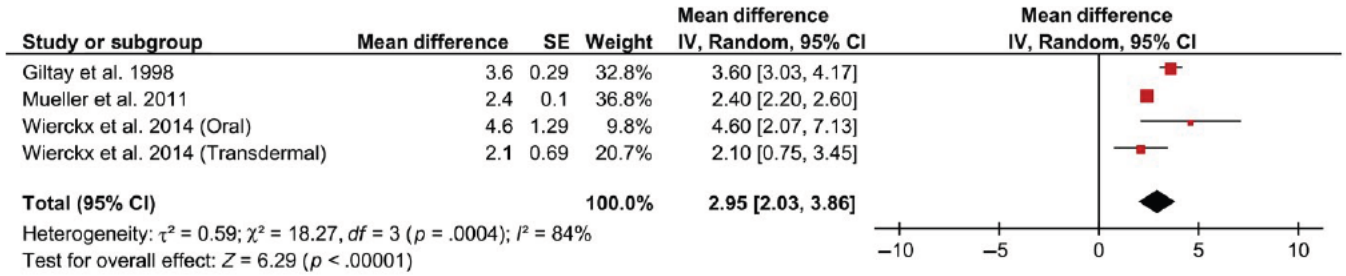
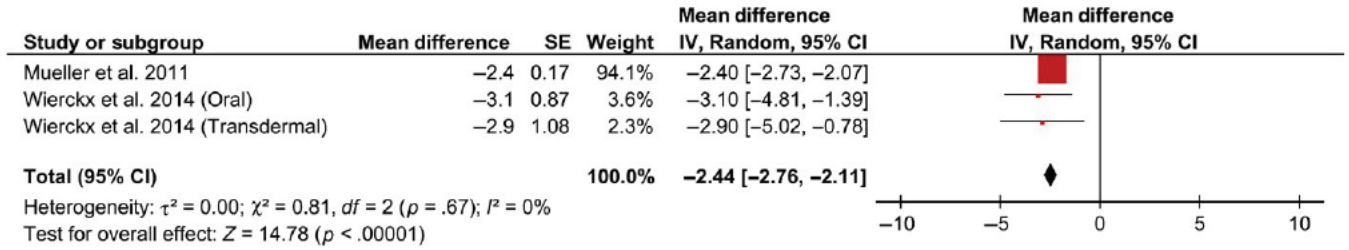


(a) Body weight (kg) in MtFs



(b) Body fat (kg) in MtFs



(c) Lean body mass (kg) in MtFs

FIGURE 1 Changes in total body weight, body fat and lean body mass in MtFs.

I^2 = 65%). In MtFs, heterogeneity was found in body weight analyses (X^2 = 40.5, p < .00001, I^2 = 93%) and analyses of body fat (X^2 = 18.3, p = .0004, I^2 = 84%) but not in lean body mass analyses (X^2 = 0.8, p = .67, I^2 = 0%).

3.5 | Meta-regression

3.5.1 | Duration of treatment

In MtFs and FtMs, respectively, one and four studies evaluated the effects on outcome measures at ≤6 months and single studies investigated the effects after 24 months of CSHT. In MtFs, although based on a single study, a trend was seen towards an increase in body weight (+1.2 kg, 95% CI −2.0;4.4) and body fat (+0.6 kg, 95% CI −0.8;2.2) in the second year of therapy, resulting in total increases of +3.0 kg (95% CI 2.4;3.6) in body weight and +3.6 kg (95% CI 3.4;3.8) in body fat after 2 years of therapy. Furthermore, a decrease in lean body mass (−1.8 kg, 95% CI −2.2; −1.3) in the second year of treatment was observed, resulting in a total decrease of −4.2 kg (95% CI −4.5; −3.9) after two years of treatment. In FtMs, in the first six months, a trend towards a large increase in body weight (+2.5 kg, 95% CI 1.0;4.0) and lean body mass (+6.0 kg, 95% CI 4.4;7.6) was seen, after which these changes from baseline tended to be smaller at 12 and 24 months of therapy (Table 2). Changes in individual studies are illustrated in Fig. 3.

3.5.2 | Type of treatment

In FtMs, increases in body weight were 1.4 kg for the Androgel® group, 1.2 kg for the Nebido® group and 3.5 kg for persons using Testoviron® with a difference between the last two groups of 2.3 kg (95% CI 0.4;4.1) (Table 2). Body fat decreased more in FtMs using Nebido® (−3.6 kg) in comparison with persons using Testoviron® (−0.7 kg) (difference of 2.9 kg, 95% CI 1.2;4.5) or Androgel® (−1.5 kg) (difference of 2.1 kg, 95% CI 0.8;3.4) (Table 2). FtMs using Sustanon® lost the most body fat (−4.8 kg), logically resulting in even larger differences with the Testoviron® group (difference of 4.1 kg, 95%

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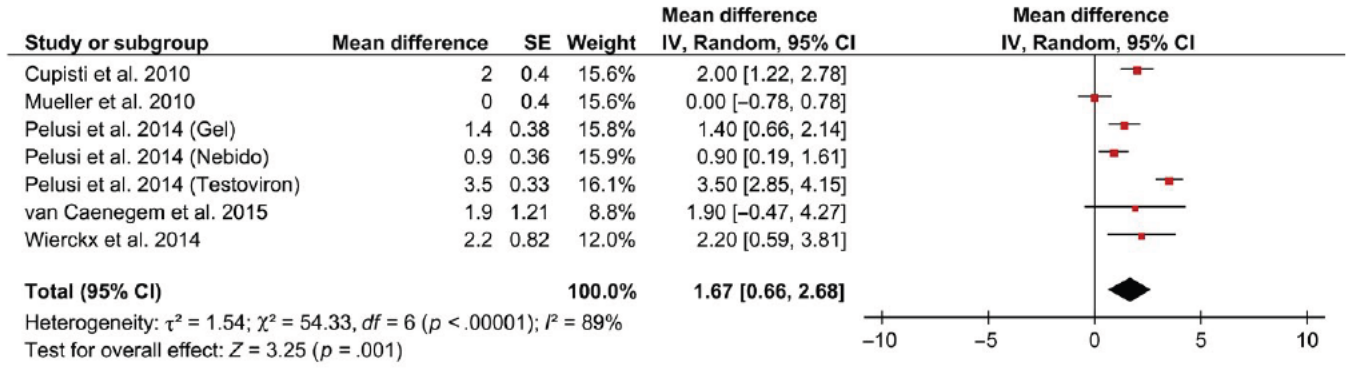
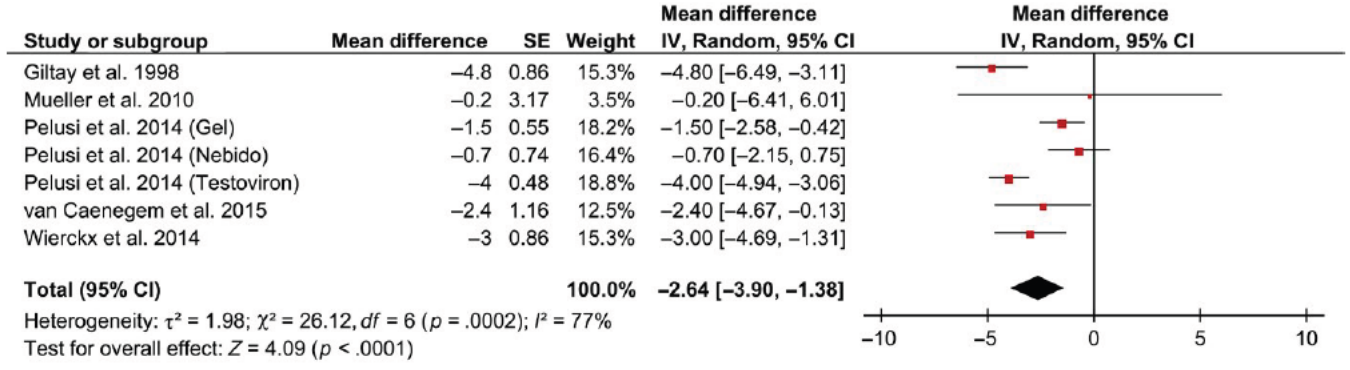
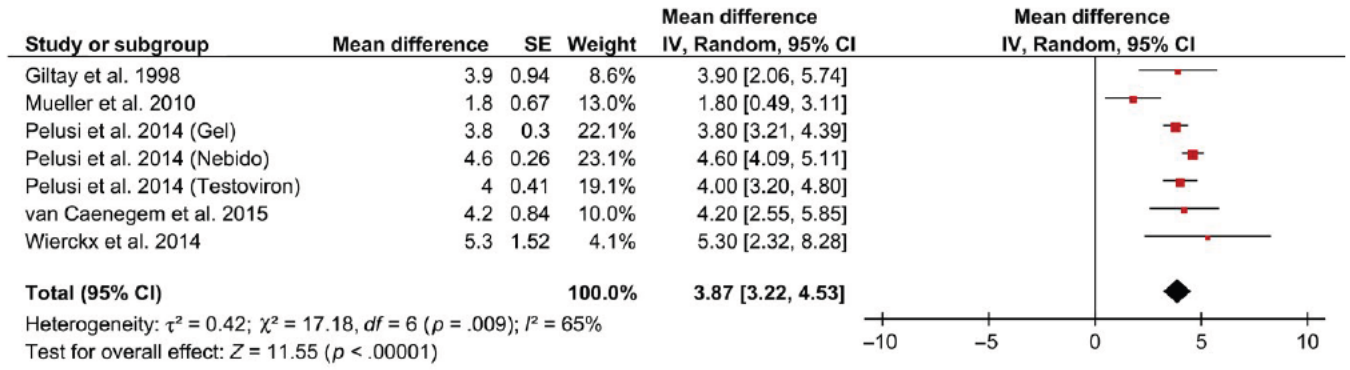


(a) Body weight (kg) in FtMs



(b) Body fat (kg) in FtMs



(c) Lean body mass (kg) in FtMs

FIGURE 2 Changes in total body weight, body fat and lean body mass in FtMs.

CI 1.9;6.3) and the Androgel® group (difference of 3.3 kg, 95% CI 1.3;5.3). MtFs using cyproterone acetate (CPA) and ethinyl oestradiol tended to gain more body weight (+3.7 kg) than persons using CPA and oestradiol valerate (orally) (+1.3 kg) (difference of 2.4 kg, 95% CI 0.0;4.8) (Table 2) and MtFs using CPA in combination with oestradiol patches (+0 kg) (difference of 3.7 kg, 95% CI 1.7;5.7).

3.5.3 | Sensitivity analyses

Multiple sensitivity analyses were performed including omitting studies one by one, which did not change our overall effect estimates of body weight, body fat and lean body mass remarkably. Another performed analysis showed that the use of varying imputed correlation coefficients seemed to have limited impact on the calculated standard errors.

4. | DISCUSSION

4.1 | Main findings

This meta-analysis confirms that CSHT increases total body weight in both MtFs and FtMs. In addition, we showed that MtFs experience a

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TABLE 2 Changes in body weight, body fat and lean body mass, subdivided into categories of varying type and duration of treatment

	Body weight			Body fat			Lean body mass		
	Δ from baseline + confidence interval	Δ with reference + confidence interval	*N*	Δ from baseline + confidence interval	Δ with reference + confidence interval	*N*	Δ from baseline + confidence interval	Δ with reference + confidence interval	*N*
MtF									
Duration (months)									
≤6	−0.6 kg (−2.8;1.6, *p* = .59)	−2.4 kg (−6.2;1.4, *p* = .22)	*N* = 1	–	–	–	–	–	–
12 (ref)	+1.8 kg (0.2;3.4, *p* = .02)	–	*N* = 3	+3.0 kg (2.0;3.9, *p* = .00)	–	*N* = 3	−2.4 kg (−2.8; −2.1, *p* = .00)	–	*N* = 3
24	+3.0 kg (2.4;3.6, *p* = .00)	+1.2 kg (−2.0;4.4, *p* = .47)	*N* = 1	+3.6 kg (3.4;3.8, *p* = .00)	+0.6 kg (−0.8;2.2, *p* = .37)	*N* = 1	−4.2 kg (−4.5; −3.9, *p* = .00)	−1.8 kg (−2.2; −1.3, *p* = .00)	*N* = 1
Type of treatment									
CPA+EV (ref)	+1.3 kg (−0.2;2.8, *p* = .09)	–	*N* = 1	+4.6 kg (2.1;7.1, *p* = .00)	–	*N* = 1	−3.1 kg (−4.8; −1.4, *p* = .00)	–	*N* = 1
CPA+EE	+3.7 kg (3.1;4.3, *p* = .00)	+2.4 kg (0.0;4.8, *p* = .05)	*N* = 1	+3.6 kg (3.0;4.2, *p* = .00)	−1.0 kg (−4.9;2.9, *p* = .62)	*N* = 1	–	–	–
CPA+ EP	0 kg (−2.1;2.1, *p* = 1.0)	−1.3 kg (−4.3;1.7, *p* = .40)	*N* = 1	+2.1 kg (0.8;3.4, *p* = .00)	−2.5 kg (−7.1;2.1, *p* = .28)	*N* = 1	−2.9 kg (−5.0; −0.8, *p* = .00)	+0.2 kg (−3.1;3.5, *p* = .90)	*N* = 1
GnRH+EV	+1.5 kg (1.0;2.0, *p* = .00)	+0.2 kg (−1.1;2.5, *p* = .90)	*N* = 1	+2.4 kg (2.2;2.6, *p* = .00)	−2.2 kg (−0.4; −4.0, *p* = .02)	*N* = 1	−2.4 kg (−2.7; −2.1, *p* = .00)	+0.7 kg (−0.6;2.0, *p* = .29)	*N* = 1
FtM									
Duration (months)									
≤6	+2.5 kg (1.0;4.0, *p* = .00)	+0.8 kg (−0.8;2.3, *p* = .32)	*N* = 4	−2.3 kg (−5.1;0.5, *p* = .11)	+0.3 kg (−3.8;4.5, *p* = .87	*N* = 1	+6.0 kg (4.5;7.5, *p* = .00)	+2.1 kg (−0.1;4.3, *p* = .06)	*N* = 1
12 (ref)	+1.7 kg (0.7;2.7, *p* = .00)	–	*N* = 6	−2.6 kg (−3.9; −1.4, *p* = .00)	–	*N* = 5	+3.9 kg (3.2;4.5, *p* = .00)	–	*N* = 5
24	+0.3 kg (−0.6;1.2, *p* = .52)	−1.4 kg (−4.1;1.4, *p* = .33)	*N* = 1	−0.3 kg (−3.6;3.0, *p* = .86)	+2.3 kg (−2.2;6.8, *p* = .31)	*N* = 1	+1.9 kg (0.5;3.3, *p* = .00)	−2.0 kg (−4.1;0.2, *p* = .07)	*N* = 1
Type of treatment									
Nebido (ref)	+1.2 kg (0.4;2.1, *p* = .00)	–	*N* = 5	−3.6 kg (−4.3; −2.8, *p* = .00)	–	*N* = 4	+3.8 kg (2.4;5.3, *p* = .00)	–	*N* = 4
Sustanon	–	–	–	−4.8 kg (−6.5; −3.1, *p* = .00)	−1.2 kg (−3.1;0.6, *p* = .19)	*N* = 1	+3.9 kg (2.0;5.8, *p* = .00)	+0.1 kg (−3.3;3.4, *p* = .97)	*N* = 1
Testoviron	+3.5 kg (2.8;4.2, *p* = .00)	+2.3 kg (0.4;4.1, *p* = .02)	*N* = 1	−0.7 kg (−2.1;0.7, *p* = .34)	+2.9 kg (1.2;4.5, *p* = .00)	*N* = 1	+4.0 kg (3.2;4.8, *p* = .00)	+0.2 kg (−2.7;3.1, *p* = .91)	*N* = 1
Androgel	+1.4 kg (0.6;2.2, *p* = .00)	+0.2 kg (−1.7;2.0, *p* = .87)	*N* = 1	−1.5 kg (−2.5; −0.4, *p* = .00)	+2.1 kg (0.8;3.4, *p* = .00)	*N* = 1	+3.8 kg (3.2;4.4, *p* = .00)	0 kg (−2.9;2.8, *p* = .98)	*N* = 1

CPA, cyproterone acetate; EV, 17ß-oestradiol valerate; EE, ethinyl oestradiol; EP, 17ß-oestradiol patch; GnRH, goserelin acetate; Sustanon, testosterone propionate 30 mg, -phenylpropionate 60 mg, -isocaproate 60 mg, -decanoate 100 mg; Testoviron, testosterone enanthate; Nebido, testosterone undecanoate; *N*, number of included studies.
Data are expressed as changes in kg with (95% confidence intervals and *p*-values).

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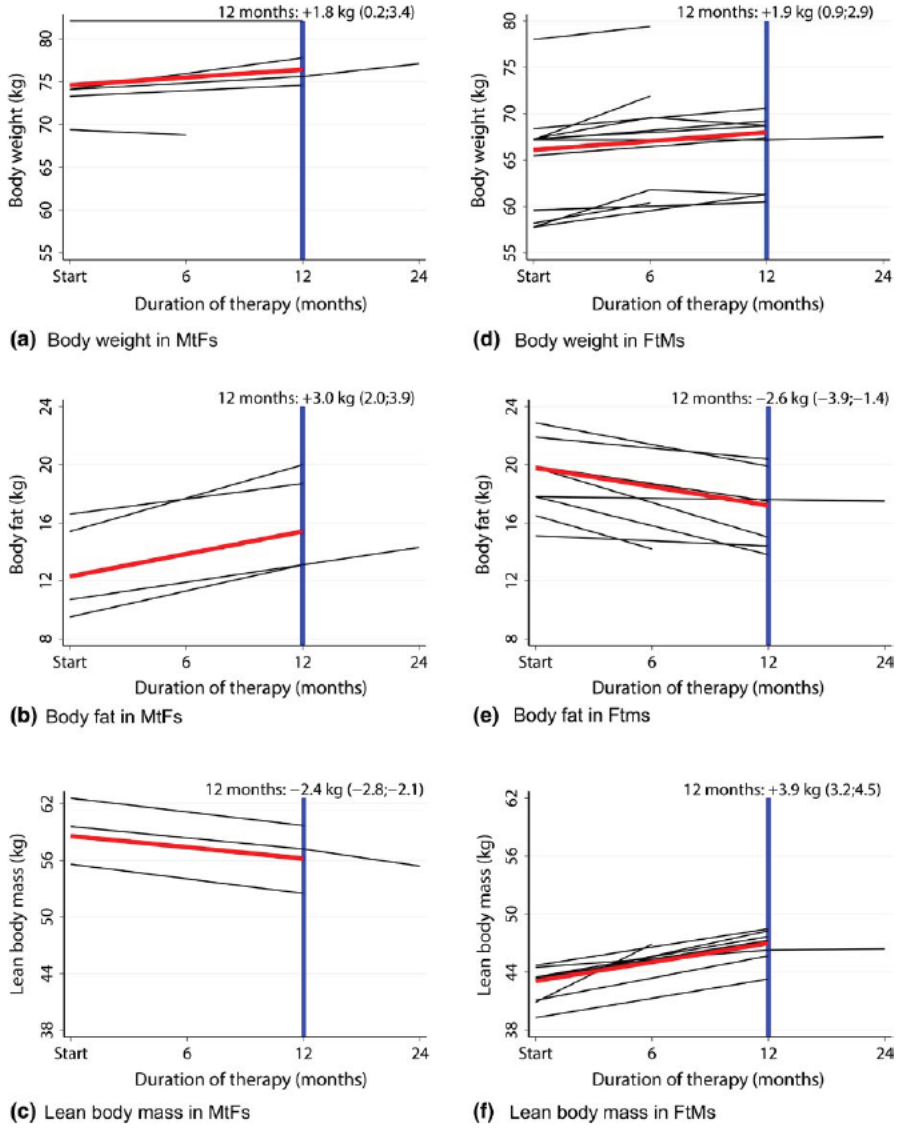

FIGURE 3 Changes in individual studies in body weight, body fat and lean body mass in MtFs and FtMs.

gain in body fat with a decrease in lean body mass, while the opposite was observed in FtMs. In MtFs, but not in FtMs, a trend of continuing effects regarding all outcomes was seen in the second year of therapy. Furthermore, we found a larger increase in body weight in FtMs using Testoviron® in comparison with patients using Nebido®. Probably, this is due to the observed smaller decrease in body fat in patients using Testoviron® in comparison with the Nebido® group as no differences in effects on lean body mass between both patient groups were seen. However, as only few studies were included for each type of treatment category, we should be cautious to draw firm conclusions.

4.2 | Strengths and limitations

This meta-analysis is the first to systematically aggregate data of the effects of CSHT on body weight and body composition. It provides clinicians with an overview of the magnitude of these effects, so clinicians are better able to estimate the consequences of CSHT on body composition and better inform their patients. A limitation of our meta-analysis is that all included studies have an observational design and did not include control groups. Therefore, it is difficult to assess whether the observed effects are due to the CSHT or to other factors such as the normal ageing process. However, the increase in body weight in MtFs and FtMs in the first year of therapy is higher than the mean yearly change in body weight in the general Dutch population (0.67 kg for men and 0.61 kg for women of 20–29 years of age) (Nooyens et al., 2009), thereby suggesting a causal effect of the CSHT.

Another limitation of our study is that we cannot fully explain the discrepancy between the estimated effects in body fat and lean body mass and the net increase in body weight in MtFs. In MtFs, we found an increase in body fat of 3.0 kg with simultaneously a 2.4 kg decrease in lean body mass, which should result in an increase in body weight of 0.6 kg. However, we found an increase of 1.8 kg. If we only select the two studies reporting all three outcome measures (Mueller et al., 2011; Wierckx et al., 2014), we find a lower weight change of 1.4 kg and a lower increase in body fat of 2.5 kg. This leaves a weight gain of 1.3 kg unexplained. These discrepancies are found in both original studies as well. In FtMs, we do not find this unexplained difference if we only select studies reporting all three outcome measures. Probably,

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the use of different measuring instruments as the weighing scale and the dual-energy X-ray absorptiometry (DEXA) or rounding to the nearest (half-)kilogram may explain these differences.

4.3 | Mechanisms of action of sex steroid hormones

Sex steroids might have direct and indirect effects on body fat and lean body mass. Direct effects could be due to the binding of estrogens to estrogen receptors stimulating pre-adipocyte proliferation (Karastergiou, Smith, Greenberg, & Fried, 2012) and lipoprotein lipase (LPL) activity which promotes body fat storage (Lovejoy & Sainsbury, 2009). In contrast, the binding of testosterone to androgen receptors inhibits LPL activity and increases adipose tissue lipolysis (Geer & Shen, 2009). Furthermore, androgens stimulate an increase in muscle protein synthesis by inhibiting their differentiation into adipogenic cells and promoting their differentiating into cells of the myogenic lineage (Miller, 2009). Indirect effects are explained by the binding of oestradiol to estrogen receptors (ERα) in the hypothalamus, or elsewhere in the brain, which may represent a mechanism by which oestradiol regulates energy expenditure, leptin sensitivity, body weight, body fat distribution and possibly physical activity (Brown & Clegg, 2010; Lovejoy & Sainsbury, 2009). Also, oestrogen is believed to regulate food intake by decreasing appetite simulating neuropeptides, such as neuropeptide Y, ghrelin and melanin-concentrating hormone, and interacting with appetite suppressing neuropeptides such as insulin, serotonin, cholecystokinin and leptin (Brown & Clegg, 2010).

4.4 | Clinical implications

The increase in body weight and body fat in MtFs may have a negative impact on their cardiovascular risk profile and might partly explain the increased occurrence of cardiovascular disease. Although FtMs gain body weight, this is attributable to an increase in lean body mass which actually might have a positive influence on their cardiometabolic risk profile. Clinicians should inform their patients in an early stage about these potential negative effects of CSHT, so that patients can start with lifestyle interventions if necessary and optimise other risk factors such as smoking, blood pressure or cholesterol levels.

Our study may have implications for other patient groups as well. Comparing our results with previous studies, our study found that, as observed in post-menopausal women (O'Sullivan et al., 2010), therapy with oral oestrogens tended to increase body fat more than transdermal oestrogens. Similar to a study performed in elderly men (Neto et al., 2015), in FtMs, lean body mass tended to increase most in the first six months of therapy with a decline in lean body mass after that. This may imply that oestrogen or testosterone therapy acts similarly in biological men and women compared to MtFs and FtMs. Furthermore, our observations in MtFs resemble the changes in body composition as seen in ageing men (with low testosterone levels) or hypogonadal men with prostate cancer, in which lean body mass decreases and body weight and body fat increases with about the same amount as we observed in MtFs (Miller, 2009). This may indicate that changes in body composition in biological men or MtFs are mainly due to changes in testosterone levels.

4.5 | Future research

Large prospective studies with multiple treatment protocols and a longer follow-up are needed to examine the effects of CSHT on the long term and the differences between the several types of treatment. Because fat stored in the visceral area (in and around organs) may exert higher cardiometabolic risk than total fat mass, future studies should focus on visceral fat. Furthermore, there is a need for studies examining the underlying mechanisms influencing body weight and body composition during CSHT, such as the effects of CSHT on metabolic rate. Finally, prospective studies with a longer follow-up time are needed to investigate the consequences of these changes in body weight and body composition on the development of type 2 diabetes and cardiovascular disease in MtFs and FtMs.

5. | CONCLUSIONS

CSHT increases body weight in both MtFs and FtMs. In MtFs, a gain in body fat and a decline in lean body mass are observed, while the opposite effects are seen in FtMs. Possibly, these changes in MtFs increase their risk of cardiometabolic disease. As a small number of studies were included, no firm conclusions can be drawn on the effects of different treatment types and varying duration of hormone treatment.

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APPENDIX A

Description of the extraction or calculation of the change scores and standard errors

Change scores and standard errors for body weight, body fat and lean body mass were derived from the papers to obtain pooled effect estimates. In case when changes scores were presented as an effect estimate with an 95% confidence interval, the standard error could easily be calculated from the formula of the confidence interval (±1.96*SE).

One study (Mueller et al., 2010) presented the standard deviation of the change score, so the standard error could be easily determined. Some studies (Giltay et al., 1998, 2004; Mueller et al., 2010; Wierckx et al., 2014) presented an *p*-value derived from a test using a t-distribution, so the standard error could be calculated through the t-statistic. For upper boundary *p*-values, for example $p < .05$, we used the upper bound to calculate the standard error.

However, most studies presented their results as pre- and post-measurements showing the mean and standard deviation of the pre- and post-measurement without mentioning a *p*-value or confidence interval. In those cases, the standard error (SE) could be determined using this formula:

$$SE = \sqrt{\left(\frac{S1^2}{n1} + \frac{S2^2}{n2}\right) - 2(r12)\left(\frac{S1}{\sqrt{n1}}\right)\left(\frac{S2}{\sqrt{n2}}\right)}$$

where, $n1$ = number of persons in the pre-measurement, $n2$ = number of persons in the post-measurement, $r12$ = correlation coefficient, $S1$ = standard deviation in the pre-measurement, $S2$ = standard deviation in the post-measurement.

To use this formula, the assumption was made that the correlation coefficient (r12) between the pre- and post-measurement was similar across studies, as recommended by Follmann et al. (Follman, Elliott, Suh, & Cutler, 1992) and previously used in published meta-analysis (Peterson, Sen, & Gordon, 2012). A weighted mean correlation coefficient was derived for each outcome measure in MtFs and FtMs from studies performed after 12 months of therapy. As no correlations were described, these were calculated for each study reporting (or providing enough data to exactly calculate) the standard deviations of the pre-measurement, the post-measurement and the change score of each outcome measure after a treatment duration of 12 months. In MtFs, a correlation coefficient was used of $r = .96$ for body weight (Wierckx et al., 2014), $r = .89$ for body fat (Wierckx et al., 2014) and $r = .91$ for lean body mass (Wierckx et al., 2014). In FtMs, a correlation coefficient was used of $r = .93$ for body weight (Wierckx et al., 2014), $r = .77$ for body fat (Mueller et al., 2010) and $r = .81$ for lean body mass (Mueller et al., 2010). Aforementioned formula was also used to calculate the standard error in studies presenting *p*-values derived from nonparametric tests.

Some studies presented data on body mass index (BMI), for which change scores and standard deviations for body weight were extracted. A weighted average of total body weight and its standard deviation at baseline were extracted from all studies reporting data on body weight, resulting in 74.1 ± 4.2 kg for MtFs (Deutsch et al., 2015; Wierckx et al., 2014) and 67.2 ± 7.1 kg for FtMs (Berra et al., 2006; Deutsch et al., 2015; Pelusi et al., 2014; Wierckx et al., 2014). In each study reporting data on BMI, the ratio of BMI scores and standard deviations (BMI-post/BMI-pre) was multiplied by the above-mentioned weighted average and standard deviation, to calculate the change score with standard deviation for body weight.

If medians and interquartile ranges were presented (Deutsch et al., 2015), a normal distribution was assumed and a mean and standard deviation were derived. If no standard deviation of the post-measurement was reported (Giltay et al., 1998), the given standard deviation of the pre-measurement was imputed.

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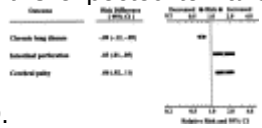
Body

FULL TEXT

The **patient** is a 900-g, 27-week gestational age baby boy. He was intubated **in** the delivery room and placed on mechanical ventilation. He received surfactant at 1 hour of age. Clinical and radiographic signs are consistent with moderately severe respiratory distress syndrome (RDS). Now, at 4 hours of age, he requires a fraction of inspired oxygen of 0.50 and a mean airway pressure of 8 cm H_2O to maintain a Pao_2 of 60 mm Hg. There is concern about the **risk** of chronic lung disease (CLD) **in** this baby and the clinician is considering using a short course of systemic corticosteroids **in** moderate dose to reduce this **risk**. The clinician wants to know if there is strong evidence that early postnatal corticosteroids are beneficial **in** reducing the **risk** of CLD **in** this clinical situation.

The clinician searches MEDLINE for a relevant Cochrane systematic review, using the search strategy **in** Box 1, and finds a reference to a recent review by Halliday et al [1]. The abstract shows that this review included 21 randomized controlled trials enrolling a total of 3072 participants. The clinician obtains the full text of the review **in** The Cochrane Library, and notes (among other effects) the results displayed **in** Fig. 1. These show that early postnatal corticosteroids do indeed reduce the incidence of CLD at 36 weeks' postmenstrual age: typical relative **risk** (RR) 0.69 (95% confidence interval [CI] 0.60 to 0.80). This effect, a 31% RR reduction, is not only statistically significant (the CI does not cross one) but seems to be clinically important. The size of effect **in** absolute terms is given by the **risk** difference (RD): typical RD −9% (95% CI −5% to −12%). Inverting this, the clinician calculates that the number needed to **treat** (NNT) is 1/0.09 = 11 (95% CI 8 to 20). That is, it is expected to have to **treat** 11



patients with early postnatal corticosteroids to prevent one from developing CLD.

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[1] [1]. H.L Halliday, R.A Ehrenkranz, L.W Doyle; Early postnatal (< 96 hours) corticosteroids for preventing chronic lung disease **in** preterm infants (Cochrane Review); The Cochrane Library, Issue 1; Update Software, Oxford (2003), .

Fig. 1. Effects on selected outcomes of early postnatal corticosteroids **in** preterm babies at **risk** of CLD, based on a systematic review of all randomized trials. (*From* Halliday HL, Ehrenkranz RA, Doyle LW. Early postnatal (< 96 hours) corticosteroids for preventing chronic lung disease **in** preterm infants (Cochrane Review). **In**: The Cochrane Library, Issue 1. Oxford: Update Software; 2003; with permission.)

The clinician notices something else. Early postnatal corticosteroids cause several short-term adverse effects, the most important being an increase **in** the incidence of intestinal perforation: typical RR 1.68 (95% CI 1.16 to 2.44); typical RD 3% (95% CI 1% to 5%). For every 33 **patients** **treated**, one expects to cause intestinal perforation **in** one **patient** (number needed to harm = 33 [95% CI 20 to 100]). Moreover, several long-term outcomes are adversely affected, including cerebral palsy: typical RR 1.69 (95% CI 1.20 to 2.38); typical RD 6% (95% CI 2% to 11%); number needed to harm 17 (95% CI 9 to 50). Statistically significant and clinically important treatment effects are occurring **in** both directions: **benefit** and harm.

Figs. 2 and 3 summarize the evidence concerning treatment effects for two other clinical strategies. First, should one use high-frequency oscillatory ventilation (HFOV) rather than conventional mechanical ventilation as the primary ventilatory strategy to reduce the **risk** of CLD **in** babies with respiratory failure requiring mechanical ventilation? Here, the evidence supports a reduction **in** CLD at 36 weeks or discharge using HFOV: typical RR 0.86 (95% CI 0.77 to 0.96); typical RD −6% (95% CI −2% to −10%). There is a trend, although not statistically significant, toward an increase **in** severe intraventricular hemorrhage (IVH) (grades 3 or 4) from HFOV: typical RR 1.11 (95% CI 0.94 to 1.32); typical RD 2% (95% CI −1% to 4%). Second, should one use supplemental vitamin A to reduce the **risk** of CLD **in** very low birth weight babies? The evidence supports an effect of supplemental vitamin A **in** reducing the incidence of CLD at 36 weeks post-menstrual age (PMA): typical RR 0.87 (95% CI 0.77 to 0.99); typical RD −7% (95% CI −1% to −14%). The discomfort to the baby of the intramuscular injections of vitamin A and the acceptability of the intervention to nurses and parents were not reported, however, and the clinician believes these factors bear on the decision as to whether to use this treatment.



Fig. 2. Effects on selected outcomes of elective high-frequency oscillatory ventilation (HFOV) versus conventional mechanical ventilation (CV) for acute pulmonary dysfunction **in** preterm infants, based on a systematic review of all randomized trials. (*From* Henderson-Smart DJ, Bhuta T, Cools F, Offringa M. Elective high frequency oscillatory ventilation versus conventional ventilation for acute pulmonary dysfunction **in** preterm infants (Cochrane Review). **In**: The Cochrane Library, Issue 4. Oxford: Update Software; 2003; with permission.)

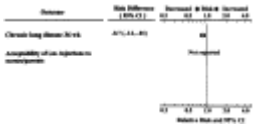

Fig. 3. Effects on selected outcomes of supplemental vitamin A **in** very low birth weight infants, based on a systematic review of all randomized trials. (*From* Darlow BA, Graham PJ. Vitamin A supplementation for preventing morbidity and mortality **in** very low birthweight infants (Cochrane Review). **In**: The Cochrane Library, Issue 1. Oxford: Update Software; 2003; with permission.)

What do these clinical scenarios have **in** common? **In** each case, there is strong evidence of an important treatment **benefit** on the primary outcome. But **in** each case, there is also a concern about one or more adverse treatment effects, either negative effects on medically defined health outcomes, or concern about the acceptability of the intervention itself.

Many if not most medical treatments have the capacity to cause both **benefits** and harms. A number of questions must be addressed **in** deciding whether to use a particular therapy. What are the major **benefits** and major **risks**? Overall, how likely are the **benefits** and the **risks**? How important are the **benefits** and the **risks**? Do the answers to these questions apply equally to all **patients** being considered for treatment? If not, how can one judge the likely **benefits** and **risks** for specific **patient** subgroups, or even the **individual patient**, to arrive at a treatment recommendation that is likely to maximize **benefit** and minimize harm for that subgroup or **individual**?

This article presents a systematic approach to particularizing or individualizing evidence-based treatment recommendations so as to optimize the **benefit**-**risk** ratio for specific subgroups or **individuals**.

Measures of treatment effect

Clinical outcomes **in** therapeutic studies are defined either **in** categorical terms (eg, death, CLD) or on a continuous scale (eg, weight gain **in** grams per day). For categorical outcomes, the proportions of **patients** **in** the **treated** and control groups who develop the outcome are reported. For outcomes measured on a continuous scale, the mean and standard deviation (or some other measure of central tendency and variance) for the **treated** and control groups are reported. Clinical outcomes that are of undoubted clinical importance are typically defined categorically. This article focuses on individualizing treatment recommendations with respect to categorical outcomes primarily, although the underlying concepts are applicable to outcomes measured on a continuous scale.

Table 1 shows the structure of a typical study that seeks to measure the effect of a treatment. There are two exposure groups (labeled as **treated** and control) and two outcome categories (labeled as event and no event). An event is a categorical outcome, conventionally defined as the negative outcome (eg, death, CLD, treatment side effect). The effect of treatment is given by comparing the event rate **in** the **treated** and control groups, expressed **in** relative or absolute terms. The RR indicates the event rate **in** the **treated** group relative to that **in** the control group. The complement of the RR (1-RR) is the relative **risk** reduction (RRR). A RR of 0.75 represents a 25% RRR. The RD indicates the absolute difference **in** event rate. The RD expresses, from the **patient**'s perspective, the probability of experiencing the **benefit** of treatment. For example, if there is an absolute **risk** reduction of 5%, the **patient**'s probability of experiencing the **benefit** of treatment is 5%. The reciprocal of the RD (1/RD) indicates the number of **patients** who must be **treated** (NNT) to prevent one **patient** developing the event. For example, if the RD is 5%, NNT is 1/.05 = 20. NNT reflects the health care provider's perspective: he or she must **treat** 20 **patients** to **benefit** one **patient**. The NNT is a particularly relevant measure for health care professionals when they must decide whether to use a treatment that is effective with respect to the primary outcome, but causes one or more important clinical side effects.

Stability of measures of treatment effect

Among **patients** who enter a clinical trial, the average **risk** of developing the event of interest, **in** the absence of the experimental treatment being tested, is shown by the control event rate (CER). But not all **patients** who enter clinical trials are at the same or similar **risk** of developing the event of interest. For example, the **risk** of death, CLD, or adverse neurodevelopment is higher among extremely preterm babies than those of more advanced gestational age. Given this variation **in** **risk** at trial entry (baseline **risk**), the question arises: are the overall estimates of treatment effect found **in** a clinical trial applicable to subgroups of **patients** at higher or lower baseline **risk**?

This question can be addressed by looking at the stability of measures of treatment effect within **individual** trials, comparing the effect **in** groups characterized at trial entry (eg, on the basis of gestational age, oxygen requirement, and so forth) as being at higher or lower baseline **risk**. It can also be addressed **in** systematic reviews of sets of trials, comparing the treatment effect observed **in** trials that enrolled populations at higher or lower **risk**. When such comparisons have been made **in** studies that show a **benefit** of the experimental treatment, it has been observed that RR is generally more stable across the range of baseline **risk** than is RD [45]. An important corollary of this observation is that if RR and RRR are reasonably stable across the range of baseline **risk**, absolute **risk** reduction must vary, being systematically higher **in** high-**risk** subgroups and lower **in** those at low baseline **risk**. Under the assumption of a constant RRR, NNT varies inversely with the product of the CER and RRR: NNT = 1/(CER · RRR). NNT is lower **in** **patients** at high baseline **risk** and higher as baseline **risk** falls.

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[4] [4]. C.H Schmid, J Lau, M.W McIntosh, J.C Capelleri; An empirical study of the effect of the control event rate as a predictor of treatment efficacy **in** meta-analysis of clinical trials; Stat Med; Vol. 17, (1998), pp. 1923-1942.

[5] [5]. J.J Deeks, D.G Altman; Effect measures for meta-analysis of trials with binary outcomes; M Egger, G Davey Smith, D.G Altman Editors; Systematic reviews **in** health care; BMJ Books, London (2001), pp. 313-335.

An example of this phenomenon is shown **in** Fig. 4. A systematic review of randomized trials of antenatal corticosteroid for the prevention of RDS **in** babies of mothers with threatened preterm delivery showed that this therapy was effective **in** reducing the incidence of RDS, with a RRR of 41% [6]. **In** this meta-analysis, RRR was fairly constant across subgroups formed on gestational age categories. The absolute **risk** reduction varied markedly, being high at short gestation but much lower at higher gestation. Fig. 4 shows NNT as a function of baseline **risk**, where NNT is calculated as 1/CER · RRR. As gestational age increases, baseline **risk** for RDS decreases, and NNT to prevent one case of RDS increases.

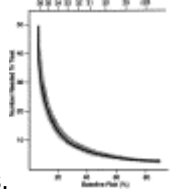

Fig. 4. Number of fetuses that need to be **treated** (NNT) with single-course antenatal corticosteroids to prevent one case of respiratory distress syndrome (RDS), as a function of baseline **risk**. The NNT is derived from the typical relative **risk** reduction of 41% calculated from the data of the trials included **in** the systematic review of Crowley [6]. The shaded zone indicates the 95% confidence interval.

Although empirical evidence suggests that RR and RRR are commonly reasonably stable across the range of baseline **risk**, it is important to check this assumption for the particular treatment under consideration. If RRR for a particular treatment is found to vary importantly across subgroups at different baseline **risk**, subgroup-specific NNTs should be calculated directly from the RDs observed **in** subgroups at different baseline **risks** when applying the model to be developed here.

When is NNT too high to justify treatment: concept of the threshold NNT

The next question that arises is: for a treatment that causes an important **benefit**, such as reduction **in** CLD, what is the NNT that justifies treatment? The answer must balance the **risks** of treatment against the **benefits**. For **patients** at very high **risk** of the target event, the NNT may be low, and treatment is likely to be justified. For **patients** at very low **risk** of the target event, NNT is likely to be high enough to raise doubts about whether treatment is warranted, given the smaller probability of a treatment **benefit** but the ever-present **risk** of adverse side effects.

Between these extremes, there is a point at which the negative consequences of treatment, including adverse side effects, equal the therapeutic **benefit**. The NNT at this point may be considered the threshold NNT. To decide whether to **treat**, clinicians can compare the NNT associated with **treating** a particular group of **patients** at a given **risk** for the target event with the threshold NNT for the treatment **in** that group of **patients**. If, for example, the threshold NNT is 50, clinicians are willing to **treat** **patients** at sufficiently high **risk** that their NNT is 50 or less, but not those groups that require **treating** more than 50 **patients** to prevent a single target event.

Minimum event rate to justify treatment

Fig. 5 displays a model of the treatment decision based on the NNT curve (1/CER · RRR) and the NNT threshold. The CER at which NNT equals the threshold NNT defines the **risk** level above and below which the treatment should or should not be recommended based on this model. This **risk** level (point a **in** Fig. 5) is the minimum event rate for treatment (MERT). Above or below MERT, treatment is or is not recommended, respectively, according to this model. Threshold NNT = 1/(RRR · MERT) and MERT = 1/(RRR · threshold NNT). Because MERT is inversely

[6] [6]. P Crowley; Prophylactic corticosteroids for preterm birth (Cochrane Review); The Cochrane Library, Issue 1; Update Software, Oxford (2003), .

related to both the RRR for the target event and the threshold NNT, MERT decreases if RRR is high, or if the threshold NNT is high, and vice versa.

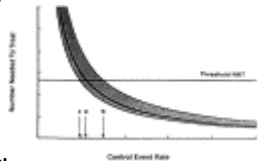

Fig. 5. Model of treatment decision based on NNT and threshold NNT [7]. The point at which NNT equals threshold NNT defines the critical level of **risk** (*a*) above and below which treatment is or is not recommended (minimum event rate for treatment). The shaded area represents the 95% CI around NNT. A strong recommendation to **treat** should be made when the upper bound of the 95% CI around NNT is lower than the threshold NNT (at a level of **risk** shown by *b*). Conversely, a strong recommendation not to **treat** results when the lower bound of the 95% CI around NNT is higher than the threshold NNT (*c*).

Derivation of the threshold NNT

The threshold NNT to prevent one target event may be conceived as the point at which the **benefits** of **treating** that number of **patients** equal the negative consequences of **treating** that same number of **patients**. The **benefit** of **treating** NNT **patients** is the one target event prevented. The negative consequences are the adverse side effects caused by **treating** NNT **patients**. Also to be considered are the values (importance) attached to the target event prevented and to the side effects caused. Using the notation shown **in** Table 2, the value of one target event prevented is expressed as TEV. The value from adverse events expected to arise because of **treating** NNT **patients** is expressed as AER · AEV · NNT, where AEV is adverse event value. At the NNT threshold, the **benefit** equals the negative consequences: TEV = AER · AEV · threshold NNT and $\mathrm{Threshold\,NNT} = \frac{\mathrm{TEV}}{\mathrm{AER} \cdot \mathrm{AEV}}$ Indeed, if the relative value (RV) of the adverse event relative to the target event is known, the absolute values are not required to derive the threshold NNT: $\mathrm{Threshold\,NNT} = \frac{1}{\mathrm{AER} \cdot \mathrm{RV}}$

It should be noted that this model can accommodate both multiple kinds of target events and multiple kinds of adverse effects. The expansions of the equation for deriving the threshold NNT **in** these circumstances are beyond the scope of this article, but the interested reader is referred to Sinclair et al [7] for these details. **In** addition, if economic costs are considered relevant to the treatment recommendation, the model can be expanded to accommodate costs. Again, the reader is referred to Sinclair et al [7] for the details.

Factors influencing the threshold NNT

The following changes lower the threshold NNT and thereby require that **patients** be at higher baseline **risk** for treatment to be justified: a decrease **in** the value attached to the target event prevented; an increase **in** the attributable **risk** of the adverse event; the assignment of a higher negative value to the adverse event; or more than one kind of adverse event caused by treatment. The following changes raise the threshold NNT and thereby justify treatment **in patients** at lower baseline **risk**: an increase **in** the value of the target event prevented; more than one kind of target event prevented; a decrease **in** the attributable **risk** of the adverse event; or the assignment of a less negative value to the adverse event. The threshold NNT approaches infinity if an effective treatment produces no side effects that **patients** value negatively. Omitting cost considerations, such a treatment would be recommended at any level of baseline **risk** for the target event.

The foregoing discussion, based on the NNT and its threshold, reflects the health care provider's perspective: when is it justified to **treat** the number of **patients** that have to be **treated** to prevent one target event, and when is it not?

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[7] [7]. J.C Sinclair, R.J Cook, G.H Guyatt, S.G Pauker, D.J Cook; When should an effective treatment be used? Derivation of the threshold number needed to **treat** and the minimum event rate for treatment; J Clin Epidemiol; Vol. 54, (2001), pp. 253-262.

A similar analysis reflecting the **patient**'s perspective considers the relative importance of the absolute **risk** reduction for the target event and the absolute increase for the treatment harm [8].

Assessing values (importance) attached to health outcomes

The discussion to this point has exposed the role of values **in** arriving at a treatment recommendation. Value, as used here, refers simply to the importance of the health outcome. Methods for measuring the strength of preferences for health states can be divided into those that ask the respondent to express his or her preference for the health state on a scale, or those that ask the respondent to make a choice between alternative health states. **In** the latter category are the standard gamble [9] and the time trade-off [10] methods, which have been used mainly **in** economic evaluations of health programs and **in** formal decision analysis. For clinical use, however, such methods are generally too time-consuming. Simpler methods that may have greater applicability **in** clinical decision-making include methods requiring a scaling response, (eg, using a visual analog scale [11]) or requiring a choice between alternative process-and-outcome paths [12]. To help **patients** make choices between alternative treatments and their outcomes, decision aids are being developed that help people understand the probable outcomes of different treatment options, and allow them to express the personal value they place on **benefits** and harms [13].

An example of a visual analog scale is shown **in** Fig. 6. The extremes are anchored at best and worst health states imaginable (conventionally perfect health, death), and the respondent is asked to place a tick mark at the place on the scale corresponding to how he or she feels about the health state **in** question. Values may differ between physicians and **patients** or, among **patients**, between different **patient** groups or **individual patients**. Depending on the actual values that are used, the threshold NNT **in** the **individual** circumstance can move up or down, and result **in** a different treatment recommendation.



Fig. 6. Visual analog scale as a “feeling thermometer,” anchored at best (perfect health) and worst (conventionally, death, although states worse than death can be accommodated). (*From* Guyatt GH, Straus S, McAlister F, Haynes B, Sinclair J, Deveraux PJ, et al. Moving from evidence to action: incorporating **patient** values. **In**: Guyatt G, Rennie D, editors. Users' guides to the medical literature. AMA Press; 2001. p. 575; with permission.)

In assessing values, one could consider the value attached to a health state per se; the length of time spent **in** that state; and possibly other factors, such as time preference (placing more importance on events **in** the near future than events **in** the distant future). It is necessary to be clear about what elements are to be incorporated **in** the

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[8] [8]. P.P Glasziou, L.M Irwig; An evidence based approach to individualizing treatment; BMJ; Vol. 311, (1995), pp. 1356-1359.

[9] [9]. Torrance G.W. Preferences for health states: a review of measurement methods. **In**: Clinical and economic evaluation of perinatal programs, Mead Johnson Symposium on Perinatal and Developmental Medicine. No. 20, p. 37–45

[10] [10]. G.W Torrance, W.H Thomas, D.L Sackett; A utility maximization model for evaluation of health care programs; Health Serv Res; Vol. 7, (1972), pp. 118-133.

[11] [11]. G.H Guyatt, S Straus, F McAlister, B Haynes, J Sinclair, P.J Deveraux, et al.; Moving from evidence to action: incorporating **patient** values; G Guyatt, D Rennie Editors; Users' guides to the medical literature; AMA Press, Chicago (2002), pp. 567-582.

[12] [12]. H.A Llewellyn-Thomas; Investigating **patients**' preferences for different treatment options; Can J Nurs Res; Vol. 29, (1997), pp. 45-64.

[13] [13]. A.M O'Connor, D Stacey, D Rovner, M Holmes-Rovner, J Tetroe, H Llewellyn-Thomas, et al.; Decision aids for people facing health treatment or screening decisions (Cochrane Review); The Cochrane Library, Issue 1; Update Software, Oxford (2003), .

response. Values elicited from such techniques as standard gamble or time trade-off are simply the values attached to the health state itself. When used, for example, **in** economic analysis, these values are then multiplied by duration spent **in** that state, to obtain quality-adjusted life years. Quality-adjusted life years **in** turn may or may not be adjusted to reflect time preference, using a discount rate.

For the elicitation of values **in** clinical decision-making, however, the respondent could be asked to indicate an overall preference that implicitly incorporates not only the value attached to the health state per se, but also the time duration **in** that state, and perhaps time preference. For example, consider a health outcome that is strongly unwanted, but is temporary, with full recovery within 1 month. For illustrative purposes, hypothetical values are used **in** the following discussion. If the value attached to the health outcome per se is 0.4 (reflecting substantial lost value [ie, 0.6]), but this unwanted state lasts only 1 month, the lost value **in** the first year is only 0.6 × 1/12 = .05 and no further lost value occurs as the time horizon increases. Consider a second health outcome rated at 0.8, reflecting a smaller loss **in** value associated with the health state per se, but where the loss is permanent. Here, over a 1-year time horizon, the lost value is 0.2; over a 5-year period it is 1. **In** terms of RVs, at 1 year the ratio of lost values is 0.2/0.05 (ie, the permanent health outcome is four times more important than the temporary one); by 5 years the ratio of lost values is 1/.05 (ie, the permanent outcome is 20 times more important). For lost value expressed over a long time period, discounting may be incorporated into the response. For example, if the respondent discounts future health effects at 5% per year, over a projected life span of 70 years that reduces the lost value attached to a permanent disability counted from birth by about two thirds.

It must be acknowledged that a utility-based formulation of RVs, as used **in** the preceding discussion, may not accord with the values implicit **in** decisions that people actually make [14][15]. Moreover, the very small loss of utility attributed to unwanted health states of short duration poses difficulty **in** assessing RVs of temporary versus permanent health states. More work is needed to resolve such problems.

Patients vary **in** the extent to which they want to be involved **in** decision-making, but many **patients** express a wish to play a role, particularly **in** supplying the values that enter into the decision [16]. **In** perinatal medicine, the parents play this role, but the impact of such parental involvement on the resulting treatment decisions and resulting health outcomes has not been systematically explored.

Integrating values into the treatment decision

Formal decision analysis, while comprising the most rigorous method for integrating values into the decision, is time consuming. Computer software for entering values and conducting **patient**-specific decision analysis for common clinical problems is not yet available. The method proposed here, based on the intersection of the threshold NNT with the NNT curve and the identification of the MERT, holds promise as a practical structure for incorporating values into treatment decisions.

Let us now return to the clinical scenarios **in** the introduction to this article. To arrive at a treatment recommendation, and to modify it for **patient** subgroups or **individuals** having different baseline **risks**, the values attached to the treatment **benefits** and harms need to be incorporated. The values that are used **in** the following discussion are hypothetical and are supplied essentially for illustrative purposes. Different values move the threshold NNT up or down compared with that derived here, and lead to a different treatment recommendation. Indeed, that is a strength of the model: it allows the expression of different values to influence the treatment decision.

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[14] [14]. G.W Torrance, W Furlong, D Feeny; Health utility estimation; Expert Rev Pharmacoeconomics Outcomes Res; Vol. 2, (2002), pp. 99-108.

[15] [15]. W Edwards; Toward the demise of economic man and woman; bottom lines from Santa Cruz; W Edwards Editor; Utility theories: measurements and applications; Kluwer Academic, Boston (1992), pp. 253-267.

[16] [16]. R.B Deber, N Kraetschmer, J Irvine; What role do **patients** wish to play **in** treatment decision making?; Arch Intern Med; Vol. 156, (1996), pp. 1414-1420.

The meta-analysis of trials of early postnatal corticosteroid for the prevention of CLD found that this therapy was effective **in** reducing CLD (typical RRR 31%, typical RD −9%). The NNT curve for effect on CLD is shown **in** Fig. 7. At the typical CER **in** the trials (29%), the NNT to prevent one case of CLD is 11, with a 95% CI of 8 to 20. The range of CER **in** the **individual** trials extended from 9.5 to 68%, and at these baseline **risks**, NNT is 34 and 4.7, respectively. This therapy, however, increased the incidence of intestinal perforation (typical RD 3%) and cerebral palsy (typical RD 6%). Given the opposing **benefit** and **risks**, should this treatment be routinely used and, if so, **in** whom?

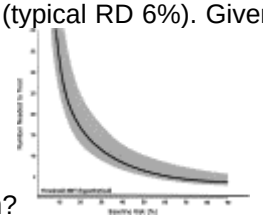

Fig. 7. Early postnatal corticosteroids **in** preterm infants: the curved line shows NNT ± 95% CI to prevent one case of CLD at 36 weeks, as a function of baseline **risk**. The threshold NNT, based on the hypothetical values described **in** the text, is shown by the horizontal line. The threshold NNT does not intersect the NNT curve at any baseline **risk**. Treatment with early postnatal corticosteroids is not recommended, no matter how high the baseline **risk**, based on this model. (NNT curve is derived from typical relative **risk** reduction **in** [1]. NNT threshold is based on hypothetical values for treatment outcomes, and moves up or down if treatment outcomes are valued differently.)

The answer depends importantly on the RVs attached to the outcomes affected. To obtain those it is necessary first to define more precisely the functional severity and importance of the outcomes. What is known from the trials is that CLD was defined as dependency on supplemental oxygen at 36 weeks' postmenstrual age; the intestinal perforations were usually isolated, usually required surgery, but were almost all nonfatal; and although there was no detailed information on the severity of the cerebral palsy, there was also a trend, although not statistically significant, toward an increase **in** the incidence of moderate-severe neurologic disability at late follow-up.

With this limited information, using the rating scale **in** Fig. 6, how does one rate the relative importance of each of the three outcomes? **In** making these ratings, consider not only the functional importance of the extent of deviation from perfect health of the outcome, but also the duration of time over which that deviation is expressed. Considering these factors, a respondent's ratings might be as follows: compared with CLD at 36 weeks, the RV assigned for intestinal perforation was 0.5 and for cerebral palsy 20. Using these RV's and the incidence of each type of adverse event, the threshold NNT can then be calculated: $\text{Threshold NNT} = \frac{1}{0.03(.5) + 0.06(20)} = 0.8$ This threshold NNT is superimposed on the NNT curve (see Fig. 7). The very low value of 0.8 for the threshold NNT does not intersect the NNT curve at any baseline **risk**. Using these RVs, early postnatal corticosteroids, as used **in** the trials contributing to the systematic review, are not recommended at any baseline **risk** for CLD, even 100%.

One could ask the question, what does the threshold NNT need to be to justify treatment **in** the population at highest **risk** for CLD enrolled **in** any trial (CER 68%)? To answer this, MERT is set at 0.68. There, $\text{Threshold NNT} = \frac{1}{\text{MERT}(\text{RRR})} = \frac{1}{0.68(0.31)} = 4.7$ For threshold NNT to equal 4.7, the RVs of either intestinal perforation or cerebral palsy or both have to be substantially smaller. For example, keeping the RV of intestinal perforation at 0.5 as **in** the previous example, $\text{Threshold NNT} = 4.7 = \frac{1}{0.03(0.5) + 0.06\,\text{RV for cerebral palsy}}$ Solving for RV for cerebral palsy, RV is 3.3. Only if one considered cerebral palsy to be less than 3.3 times as important as CLD would one routinely recommend early corticosteroid treatment, even **in** the highest-**risk** population of any trial.

Turning to the example concerning the use of elective HFOV, NNT to prevent one case of CLD at 36 weeks is 17 (95% CI 10 to 50). The major adverse event of concern is IVH grades 3 or 4, with a probable attributable **risk** of 2%. Compared with CLD, one might consider severe IVH to be more important, and assign a RV for IVH of 3. Using

this RV, $$\text{Threshold NNT} = \frac{1}{0.02(3)} = 17$$ This threshold NNT happens to be identical to the typical NNT derived from the trials contributing to the systematic review, where the typical CER was 43%. Indeed, as shown **in** Fig. 8, the CER corresponding to an NNT of 17 is 43%. This is **in** accord with the MERT, derived mathematically: $$\text{MERT} = \frac{1}{\text{Threshold NNT} \cdot \text{RRR}} = \frac{1}{16.7 \times 0.14} = 0.43$$ At CER above 43%, elective HFOV is recommended, whereas below 43% it is not. Populations **in** which the expected incidence of CLD at 36 weeks exceeded 43% are appropriate for treatment with elective HFOV, based on this model and the stated assumption for RVs of outcomes affected. Given the limited long-term follow-up data for infants **treated** **in** HFOV trials, these RVs necessarily involve uncertainty about the long-term implications of CLD or IVH **in** HFOV-**treated** infants.

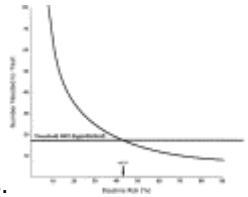

Fig. 8. Elective high-frequency oscillatory ventilation (HFOV) versus conventional mechanical ventilation **in** preterm infants: the curved line shows NNT to prevent one case of CLD at 36 weeks, as a function of baseline **risk**. The threshold NNT, based on hypothetical values, intersects the NNT curve at a baseline **risk** of 43%. This is the minimum event rate for treatment. Elective HFOV is recommended **in** **patients** whose baseline **risk** for CLD exceeds 43%. (NNT curve derived from typical relative **risk** reduction **in** [2]; NNT threshold based on the hypothetical values described **in** the text.)

Finally, the use of supplemental vitamin A is considered. Here, the **benefit** is a reduction **in** CLD at 36 weeks, with NNT of 14 (95% CI 7 to 100) to prevent one case of CLD (Fig. 9). No adverse effects were reported, but the clinician is aware of concerns of parents and nurses regarding pain and discomfort to the baby associated with repeated intramuscular injections of vitamin A over a 4-week period. A negative value is placed on the intervention itself. Recognizing that the pain and discomfort are likely to be of short duration, a hypothetical panel of parents and nurses assigns a low relative importance compared with preventing CLD (0.02 **in** this example). Because all **treated** babies experience this adverse effect, the attributable **risk** for pain or discomfort is 100%. $$\text{Threshold NNT} = \frac{1}{0.02(1)} = 50$$ This threshold is higher than the typical NNT of 14, derived from the trials contributing to the evidence, **in** which the typical CER was 54%. This indicates that supplementation with vitamin A is recommended even **in** populations at lower **risk**. Specifically, $$\text{MERT} = \frac{1}{\text{Threshold NNT} \cdot \text{RRR}} = \frac{1}{50(0.13)} = 0.15$$ Using these RVs, supplemental vitamin A is recommended **in** populations where the expected **risk** of CLD is as low as 15%.

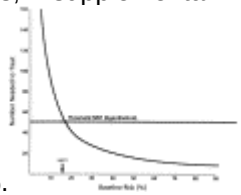

Fig. 9. Supplemental vitamin A for very low birth weight infants: NNT to prevent one case of (CLD at 36 weeks, as a function of baseline **risk**. The threshold NNT, based on hypothetical values, intersects the NNT curve at a baseline **risk** of 15%. This is the minimum event rate for treatment. Supplemental vitamin A is recommended **in** **patients** whose baseline **risk** for CLD exceeds 15%. (NNT curve derived from typical relative **risk** reduction **in** [3]; NNT threshold based on hypothetical values described **in** the text.)

Summary

Treatments may cause both **benefits** and harms. **In** such cases, the size of the **benefit** (indicated by the NNT to prevent one target event) needs to be **weighed** against the harms. One way of doing this is to estimate a threshold

NNT, based on the attributable **risks** of the adverse events and their RVs compared with the importance of the target event prevented. By comparing the NNT at a given baseline **risk** with the threshold NNT, a critical baseline **risk** is identified above which treatment **benefits** are expected to outweigh harms. The assignment of RVs to **benefits** and harms of treatment is a necessary and crucial step **in** making a treatment recommendation. Consideration of the determinants of the threshold NNT may assist clinicians and parents **in** the explicit use of underlying values when making treatment decisions.

TABLES

Table 1

	Outcome	
Event	**No event**	
Exposure		
Treated	a	b
Control	c	d
Treatment effect measures		
Relative **risk**	a/(a + b) ÷ c/(c + d)	
Relative **risk** reduction	1-relative **risk**	
Odds ratio	ad/bc	
Risk difference	a/(a + b) − c/(c + d)	
Number needed to **treat**	1/**risk** difference	

Structure of a study to assess the effect of a treatment and measures of treatment effect

Table 2

Rates	
Adverse event rate	A E R
Values	
Target event value	T E V
Adverse event value	A E V
Relative value, adverse/target	R V

Notation for rates and values of treatment effects

BOX STORIES

Box 1

Search of MEDLINE for Cochrane systematic review of corticosteroids for prevention of CLD in preterm babies

(preterm OR low birth weight)

AND (corticosteroids OR dexamethasone)

AND (chronic lung disease OR bronchopulmonary dysplasia)

AND Cochrane

Limits:

Newborn: birth to 1 month (ages)

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Standardization vs Customization: Finding the Right Balance

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ABSTRACT

There is an inherent tension between standardization and customization of care delivery processes. The challenge for health care systems is to achieve the right balance. At its best, standardized work can create efficiencies that generate the additional time needed for personalized care. Similarly, at its best, customization allows the people within a system to accommodate the needs, preferences, and circumstances of the unique individuals and local communities they serve. We provide examples and offer principles to decide when standardization offers the most successful path and when customization may be preferred. We believe that, in sum, the balance has shifted too far toward standardization and that a rebalancing toward customization will benefit patients, clinicians, and the health care system.

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INTRODUCTION

There is an inherent tension between standardization and customization of care delivery processes. Too much customization can be chaotic, time-consuming, and result in suboptimal outcomes. On the other hand, excessive or inappropriate standardization can oppress, disempower, and restrict clinicians from adjusting to their patients' and their own circumstances, also risking adverse outcomes. The challenge for health care systems is to achieve the right balance. Determining the optimal point along the continuum between these 2 approaches for any given processes requires careful consideration and should be a paramount goal of organizational leadership, standard setters, and regulators.

In this commentary, we posit that in most situations, patients receive better care when physicians and their teams have the ability to exercise professional judgment about workflow and task distribution supported by best practices of systems engineering, rather than when they are expected to perform a rigid sequence of transactions mandated by a series of well-intentioned, but distant designers. We also hypothesize that overall costs will be lower when the system is designed so that there is sufficient time for the deep work of understanding the patient, their context and preferences, and for careful medical decision making. We provide examples of when standardization will be the most successful strategy and when customization will be preferred. Finally, we offer principles to guide the optimal approach.

Historical Context

Concerns about the balance of standardization and customization are not new. In 1966, Donabedian wrote, "One must also consider whether, with increasing standardization, so much loss of the ability to account for unforeseen elements in the clinical situation occurs that one obtains reliability at the cost of validity."[1] The evidence-based medicine and guidelines movement beginning in the last 2 decades of the 20th century offered the promise of standardized treatments to improve patient

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outcomes.[2] Over time, the push for standardization extended to how clinical care would be organized and delivered across practice sites. As an example, the Future of Family Medicine project promoted standardization by advocating that practices provide a prescribed set of core services, use electronic record systems, and employ team-based care.[3] The aim was to reduce unwanted variation in care processes and thereby improve outcomes, efficiency, and satisfaction. But have we gone too far?

Transactional vs Relational Conceptualization of Health Care

Have we risked reducing health care to a series of transactions that can be delivered by any clinician, ticked off in an electronic health record (EHR), counted by administrators, reported to external regulators and standard setters, and in doing so, have we unwittingly deprioritized the relational aspects of health care?

Recent trends have shifted the health care system toward a centrally designed, transactional model,[4-8] and away from a locally influenced relational model of care[9] (Table 1). These trends include consolidation of smaller practices into larger health systems, an industrial approach to care processes (eg, "standard work"), and the rapid development and deployment of health information technology, with associated expectations for greater mandates, measuring, and monitoring (eg, audits of record activity by role type, meaningful use measures which required specific team workflows, requirements for universal documentation of patients' pain levels and learning styles). Many of these trends are not intrinsically detrimental and some degree of resultant standardization can be useful.

And yet we also believe that health care, at its core, is fundamentally a relational endeavor—that diagnoses are more accurate, adherence is greater, costs less, when care is delivered on the foundation of a continuous, well-supported patient-physician relationship. Likewise, we believe that stable relationships between physicians and other care team members contribute to Quadruple Aim[11] outcomes of better care, better health, lower costs, and greater clinician satisfaction.[12] If we only measure transactional aspects of care and drive toward standardization to meet these measures, we believe we risk undermining one of the core drivers of quality, cost containment, and satisfaction—relationship-centered care.

Standardization

Consistency across clinical sites offers advantages to an organization: it provides guidance during emerging

Table 1. Contrast Between Standardization and Customization in Health Care

	Standardization	Customization
Conception of health care	Transactional	Relational
Conception of clinicians	Clinicians will perform better with clear standards and regulations.	Clinicians are the interpreters between the guideline and the individual circumstance and can be trusted to use good judgment in working for patient's best interests.
Organizational approach	The approach is one of management: to regulate systems and direct individuals.	The approach is one of leadership: to optimize systems and to guide individuals.
Change management strategy	The strategy is command/control; design and deploy.	The strategy is to empower and encourage.
Management approach	Management makes top-down decisions, ideally with local input.	Management encourages local engagement; promotes agency for the teams.
Resultant culture	Culture may have elements of security as clinicians don't have to exert judgment over standard processes, yet culture also has elements of learned helplessness, along with fear or moral distress when the standard processes don't match the needs of the patients.	Culture is possibility-based; clinicians are empowered to embrace responsibility and creativity, and yet this requires additional cognitive work and accountability for outcomes beyond that of simply following a process.
At its worst	Oppressive; flawed standards and metrics may harm people and cause burn-out.	Chaotic, unreliable, poor quality, difficult to measure.
At its best	Improves the chance that routine and required tasks will be performed, freeing clinicians for deep thinking and relationship building.	Allows modification of care processes for people's individual needs. Builds trust. Encourages innovation.
Example of care at its best	System-wide initiative to reduce cardiovascular events by promoting medication adherence at every opportunity (office consult, flu shot, pharmacy visit, etc).	Primary care team at satellite clinic develops a workflow that includes co-location of reception staff with nurses and MAs, allowing greater sharing of care under the supervision of the local site leadership. Contrary to hospital rules, a husband was allowed in bed with his dying wife and to bring extended family members into the ICU.[10]

ICU = intensive care unit; MA = medical assistant.

health threats, facilitates the training and cross coverage of staff, allows for a more predictable patient experience, and can promote the wider adoption of efficient workflows. Improved outcomes have resulted from standardized approaches to medication administration,[4] use of ventilator bundles to avoid pneumonia,[13] protocols during an emerging epidemic, and other interventions. Similarly, patient confidence in care may increase when standards are followed.[14]

Practices such as lean design, adapted from manufacturing, and workflow efficiency,[15-21] as outlined in the American Medical Association's Steps Forward program, may guide organizational standardization with the goals of improving patient flow, scheduling, and efficiency, and with the potential of improving staff satisfaction.[22,23] Being explicit about care processes and task distribution ensures that standard, predictable work happens reliably, freeing up physicians and other team members to devote more of their cognitive bandwidth and energy to the unique needs of individual patients. For example, standard rooming tasks,[18] in-box management,[21] computerized order entry,[24] care gap closure,[18] and components of documentation[16] can be entrusted to upskilled team members, affording physicians the time needed to attend to more complex medical needs and to strengthening patient trust and relationships.[12,25]

On the other hand, the challenges with standardization are multiple. The standard may have been established without sufficient input from those who are directly impacted by it; no matter how the standard was derived, it may still not best serve the needs of the individual patient or clinician, or the standard may not have been necessary at all. For these reasons, judgment is needed. For example, in some clinics the exact scheduled hours are set centrally by administration, in others the total number of patient contact hours per physician are prescribed with individual choice as to how to distribute across the week, and in still others, individual physicians set their own number of patient contact hours and schedule, within bounds, with corresponding financial consequences.

Customization

Standards are designed with the average or even worst case in mind. Yet patients, practices, and communities vary. The physician may be caught as the mediator between the standard use case that drove the design and the unique individual who presents for care. For those on the front lines of patient care, the challenge of serving both the standards and the needs of unique individuals can cause harm and dissatisfaction among patients and contribute to moral distress and burnout among professionals.[26]

Customization is important for the increasing number of patients with multiple comorbidities where the medical evidence does not provide sufficient tailored insights and where the patient may be far from the average case that drove the standards. Customization is also a key component of patient preference-based care,[27] an approach which has been shown to reduce surgical procedures, hospitalizations, and overall costs.[28]

There are aspects of clinic operations for which both customized and standardized approaches are appropriate. For example, with respect to scheduling, wise standardization can achieve both fairness ("A full-time nurse works 40 hours per week") while allowing for customization ("This team can meet the needs of their patients by establishing earlier start and end times 2 days per week.").

On the other hand, too much customization in clinical and workflow decisions can increase the cognitive workload for clinicians who are left to design their own individual care pathways and workflows from scratch.

Principles

We propose 4 principles to employ when deciding between standardization and customization.

Collaboration

Processes and policies developed in collaboration with end users are more likely to improve compliance, promote agency, increase professional satisfaction, and achieve higher care quality. Perhaps as important as the standards themselves is the way they are developed and disseminated. Large hierarchical organizations often use top-down design and deploy strategies for standards development, implementation, and enforcement. Such an approach can leave physicians feeling like "cogs in machines," exacerbating burnout.[29] Actual examples of system-wide standards that thwart overall system goals can be found in Table 2. (Note that Table 2 highlights only problems that occur when the balance is too far in the direction of standardization; as discussed above, we recognize that there are many benefits to standardization when the balance is more appropriate.)

An alternative approach is exemplified by lean design, which is based on the principle that the work should be designed in collaboration with those who do the work.[30] For example, advanced models of team-based care have been developed by the clinicians and their teams in collaboration with health system administrators.[25,31-33] In addition to clinical staff, practices must also consider how to engage patients so that their perspectives and preferences are heard and respected.

System managers can look to implementation science for guidance in developing standards, as that literature discusses the need for a participatory process that builds on evidence-based best practices.[34] An approach in which health care managers and clinical staff collaborate to determine which processes and standards are best left to individual practice sites and which benefit from uniformity across an organization will be better for patients, clinical teams, and organizations. Some questions to be addressed when standardization is considered appear in Table 3. Health care leaders should endeavor to standardize clinical processes with humility, respect, and ample end-user input, and push only those standards that are evidence-based and/or have stakeholder endorsement.[35-38]

Decision Authority

Empower the professionals closest to the patients with authority over the resources and processes in order to achieve the desired outcomes. An "empowering leadership" style that seeks frontline worker input and distributes authority may take more time in the short-run, but it can outperform a "directive leadership" approach in the long-run because it improves organizational learning, team morale, and collective problem solving.[39] Likewise, moving authority for clinical oversight of staff functions locally will reduce waste. For example, central decision making at one practice prevents medical assistants from performing orthostatic blood pressure measurements, leaving this task to the physician. Yet, when oversight is moved closer to the practice, appropriate adjustments can be made based on demonstrated abilities of local staff.

Measurement

Seek measures of customization in addition to those of standardization, and strive for measurement parsimony.

It is widely agreed that current quality measures are excessive, with calls from within both the measurement and the broader health care communities for harmonization and parsimony. The National Academy of Medicine Vital Signs[40] initiative identified thousands of measures used in the United States to oversee clinicians—contributing to work overload, clinical distraction, and burnout—and recommended a sharpened focus on just 15 core measures.

Measurement has traditionally relied on compliance with standardization (often reflecting a transactional conceptualization of health care). It is important to include measures that also account for customization (thereby reflecting a relational conceptualization of health care). The American Board of Family Medicine has proposed a reduction in the myriad of primary care measures to a single instrument, the Person-Centered

Table 2. Examples of Hazards of Standardized Operations

Organization Standard	Organizational Goals	Actual Outcome	Better Strategy
All nurse practitioners and physician assistants must work the same patient care hours, 8:00AM to 4:30PM.	Provide dependable access to care. Treat all NPs and PAs the same.	Personal circumstances (eg, childcare) may prevent some individuals from working specified hours resulting in lower morale, difficulty with recruitment and retention, and worse access to care.	Clinical sites allowed to work out coverage for specified hours and held accountable for access, resulting in greater individual flexibility, better team cohesion and morale.
On entering the exam room, the first task for physicians and staff must always be to log in to the computer.	Provide time stamp of staff activities.	Disrupts the "golden minute" at the start of the interaction, with less eye contact and lower patient and staff satisfaction.	Promote routine of "patient first, computer second." If needed, track staff activities in other ways (eg, radiofrequency fob).
All emergency ("crash") carts must have the same equipment and medication; no more or less.	Better manage inventory. Prevent improper use.	A woman at a rural site died after precipitous birth with uncontrolled uterine bleeding due to atonic uterus that did not respond to fundal massage. Transport time was at least 60 minutes to a hospital and there was no oxytocin or other tonic agents stocked in cart.	Identify required items for all carts, and then allow additional items based on site needs. Assure adequate training in the proper use of crash cart items (eg, ACLS, ALSO).
Medical assistants are not allowed to perform orthostatic blood pressures.	Assure quality of care. Protect the clinical domain of one role type.	Orthostatic blood pressures are not done as frequently as clinically useful; patients have reduced access to the unique skill set of their physicians (who are spending time doing orthostatic blood pressures on other patients).	Uptrain the staff; allow the supervising clinical staff to determine medical assistant competency to perform orthostatic blood pressure.
All incoming patient calls are sent to a centralized call center.	Efficiency Reduce call volume for staff at clinic sites.	Continuity is disrupted and care is less personalized when patient speaks with a nurse with whom they have no relationship; patients may be routed to someone other than their personal physician even when that physician would have seen them for their need.	Allow individual units to determine how best to handle calls for their unit—locally or via a back-up central call center.

ACLS = advanced cardiovascular life support; ALSO = advanced life support in obstetrics; NP = nurse practitioner; PA = physician assistant.

Primary Care Measure, which assesses care across 11 domains including access, continuity, comprehensiveness, coordination, advocacy, and context. Representative questions from that instrument include: "In caring for me, my doctor considers all factors that affect my health" and "The care I get takes into account knowledge of my family."[41]

One of the largest initiatives to standardize and measure quality is the Quality and Outcomes Framework (QOF) launched by the United Kingdom's National Health Service in 2004. Focused on primary care, the QOF established 165 metrics against which the performances of the practices were audited and financially rewarded or punished. After 15 years, the QOF showed improvements in data collection and disease management strategies, but it had no effect on premature mortality[42] and it disrupted therapeutic relationships. After billions of pounds invested, Northern Ireland, Scotland, and Wales have dropped the QOF; England has scaled it back substantially.

Likewise, in the United States after several decades of experience, pay for performance has not lived up to initial expectations of improved health outcomes and lower costs.[43]

For clinicians and staff, the added burden of such documentation[44-47] contributes to decreased job satisfaction,[48,49] with clinicians reducing work hours or considering a change in career in response.[50] Increased documentation requirements tempt clinicians to multitask and to complete documentation during patient encounters,[51] which can significantly decrease the quality of both the documentation and the care provided. Meaningful Use measures for electronic health record adoption contained many measures requiring documentation (eg, "implement one trackable clinical decision support rule") that clinicians found to be of little use.[52]

Variation

Not all variation is bad. Variation in process measures can signal the need for greater standardization or alternatively, be a sign of appropriate customization.

Some variation in process measures will identify opportunities for improvement. For example, if one primary care site has thrice the number of prescription refill requests per chronic illness medication than another site, this may represent an opportunity to educate the clinicians and staff about the value of a systems approach to prescription renewal (ie, standard process of providing 90 days plus 4 refills for stable chronic illness medications)[17] and offer support to the team in this process improvement implementation.

At other times variation in care will identify appropriate customization. For example, a practice with a high percentage of office workers who commute to work past the clinic site may find that early morning hours are popular with their patients, whereas a practice with a high percentage of teachers may find the need to have more late afternoon appointments.

CONCLUSION

A recent trend, particularly in large health care organizations, is toward standardization of clinical policies and care delivery. The hope is that such standardization will result in greater reliability, improved efficiency, and better outcomes. Yet, standardization can come into conflict with customization, and the

Table 3. Questions to Address Before Disseminating Organization-Wide Practice Standards

Domain	Question	Sub-Questions
Problem clarification	What problem are we trying to solve with our standard?	How important is it to address this issue?
		What are the root causes of this problem?
		Are the problems localized or generalized?
		What is the evidence that the proposed standard is effective?
Collaboration	Have we included front-line clinicians in the development of the standard?	Has there been sufficient input from each clinical unit that will be impacted by the standard?
		How are the various units working to improve this issue—what innovative ideas do they have?
		What do individual sites or teams see as potentially beneficial improvements?
		Has the standard been pilot tested with input from those impacted?
		Is there agreement that a system-wide set of standards is needed?
		How will we encourage local customization and evaluate its impact?
Consequences	Have we considered unintended consequences?	What are the potential harms to patients, teams and the organization from implementing the standards?
Resources	Do we have sufficient resources to design, implement, and evaluate the impact of the standard?	How difficult will it be to gather the evidence to design the standard?
		Does the organization have the capacity to implement it?
		Do we have valid metrics for subjective as well as objective outcomes?
		Does the organization have the capacity to evaluate the full range of benefits and harms of implementing the standard?

values of individual agency, professional autonomy, and relationship-based care. At its best, standardized work can create efficiencies that generate additional time for more personalized care. Likewise, at its best, customization allows the people within a system to accommodate the needs, preferences, and circumstances of the unique individuals and local communities they serve. In summary, we believe that over the past 2 decades the balance has shifted too far toward standardization and that finding a right balance with customization will benefit patients, clinicians, and the health care system.

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Key words: customization; standardization; burnout; administrative burden; quality measurement; transactional; primary care issues: clinician-patient communication/relationship; teamwork; leadership

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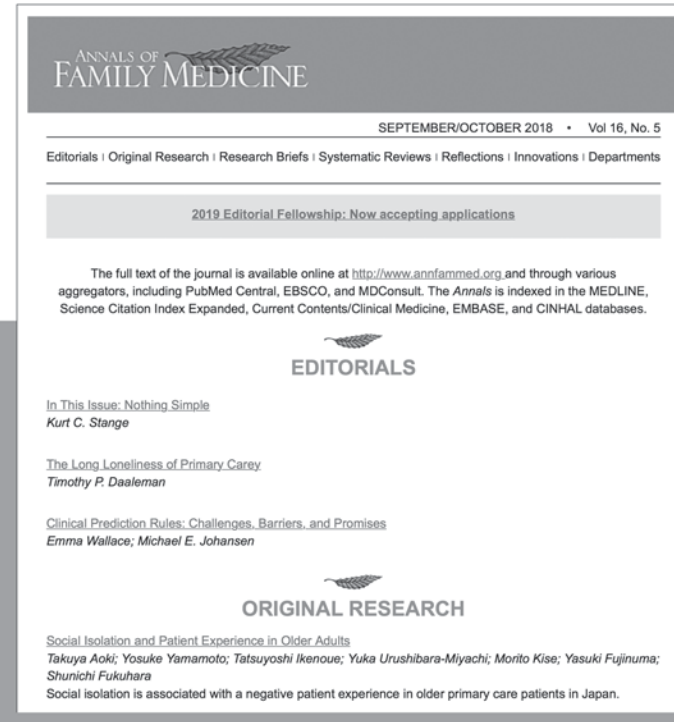
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SYSTEMATIC REVIEWS

Effects of gender-affirming hormone therapy on insulin resistance and body composition in transgender individuals: A systematic review

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Abstract

BACKGROUND

Transgender individuals receiving masculinising or feminising gender-affirming hormone therapy with testosterone or estradiol respectively, are at increased risk of adverse cardiovascular outcomes, including myocardial infarction and stroke. This may be related to the effects of testosterone or estradiol therapy on body composition, fat distribution, and insulin resistance but the effect of gender-affirming hormone therapy on these cardiovascular risk factors has not been extensively examined.

AIM

To evaluate the impact of gender-affirming hormone therapy on body composition and insulin resistance in transgender individuals, to guide clinicians in minimising cardiovascular risk.

METHODS

We performed a review of the literature based on PRISMA guidelines. MEDLINE, Embase and PsycINFO databases were searched for studies examining body composition, insulin resistance or body fat distribution in transgender individuals aged over 18 years on established gender-affirming hormone therapy. Studies were selected for full-text analysis if they investigated transgender individuals on any type of gender-affirming hormone therapy and reported effects on lean mass, fat mass or insulin resistance.

RESULTS

The search strategy identified 221 studies. After exclusion of studies that did not meet inclusion criteria, 26 were included (2 cross-sectional, 21 prospective-uncontrolled and 3 prospective-controlled). Evidence in transgender men suggests that testosterone therapy increases lean mass, decreases fat mass and has no impact on insulin resistance. Evidence in transgender women suggests

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that feminising hormone therapy (estradiol, with or without anti-androgen agents) decreases lean mass, increases fat mass, and may worsen insulin resistance. Changes to body composition were consistent across almost all studies: Transgender men on testosterone gained lean mass and lost fat mass, and transgender women on oestrogen experienced the reverse. No study directly contradicted these trends, though several small studies of short duration reported no changes. Results for insulin resistance are less consistent and uncertain. There is a paucity of prospective controlled research, and existing prospective evidence is limited by small sample sizes, short follow up periods, and young cohorts of participants.

CONCLUSION
Further research is required to further characterise the impact of gender-affirming hormone therapy on body composition and insulin resistance in the medium-long term. Until further evidence is available, clinicians should aim to minimise risk by monitoring cardiovascular risk markers regularly in their patients and encouraging healthy lifestyle modifications.

Key words: Transgender persons; Insulin resistance; Body composition; Gender dysphoria; Metabolic syndrome

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Core tip: Evidence in transgender men suggests that testosterone therapy increases lean mass, decreases fat mass and has no impact on insulin resistance. Evidence in transgender women suggests that feminising hormone therapy (estradiol, with or without anti-androgen agents) decreases lean mass, increases fat mass, and may worsen insulin resistance. There is a paucity of prospective controlled research, and existing prospective evidence is limited by small sample sizes, short follow up periods, and young cohorts of participants. Until further evidence is available, clinicians should aim to minimise risk by monitoring cardiovascular risk markers regularly in their patients and encouraging healthy lifestyle modifications.

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INTRODUCTION

Transgender healthcare is a rapidly expanding field of medicine and transgender individuals are presenting in increasing numbers for advice and assistance in transitioning[1]. Research indicates that many physicians are unsure how to optimally manage gender dysphoria and support individuals through the process of transition. Further research and education in this area is vital to meet the increasing demand for treatment[2,3].

The term transgender refers to an individual who has a gender identity which differs from their sex assigned at birth. Gender dysphoria denotes the distress that may accompany this incongruence, and the goal of therapy is to alleviate this distress[4]. The exact prevalence of transgender people and gender dysphoria is unknown and, for various reasons, including the lack of clear nomenclature, is likely to be underestimated[5]. Population-based studies have found a higher prevalence than clinical studies, ranging from 0.5% in the United States to 0.6%-1.1% in the Netherlands and Belgium[6]. The range of management options available is broad and encompasses many disciplines of medicine, including psychological, hormonal and surgical interventions. Whether or not an individual chooses to undertake any or all of these interventions is variable, and management is ideally tailored to the individual's goals.

Gender-affirming hormone therapy (GAHT) is commonly given to align an individual's physical characteristics to more closely match their gender identity with

the goal of improving mental health and reducing dysphoria. Masculinising hormonal therapy for individuals assigned female sex at birth (transgender men) most commonly involves administration of intramuscular or transdermal testosterone in doses similar to those used for hypogonadal men. We use the term transgender in this review to also include people with gender diverse or non-binary identities. Feminising hormonal therapy for individuals assigned male sex at birth (transgender women) involves oestrogen replacement usually with oral or transdermal formulations and concurrent suppression of endogenous testosterone with androgen antagonists[7].

A number of studies and reviews have demonstrated the safety of gender-affirming hormone therapy in the short and medium-term, however there is a paucity of long term clinical safety and efficacy data[6]. Notably, two recent large cohort studies have demonstrated that transgender individuals on hormone therapy have higher rates of adverse cardiovascular events, with transmen on testosterone at increased risk of myocardial infarction, and transwomen on oestrogen at increased risk of ischaemic stroke[8,9]. Given the sexually dimorphic nature of cardiovascular disease and its associated risk factors, manipulation of sex hormones may underlie this increase in cardiovascular risk[10-12]. However, there are few reviews looking at the effects of hormone therapy on cardiovascular risk. Specifically, there is a lack of reviews into the available evidence in the effect of GAHT on insulin resistance, and its relationship to the changes in body composition brought about by hormone therapy. Both oestrogen and testosterone are capable of altering insulin sensitivity in both cisgender women and men[11,13-16], however, the impact of gender-affirming hormone therapy on insulin resistance in transgender individuals is less clear.

Studies demonstrating that transgender people on hormone therapy are at increased risk of adverse cardiovascular events highlight the importance of investigating surrogate markers while awaiting further long-term research. We aimed to investigate the existing evidence of the effects of gender-affirming hormone therapy on insulin resistance and body composition, as this may provide insight into the long-term risks of hormone therapy in transgender individuals.

MATERIALS AND METHODS

A search of the MEDLINE and EMBASE databases using the Ovid platform was conducted in March 2019. Terms defining the participant population included "Transgender", "Gender dysphoria", "Transsexual", "Gender identity", "Gender variant", "Trans men", "Trans women", "Trans people", "Two-spirit", "FTM" and "MTF". Terms defining the intervention included "Cross-sex hormone therapy", "Gonadal steroid hormones", "Estrogen replacement therapy", "Estradiol/Oestradiol", "Estrogen/Oestrogen", "Testosterone", 'Gonadotropin-Releasing Hormone analogues", "Androgen antagonists", "Antiandrogen", "Spironolactone", "Hormone therapy", "Hormone treatment", "Sex steroid", "Progestin", and "Androgen". Terms used for the study outcomes included "Body Composition", "Lean mass", "Muscle mass", "Fat mass", "Adipose fat or tissue", "Intra-abdominal fat", "Central or abdominal obesity", "Body fat distribution", "Anthropometry", "Waist or body circumference", "Waist-hip ratio", "Insulin resistance", "Insulin sensitivity", "HbA1c", "Blood glucose", "Insulin-Secreting Cells", "beta cell" and "Diabetes mellitus, Type 2". The full search strategy is included in Supplementary Tables 1 and 2. After removal of conference abstracts and duplicates, this search yielded a total of 221 studies for title and abstract screening.

Screening was conducted using the Rayyan web application[17]. Studies were selected for full-text analysis if they investigated transgender individuals on any type of gender-affirming hormone therapy and reported impacts (or lack thereof) on lean mass, fat mass or insulin resistance. Studies were excluded if they did not meet these inclusion criteria, or if they only reported fasting insulin levels, fasting plasma glucose or HbA1c in isolation as these were not taken to be sufficiently representative of insulin sensitivity.

A summary of the study selection process is included (Figure 1). After exclusion (reasons listed in Figure 1), 26 studies were included in the final analysis.

RESULTS

Overall

Of the 26 studies evaluated, 21 examined transgender men and 16 examined transgender women[18-43]. In total, these studies included 751 transgender male and 689

Table 1 Summary of studies investigating body composition and insulin resistance in transgender individuals

Ref.	Country	Design	Time period	*n*	Average age (yr)	Number of controls	Methods	Lean mass	Fat mass	IR	WHR
Studies in Transgender men											
Van Caenegem *et al*[41]	Belgium	Prospective controlled	12 mo	23	27 (9)	23 age-matched	DXA and pQCT	↑10.4%	↓9.7%		↔
Haraldsen *et al*[31]	Norway	Prospective controlled	3 mo, 12 mo	21	25.1 (4.8)	45, not age-matched	DXA	↑	↔		
Cupisti *et al*[24]	Germany	Prospective controlled	12 mo	29	29.9 (18-40)	240 PCOS, age-matched	HOMA-IR			↔	
Aranda *et al*[19]	Spain	Prospective	6 mo, 12 mo	20	27.1 (8.0)		DXA and HOMA-IR	↑5.8%	↓6.3%	↔	↑A:G ratio
Auer *et al*[21]	Germany	Prospective	13 mo	45	27.5 (1.3)		DXA and HOMA-IR	↑	↓	↓	↔
Klaver *et al*[32]	The Netherlands and Belgium	Prospective	12 mo	162	24 (18-58)		DXA	↑10%	↓9%		↑
Gava *et al*[30]	Italy	Prospective	12 mo, 36 mo, 60 mo	50	30.1 (6.1)		DXA and HOMA-IR	↑	↔	↔	↔
Aranda *et al*[18]	Spain	Prospective	6 mo, 12 mo	12	27.1 (17-43)		HOMA-IR			↔	WC ↔
Auer *et al*[20]	Belgium and Norway	Prospective	12 mo	20	NR		DXA and HOMA-IR	↑	↔	↔	↔
Colizzi *et al*[23]	Italy	Prospective	12 mo, 24 mo	43	28.8 (5.6)		HOMA-IR			↔	WC ↑
Pelusi *et al*[37]	Italy	Prospective	30 wk, 54 wk	45	29.5		DXA and HOMA-IR	↑	↓	↔	↔
Wierckx *et al*[42]	Belgium	Prospective	12 mo	53	24.5 (7.0)		DXA	↑	↓		↑
Mueller *et al*[35]	Germany	Prospective	12 mo, 24 mo	45	NR		DXA	↑	↔		
Yahyaoui *et al*[43]	United States	Prospective	12 mo, 24 mo	47	25.7 (6.0)		HOMA-IR			↓	
Meriggiola *et al*[34]	Italy	Prospective	12 mo	15	35.7 (5.0)		DXA and HOMA-IR	↑	↔	↔	↑ (NS)
Berra *et al*[22]	Italy	Prospective	6 mo	16	NR		BIA and HOMA	↑	↓	↔	WC ↔
Elbers *et al*[27]	The Netherlands	Prospective	12 mo	17	23 (16-34)		MRI and EGC		↑ in VAT	↔	
Elbers *et al*[25]	The Netherlands	Prospective	4 mo, 12 mo	15	23 (16-34)		MRI and BIA		↓		
Elbers *et al*[26]	The Netherlands	Prospective	12 mo, 36 mo	10	24 (16-33)		MRI	↑ thigh muscle	↑ in VAT		
Polderman *et al*[38]	The Netherlands	Prospective	4 mo	13	23.1 (18-33)		BIA and EGC	↑		↑	
Van Caenegem *et al*[39]	Belgium	Cross-sectional	10 yr on GAHT (3-28)	50	37 (8)	50 age-matched	DXA and pQCT	9% more	30% less		Larger
Studies in Transgender women											
Haraldsen *et al*[31]	Norway	Prospective controlled	3 mo, 12 mo	12	29.3 (7.8)	77, not age-matched	DXA	↓	↑		
Auer *et al*[21]	Germany	Prospective	12 mo	24	34.8(1.4)		DXA and HOMA-IR	↔	↑	↑	↓

Klaver *et al*[32]	The Netherlands and Belgium	Prospective	12 mo	179	29 (18-66)		DXA	↓3%	↑28%		↓
Fighera *et al*[28]	Brazil	Prospective	31 mo	46	33.7 (10.3)		DXA	↓	↑		
Aranda *et al*[18]	Spain	Prospective	6 mo, 12 mo	6	18.8 (16-21)		HOMA-IR			↔	WC ↑
Auer *et al*[20]	Belgium and Norway	Prospective	12 mo	20	NR		DXA and HOMA-IR	↓	↑	↑	↔
Gava *et al*[29]	Italy	Prospective	12 mo	40	31.2 (9.8)		DXA and HOMA-IR	↓ (NS)	↑	↔	↔
Colizzi *et al*[23]	Italy	Prospective	12 mo, 24 mo	79	30.2 (9.6)		HOMA-IR			↑	WC ↑
Van Caenegem *et al*[40]	Belgium	Prospective	12 months, 24 months	46	33 (12)	49 (not followed prospectively)	DXA and pQCT	↓	↑		↓
Wierckx *et al*[42]	Belgium	Prospective	12 mo	53	30.3 (14.0)		DXA	↓	↑		↓
Mueller *et al*[36]	Germany	Prospective	12 mo, 24 mo	84	NR		DXA	↓	↑		
Yahyaoui *et al*[43]	United States	Prospective	12 mo, 24 mo	22	23.1 (9.4)		HOMA-IR			↔	
Elbers *et al*[27]	The Netherlands	Prospective	12 mo	20	26 (18-36)		MRI and EGC		↑ VAT	↑	
Elbers *et al*[25]	The Netherlands	Prospective	4 mo, 12 mo	17	26 (18-37)		MRI and BIA		↔		
Polderman *et al*[38]	The Netherlands	Prospective	4 mo	18	26.5 (18-36)		BIA and EGC	↓ (NS)		↑	
Lapauw *et al*[33]	Belgium	Cross-sectional	8 yr on GAHT (4-20)	23	41 (7)	46, age-matched	DXA, pQCT	20% lower	30% higher		

A:G ratio: Android-Gynoid ratio; BIA: Bioelectrical Impedance Analysis; DXA: Dual-energy X-ray Absorptiometry; ECG: Euglycaemic clamp; HOMA-IR: Homeostasis model assessment of Insulin Resistance; IR: Insulin resistance; MRI: Magnetic Resonance Imaging; NR: Not reported; NS: Not significant; pQCT: Peripheral Quantitative Computed Tomography: VAT: Visceral adipose tissue; WC: Waist circumference; WHR: Waist-hip ratio. Ages given as mean (SD or range).

transgender female participants. A large majority of the research was conducted in the Netherlands and Belgium (11 studies) and other European countries (6 Italian, 4 German, 2 Spanish, 1 Norwegian). Two studies were conducted outside Europe; 1 in the United States and 1 in Brazil. Results are summarised in Table 1.

All studies managed transgender men with testosterone and transgender women with oestrogen. With the exception of one study[31] all transgender women also received antiandrogen therapy (cyproterone acetate 50-100 mg or, in one study, goserelin acetate[36]) unless they were post-orchiectomy. The majority of studies treated transgender men with testosterone undecanoate 1000 mg IM every 12 wk (n = 12), or testosterone esters 250 mg IM every 2-3 wk (n = 6). Regimens in transgender women were more variable, though most studies used ethinyl estradiol or estradiol valerate in dosages of 100 g or 1-4 mg, respectively.

Transgender men

Controlled prospective studies: There are few controlled prospective studies (Table 1). Only 3 studies in transgender men included cisgender female control participants[24,31,41]. An initial 2007 study assessed 21 transgender men at initiation of testosterone therapy and followed them for 12 mo[31]. Comparisons were made with controls at baseline only and notably were not age-matched, with female controls almost 10 years older than the transgender male participants. This study noted no differences between groups at baseline, and that transgender men gained lean mass and lost fat mass, becoming more similar in body composition to male references over the 12-mo time period. These changes were noted as early as 3 mo after commencing hormone therapy[31].

A Belgian study of 23 transgender men compared them with 23 age-matched

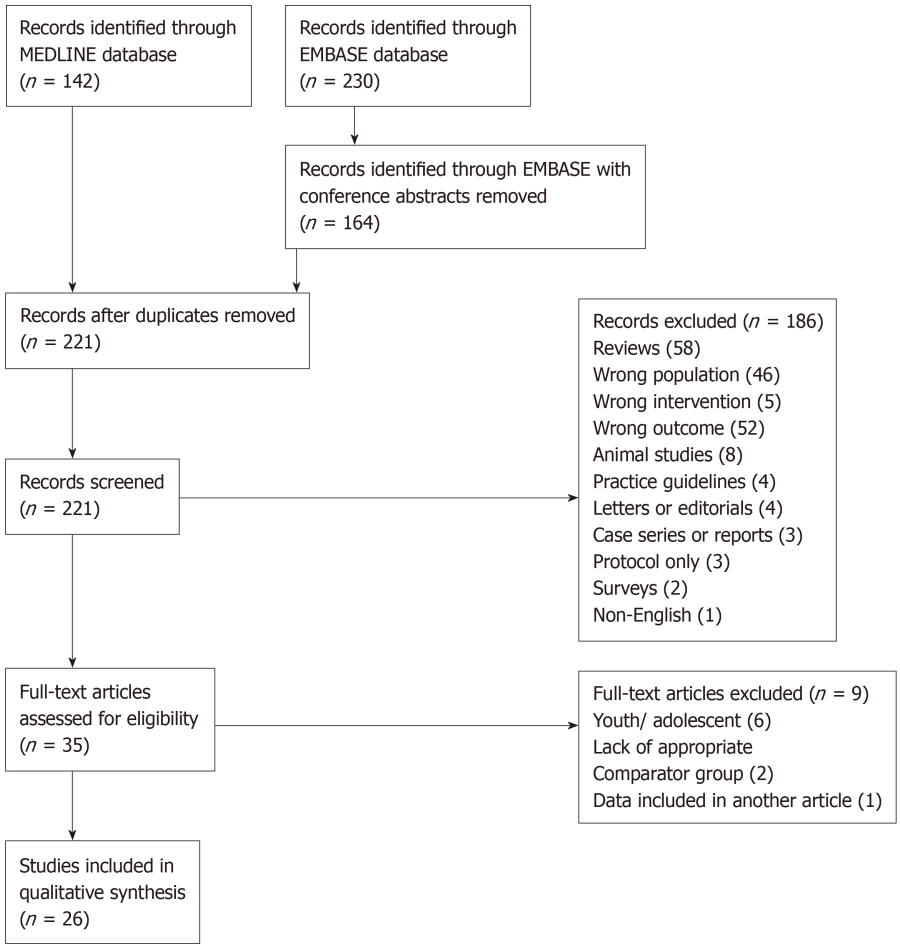

Figure 1 Study selection flowchart.

control women over 12 mo and found that treated transgender men gained lean mass and lost fat mass while the control women gained fat and lost lean mass and muscle strength[41]. The researchers also used peripheral quantitative computed tomography (pQCT) to investigate cross-sectional muscle area, finding significant increases in transgender men, along with increased grip strength.

To examine insulin resistance, 29 transgender men before and after commencing testosterone therapy were compared to 240 cisgender women with polycystic ovary syndrome (PCOS)[24]. Whilst the control women with PCOS and had significantly higher insulin resistance than the transgender men at baseline, there did not appear to be any induction of insulin resistance with testosterone therapy. Further, there was no correlation between serum testosterone concentrations and insulin resistance.

Prospective studies without controls: All uncontrolled prospective studies examining body composition have found that testosterone was associated with increases in lean mass (Table 1). The majority also found an associated decrease in fat mass, but despite this two imaging studies showed that testosterone was associated with an increase in visceral fat area[26,27]. The magnitude of visceral adipose tissue (VAT) gain was as high as 47% and correlated with the relative amount of weight gained during therapy. Although more recent studies have failed to report on visceral fat accumulation, several report an increase in waist-to-hip ratio. Increases in android-to-gynoid (A:G) fat ratios[19] occur, driven primarily by decreases in gynoid region fat (-14%), without increases in the android region[32].

Prospective studies reporting on insulin resistance are somewhat conflicting. Testosterone treatment was associated with increased insulin resistance measured by the hyperinsulinaemic euglycaemic clamp technique in only one study, which followed 13 people over 4 mo[38]. In contrast, no changes were seen in insulin sensitivity over 1 year in 17 healthy, nonobese young transgender men[27]. Many studies summarised in Table 1 have demonstrated no change (n = 10), or in two cases, decreased resistance. The largest prospective study of 50 transgender men followed

for 5 years found that testosterone had no impact on insulin resistance[30].

Cross-sectional evidence: All of the above studies assessed transgender men newly commencing testosterone therapy. However, when comparing transgender men on established therapy (mean treatment duration 10 years) compared with age-matched cisgender female controls, lean mass remained higher and fat mass remained lower suggesting persistence of changes over time[39].

Transgender women

Prospective studies with controls: Body composition changes are summarised in Table 1. Whilst two studies made comparisons to controls at baseline[31,40], there were no studies that followed the control group over time. There were baseline differences between transgender women and control men; with transgender women having less lean mass and more fat mass than control males even before commencing any kind of hormone therapy. Over time oestrogen therapy induced a loss of lean mass and gain of fat mass in their participants, which is consistent across studies in this review.

Prospective studies without controls: As shown in Table 1, almost all prospective data in transgender women is consistent. In transgender women commencing estradiol therapy, lean mass decreases and fat mass increases. There is also a shift in body fat distribution with a decrease in waist-to-hip ratio seen in 4 studies, and rise in gynoid fat[21,32,40,42]. The largest study involving 179 transgender women, demonstrated a 42% increase in leg fat and 34% increase in gynoid fat, compared to a more modest 18% increase in android fat[32]. These changes persist over the first two years of hormone therapy[36]. Oestrogen therapy was additionally associated with an 18% increase in VAT over 12 mo, along with a 38% increase in subcutaneous fat[27].

Whether feminising hormone therapy is associated with insulin resistance is unclear. Five studies noted increases in insulin resistance and three others found no change (Table 1). Of the studies reporting increased resistance, the largest and longest-running is Colizzi *et al*[23], who followed 79 participants for two years. The participants, who were metabolically healthy at baseline, had an increase in Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) values of 72% in the first year of treatment and by a further 9% over the second year, suggesting that the first 12 mo is an important period. A confounding factor was the presence of participants with psychiatric comorbidities who may have been on other medications capable of altering their insulin sensitivity, however there were only 12 participants in this category. Both of the studies employing the gold-standard euglycaemic clamp method found that GAHT in transgender women decreased peripheral glucose uptake, and simultaneously noted an increase in fasting insulin of up to 50%[27,38]. This would support the notion that oestrogen therapy has negative effects on insulin sensitivity. In addition, two of the three the studies reporting no change are limited by small participant numbers (n = 22 and n = 6)[19,43].

Cross sectional evidence: One cross-sectional study compared 23 transgender women who had been on GAHT for a mean of 8 years with 46 age-matched controls[33]. Fat mass was higher and lean mass was lower than controls including a 25% decrease in lower limb muscle area measured by pQCT.

DISCUSSION

There is evidence that hormone therapy can have a significant effect on body composition within 12 mo and these changes persist long-term. The effect on insulin resistance is uncertain. Changes to body composition were consistent across almost all studies: Transgender men on testosterone gained lean mass and lost fat mass, and transgender women on oestrogen experienced the reverse. No study directly contradicted these trends, though several small studies of short duration reported no changes. These results are consistent with a recent meta-analysis investigating body composition in individuals on GAHT, which found that hormone therapy in transgender individuals affects lean and fat mass significantly, with an increase in fat mass and decrease in lean mass observed in transwomen and the reverse occurring in transmen[44]. Results for insulin resistance are less consistent and uncertain.

It would be unethical to conduct a randomised controlled trial using hormone therapy and placebo, therefore prospective cohort studies represent the highest available level of evidence. However, there is a paucity of prospective controlled data and research with a longer follow-up duration is needed. It should also be noted that most of the participants in these studies are of Caucasian ethnicity, which limits the generalisability of the findings to transgender individuals of other backgrounds.

Insulin resistance, body composition and cardiovascular risk

Insulin resistance has been shown to independently predict a variety of poor outcomes including hypertension, obesity, and dyslipidaemia, as well as cardiovascular and all-cause mortality, even in non-diabetic metabolically well individuals[45-47].

In 2015, increased body mass index contributed to 4.0 million deaths globally (7.1% of the total number of deaths from any cause). 39% of these deaths occurred in people with body mass index less than 30, indicating that this increased risk is not confined to people who are clinically obese, and that small changes in body fat have the potential to influence long term mortality risk[48]. The distribution of body is also important, as central or "abdominal" obesity has been shown to confer a higher risk, and an elevated waist-hip ratio correlates with adverse cardiovascular outcomes more strongly than body mass index[49]. This is significant from the perspective of gender, as male "android" obesity which is more centrally distributed is therefore more predictive of poor outcomes than female "gynoid" obesity, which involves storage of fat around the hips, thighs and buttocks[12,50].

Body fat distribution and insulin resistance are interrelated[51]. Adipose tissue has been shown to decrease sensitivity to insulin through release of multiple mediators including free fatty acids, steroid hormones and proinflammatory cytokines[51]. There is some debate about whether visceral fat in particular has a greater influence over insulin sensitivity than subcutaneous fat. Visceral adipose tissue is more metabolically active, and its proximity to portal circulation may bestow a greater impact on hepatic lipid and glucose production[12]. However, some research suggests subcutaneous fat mass is more highly correlated with insulin resistance and attribute this to its greater contribution to circulating free fatty acid levels[50]. No association between fat distribution and insulin sensitivity is evident[27], suggesting that GAHT may influence insulin resistance by mechanisms other than body fat, including direct action on tissues. More research investigating the relationships between body fat distribution and insulin resistance in transgender people on hormone therapy is needed.

Impact of testosterone therapy in transgender men

Testosterone and body composition: Testosterone therapy in transgender men is associated with an increase in lean mass and decrease in fat mass. Data suggests that changes emerge within three months. Changes seen in the early years of hormone therapy are likely to persist in the longer term, with analysis of participants on hormone therapy for 10 years demonstrating consistent changes in body composition[39].

Testosterone and visceral fat: The evidence that testosterone decreases fat mass is strong however the effects on visceral fat specifically are less clear. Whilst testosterone appears to be associated with increased VAT; there are few studies, sample sizes are small with short follow-up, and the lack of controls do not allow for the comparison with normal visceral fat accumulation with time. More recent studies reporting an increase in waist-to-hip ratio in transgender men may indicate that increases in VAT are occurring. This is supported by evidence of raised android-to-gynoid fat ratios, suggestive of changes in body fat distribution[32]. Of note, Elbers *et al*[26] found no changes in VAT after 12 mo, but significant increases after 3 years, indicating these changes may take time to develop. Further controlled prospective studies are required to assess not only VAT but cardiovascular outcomes and mortality.

Testosterone and insulin resistance: The effects of testosterone on insulin resistance are unclear, even in cisgender populations. In cisgender men, testosterone deficiency is associated with insulin resistance, and this improves with testosterone replacement[15,16]. In men with both hypogonadism and established diabetes, testosterone replacement does not appear to improve glycaemic control[52]. Elevated levels of testosterone in cisgender women as occurs in PCOS, are associated with increased insulin resistance. In animal models, testosterone is associated with a decrease in insulin sensitivity[11]. This review suggests that testosterone therapy has no negative effect on insulin sensitivity and may even be associated with an improvement. This raises the possibility that the impairment in insulin sensitivity in PCOS is independent of hyperandrogenism.

Impact of estradiol therapy in transgender women

Estradiol and body composition: Estradiol therapy in transgender women appears to be associated with an increase in fat mass and decrease in lean mass, although prospectively controlled data is limited. Interestingly, the studies that were controlled demonstrate these differences at baseline[31,40]. Several studies have reported significantly less weekly physical activity in transgender women compared to control

men[33,39] possibly as a way to intentional to minimise muscle mass and influence body shape.

The increase in body fat associated with oestrogen therapy raises questions about the effect on cardiovascular risk. Elbers *et al*[27]noted that oestrogen and antiandrogen therapy was associated with a visceral fat increase of 18%, and subcutaneous fat increase of 38% over 12 mo. This represents an increase in the absolute amount of visceral fat, but a reduction in the ratio of visceral to subcutaneous fat. The implications for long-term cardiovascular health are unclear.

Estradiol and insulin resistance: Five of the eight studies reporting on insulin resistance in transwomen found that oestrogen therapy was associated with a worsening in insulin resistance measures. The remaining three studies were limited by small sample sizes. This is consistent with other high-oestrogen states such as women taking the oral contraceptive pill who have increased insulin resistance, as well as gestational diabetes mellitus during pregnancy[11]. Other research suggests that oestrogen has a protective role. Insulin sensitivity in cisgender women decreases after menopause and improves with menopausal hormone therapy[14]. Selective oestrogen receptor modulators have been shown to decrease insulin sensitivity, while Tamoxifen is associated with a 24% increase in diabetes risk in breast cancer survivors[13]. In cisgender men, decreased oestrogen production also induces insulin resistance[11]. The mechanism underlying this protective effect is largely unknown. Oestrogen has been shown to enhance peripheral insulin sensitivity *via* actions on skeletal muscle, liver and adipose tissue, and also has a role regulating energy intake and expenditure[13]. This review as well as other studies of high-oestrogen states may indicate that supra-physiological levels of oestrogen, in both men and women, can impair insulin sensitivity through a mechanism which is not entirely understood.

Gender-affirming hormone therapy has differing effects on body composition and insulin resistance in transgender men and women. Transgender men taking testosterone therapy have an associated gain in lean mass and decrease in fat mass. Transgender women taking oestrogen therapy have an associated decline in lean mass and gain in fat mass. The data examining the effect of hormone therapy on insulin resistance is so far inconsistent and limited. It is possible that oestrogen therapy in transgender women has a negative impact on insulin sensitivity. Both body fat and insulin resistance are known to impact cardiovascular risk and it is reasonable to conclude that gender-affirming hormone therapy may have an impact on long-term cardiovascular health.

The studies reviewed are limited by small sample sizes, young participants who may be yet to develop insulin resistance and short duration of follow-up. There is a paucity of controlled prospective research. These limitations make it difficult to draw conclusions about the long-term effects of gender-affirming hormone therapy on cardiovascular risk.

The long-term effects of hormone therapy on body composition and insulin resistance are unknown. Significant changes in body composition occur, most detrimentally in transgender women who gain fat mass and also have an increase in insulin resistance. Further research is therefore needed and given the long-term nature of cardiovascular disease progression, large prospectively controlled cohort studies are required. In the meantime, further research into the impact of hormone therapy on surrogate markers of cardiovascular risk is encouraged, and it would be prudent for clinicians to monitor markers of cardiovascular risk in patients taking gender-affirming hormone therapy.

ARTICLE HIGHLIGHTS

Research background

Transgender individuals receiving masculinising or feminising gender-affirming hormone therapy with testosterone or estradiol respectively, are at increased risk of heart disease and stroke. Testosterone and estradiol play important roles in regulating body fat and muscle and in the general population, males who have relatively high levels of testosterone compared with females are at higher risk for heart disease. The increased risk of heart disease may be related to the effects of testosterone or estradiol therapy on fat and muscle distribution, as well as insulin resistance, a measure of diabetes and heart disease risk. The effect of gender-affirming hormone therapy on these cardiovascular risk factors has not been extensively examined.

Research motivation

Studies demonstrating that transgender people on hormone therapy are at increased risk of adverse cardiovascular events highlight the importance of investigating surrogate markers while awaiting further long-term research. Both oestrogen and testosterone are capable of altering insulin resistance in both cisgender women and men, however, the impact of gender-affirming

hormone therapy on insulin resistance in transgender individuals is less clear. This review was conducted to examine the relationship between insulin resistance and its relationship to the changes in body composition brought about by hormone therapy in order to enable clinicians to proactively lower risk factors which may contribute to heart disease and diabetes.

Research objectives
We aimed to investigate the existing evidence of the effects of gender-affirming hormone therapy on insulin resistance and body composition, as this may provide insight into the long-term risks of hormone therapy in transgender individuals.

Research methods
We performed a systematic review of the literature based on PRISMA guidelines. MEDLINE, Embase and PsycINFO databases were searched for studies examining body composition, insulin resistance or body fat distribution in transgender individuals aged over 18 years on established gender-affirming hormone therapy. Studies were selected for full-text analysis if they investigated transgender individuals on any type of gender-affirming hormone therapy and reported effects on lean mass, fat mass or insulin resistance.

Research results
The search strategy identified 221 studies. After exclusion of studies that did not meet inclusion criteria, 26 were included (2 cross-sectional, 21 prospective-uncontrolled and 3 prospective-controlled). Evidence in transgender men suggests that testosterone therapy increases lean mass, decreases fat mass and has no impact on insulin resistance. Evidence in transgender women suggests that feminising hormone therapy (estradiol, with or without anti-androgen agents) decreases lean mass, increases fat mass, and may worsen insulin resistance. Changes to body composition were consistent across almost all studies: transgender men on testosterone gained lean mass and lost fat mass, and transgender women on oestrogen experienced the reverse. No study directly contradicted these trends, though several small studies of short duration reported no changes. Results for insulin resistance are less consistent and uncertain. There is a paucity of prospective controlled research, and existing prospective evidence is limited by small sample sizes, short follow up periods, and young cohorts of participants.

Research conclusions
Masculinising gender-affirming hormone therapy increases lean mass, decreases fat mass and has no impact on insulin resistance. Feminising gender-affirming hormone therapy decreases lean mass, increases fat mass, and may worsen insulin resistance. Further research is required to further characterise the impact of gender-affirming hormone therapy on body composition and insulin resistance in the medium-long term. Until further evidence is available, clinicians should aim to minimise risk by monitoring cardiovascular risk markers regularly in their patients and encouraging healthy lifestyle modifications is paramount.

Research perspectives
Clinicians need to be aware of body composition changes and potential insulin resistance changes. Proactive lowering of cardiovascular risk factors such as optimising diet and physical activity as well as managing weight, lipids, blood pressure and glucose are important. Long-term prospective controlled studies will provide further insights in the future.

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SYSTEMATIC REVIEW

20 ANOS DA VISIBILIDADE TRANS NO BRASIL

Hormone therapy and cancer risks in transgender people: a systematic review

A hormonioterapia e os riscos de câncer em pessoas transgênero: revisão sistemática

La hormonoterapia y los riesgos de cáncer en personas transgénero: revisión sistemática

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ABSTRACT

Objective: To identify the available evidence on the risk of developing cancer in transgender people undergoing hormone therapy. **Methods:** This was a rapid systematic review conducted in the PubMed, Embase, Virtual Health Library, Cochrane Library and Epistemonikos databases. Screening and data extraction were performed by independent reviewers using the Rayyan platform. Data extraction was carried out by 3 independent reviewers. We used the Joanna Briggs Institute checklists specific to cohort and case-control studies to assess the methodological quality of the included studies. **Results:** Five studies were included, 4 cohort studies and 1 case-control. The risk of transgender people developing cancer while on hormone therapy was identified by 2 studies and not identified in 3 studies. **Conclusion:** Despite studies with large sample sizes and rigorous selection criteria, the literature does not present a consensus on the association between hormone therapy and the development of cancer in transgender people.

Keywords: Transgender People; Malignant Neoplasms; Hormonal; Hormone Therapy; Systematic Review.

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INTRODUCTION

The concept of transgender or gender nonconforming refers to individuals whose gender identity differs from that assigned at birth.[1,2] This divergence may lead to gender transition, which includes hormone therapy and gender affirming surgeries, aimed to align the body with the individual's gender identity. Approximately 0.6% of the United States population identifies as transgender.[3] In Brazil, about 2% of the population is transgender.[4]

The World Professional Association for Transgender Health emphasizes the need for individualized clinical care for transsexual, transgender, and gender-nonconforming individuals. In line with the association's guidelines, which stress the importance of personalized care, studies have shown that gender-affirming surgery yields better outcomes when performed by multidisciplinary teams specialized in transgender healthcare. [5]

The National Policy for Comprehensive Health of Lesbians, Gays, Bisexuals, Transvestites and Transsexuals[6] and the guidelines for the transsexualization process in the Brazilian National Health System[7] highlight the fundamental need to guarantee access to outpatient care for transgender individuals undergoing the transsexualization process. This underscores the importance of multidisciplinary work within the Brazilian National Health System.[6-8]

The number of services and health professionals capable of providing comprehensive health care for transgender people remains insufficient, which demonstrates a gap in healthcare for this population in the country. As of 2022, only 11 services in Brazil were accredited to provide specialized care within the transsexualization process. In 2023, an additional 10 services were accredited.[9]

Hormone therapy enhances secondary sexual characteristics to align with an individual's gender identity. Transgender individuals may receive steroid hormones, prescribed by healthcare professionals, to reduce psychological distress and induce desired physical changes such as reduced skin oiliness, changes in body fat distribution, and hair growth/loss.[10] Gender-affirming hormone therapy may be administered in high doses over several decades[3]

The potential cancer risk associated with hormonal therapy in transgender individuals is a significant concern.[11] This potential risk is often used as a justification for contraindicating or discontinuing hormone therapy. The use of hormones, especially estrogen, may influence the development of cancer cells, which increases the risk of certain types of cancer, such as breast cancer. It is important to note that the risk varies according to several factors, including the type of hormone, the dose and the duration of treatment. Other risk factors,

Study contributions	
Main results	Five studies published between 2013 and 2021 were identified. The risk of developing cancer in transgender people undergoing hormone therapy was found in two studies, but there is no clear consensus for recommendations.
Implications for services	It contributes to comprehensive healthcare for transgender people. It supports more informed decision-making in the hormone therapy process and enhances the options available within the healthcare network for this population.
Perspectives	The review highlights the need for more randomized, long-term studies to assess the risks and benefits of hormone therapy in transgender people, in different subgroups, such as age, duration of use and types of hormones.

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such as family history and lifestyle habits, can also contribute to the development of the disease.

The benefits of hormone therapy for the mental health and well-being of transgender people are undeniable. Identifying cancer risks is crucial for guiding, shaping, and informing public health policies and raising awareness of the health issues affecting transgender individuals.

This rapid systematic review aims to identify the available evidence on the risk of developing cancer in transgender people undergoing hormonal therapy.

METHODS

This was a rapid review, following the steps outlined by the Cochrane Rapid Reviews Methods Group[12] to investigate the risk of developing cancer in transgender people undergoing hormone therapy. The rapid review methodology aims to enhance the efficiency of conducting the review while seeking to minimize the impact on the study's quality and bias.[13] The research question of this review was constructed based on the PECOS framework (population, exposure, comparator, outcomes and type of study) (Box 1). This rapid review was focused on the question: What is the risk of cancer development in transgender individuals using hormone therapies?

Methodological shortcuts included limiting the review to studies published in Portuguese, English, or Spanish, and conducting a quality assessment by one reviewer, later verified by a second. The protocol was registered on the Zenodo.org repository before study selection began.

The literature search was performed in October 2023 across PubMed, Embase, Cochrane Library, the Virtual Health Library (VHL), and Epistemonikos, without date restrictions. The search strategies were based on controlled vocabularies, including Medical Subject Headings (MeSH) from PubMed, Emtree from Embase, and Health Sciences Descriptors (DeCS) from Virtual Health Library (VHL). Uncontrolled terms, such as keywords and synonyms, were also used in developing the strategies (Box 2).

The following inclusion criteria were considered: studies that analyzed the risk of developing cancer in transgender people undergoing hormone therapy, published in Portuguese, English, and Spanish without date restrictions; and study designs included systematic reviews, cohort studies, non-randomized and randomized clinical trials. Cross-sectional studies were not included due to the difficulty in establishing a causal relationship between exposure and outcome. Three reviewers independently screened titles and abstracts according to predefined criteria, aided by the Rayyan reference manager. Data extraction was conducted independently by three blinded reviewers and organized in an Excel spreadsheet under topics such as author, year, study type, intervention description, cancer type reported, target population characteristics,

Box 1 – Research question structured by population, exposure, comparator, outcomes and study types

P	Transgender people
E	Hormone therapy (progesterone, testosterone, estrogen)
C	People without hormone therapy
O	Risk of developing any type of cancer
S	Systematic review, cohort study, non-randomized clinical trials, randomized clinical trials and case-control studies

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Box 2 – Search strategy and results obtained from each bibliographic database

Database	Search strategy	Results
PubMed	(((“Transgender Persons”[Mesh] OR Person, Transgender OR Transgender Person OR Transgenders OR Transgender OR Transgendered Persons OR Person, Transgendered OR Persons, Transgendered OR Transgendered Person OR Two-Spirit Persons OR Person, Two-Spirit OR Two Spirit Persons OR Two-Spirit Person OR Transsexual Persons OR Person, Transsexual OR Transsexual Person OR Transsexuals OR Transsexual) OR (“Transsexualism”[Mesh] OR Transgenderism)) AND ((((“Hormone Replacement Therapy”[Mesh] OR Therapy, Hormone Replacement OR Hormone Replacement Therapies OR Replacement Therapies, Hormone OR Therapies, Hormone Replacement OR Replacement Therapy, Hormone) OR (“Testosterone”[Mesh] OR “Testosterone therapy”)) OR (“Progesterone”[Mesh] OR “Progesterone therapy”)) OR (“Estrogen Replacement Therapy”[Mesh] OR Estrogen Replacement Therapies OR Replacement Therapies, Estrogen OR Therapies, Estrogen Replacement OR Therapy, Estrogen Replacement OR Replacement Therapy, Estrogen OR Estrogen Replacement OR Estrogen Replacements OR Replacements, Estrogen OR Replacement, Estrogen OR Estrogen Progestin Replacement Therapy OR Estrogen Progestin Combination Therapy))) AND (“Neoplasms”[Mesh] OR Tumor OR Neoplasm OR Tumors OR Neoplasia OR Neoplasms OR Cancer OR Cancers OR Malignant Neoplasm OR Malignancy OR Malignancies OR Malignant Neoplasms OR Neoplasm, Malignant OR Neoplasms, Malignant OR Benign Neoplasms OR Benign Neoplasm OR Neoplasms, Benign OR Neoplasm, Benign)	139
Cochrane Library	1 MeSH descriptor: [Transgender Persons] explodes all trees #2 (Transgender Person OR Transgenders OR Transgender OR Transgendered Persons OR Person, Transgendered OR Persons, Transgendered OR Transgendered Person OR Two-Spirit Persons OR Person, Two-Spirit OR Two-Spirit Persons OR Two-Spirit Person OR Transsexual Persons OR Person, Transsexual OR Transsexual Person OR Transsexuals OR Transsexual): ti ,ab,kw #3 MeSH descriptor: [Transsexualism] explodes all trees #4 (Transsexualism OR Transgenderism): ti ,ab,kw #5 MeSH descriptor: [Hormone Replacement Therapy] explodes all trees #6 (Therapy, Hormone Replacement OR Hormone Replacement Therapies OR Replacement Therapies, Hormone OR Therapies, Hormone Replacement OR Replacement Therapy, Hormone): ti ,ab,kw #7 MeSH descriptor: [Testosterone] explodes all trees #8 (“Testosterone therapy”): ti ,ab,kw #9 MeSH descriptor: [Progesterone] explodes all trees #10 (“Progesterone therapy”): ti ,ab,kw #11 MeSH descriptor: [Estrogen Replacement Therapy] explodes all trees #12 (Estrogen Replacement Therapies OR Replacement Therapies, Estrogen OR Therapies, Estrogen Replacement OR Therapy, Estrogen Replacement OR Replacement Therapy, Estrogen OR Estrogen Replacement OR Estrogen Replacements OR Replacements, Estrogen OR Replacement, Estrogen OR Estrogen Progestin Replacement Therapy OR Estrogen Progestin Combination Therapy): ti ,ab,kw #13 MeSH descriptor: [Neoplasms] explodes all trees #14 (Tumor OR Neoplasm OR Tumors OR Neoplasia OR Neoplasms OR Cancer OR Cancers OR Malignant Neoplasm OR Malignancy OR Malignancies OR Malignant Neoplasms OR Neoplasm, Malignant OR Neoplasms, Malignant OR Benign Neoplasms OR Benign Neoplasm OR Neoplasms, Benign OR Neoplasm, Benign): ti ,ab,kw #15 #1 OR #2 OR #3 OR #4 #16 #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 #17 #13 OR #14 #18 #15 AND #16 AND #17	2

To be continued

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Continuation

Box 2 – Search strategy and results obtained from each bibliographic database.

Database	Search strategy	Results
Embase	#1('transgender'/exp OR 'transgender') AND[embase]/ lim #2 (transsexual: ab,ti OR transsexualism:ab,ti OR transgenderism:ab,ti) AND [embase]/lim #3 'transsexualism'/exp AND [embase]/ lim #4 ('hormone substitution'/exp OR 'hormone substitution') AND [embase]/ lim #5 'hormone replacement ': ab ,ti AND [embase]/ lim #6 ('estrogen therapy'/exp OR 'estrogen therapy') AND [embase]/ lim #7 'estrogen replacement ': ab ,ti AND [embase]/ lim #8 'testosterone'/exp AND [embase]/ lim #9 'testosterone therapy ': ab ,ti AND [embase]/ lim #10 'progesterone'/exp AND [embase]/ lim #11 'progesterone therapy ': ab ,ti AND [embase]/ lim #12 (tumor *: ab ,ti OR neoplasm:ab,ti OR neoplasia*: ab,ti OR cancer*: ab,ti) AND [embase]/ lim #13 'neoplasm'/ mj AND [embase]/ lim # 14 # 1 OR #2 OR #3 # 15 # 4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 # 16 # 12 OR #13 # 17 # 14 AND #15 AND #16	212
Virtual Health Library	(Transgender people OR transgender persons OR transgender people OR transsexualisme OR transsexualidade OR transexualismo OR transexual) AND (hormone replacement therapy OR hormone replacement therapy OR hormone replacement therapy OR hormone replacement) AND (tumeurs OR neoplasms OR neoplasias OR câncer OR cancer OR tumor*) AND (db :("LILACS" OR "IBECS" OR "WPRIM" OR "BINACIS" OR "LIPECS" OR "BDENF" OR "SES-SP"))	101
Epistemonikos	(title :(Transgender OR Transsexual OR Transsexualism) OR abstract:(Transgender OR Transsexual OR Transsexualism)) AND (title:("Hormone Replacement" OR Progesterone OR Testosterone OR Estrogen) OR abstract:("Hormone Replacement" OR Progesterone OR Testosterone OR Estrogen)) AND (title:(Cancer OR tumor OR tumors) OR abstract:(Cancer OR tumor OR tumors))	22
Total		476

results, and study quality assessment. A narrative synthesis was performed due to methodological heterogeneity and outcome measure variability, which prevented a meta-analysis.

The methodological quality of the included studies was assessed using the Joanna Briggs Institute's critical appraisal tools. Checklists were used for cohort and case-control studies. Quality assessments were conducted by one reviewer and verified by a second.

RESULTS

A total of 476 publications were identified in the electronic databases. Of these, 380 were screened by title and abstract after duplicate removal, with 359 excluded. A total of 21 publications were accessed for full-text eligibility, and 5 publications were ultimately included in this rapid review.

Figure 1 shows the flowchart of the review with the numbers of studies included and excluded at stage of the review. The full list of studies excluded after full-text reading, along with the reasons for exclusion, can be found in the review protocol (https://doi.org/10.17605/OSF.IO/F7DK8). Of the studies included for this review, 4 were cohort studies;[17-20] 1 was a case-control study; [21] 2 studies were published in 2013;[17,21] 1 was published in 2019;[18] 1, in 2020;[19] and 1, in 2021,[20] with sample sizes ranging from 447 to 3,489 individuals (Table 1).

The outcomes analyzed in transgender people undergoing hormone therapy were diverse: 1 study analyzed the prevalence of cancer;[21] 2 studies analyzed the incidence of cancer;[17,18] and 2 studies, the rates of epithelial cell abnormalities and histopathological changes[19,20] (Table 2).

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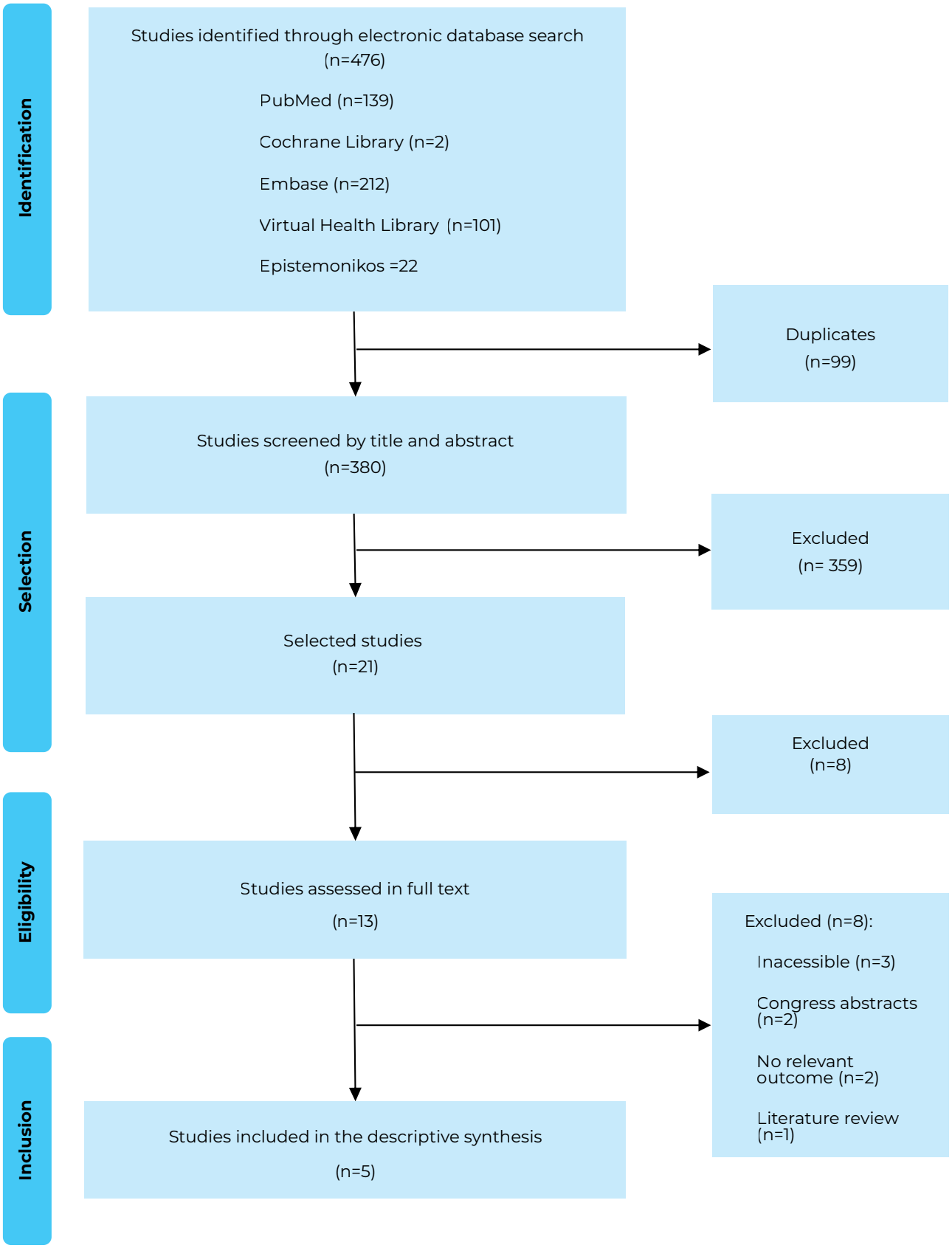

Figure 1 – Process of including studies in the review

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Table 1 – Characteristics of the included studies

Study	Location	Design	Date	N (% women)	Quality score
Gooren 2013[17]	Netherlands	Cohort	1975-2006	3,102 (74.3)	8/11
Block 2019[18]	Netherlands	Cohort	1972-2016	3,489 (64.7)	8/11
Williams 2020[19]	United States	Cohort	2009-2019	0[a]	8/11
Baker 2021[20]	United States	Cohort	2013-2019	447 (no information provided)	7/11
Wierckx 2013[21]	Belgium	Case-control	1986-2012	352 transgender (60.7); 1,033 cisgender (59.9)	8/10

a) Study involving transgender and cisgender men.

Table 2 – Outcomes analyzed in the included studies

Study	Type of cancer	Outcomes
Gooren 2013[17]	Breas	Cancer incidence in transgender men: 4.1/100,000, (95%CI 0.8;13.0) Transgender women: 5.9/100,000 (95%CI 0.5;27.4)
Block 2019[18]	Breast	Cancer incidence in combined transgender women and men: 43/100,000
Williams 2020[19]	Not specified	Atypical squamous cells of undetermined significance: Transgender men: 5.9%
Baker 2021[20]	Breast	Histopathological alterations Atypical lesions: 11/447
Wierckx 2013[21]	Not specified	Cancer prevalence Transgender men: 0 Transgender women 28/1,000 people

Regarding cancer incidence, 2 Dutch cohort studies did not identify a significant increase in new cases of breast cancer in the transgender population.[17,18] The incidence rate of breast cancer in transgender women was lower than that of cisgender women, but within the expected range for cisgender men. The breast cancer incidence rate in transgender men was lower than expected for cisgender women but within the expected range for cisgender men. Breast cancer incidence in both transgender groups was comparable to that of male breast cancers.

Another study[18] identified a higher risk of breast cancer in transgender women compared to cisgender men. It also identified a lower risk in transgender men compared to cisgender women. Most of the tumors identified were of ductal origin with estrogen and progesterone receptors, and 8.3% were attributed to the protein responsible for the mammary cell growth. Another important finding was that breast cancer in transgender individuals was diagnosed at a younger age compared to cisgender women. The absolute risk of breast cancer in transgender people remained low; therefore, breast cancer screening should follow the guidelines for cisgender people.[18]

A study from Belgium[21] showed that the cancer rate in transgender individuals was similar to or lower than that of cisgender men and women in the control group – none of the transgender men developed cancer during the follow-up period. The transgender women in this study had undergone hormone therapy for an average of 7.7 years (ranging from 3 months to 35 years); of these, 42.5% had received oral estrogen. The majority of transgender

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women (65%) had undergone orchiectomy. Transgender men had been on testosterone replacement therapy for an average of 9.4 years (ranging from 3 months to 49 years), and 65% of these individuals had received intramuscular testosterone treatment using a mixture of testosterone esters. Among transgender men, 86% had undergone hysterectomy and/or oophorectomy.[21]

Two U.S. studies[19,20] on epithelial cells and histopathological changes also showed no increased risk of cancer in transgender people. One of them analyzed Pap smear results in a group of cisgender women and transgender men. No significant relationship was found between the duration of testosterone therapy and the presence of transitional metaplastic cells or small cells in the Pap smears of transgender patients. The difference in epithelial cell abnormality rates between the two cohorts was not statistically significant.[19]

A total of 447 surgical breast specimens from gender-confirming chest contouring surgeries were reviewed and histopathological findings were compared between transgender men and male-centered gender nonconforming individuals who did and did not receive testosterone therapy. Intramuscular testosterone was administered to 85.6% of the sample, followed by 7.9% who used transdermal testosterone gel or cream. The majority of individuals who had undergone hormone therapy for at least 12 months had moderate lobular atrophy (p-value<0.001). Atypical lesions were detected in 2.5% of individuals who had undergone hormone therapy. The study's results indicated that hormone therapy did not lead to clinically significant changes in breast morphology (i.e., an increased frequency of atypical lesions or carcinoma), even after more than 12 months of use.[20]

Although the study population was small and young, with findings based on a limited sample, routine breast cancer screening of residual tissue following chest contouring surgery for transgender men and male-centered gender nonconforming individuals was considered important.[20] In addition to cancer, other morbidities such as venous thrombosis and/or pulmonary embolism, acute myocardial infarction, and cerebrovascular disease were tracked. Five percent of transgender women had venous thrombosis and/or pulmonary embolism. Transgender women had more myocardial infarctions than cisgender women in the control group (p-value 0.001), but the proportion was similar to that of men in the control group. The prevalence of cerebrovascular disease was higher in transgender women than in cisgender men in the control group (p-value 0.03). Rates of myocardial infarction and cardiovascular disease in transgender men were similar to those in cisgender individuals in the control group. The prevalence of type 2 diabetes was higher in both transgender men and women when compared to their respective controls.[21]

DISCUSSION

This review included five studies and aimed to identify scientific evidence on the risk of cancer in transgender people undergoing hormone therapy. Two of these studies[17,19] indicated an overall increased risk of neoplasia in this group, while the others[16,18,20] did not find this association. The studies included in this rapid systematic review presented robust methodologies with considerable population samples and well-defined inclusion and exclusion criteria. Breast cancer was the neoplasm most likely to develop in transgender individuals using hormone therapy.[17,19] It is noteworthy that the magnitude of this risk was not thoroughly evaluated in this review. Further research is needed to confirm and quantify this association.

Reliable epidemiological data remains scarce despite advances in studies in this field. Transgender people can develop cancer in

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organs related to the sex assigned at birth, as well as in newly formed organs.[17,19]

The increased cancer risk in transgender people, compared with the cisgender population, is multifactorial. This includes the high prevalence of sexually transmitted infections, increased exposure to risk factors such as smoking and alcohol consumption, and lack of adequate access to cancer screening.[11] Several publications have identified cancer as a priority in studies on transgender people health and have recognized the importance of large-scale population-based studies.[11,21]

Estrogen and testosterone therapy in transgender people must be continuously monitored due to the relative risk of other morbidities, such as the development of cardiovascular diseases.[20] Doses and methods of administration may also vary during hormone replacement, which reinforces the need for close monitoring by healthcare teams for transgender people on hormone therapy.[22]

Transgender people may present a distinct risk of developing chronic conditions and health conditions, as well as risk factors for these diseases and health conditions.[22] Specific recommendations for transgender people regarding cancer and other comorbidities are necessary for better comprehensive health care. However, there are uncertainties about cancer screening protocols for transgender people.[22]

The transsexualization process within the Brazilian National Health System is constantly marked by the lack of network coordination. Consequently, transgender people are often responsible for navigating their own therapeutic pathway, which frequently leads to seeking care in alternative spaces. These factors result in the abusive use of hormones, a lack of assistance from health professionals and treatment abandonment.

This situation worsens the health conditions of transgender people and contributes to the normalization of care neglect and the perpetuation of inequities.[23]

One of the limitations of this rapid review was the unavailability of two systematic reviews due to lack of access to full texts and the exclusion of cross-sectional studies. Rapid reviews are conducted using some shortcuts to shorten the execution time and, therefore, no contact was made with the authors to request the full text and analyze bias. The exclusion of cross-sectional studies is justified by the difficulty in establishing causal relationships in this type of design.

The absence of a meta-analysis prevents a more accurate and robust analysis of data, which limits the ability to generate accurate estimates of the effects of hormone therapy on neoplasms. Although the studies included in this review were not set in the Brazilian context, the findings of this review may support the development of public policies regarding the follow-up of transgender people undergoing hormone therapy.

Few studies were included, and neither a systematic review nor a randomized clinical trial, which are considered the highest levels of scientific evidence, were included. The evidence retrieved showed that certain types of studies, such as randomized clinical trials, are still lacking to better answer the research question.

The main objective of this review was to investigate the risk of developing cancer in transgender individuals undergoing hormone therapy. Although the results of the included studies were heterogeneous, making it difficult to establish a definitive conclusion on the increased risk, the need for further research in this area is evident, especially in the Brazilian context. Given the specificities of the Brazilian transgender population and the existing knowledge gaps, future studies should deepen the investigation of risk factors, the most prevalent types of cancer, and the best practices for monitoring the health of this population.

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A potential association with an increased incidence of cancer should not be used at this time as a contraindication for hormone therapy, but should support the development of recommendations for the follow-up of the transgender population undergoing hormone therapy. This aims at population screening and early diagnosis of cancer.

AUTHOR CONTRIBUTIONS

Uchimura LYT and Yonekura T collaborated with the study conception and design, analysis and interpretation of the results, drafting and critical reviewing of the manuscript content. Figueiró MF collaborated with the data analysis and interpretation, drafting and critical reviewing of the manuscript content. Quintans JR collaborated with the drafting and critical reviewing of the manuscript content. Freire P and Maia FHA collaborated with the conception, drafting and critical review of the manuscript content. All authors have approved the final version of the manuscript and declared themselves to be responsible for all aspects of its content, including ensuring its accuracy and integrity.

CONFLICTS OF INTEREST

The authors declare they have no conflicts of interest.

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RESUMO

Objetivo: *Identificar as evidências disponíveis sobre o risco de desenvolver câncer em pessoas transgênero que se tratam por meio de hormonioterapia.* ***Métodos:*** *Trata-se de uma revisão sistemática rápida nas bases de dados PubMed, Embase, Biblioteca Virtual em Saúde, Cochrane Library e Epistemonikos. A triagem e a extração de dados foram conduzidas por revisores independentes na plataforma Rayyan. A extração dos dados foi realizada por 3 revisores independentes. Utilizamos os checklists do Instituto Joanna Briggs específicos para estudos de coorte e caso-controle para avaliar a qualidade metodológica dos estudos incluídos.* ***Resultados:*** *Foram incluídos 5 estudos, sendo 4 estudos de coorte e 1 caso-controle. O risco de pessoas transgênero desenvolverem câncer em hormonioterapias foi identificado por 2 estudos e não identificado por 3 estudos.* ***Conclusão:*** *Apesar de estudos com grandes amostras e critérios de seleção rigorosos, a literatura não apresenta consenso sobre a associação entre a hormonioterapia e o desenvolvimento de câncer em indivíduos transgênero.*

Palavras-chave: *Pessoas Transgênero; Neoplasias Malignas; Hormonal; Hormonioterapia; Revisão Sistemática.*

RESUMEN

Objetivo: *Identificar las evidencias disponibles sobre el riesgo de desarrollar cáncer en personas transgénero que reciben tratamiento con hormonoterapia.* ***Métodos:*** *Se trata de una revisión sistemática rápida en las bases de datos PubMed, Embase, Biblioteca Virtual en Salud, Cochrane Library y Epistemonikos. La selección y extracción de datos fueron realizadas por revisores independientes en la plataforma Rayyan. La extracción de datos fue llevada a cabo por tres revisores independientes. Utilizamos las listas de verificación del Instituto Joanna Briggs específicas para estudios de cohortes y casos y controles para evaluar la calidad metodológica de los estudios incluidos.* ***Resultados:*** *Se incluyeron cinco estudios, de los cuales cuatro fueron estudios de cohortes y uno fue un estudio de caso y control. El riesgo de desarrollar cáncer en personas transgénero bajo hormonoterapia fue identificado en dos estudios y no identificado en tres estudios.* ***Conclusión:*** *A pesar de la existencia de estudios con muestras grandes y criterios de selección rigurosos, la literatura no presenta un consenso sobre la asociación entre la hormonoterapia y el desarrollo de cáncer en individuos transgénero.*

Palabras clave: *Personas Transgénero; Neoplasias Malignas; Hormonal; Hormonoterapia; Revisión Sistemática.*

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REVIEW

The Effect of Gender-Affirming Hormones on Gender Dysphoria, Quality of Life, and Psychological Functioning in Transgender Individuals: A Systematic Review

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Abstract

Gender-affirming hormone therapy (GAHT) is an essential part of gender affirmation for many transgender (including people with binary and nonbinary identities) individuals and although controlled studies are unethical, there remains limited evidence on the impact of GAHT on gender dysphoria, quality of life (QoL), and psychological functioning. Some clinicians and policy makers use the lack of evidence to argue against providing gender-affirming care. The aim of this review is to systematically and critically assess the available literature on the influence of GAHT on improving gender- and body-related dysphoria, psychological well-being, and QoL. Using Preferred Reporting Items for Systematic Review and Meta-analysis guidelines, we searched Ovid MEDLINE®, Embase®, and Ovid PsycINFO® from inception to March 6, 2019 to assess the influence of GAHT on (1) gender dysphoria, (2) body uneasiness, (3) body satisfaction, (4) psychological well-being, (5) QoL, (6) interpersonal and global functioning, and (7) self-esteem. Our search strategy found no randomized controlled trials. Ten longitudinal cohort studies, 25 cross-sectional studies, and 3 articles reporting both cross-sectional and longitudinal data were identified. While results are mixed, the majority of studies demonstrate that GAHT reduces gender dysphoria, body dissatisfaction, and uneasiness, subsequently improving psychological well-being and QoL in transgender individuals. However, all current researches are of low to moderate quality comprising longitudinal cohort studies and cross-sectional studies, making it difficult to draw clear conclusions and do not reflect external social factors unaffected by GAHT, which significantly impact on dysphoria, well-being, and QoL.

Keywords: gender-affirming hormone therapy; gender dysphoria; gender identity; mental health; quality of life; transgender

Introduction

Gender-affirming hormone therapy (GAHT) plays an important role in gender affirmation for many transgender (including people with binary and nonbinary identities) individuals.[1] Testosterone, the mainstay of masculinizing hormone therapy, aims to induce masculine secondary sex characteristics, as well as suppress/minimize feminine characteristics. Estrogens are the primary class of medications used to feminize.[1] Antiandrogens are an adjunct to estrogens, which suppress testosterone and include cyproterone acetate, spironolactone, and gonadotrophin-releasing hormone agonists.[2] By better aligning an individual's physical appearance with their gender identity, GAHT aims to reduce body and gender dysphoria, subsequently improving psychological well-being and quality of life (QoL).[2]

Awareness around the unique health care issues transgender people experience is on the rise, but there are still significant gaps in the research considering an

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estimated 0.3–0.5% of the population identify as transgender.[3] Transgender, including gender diverse and nonbinary people, experience many barriers to accessing health care, including difficulty in finding providers, discrimination, and the limited evidence to support gender-affirming treatments.[4] Gender-affirming treatments have been deemed medically necessary for many individuals,[5] but there is still limited evidence in the efficacy and long-term effects of these treatments.[6] Some clinicians and policy makers use the limit in outcome data to argue against providing gender-affirming care.[7] These factors compound the mental and physical health outcomes of transgender people.[4] It should be noted that untreated control group of transgender people is unethical and therefore cannot be the gold standard as evidence for this population. However, this should not preclude more robust longitudinal research, which would be of significant benefit and necessary to improve health care outcomes in transgender people. As such, the aim of this review is to systematically and critically assess the available literature on the influence of GAHT on improving gender- and body-related dysphoria, psychological well-being, and QoL.

Methods

This systematic review utilized the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) guidelines.[8]

Eligibility criteria

Observational studies (i.e., cross-sectional and longitudinal studies) were included, provided they were in English and in a peer-reviewed journal. Case reports and qualitative studies were excluded. Studies were eligible for inclusion provided they were assessing a transgender population on GAHT. This review did not exclude articles where no official diagnosis of gender dysphoria/gender identity disorder had been made according to the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM*) or equivalent. The review accepted all types, dosages, administrations, and durations of GAHT, self, or physician prescribed. Studies where the primary intervention was either gender-affirming surgeries or puberty blockers, or where the primary population was people with disorders of sexual development were excluded. All ages were included. We did not specifically exclude studies that included adolescents, but the youngest reported participant was 15 years.

To assess the efficacy of GAHT in improving gender- and body-related dysphoria, as well as psychological well-being and QoL, this review included both cross-sectional and longitudinal studies assessing the influence of GAHT on (1) gender dysphoria, (2) body uneasiness, (3) body satisfaction, (4) psychological well-being, (5) QoL, (6) interpersonal and global functioning, and (7) self-esteem.

Information sources and search strategy

The first author consulted an expert reference librarian for advice in conducting the electronic database search with input from the last author. Eligible studies were identified using Ovid MEDLINE®, Embase®, and Ovid PsycINFO®, from inception to March 6, 2019. The search used controlled vocabulary and keywords to outline the population (transgender individuals), intervention (GAHT), and outcomes (gender dysphoria, body uneasiness, body satisfaction, mental health, QoL, interpersonal and global functioning, and self-esteem).

The bibliographies of all relevant studies were used to uncover further articles.

Results

Search of the databases Ovid MEDLINE, Embase, and Ovid PsycINFO identified 1193 articles. Duplicates were removed, leaving 973. After abstract and title screening, 904 articles were excluded, leaving 69 for full-text screening. After full-text screening, 32 articles were identified. Six articles were sourced from the bibliographies of articles from the original search, giving a total of 38 (Fig. 1). All studies were observational; 10 were longitudinally designed (Table 1), 25 cross-sectional (Table 2), and 3 utilized both (Table 3). No randomized control trials were identified.

The influence of gender-affirming hormones on gender dysphoria

A dual design study (Table 3) first completed cross-sectional analysis of 359 transgender individuals (167 on GAHT, 192 not on GAHT), with unexpectedly higher reported levels of self-reported global gender dysphoria in people using masculinizing or feminizing GAHT.[9] When the questionnaire was broken into domains of subjective, social, sociolegal, and somatic indicators of gender identity, different patterns emerged for transgender people using feminizing and masculinizing hormone therapy. People using feminizing GAHT reported lower subjective, but higher levels of gender dysphoria related to social indicators of gender

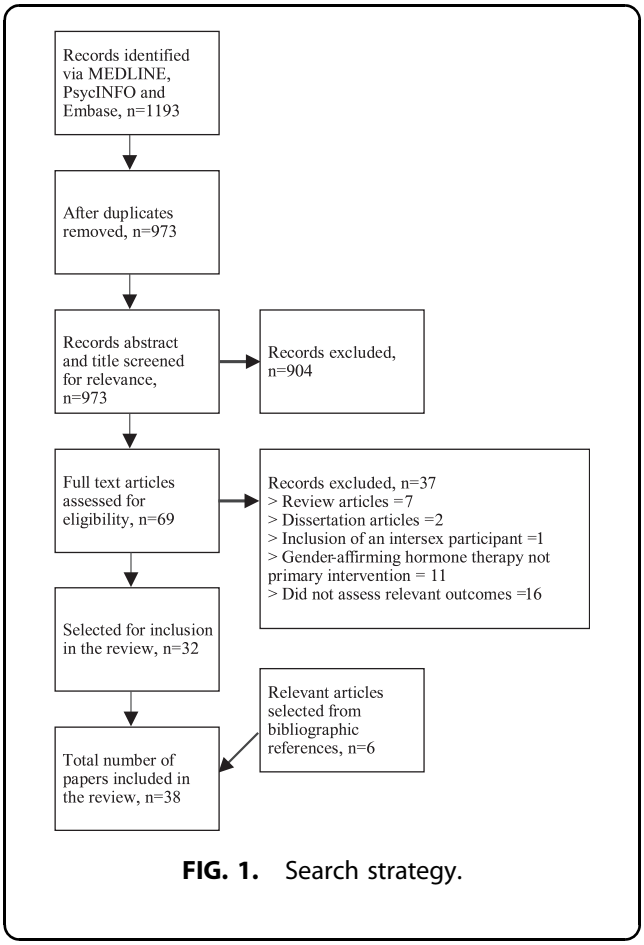

FIG. 1. Search strategy.

identity, compared to transgender people not on hormone therapy. Transgender people using masculinizing GAHT reported higher levels of gender dysphoria related to sociolegal indicators of gender identity, compared to transgender people not on hormone therapy.[9] Fifty-four of the 192 participants not on GAHT at cross-sectional analysis commenced GAHT, and gender dysphoria was measured after 3, 6, 12, and 24 months.[9] Global levels of gender dysphoria decreased at 3 months, then increased across all other time points. When separating subscales, over time, there was lower subjective gender dysphoria, whereas levels of gender dysphoria related to social and sociolegal aspects of gender identity increased.[9]

Another study completed across four European gender identity clinics, measured gender dysphoria at admission to clinic, then again at follow-up, which ranged between 4 and 6 years depending on the participant (Table 1).[10] Using the same questionnaire at both time points, they reported less gender dysphoria in groups that had either commenced GAHT after admission to the clinic, or had received no intervention, but had socially transitioned. No significant differences emerged between these two groups at follow-up.[10]

Only one study was identified examining the influence of GAHT on gender congruence (Table 2).[11] Gender congruence was measured using the Transgender Congruence Scale, a self-reported 15-item instrument assessing levels of an individual's comfort with their gender identity and body-gender congruence. For all transgender people (both those on masculinizing and feminizing hormone therapy), body-gender congruence and body image satisfaction were higher among individuals who had a greater number of gender-affirming treatments (from no treatment to hormones, partial top, partial bottom, and definitive bottom surgery).[11]

The influence of gender-affirming hormones on body uneasiness and body satisfaction

Longitudinal studies reported improvements in body uneasiness[9,12] and body image satisfaction following GAHT (Tables 1 and 3).[10,13] One reported less body uneasiness after 3, 6, 12, and 24 months of GAHT in both transgender people using feminizing and masculinizing hormone therapy.[9] Another reported improvements in body uneasiness in transgender people following 6 months of masculinizing hormone therapy, but found that it was still significantly worse compared to cisgender female control participants before and after GAHT.[12] Utilizing the Body Image Scale (BIS), one study in a sample of seven reported a nonsignificant trend toward higher levels of body satisfaction 3–10 months posthormone therapy.[13] Also using the BIS, higher levels of body satisfaction were reported after 4–6 years of GAHT, compared to scores when first admitted to gender identity clinic. Satisfaction scores at follow-up were also higher in those who had received GAHT compared to individuals who had received no intervention.[10]

When examining cross-sectional evidence, transgender people using feminizing hormone therapy reported less body uneasiness compared to transgender people not using feminizing hormones, with cumulative estradiol dose and androgen blockers predicting body uneasiness scores.[14] The same study reported no difference in body uneasiness between transgender people using masculinizing hormone therapy compared to transgender participants not using masculinizing hormones (Table 2).[14] A later study by the same primary author reported less body uneasiness in transgender

Table 1. Prospective Studies

Author	Year	Country	Defined study population	Age range	Types of GAHT	Follow-up period/duration of GAHT	Outcome measures (relevant)	Main finding(s)
Colizzi et al.[34]	2014	Italy	$N=107$, $n=78$ TF, $n=29$ TM, no prior surgery Newly assessed at gender clinic (formal diagnosis of GID based on DSM-IV)	≥18 Years	TF: transdermal estradiol gel (1.82 ± 0.53 mg/day) + cyproterone acetate (100 mg/day). TM: testosterone esters depot (250 mg every 26.24 ± 2.71 days).	12 Months	Anxiety (SAS); depression (SDS); psychopathology (SCL-90-R)	Less anxiety, depression, psychopathology, and functional impairment after GAHT. No significant differences between TF and TM participants.
Costantino et al.[43]	2013	Italy	$N=50$ TM, no prior surgery Formal diagnosis of GID based on DSM-IV	18–45 Years	Various. Testosterone enanthate, oral testosterone undecanoate, testosterone gel, intramuscular testosterone undecanoate.	12 Months	24 Questions related to mood, well-being and aggressive behavior (6-point-likert scale)	No change in mood and well-being after GAHT.
Defreyne et al.[40]	2018	United Kingdom	$N=155$, $n=91$ TF, $n=64$ TM Assessment at national gender clinic, no criteria reported	Median 27 years IQR 19–45	Not reported.	12 Months	Anxiety and depression (HADS)	Less depression after GAHT in TM and TF, no significant change in anxiety levels.
Heylens et al.[32]	2014	Belgium	$N=57$, $n=46$ TF, $n=11$ TM (Baseline = 56,[a] after GAHT = 47) Formal diagnosis of GID based on DSM-IV	Not reported	Not reported.	3–6 Months	Psychopathology (SCL-90)	Less psychopathology after GAHT. SCL-90 scores similar to mean SCL-90 scores of the general population following GAHT.
Keo-Meier et al.[33]	2015	United States	$n=48$ TM, $n=53$ cisgender control males, $n=62$ cisgender control females Criteria not reported	16–54 Years	Intramuscular depo-testosterone cypionate or ethanate ($n=46$). Transdermal testosterone ($n=2$).	3 Months	Psychopathology (MMPI-2)	Less psychopathology in TM after 3 months of testosterone therapy, relative to both female and male cisgender controls.
Lindgren and Pauly[13]	1975	United States	$N=7$, $n=4$ TM, $n=3$ TF Criteria not reported	17–46 Years	Not reported.	3–10 Months	Body image satisfaction (BIS)	No significant change after GAHT, but trended toward improved body satisfaction.
Manieri et al.[20]	2014	Italy	$N=83$, $n=56$ TF, $n=27$ TM Formal diagnosis of GID based on DSM-IV	Mean 33.7 ± 5.4 years	TF: Oral 17-beta-estradiol or transdermal estradiol + cyproterone acetate or spironolactone. TM: transdermal testosterone gel or intramuscular testosterone enanthate.	12 Months	Quality of life (WHOQOL-100)	TF: improved overall quality of life and improved quality of life related to sexual life, body image, and interpersonal relationships after GAHT. TM: improved quality of life related to body image and interpersonal relationships after GAHT.

(*continued*)

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Table 1. (Continued)

Author	Year	Country	Defined study population	Age range	Types of GAHT	Follow-up period/duration of GAHT	Outcome measures (relevant)	Main finding(s)
Turan et al.[12]	2018	Turkey	$N=77$, $n=37$ TM, $n=40$ cisgender female controls (matched for age and educational status) Formal diagnosis of GD via DSM-V at medical faculty	Mean 24.6±4.9 years	Intramuscular testosterone esters or intramuscular testosterone undecanoate.	6 Months	Body uneasiness (BUT); psychopathology (SCL-90-R)	Less body uneasiness and psychopathology in TM participants after GAHT. Body uneasiness and psychopathy worse in TM participants compared to cisgender female controls at baseline and 6 months.
van de Grift et al.[10]	2017	Netherlands, Germany, Belgium and Norway	$n=29$ no treatment, $n=36$ GAHT only, $n=136$ GAHT and gender-affirming surgery Formal diagnosis of GID based on DSM-IV	TF: mean 39.2±12.8 years, TM: mean 30.6±11.3 years	TF: oral estradiol valerate 4 mg daily + cyproterone acetate 50 mg daily or transdermal estradiol in those aged >45 years. TM: intramuscular testosterone undecanoate or testosterone gel or intramuscular testosterone esters.	Mean (SD) TF: 4.6 (2.3) years TM: 4.9 (1.6) years	Body image (BIS); GD (UGDS)	Less GD at follow-up. No difference in levels of GD between GAHT vs. no-GAHT group at follow-up. Baseline GD scores in no-GAHT group were significantly lower vs. intervention group. Improved body satisfaction at follow-up. Higher levels of body satisfaction in GAHT vs. no-GAHT group at follow-up.
van Kemenade et al.[41]	1989	Netherlands	$N=14$ TF, no prior surgery Criteria not reported	19–33 Years	Anadron (antiandrogen) without estradiol.	8 Weeks	Anxiety (STAI); Depression (SDS)	No change in the levels of anxiety and depression after GAHT.

[a]One participant did not complete baseline SCL-90.

BIS, Body Image Scale; BUT, Body Uneasiness Test; DSM-IV, The Diagnostic and Statistical Manual of Mental Disorders Fourth Edition; GAHT, Gender-Affirming Hormone Therapy; GD, gender dysphoria; GID, gender identity disorder; HADS, Hospital Anxiety and Depression Scale; IQR, interquartile range; MMPI-2, Minnesota Multiphasic Personality Inventory (Version 2); SAS, Zung Self-Rating Anxiety Scale; SCL-90, Symptom Checklist-90; SCL-90-R, Symptom Checklist-90 Revised; SD, standard deviation; SDS, Zung Self-Rating Depression Scale; STAI, State-Trait Anxiety Inventory; TF, transfeminine; TM, transmasculine; UGDS, Utrecht Gender Dysphoria Scale; WHOQOL-100, The World Health Organization Quality of Life-100.

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Table 2. Cross-Sectional Studies

Author	Year	Country	Defined study population	Age range	Types of GAHT	Duration of GAHT	Outcome measures (relevant)	Main finding(s)
Bartolucci et al.[22]	2015	Spain	$N=103$, no prior surgery $n=67$ TF (31 GAHT, 36 no-GAHT) $n=36$ TM (10 GAHT, 26 no-GAHT) Formal diagnosis of GID based on DSM-IV	Mean 30.5 ± 9.47 years	TF: oral estradiol valerate (2–4 mg/day), conjugated estrogen tablets (2.5 mg/day), or transdermal 17 beta estradiol patches (6 mg/day) + cyproterone acetate (25–50 mg/day). TM: intramuscular testosterone undecanoate or transdermal testosterone gel.	Not reported	Sexual quality of life (WHOQOL-100)	Better sexual quality in those on GAHT vs. no-GAHT.
Blanchard et al.[46]	1983	Canada	$N=55$ TF, $n=34$ GAHT, $n=21$ no-GAHT Formal diagnosis at gender identity clinic, no criteria reported	Not reported	Not reported.	Not reported	Psychopathology—depression and tension (MMPI)	No significant difference in levels of depression or tension in TF GAHT vs. no-GAHT.
Bonierbale et al.[37]	2016	France	$N=106$ TF, $n=37$ GAHT, $n=16$ no-GAHT TM, $n=15$ GAHT, $n=38$ no-GAHT Formal diagnosis of GID based on DSM-IV	18–58 Years	Not reported.	Minimum 3 months	Psychopathology (MMPI-2)	Less psychopathology in group on GAHT vs. no-GAHT.
Bouman et al.[31]	2016	United Kingdom	$N=71$ TF (38 GAHT, 33 no-GAHT) $n=3$ TM (excluded from analysis due to small numbers) Formal diagnosis at gender identity clinic, no criteria reported	>50 Years, mean 58.9 ± 6.5 years	TF: Oral or patch estradiol. Antiandrogen in 52%. TM: Not reported.	Not reported	Anxiety and depression (HADS); Self-esteem (RSES); interpersonal functioning (IIP-32)	TF on GAHT had less anxiety, less interpersonal problems, improved self-esteem vs. no-GAHT. No difference in levels of depression in GAHT vs. no-GAHT. When controlling for socialization, differences in anxiety, but not in self esteem remained between GAHT vs. no-GAHT.
Bouman et al.[47]	2017	United Kingdom	$N=1184$ cisgender controls $N=899$ trans people $n=259$ GAHT (179 TF, 80 TM) $n=640$ no-GAHT (393 TF, 247 TM) Self identified as transgender attending transgender health service	15–79 Years	Not reported.	Not reported	Anxiety and depression (HADS)	Overall trans people on GAHT had less anxiety vs no GAHT. TF on GAHT had less anxiety vs. no-GAHT. No difference in anxiety levels in TM GAHT vs. no-GAHT. Nearly threefold increased risk anxiety disorder in no-GAHT group vs. age-matched cisgender controls. Interpersonal problems and low self esteem appeared to predict anxiety symptoms.

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Table 2. (Continued)

Author	Year	Country	Defined study population	Age range	Types of GAHT	Duration of GAHT	Outcome measures (relevant)	Main finding(s)
Colton Meier et al.[21]	2011	United States	$N = 100$ TM $n = 66$ GAHT $n = 34$ no-GAHT Self identified as transgender	18–68 Years	Not reported.	Not reported	Depression, anxiety, and stress (DASS); Quality of life/functional health and well-being (SF-36v2)	TM on GAHT had less anxiety, less depression, less stress and improved health related quality of life.
Fisher et al.[14]	2014	Italy	$N = 125$ $n = 66$ TF (42 GAHT, 24 no-GAHT) $n = 59$ TM (26 GAHT, 33 no-GAHT Formal diagnosis of GID based on DSM-IV	TF: 33.1 ± 10.25 years TM 28.7 ± 6.5 years	TF: 28.6% estradiol valerate, 28.6% transdermal estradiol hemihydrate, 14.3% estradiol gel, 92.9% cyproterone acetate TM: 54.5% testosterone enanthate, 4.5% parenteral testosterone undecanoate, 40.9% transdermal testosterone.	Mean ± SD TF: 467 ± 323 days TM: 1,940 ± 2,595 days	Body uneasiness (BUT); psychopathology (SCL-90-R)	Less body uneasiness in TF on GAHT vs. no-GAHT. No difference in body uneasiness in TM on GAHT vs. no-GAHT. Cumulative estradiol dose predicted less body uneasiness in TF. No difference in SCL-90-R GAHT vs. no-GAHT.
Gomez-Gil et al.[38]	2008	Spain	$N = 163$ $n = 107$ TF (69 GAHT, 38 no-GAHT) $n = 56$ TM (10 GAHT, 46 no-GAHT Formal diagnosis of GID based on DSM-IV	TF Mean 29.9 ± 9 years, 27.6 ± 7.5 years	Not reported.	≥12 Months	Psychopathology (MMPI-2)	TF on GAHT reported less psychological distress. No difference in scores between TM GAHT vs. no-GAHT.
Gomez-Gil et al.[44]	2012	Spain	$N = 187$ $n = 113$ TF (84 GAHT, 29 no-GAHT) $n = 74$ TM (36 GAHT, 38 no-GAHT) Formal diagnosis of GID based on DSM-IV	15–61 Years	TF: either oral route (conjugated estrogens 1.8–2.4 mg/day or estradiol valerate 2–4 mg/day) or transdermal estradiol patches (3 mg twice per week/100 mg/day) generally with cyproterone acetate (25–50 mg/day) TM: either intramuscular injection of testosterone esters depot (1000 mg every 10–14 weeks) or daily transdermal testosterone gel (50 mg daily).	Mean ± SD TF: 11 ± 9.9 years TM: 4.7 ± 5.2 years	Social anxiety (SADS); anxiety and depression (HADS)	Less anxiety and depression in those on GAHT vs. no GAHT. No effect of GAHT duration on anxiety or depression.
Gomez-Gil et al.[23]	2014	Spain	$N = 193$ ($n = 119$ TF, $n = 74$ TM) $n = 120$ GAHT $n = 73$ no-GAHT Formal diagnosis of GID based on DSM-IV or ICD-10	16–67 Years	Not reported.	Not reported	Quality of life (WHOQOL-BREF)	Improved psychological and social quality of life in those on GAHT.
Gooren et al.[28,a]	2013	Thailand	$N = 60$ TF (kathoeys) $n = 44$ GAHT $n = 16$ no-GAHT Self identified as transgender	Mean 30.5 ± 17.5 years	Oral contraceptives predominantly.	Mean ± SD 9.7 ± 6.1 years	Quality of life/functional health and well-being (SF-36)	No differences in functional health and mental well-being/quality of life between TF GAHT vs. no GAHT.

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Table 2. (Continued)

Author	Year	Country	Defined study population	Age range	Types of GAHT	Duration of GAHT	Outcome measures (relevant)	Main finding(s)
Gooren et al.[29,a]	2015	Thailand	$N=120$ $n=60$ TF (kathoeys; 44 GAHT, 16 no-GAHT) $n=60$ TM (toms; 21 GAHT, 39 no-GAHT) Self identified as transgender	TM: Mean 24.8 ± 4.7 years	Not reported.	Mean ± SD TF: 11.7 ± 6.1 years TM: 9.5 ± 4.7 years	Quality of life/functional health and well-being (SF-36)	In TF no differences in functional health and mental well-being/quality of life GAHT vs. no-GAHT. In TM worse bodily pain, vitality, mental health, and general health in those on GAHT vs. no-GAHT.
Gorin-Lazard et al.[24]	2012	France	$N=61$ $n=31$ TF (25 GAHT, 6 no-GAHT) $n=30$ TM (19 GAHT, 11 no-GAHT) Formal diagnosis of GID based on DSM-IV	Mean 34.7 ± 10.3 years	TF: Estrogens + antiandrogens. TM: Testosterone + synthetic progestogens.	≥ 12 Months	Quality of life/functional health and well-being (SF-36)	Improved social, mental, and emotional quality of life in those on GAHT vs. no-GAHT. No difference to age- and sex-matched controls except for physical (worse) and general health (better).
Gorin-Lazard et al.[25]	2013	France	$N=67$ $n=36$ TF (29 GAHT, 7 no-GAHT) $n=31$ TM (20 GAHT, 11 no-GAHT) Formal diagnosis of GID based on DSM-IV	Mean 35.1 ± 10.2 years	TF: Estrogens + antiandrogens. TM: Testosterone + synthetic progestogens.	≥ 12 Months	Self-esteem (SSEI); depression (BDI); quality of life analysis (SQUALA); global assessment of functioning scale (GAF)	Better self-esteem, better quality of life, and less depression in those on GAHT vs. no-GAHT. No difference in global functioning between groups.
Jones et al.[16]	2018	United Kingdom	$N=563$ $n=139$ GAHT ($n=44$ female at birth, $n=95$ male at birth) $n=416$ no-GAHT ($n=166$ female at birth, $n=250$ male at birth) $n=8$ no data Formal diagnosis/assessment at transgender health service, no criteria reported	Mean 29.5 ± 13.7 years	Not reported.	Not reported	Body dissatisfaction (EDI-2); self esteem (RSES); anxiety, and depression (HADS)	Higher levels of self-esteem, less anxiety, less depression, and less body dissatisfaction in those on GAHT vs. no-GAHT.
Jones et al.[15]	2018	United Kingdom	$N=343$ $n=102$ GAHT $n=241$ no-GAHT Formal diagnosis/assessment at transgender health service, no criteria reported	Mean 30.2 ± 11.9 years	Not reported.	Not reported	Body satisfaction (HBDS); anxiety and depression (HADS); self esteem (RSES)	Higher levels of body satisfaction and self-esteem and less anxiety and depression in those on GAHT vs. no-GAHT.
Leavitt et al.[39]	1980	United States	$N=41$ TF $n=22$ GAHT $n=19$ no-GAHT Criteria not reported	18–35 Years	Oral conjugated estrogens (Premarin) and medroxyprogesterone acetate.	≥ 12 Months	Psychopathology (MMPI)	Less psychopathology in TF on GAHT vs. no-GAHT. Longer duration GAHT related to less psychopathology. Some MMPI domains in GAHT treated individuals were in normal limits.

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Table 2. (Continued)

Author	Year	Country	Defined study population	Age range	Types of GAHT	Duration of GAHT	Outcome measures (relevant)	Main finding(s)
Newfield et al.[26]	2006	United States	$N=365$ TM $n=248$ GAHT $n=117$ no-GAHT Self identified as transgender	Mean 32.8±11.2 years	Not reported.	Majority <5 years	Quality of life/functional health and well-being (SF-36v2)	Better functional health and mental well-being/quality in those on GAHT vs. no-GAHT.
Owen-Smith et al.[11]	2018	United States	$N=262$ $n=87$ TM (76 GAHT, 11 no-GAHT) $n=175$ TF (158 GAHT, 17 no-GAHT) Formal diagnosis of GID based on ICD-9	18 to >55 Years	Not reported.	Not reported	Body-gender congruence (TCS); body image satisfaction (RPSPP); anxiety (BAI); depression (CES-D-10)	Higher levels of body congruence and body image satisfaction in those on GAHT vs. no-GAHT. Lower levels of depression and anxiety in those on GAHT vs. no-GAHT.
Pauly and Lindgren[17]	1977	United States	$N=131$ $n=30$ TF (14 GAHT, 16 no-GAHT) $n=27$ TM (13 GAHT, 14 no-GAHT) Criteria not reported	Not reported	Not reported.	5 Months to 10 years	Body image satisfaction (BIS)	Improved body satisfaction in those on GAHT vs. no-GAHT.
Simbar et al.[18]	2018	Iran	$N=60$ $n=30$ GAHT $n=30$ no-GAHT Formal diagnosis of GID, no criteria reported	18–45 Years	Not reported.	≥6 Months	Quality of life (WHOQOL-BREF); Body Image Satisfaction (FBIQ)	No difference in quality of life or body satisfaction between GAHT vs. no-GAHT.
Valashany and Janghorbani[27]	2018	Iran	$N=71$ $n=30$ TF (6 GAHT, 24 no-GAHT) $n=41$ TM (10 GAHT, 31 no-GAHT) Formal diagnosis of GD based on DSM-V	TF: Mean 23.8±5.6 years. TM: Mean 24.2±6.3 years	Not reported.	Mean (SD) TF: 2.7 (9.6) years TM: 4.8 (13.0) years	Quality of life/functional health and well-being (SF-36)	Improvement in some aspects of quality of life when controlling for GAHT duration. Poorer quality of life compared to age- and gender- matched cisgender controls.
van de Grift et al.[19]	2016	Netherlands, Germany, Belgium and Norway	$N=660$ $n=374$ TF ($n=81$ GAHT, $n=293$ no-GAHT) $n=286$ TM ($n=16$ GAHT, $n=270$ no-GAHT) Formal diagnosis of GID based on DSM-IV	TF: mean 34.1±12.6 years. TM: mean 27.0±9.6 years	TF: oral estradiol valerate 4 mg daily + cyproterone acetate 50 mg daily or transdermal estradiol in those aged >45 years. TM: intramuscular testosterone undecanoate or testosterone gel or intramuscular testosterone esters.	Not reported	Body satisfaction (BIS)	No difference in body satisfaction between GAHT vs. no-GAHT.
Witcomb et al.[45]	2018	United Kingdom	$N=913$ $n=261$ GAHT $n=638$ no-GAHT $n=14$ missing data Self identified as transgender	15–79 Years	Not reported.	Not reported	Anxiety and depression (HADS)	Less depression in those on GAHT vs. no-GAHT.
Yang et al.[30]	2016	China	$N=209$ TF $n=37$ no-GAHT $n=172$ no-GAHT Self identified as transgender	18–45 Years	Not reported.	Not reported	Quality of life/functional health and well-being (SF-36)	Lower physical and mental quality of life in those on GAHT vs. no-GAHT.

[a]Same TF group.

BAI, Beck Anxiety Index; BDI, Beck Depression Inventory; CES-D-10, 10-item Center for Epidemiologic Studies Depression Scale; DASS, Depression, Anxiety, and Stress Scale; EDI-2, Eating Disorder Inventory-2; FBIQ, Fisher Body Image Questionnaire; GAF, Global Assessment of Functioning Scale; HBDS, Hamburg Body Drawing Scale; ICD-9, International Classification of Diseases Ninth Revision; ICD-10, International Classification of Diseases Tenth Revision; IIP-32, Inventory for Interpersonal Problems (Short Version); MMPI, Minnesota Multiphasic Personality Inventory; RPSPP, Revised Physical Self-perception Profile; RSES, Rosenberg Self Esteem Scale; SADS, The Social Anxiety and Distress Scale; SF-36, Short Form Health Survey; SF-36v2, Short Form Health Survey Version 2; SQUALA, Subjective Quality of Life Analysis; SSEI, Social Self-Esteem Inventory; TCS, Transgender Congruence Scale; WHOQOL-BREF, World Health Organization Quality of Life Assessment (Abbreviated Version).

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Table 3. Dual Design Studies

Author	Year	Country and design	Defined study population	Age range	Types of GAHT	GAHT duration	Outcome measures (relevant)	Main finding(s)
Fisher et al.[9]	2016	Italy Cross-sectional analysis	$N = 359$ $n = 219$ TF (125 GAHT, 94 no-GAHT) $n = 140$ TM (42 GAHT, 98 no-GAHT)	GAHT group: mean 33.9 ± 9.2 years and no GAHT group: mean 29.1 ± 9.3 years	TF: oral estradiol valerate 55%, oral ethinyl estradiol 26.4%, transdermal estradiol hemihydrate 28%, estradiol gel 19.2%, oral finasteride 3.2%, oral dutasteride 4%, cyproterone acetate 78.4%, and spironolactone 1.6%. TM: testosterone enanthate 53%, testosterone undecanoate in 23.3% and transdermal testosterone in 23.3%.	Mean (minimum; maximum) TF: 1331 (31; 13,445) days TM: 323 (33; 1,095) days	Body uneasiness (BUT); psychopathology (SCL-90-R); GD (GIDYQ-AA); depression (BDI II)	In GAHT vs. no-GAHT: Less body uneasiness TF and TM. No difference in levels of psychopathology. Global GD worse TF and TM. Subjective GD better in TF. Social GD worse in TF. Sociolegal GD worse in TM. Less depressive symptoms in TM.
		Longitudinal analysis	$N = 54$ $n = 28$ TF $n = 26$ TM Formal diagnosis of GD based on DSM-V			3, 6, 12 and 24 Months	Body uneasiness (BUT); psychopathology (SCL-90-R); GD (GIDYQ-AA); depression (BDI II)	Reduced body uneasiness. Reduced psychopathology. Global GD improved at 3 months then got worse at 6, 12, 24 months. Subjective GD improved with time. Social and sociolegal GD worsened with time. Less depressive symptoms.
Miles et al.[42]	2006	United Kingdom Cross-sectional analysis	$N = 103$ $n = 74$ TF (47 GAHT, 27 no-GAHT)		Oral conjugated equine estrogens or ethinylestradiol ± cyproterone acetate ± medroxyprogesterone acetate.	Either ≥28 or ≥3 months	Mood (POMS)	Higher mood scores on composed and confident scales in GAHT vs. no-GAHT groups.
		Longitudinal analysis	$N = 103$ (1) $n = 27$ TF (2) $n = 27$ TF (3) $n = 20$ TF Formal diagnosis of GID based on DSM-IV	(1) Mean 37.1 ± 8.7 years (2) Mean 39.6 ± 9.7 years (3) Mean 40.3 ± 7.5 years		(1) Before and after 3–12 months GAHT (2) ≥28 Months GAHT then ≥8 weeks withdrawal from GAHT (3) ≥3 Months GAHT then re-tested 3–12 months later	Mood (POMS)	(1) No change in mood with GAHT except for higher scores on composed and confident scales. (2) No influence of withdrawal of GAHT on mood. (3) No influence of duration of GAHT on mood.

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AR-002894

Table 3. (Continued)

Author	Year	Country and design	Defined study population	Age range	Types of GAHT	GAHT duration	Outcome measures (relevant)	Main finding(s)
Oda and Kinoshita[35]	2017	Japan Cross-sectional analysis	$N = 155$ TM $n = 53$ GAHT $n = 102$ no-GAHT	15–43 Years	Not reported.	Not reported	Psychopathology (MMPI)	No significant differences in psychopathology between GAHT vs. no-GAHT.
		Longitudinal analysis	$N = 14$ TM Formal diagnosis of GID based on DSM-IV			Mean ± SD 519 ± 365 days	Psychopathology (MMPI)	Improvements in psychopathology with GAHT. Psychotherapy and GAHT combined reduced symptoms of psychotherapy compared to GAHT alone.

BDI II, Beck Depression Inventory 2; GIDYQ-AA, Gender Identity/Gender Dysphoria Questionnaire for Adolescents and Adults; POMS, Profile of Mood States.

people both using masculinizing and feminizing hormones compared to those not on hormone therapy (Table 3).[9] Not all studies have been consistent when looking at cross-sectional data on body satisfaction. Some report higher levels of body satisfaction in those on GAHT,[11,15–17] whereas others report no difference between groups (Table 2).[18,19]

The influence of gender-affirming hormones on QoL

One longitudinal study reported improved QoL following 12 months of GAHT (Table 1).[20] In transgender people commencing feminizing hormone therapy, average QoL scores, as well as QoL related to body image, quality of sexual life, and interpersonal relationships significantly improved after 12 months of GAHT. Similarly, QoL related to body image and interpersonal relationships significantly improved following 12 months of testosterone therapy in people seeking masculinization.[20]

Cross-sectional evidence examining QoL in people using GAHT were conflicting and inconsistent. Some studies reported better QoL in those on GAHT,[21–27] while others reported no difference[18,28] and even worse QoL in people using masculinizing[29] and feminizing[30] GAHT (Table 2). One article assessed sexual QoL only, reporting higher sexual QoL in those on GAHT, compared to those not on hormone therapy (Table 2).[22] One study also reported family support and having an occupation as additional factors associated with improved QoL (Table 2).[23]

The influence of gender-affirming hormones on self-esteem, interpersonal, and global functioning

One longitudinal study assessed the influence of GAHT on interpersonal functioning over time. Both transgender people who used masculinizing and feminizing GAHT reported higher levels of QoL related to interpersonal relationships following GAHT (Table 1).[20] No longitudinal studies examining the influence of GAHT on self-esteem or global functioning were identified.

Cross-sectional studies reported higher levels of self-esteem[15,16,25,31] and less interpersonal problems[31] in participants on GAHT compared to those who were not (Table 2). However, when controlling for interpersonal issues, in particular, socialization, no significant difference between levels of self-esteem between groups was apparent.[31] No differences in the levels of global

functioning were reported between groups who had received GAHT compared to those who had not received hormone therapy.[25]

The influence of gender-affirming hormones on levels of psychopathology

Six longitudinal studies reported less psychopathology following GAHT,[9,12,32–35] all with differing follow-up periods (Tables 1 and 3). Two main questionnaires were utilized, the Minnesota Multiphasic Personality Inventory (MMPI)[33,35] and Symptom Checklist-90 (SCL-90),[9,12,32,34] both are designed to assess a broad range of psychological problems to measure progress of psychological treatments and have been revised and translated over time. The SCL-90 for example measures dimensions, including somatization, obsessive-compulsive, interpersonal sensitivity, hostility, anxiety, depression, paranoid ideation, phobic anxiety, and psychoticism.[36] Psychopathology appeared to be higher in transgender people using masculinizing hormone therapy compared to cisgender female controls matched for age and educational status at baseline and 6 months post-GAHT.[12] Psychotherapy and GAHT combined reduced symptoms of psychopathology compared to GAHT alone[35] and were similar to mean scores in the general population following 3–6 months of GAHT.[32]

Cross-sectional studies also utilized the MMPI[35,37–39] and SCL-90[9,14] to assess psychopathology, with mixed results (Tables 2 and 3). Studies reported less psychopathology in those on GAHT[37,39] or saw no difference between groups.[9,14,35] One study reported less psychopathology in transgender people using feminizing GAHT, but saw no difference between transgender people using masculinizing GAHT compared to transgender people not on hormone therapy.[38] Longer duration of GAHT was related to less psychopathology.[39] In addition, some domains of the MMPI in hormone-treated individuals were reported to be within normal limits.[39]

The influence of gender-affirming hormones on depression, anxiety, and other mood states

Longitudinal studies comparing levels of depression before and after GAHT either reported improvements[9,34,40] or no change (Tables 1 and 3).[41] Anxiety levels were found to improve[34] or in some studies, not change following GAHT.[40,41] One multidesign study examined mood states uniquely in a group of transgender people receiving feminizing GAHT at multiple time points on and off estrogen.[42] Utilizing the Profile of Mood States questionnaire, which measured six mood constructs on a scale (Composed/Anxious; Agreeable/Hostile; Elated/Depressed; Confident/Unsure; Energetic/Tired; and Clearheaded/Confused), the "Composed" scale and "Confident" scale were higher in people on estrogen compared to off estrogen (Table 3).[42] Another longitudinal study found no change in mood and well-being following 12 months of GAHT in a group of transgender people starting masculinizing hormone therapy (Table 1).[43]

Cross-sectional studies comparing levels of depression either reported less depressive symptoms in those on GAHT compared to those not on hormone therapy (Table 2)[11,15,16,21,25,44,45] or saw no difference between groups (Table 2).[31,46] One article reported less depression in transgender people receiving masculinizing GAHT compared to transgender people not on GAHT, but no differences were observed in transgender people receiving feminizing GAHT compared to those not on hormone therapy (Table 3).[9] Anxiety was also lower in those on GAHT compared to participants not on hormone therapy (Table 2).[11,15,16,21,31,44,47] While transgender people on GAHT had lower rates of possible or probable anxiety (53%) compared with transgender people not on GAHT (69%), rates still appeared higher than the 35% reported in the general population.[47] After matching participants to members of the general population based on age and experienced gender, those not on GAHT had almost a threefold increased risk of having an anxiety disorder.[47]

Discussion

This review was designed to examine the influence of GAHT on symptoms of gender dysphoria, including its effects on body satisfaction, QoL, and psychological well-being. The best quality evidence to date are longitudinal (but uncontrolled) studies examining the influence of GAHT over time. Most longitudinal evidence suggests that GAHT improves these outcomes, whereas the cross-sectional data are less consistent. Studies were conducted across different countries and cultures, some with limited access to gender-affirming treatments. Many cross-sectional studies had differing duration and doses of GAHT, with little or no control of confounding variables. This makes it difficult to both compare the research, as well as draw solid conclusions.

Gender dysphoria

Studies examining the influence of GAHT on gender dysphoria/body congruence show mixed results.[9–11] This may reflect the limited nature of existing

measures, as well as highlight the necessity of developing appropriate measures to provide equitable health care to transgender people. While subjective levels of gender dysphoria improved, global-, social-, and sociolegal-related levels of gender dysphoria worsened and this is likely explained by the many cultural and sociolegal difficulties that transgender people face.[9] Factors contributing to gender dysphoria are complex, and it is unrealistic to expect GAHT alone to completely relieve dysphoria and distress. For example, while testosterone therapy may very effectively masculinize physical characteristics such as voice and facial hair, chest size is typically unaffected and so chest dysphoria can worsen due to discordance with other masculinizing physical changes.[1] Alternatively, transgender people who begin feminizing hormone therapy and socially transition may experience increased social distress due to micro- and macroaggressions from others given that many physical changes of their endogenous puberty such as voice are not affected by GAHT.[1] Most societies place value in masculinity, and when it is perceived that someone is giving up this power and taking on feminine characteristics in some form, this can be the target of harassment and violence.

Existing data assessing the impact of GAHT on gender dysphoria were also limited by the comparison of unmatched groups, as well as a lack of control of potential confounding variables, including the effects of both social transition and psychological counseling on levels of gender dysphoria.[10] Studies are also limited by their use of questionnaires. Some have male and female versions, based on sex assigned at birth[48] and their applicability post-transition as well as which questionnaire researchers and clinicians should administer comes into question. The binary nature of the questionnaires does also not allow for assessment of nonbinary and genderqueer identities.[49]

Body uneasiness and body satisfaction

Gender-affirming hormones appear to improve body satisfaction and body uneasiness. Better quality data are longitudinal, all which reported improvements, but in small samples.[9,10,12,13] In addition, only some separated out analysis for feminizing and masculinizing hormone therapy in their sample[9,14] when differences in body dissatisfaction between these groups have been previously reported.[50,51] However, not all studies reported improvements in levels of body satisfaction with GAHT.[18,19] The authors of these suggested that the self-administering nature, dosages, and duration of GAHT might not have been sufficient to achieve desired results. Articles also varied in their use of questionnaires to assess body satisfaction and uneasiness. Some were not developed for transgender populations[52,53] or were noted to be limited in their ability to assess other indicators of body image, such as behaviors, cognition, and feelings.[10]

Quality of life

The literature supports the notion that GAHT improves QoL, however, only one longitudinal study was identified; all others were cross-sectional. Most studies did not control for confounding variables, such as societal factors that may also influence QoL, which is critically important. Studies reporting no difference[18,28] or worse QoL in those on GAHT[29,30] included participants with uncontrolled hormone usage, most outside of medical care. One study conducted in China reporting worse QoL in participants on GAHT stated that at the time of publication, no public hospitals provided professional health care services for transgender people, nor did many provide legal hormone therapy.[30] Results may reflect the health care barriers and discrimination that transgender people face, as well as potential consequences on well-being and QoL.

Self-esteem, interpersonal and global functioning

Gender-affirming hormones appear to improve self-esteem and interpersonal functioning. By influencing physical appearance, GAHT may increase self-perceived gender congruence and lead to improved social skills, self-confidence, and comfort in interacting with others.[25,26] The influence of GAHT on these factors is significant, as interpersonal problems increase the vulnerability of transgender people developing mental health problems.[54] In addition, low self-esteem and poor interpersonal functioning have both been linked to higher rates of anxiety[31,47] and depression[45] in transgender people. One cross-sectional article conducted in France reported no difference in global functioning between transgender individuals on GAHT or not.[25] Those residing in France may more easily access free health care, making it difficult to compare the transgender individuals of the study to those outside of organized care.[25]

Psychopathology, depression, and anxiety

Gender-affirming hormones may have a positive influence on mental health, most reporting less psychopathology, depression, anxiety, and improved mood following GAHT. Some reported levels in hormone

and nontreated individuals to be within normative ranges.[34,38,44] A sample of participants on masculinizing GAHT shifted toward a healthier direction 3 months post-GAHT compared to both matched cisgender male and female controls.[33] This finding is similar to what has been discussed in another review.[55] Studies were completed across different countries and cultures, with different health services and legislation, making cross-cultural validation difficult.[55]

The variability opens up the question as to why transgender people experience psychological distress and why it may improve with hormone therapy. One notion is that the psychological distress that transgender people experience is related to gender incongruence. Undergoing GAHT induces desirable physical characteristics more in keeping with their gender identity, therefore improving psychological well-being.[56] However, other research suggests that the distress and dysfunction transgender people experience is actually more closely linked to the violence and stigmatization they encounter, rather than gender incongruence itself.[57] One study[34] also highlighted the importance of controlling for variables, including life experiences, stigma, and discrimination, as well as exploring the benefit of concurrent psychological counseling on mental health outcomes.

Summary

It appears that GAHT may improve subjective gender- and body-related dysphoria, psychological well-being, and QoL. However, most evidence is of low to moderate quality, predominantly cohort studies and cross-sectional studies. Alleviation of gender dysphoria is the primary goal of GAHT, but we lack a quality measurement tool to assess it.[55] Assessment of secondary outcomes, including mental health and QoL, which arguably may be the most important outcomes of gender-affirming treatments may provide evidence as to the efficacy of GAHT.

There are several limitations to this review. The first being the lack of high-level evidence with most studies lacking control groups of transgender people not using GAHT. While we included articles where the primary intervention was GAHT, it was not always clear whether gender-affirming surgery had occurred during the studies and its impact on articles included in this review is unclear. The importance of subjective experiences of GAHT can also not be ignored; as such, the exclusion of qualitative evidence is another limitation to the review.

Many of the studies also reported varying durations, doses, and types of hormones, or did not report these data. When people are assessed at different stages of their transition, it makes it difficult to draw clear conclusions. Most studies did not separate out results by type of GAHT, and they also did not recognize gender diverse, including nonbinary individuals, which would have enabled assessment of their unique experiences while undergoing GAHT. In addition, most utilized the *DSM* or equivalent criteria as an inclusion requirement for study entry. As such, these individuals can be considered to be under medical supervision, with some receiving concurrent psychological intervention. This restricts study samples to only treatment seeking populations and so limits their applicability to the transgender population as a whole. The inclusion of studies in this review of participants outside of medical care, without a formal diagnosis, and who were self-prescribing hormones also possibly confounds results and potentially underestimates the influence of hormones on those with a diagnosis of gender dysphoria.

Conclusion

GAHT may be linked to improvements in gender dysphoria, body satisfaction, and uneasiness, subsequently improving psychological well-being and QoL in transgender individuals. However, all current research is of low to moderate quality, making it difficult to draw clear conclusions and do not reflect external social factors, which significantly impact on dysphoria, well-being, and QoL. Research that is ethical precludes high-quality studies. Ideally, more robust longitudinal studies examining the impact of GAHT will provide clinical benefit, allowing for realistic expectations, development of necessary support measures, and guide policy in transgender health. The lack of high-quality studies does not represent the absence of benefit, and our call for more research should not preclude the provision of gender-affirming care based upon published expert consensus guidelines.

Authors' Contributions

Conceptualization, T.R.v.L., J.D.Z., and A.S.C.; methodology, T.R.v.L., J.D.Z., and A.S.C.; investigation, T.R.v.L. and A.S.C.; formal analysis, T.R.v.L. and A.S.C.; writing—original draft, T.R.v.L. and A.S.C.; writing—review and editing, T.R.v.L., J.D.Z., and A.S.C.; funding acquisition, A.S.C.; supervision, A.S.C.

Author Disclosure Statement

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Abbreviations Used

BAI = Beck Anxiety Index
BDI = Beck Depression Inventory
BDI II = Beck Depression Inventory 2
BIS = Body Image Scale
BUT = Body Uneasiness Test
CES-D-10 = 10-item Center for Epidemiologic Studies Depression Scale
DASS = Depression, Anxiety, and Stress Scale
DSM = The Diagnostic and Statistical Manual of Mental Disorders
DSM-IV = The Diagnostic and Statistical Manual of Mental Disorders Fourth Edition
DSM-V = The Diagnostic and Statistical Manual of Mental Disorders Fifth Edition
EDI-2 = Eating Disorder Inventory-2
FBIQ = Fisher Body Image Questionnaire
GAF = Global Assessment of Functioning Scale
GAHT = gender-affirming hormone therapy
GD = gender dysphoria
GID = gender identity disorder
GIDYQ-AA = Gender Identity/Gender Dysphoria Questionnaire for Adolescents and Adults
HADS = Hospital Anxiety and Depression Scale
HBDS = Hamburg Body Drawing Scale
ICD-9 = International Classification of Diseases Ninth Revision
ICD-10 = International Classification of Diseases Tenth Revision
IIP-32 = Inventory for Interpersonal Problems (Short Version)
IQR = interquartile range
MMPI = Minnesota Multiphasic Personality Inventory
MMPI-2 = Minnesota Multiphasic Personality Inventory (Version 2)
POMS = Profile of Mood States
QoL = quality of life
RPSPP = Revised Physical Self-perception Profile
RSES = Rosenberg Self Esteem Scale
SADS = The Social Anxiety and Distress Scale
SAS = Zung Self-Rating Anxiety Scale
SCL-90 = Symptom Checklist-90
SCL-90-R = Symptom Checklist-90 Revised
SD = standard deviation
SDS = Zung Self-Rating Depression Scale
SF-36 = Short Form Health Survey
SF-36v2 = Short Form Health Survey Version 2
SQUALA = Subjective Quality of Life Analysis
SSEI = Social Self-Esteem Inventory
STAI = State-Trait Anxiety Inventory
TCS = Transgender Congruence Scale
TF = transfeminine
TM = transmasculine
UGDS = Utrecht Gender Dysphoria Scale
WHOQOL-100 = The World Health Organization Quality of Life-100
WHOQOL-BREF = World Health Organization Quality of Life Assessment (Abbreviated Version)

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Systematic Review and Meta Analysis

Cardiovascular disease in transgender people: a systematic review and meta-analysis

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Abstract

Objective: Hormone therapy in transgender people might be associated with an increased risk of cardiovascular disease (CVD). We aimed to investigate whether the risk of CVD is increased in transgender people compared with people of the same birth sex.

Design and methods: PubMed, Cochrane, Embase, and Google Scholar were searched until July 2022. Studies evaluating cardiovascular events in transgender women or men were included. Primary outcomes were stroke, myocardial infarction (MI), and venous thromboembolism (VTE). The risk for transgender women versus cisgender men and for transgender men versus cisgender women was analysed through random-effects meta-analysis.

Results: Twenty-two studies involving 19 893 transgender women, 14 840 transgender men, 371 547 cisgender men, and 434 700 cisgender women were included. The meta-analysis included 10 studies (79% of transgender women and 76% of transgender men). In transgender women, incidence of stroke was 1.8%, which is 1.3 (95% confidence interval [CI], 1.0-1.8) times higher than in cisgender men. Incidence of MI was 1.2%, with a pooled relative risk of 1.0 (95% CI, 0.8-1.2). Venous thromboembolism incidence was 1.6%, which is 2.2 (95% CI, 1.1-4.5) times higher. Stroke occurred in 0.8% of transgender men, which is 1.3 (95% CI, 1.0-1.6) times higher compared with cisgender women. Incidence of MI was 0.6%, with a pooled relative risk of 1.7 (95% CI, 0.8-3.6). For VTE, this was 0.7%, being 1.4 (95% CI, 1.0-2.0) times higher.

Conclusions: Transgender people have a 40% higher risk of CVD compared with cisgender people of the same birth sex. This emphasizes the importance of cardiovascular risk management. Future studies should assess the potential influence of socio-economic and lifestyle factors.

Keywords: transgender, gender dysphoria, gender-affirming hormone therapy, cardiovascular disease, stroke, myocardial infarction, thrombosis

Significance

The use of hormone therapy might be associated with an increased risk of cardiovascular disease in transgender people, but evidence is limited. By conducting an extensive literature search, we found that both transgender women and men have an increased risk of major cardiovascular events compared with people with the same birth sex. These findings highlight the potential influence of socio-economic and lifestyle factors on cardiovascular health in this population. Our study is the first to compare cardiovascular risk between transgender and cisgender people of the same birth sex and provides the most extensive literature search yet, making it a pioneering contribution to the field. Our results emphasize the importance of implementing effective cardiovascular risk management strategies for transgender people.

Introduction

Transgender people often use gender-affirming hormone therapy to align their physical appearance with their gender identity. The demand for medical assistance to initiate hormone therapy increases annually.[1] For trans women (assigned male at birth, female gender identity), hormone therapy consists of estradiol preparations, usually combined with anti-androgens to suppress testosterone. Trans men (assigned female at birth, male gender identity) use testosterone preparations.[2]

It is hypothesized that sex hormones play a significant role in cardiovascular risk: cisgender men (assigned male, male gender identity) generally have a greater propensity to develop cardiovascular disease (CVD) compared with cisgender women (assigned female, female gender identity).[3,4] Decreasing oestrogen in perimenopausal cis women coincides with the development of cardiovascular risk factors (eg, higher levels of low-density lipoprotein cholesterol and blood pressure) and increased cardiovascular events.[4-9] Hence, oestrogen is hypothesized to protect the heart and vasculature.[4,10] However, past studies failed to demonstrate this. For example, the Women's Health Initiative Trials, where oral oestrogen was administered to postmenopausal cis women, had to be

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terminated prematurely due to an increase in cardiovascular events.[11] A similar outcome was observed in another study with postmenopausal women.[12] Considering this, oestrogen administration may increase cardiovascular risk.

Besides in cisgender people, hormone therapy appears to affect cardiovascular risk in transgender people as well: testosterone use in transgender men is associated with lipid and blood pressure elevations.[13-16] In contrast, feminizing hormone therapy presents an interesting paradox: while it improves blood pressure and lipid profiles, transgender women still seem to experience a higher incidence of cardiovascular events, such as stroke and myocardial infarction (MI).[17-19] To date, a definite explanation for this contradiction remains elusive. In addition to stroke and MI, the risk of venous thrombosis appears to be the most prominent in transgender women.[17,18] This is in line with previous evidence from studies with cisgender women who use estradiol as oral contraceptive or hormone replacement therapy.[11,20] Alterations in coagulation factors influenced by feminizing hormone therapy could be the mechanism behind this.[21]

It is apparent that socio-economic and lifestyle factors may also have a substantial impact on CVD development. A Danish study revealed lower socio-economic status and increased cardiovascular mortality in people with Klinefelter syndrome.[22] Two studies found that socio-economic status based on income or social and legal conditions is lower for transgender people as well.[23,24] Additionally, discrimination and stigma experienced by transgender people could lead to risk behaviour and decreased health and socio-economic outcomes.[25,26]

Knowledge about cardiovascular risks for transgender people is limited due to small study populations and variations in follow-up durations and hormone types (ie, different administration routes, different types of anti-androgens, and different pharmaceutical formulations of estradiol). Nonetheless, studies indicate an increased incidence of cardiovascular events among transgender men and women.[17,27] Available meta-analyses on cardiovascular events did not compare the risk estimates of the trans population with those of the cisgender population. Therefore, the aim of this systematic review and meta-analysis is to determine whether the risk of several major cardiovascular events, the risk of any CVD, and the risk of death due to any CVD are increased in transgender people compared with cisgender people of the same birth sex. Additionally, this review aims to explore potential factors associated with CVD in transgender individuals by analysing and interpreting any observed heterogeneity among the studies.

Methods

Literature search

A systematic search of the following 4 databases was conducted from database inception up to July 2022: PubMed, Cochrane, Embase, and Google Scholar. The exact date and strategy of each search are displayed in Supplemental Material S1.

Study selection

All titles and abstracts were screened for eligibility by 2 reviewers (M.Z. and C.W.) distinctively according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines,[28] after the automatic removal of duplicate records. Afterwards, the remaining studies were read in full text to obtain a final selection of included articles. In cases of uncertainty regarding article inclusion, decisions were made through discussion among the 2 reviewers and a third person. Included were peer-reviewed studies of any language assessing cardiovascular events for trans women and/or men separately, when full text was available. Studies were excluded when only perioperative cardiovascular events were described. Case reports, case series, review articles, systematic reviews, and meta-analyses were excluded. References of the included studies were screened for additional eligible studies. Studies were checked for duplicates and overlapping data based on author(s), institution, and study design. Authors were contacted in case of doubt about overlapping data or when full text was not available.

Outcomes and data extraction

The main outcomes of interest were the major adverse cardiovascular events stroke, MI, and venous thromboembolism (VTE; deep vein thrombosis as well as pulmonary embolism). The secondary outcomes were overall occurrence of any CVD and death due to any CVD. Data were extracted from each study by 2 reviewers (M.Z. and C.W.) cooperatively and included study design, sample size of transgender group and cisgender group, age, follow-up duration, and outcomes. Data on cardiovascular events were extracted as observed cases and as odds ratio, standardized incidence ratio, or hazard ratio as effect estimator with confidence intervals (CI). Incidence proportions per outcome measure were calculated from observed cases. Risk estimates for trans women were compared with those for cis men and for trans men compared with cis women.

Statistical analysis

Statistical analyses were performed using STATA®, version 15.1. Included in the meta-analysis were studies comparing risk estimates of either trans women or trans men with those of cisgender people of the same birth sex. Studies without a control group compromising cisgender people of the same birth sex were ineligible for inclusion in the meta-analysis. When merely observed cases or incidence rates were available for transgender and cisgender groups, these were used to calculate odds ratios or incidence rate ratios, respectively. For outcomes with zero events in one or both arms, relative risks and CIs were calculated using the treatment arm continuity correction approach to account for uneven sample sizes.[29,30] The used formulas are shown in Supplemental Material S2.

Odds ratios, hazard ratios, incidence rate ratios, standardized incidence ratios, and relative risks were treated as equivalent measures of risk. The effect sizes and 95% CIs were log-transformed before analysis. Standard errors needed for conducting the meta-analysis were calculated based on the log-transformed CIs. Symmetry of the CIs was checked based on the logarithmic upper and lower borders. In case of asymmetry, the longest arm of the CI was used to calculate the corresponding standard error. The used formulas are shown in Supplemental Material S2. A random-effects meta-analysis for each outcome measure was conducted by using the log effect sizes and standard errors, which were then back-transformed for presentation.

A sensitivity analysis examined the impact of studies where transgender participants did not use hormones, by omitting

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studies from the meta-analysis in which less than 50% of the transgender participants used hormones or when hormone use could not be assumed based on information in the article. The newly pooled relative risks were compared against the initially found effects to evaluate any disparities between them.

Assessment of bias and heterogeneity

A risk of bias assessment for studies with a control group was performed using the Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I) tool.[31] The Robvis visualization tool was used to visualize the risk of bias for these studies.[32] Risk of bias for studies without a control group was assessed according to the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Studies Reporting Prevalence Data.[33] All evidence on CVD in the transgender population is regarded as equally valuable in this field of research. We therefore did not assess publication bias. An assessment of heterogeneity was performed for each outcome measure by means of I^2 index and *P*-value.

Results

Included studies

The systematic search yielded 1215 articles (PubMed $n = 447$; Cochrane $n = 44$; Embase $n = 573$; Google Scholar $n = 151$). After the removal of duplicates, 894 articles remained. Based on the title and abstract, 799 articles were excluded for not meeting the inclusion criteria. The remaining 95 articles were assessed for eligibility. Seventy-four studies were excluded for reasons including incorrect article type, unavailability of full text, cohort overlap, and evaluating cardiovascular events for trans women and men as one group. Three studies were found by backward reference searching of included articles, of which one met the inclusion criteria. One additional eligible study was found via an email notification. Finally, 22 studies were included in the review.[18,34-54] Figure 1 shows the PRISMA flow diagram of study selection.[28]

Participant and treatment characteristics

A total of 19 893 trans women, 14 840 trans men, 371 547 cis men, and 434 700 cis women participated in the included studies. For both trans women and men, a wide age range from 3 to 74 years was observed, with the majority between 18 and 50 years. Follow-up duration varied from 3 months to 35 years for trans women and from 3 months to 49 years for trans men.

Hormone therapy for trans women consisted of estradiol tablets, transdermal patch or gel, or injections. In only one study, 5 trans women used ethinylestradiol in doses of 30-50 mcg as only type of estradiol. Additionally to estradiol, most trans women used anti-androgens to suppress the production or effects of testosterone. The types of anti-androgens used were gonadotropin-releasing hormone agonist (GnRHa) injections, oral cyproterone acetate (CPA), or oral spironolactone. In a few studies, oral finasteride or progestin was also used to suppress testosterone.

Types of hormones used by trans men were mostly intramuscular testosterone injections. Oral tablets and transdermal gel or patches were used less often. In 1 study, trans men additionally used oral lynestrenol tablets of 5 mg/day when sex reassignment surgery had not taken place.

One study included adolescents who merely used GnRHa or progestins as puberty blockers. In some studies, the specific types of used hormones were not specified. In 2 studies, the use of hormone therapy was not mentioned at all. In some

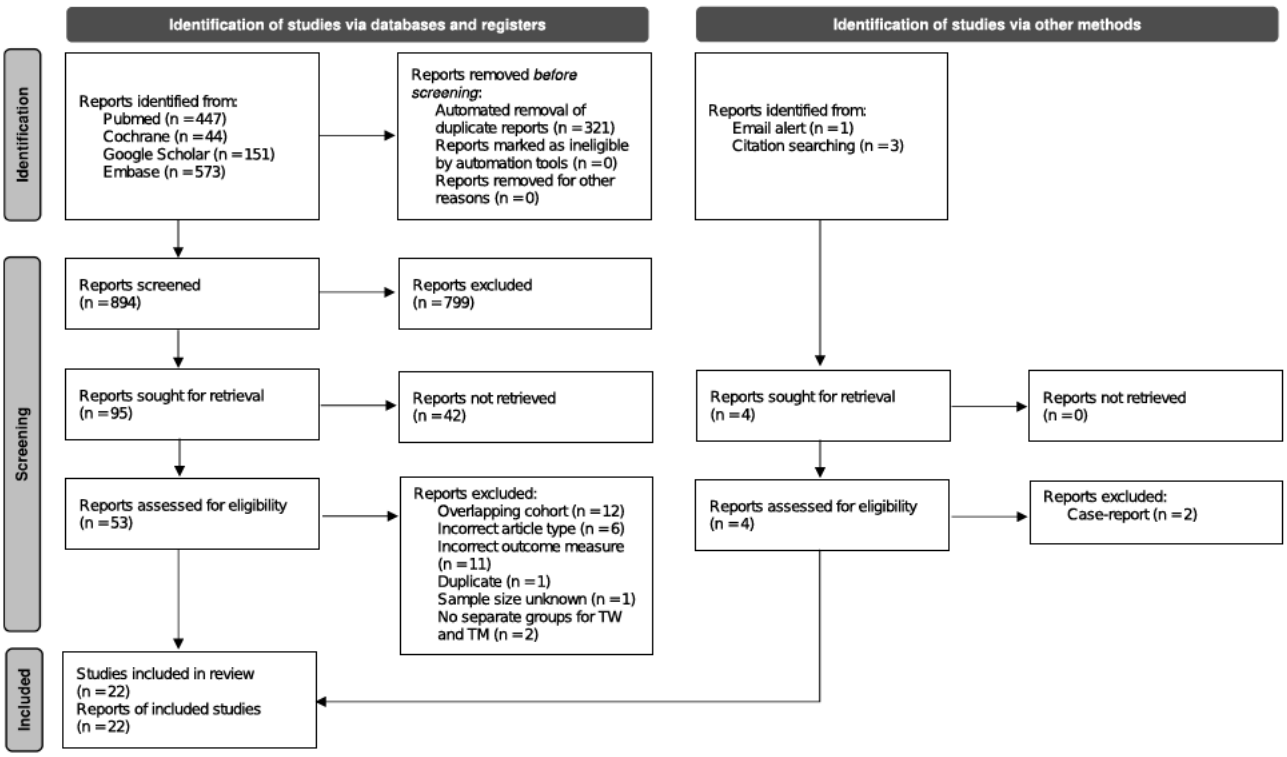

Figure 1. PRISMA 2020 flow diagram of study selection. TM, trans men; TW, trans women.

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Table 1. Summary of study characteristics of included studies on trans women.

Study	Population	Age (years)[a]	Study design	Hormone treatment	Follow-up duration	Outcome measure	Trans women		Cis men		Effect estimator	Effect (95% CI)
Arnold et al. (2016)	676 TW	33.2 ± 10.8	Retrospective	Oral estradiol, mostly with spironolactone	Total: 1286 person-years Mean: 1.9 years	VTE	$n = 1$	0.1%				
Caceres et al. (2019)	1373 TW 291 911 CM	Range 18-65+	Cross-sectional	Unknown	n/a	Stroke MI Any CVD					AOR AOR AOR	1.62 (0.99-2.63) 1.32 (0.95-1.85) 1.38 (1.01-1.88)
De Blok et al. (2021)	2927 TW	30 (24-42)	Retrospective	Estradiol, mostly with anti-androgens (CPA or spironolactone)	Total: 40 232 person-years Median: 11 years	Death due to any CVD	$n = 50$	1.7%			SMR	1.4 (1.0-1.8)
Dhejne et al. (2011)	191 TW 1910 CM	36.3 ± 10.1 at moment of gonadectomy	Retrospective	Not specified, but expected since all participants had gonadectomy	Median: 9.1 years Counted from gonadectomy	Death due to any CVD	$n = 6$	3.1%			HR	2.3 (0.9-5.7)
Dittrich et al. (2005)	60 TW	38 ± 11	Prospective	Oral estradiol 6 mg daily + goserelin injection 3.8 mg every 4 w	Total: 120 person-years 2 years per person	VTE	$n = 1$	1.7%				
Getahun et al. (2018)	2842 TW 27 906 CM	Range 18-55+	Retrospective	Feminizing drugs (such as estradiol and spironolactone)	Mean: 4.0 ± 3.0 years	Stroke MI VTE	$n = 54$ $n = 33$ $n = 61$	1.9% 1.2% 3.3%			AHR AHR AHR	1.2 (0.9-1.7) 0.9 (0.6-1.5) 1.9 (1.4-2.7)
Glintborg et al. (2022)	1325 TW 6463 CM	26 (21-39)	Retrospective	$n = 381$ TW used HT	Mean: 5.7 ± 4.8 years	Any CVD					AHR[b]	0.99 (0.71-1.37)
James et al. (2020)	49 TW	Median 24 Range 5-74	Retrospective	67.3% used hormones. Adolescents: GnRHa or progestins. Adults: estradiol + anti-androgens (spironolactone or GnRHa)	Median: 40.5 months Range: 1-506 months	Stroke MI VTE	$n = 2$ $n = 0$ $n = 4$	4.1% 0.0% 8.2%				
Karalexi et al. (2022)	847 TW 7890 CM	31 ± 13	Retrospective	Oral or transdermal estradiol ± anti-androgens	Differs per outcome measure; around 2020 person-years	Stroke VTE Any CVD Death due to any CVD	$n = 3$ $n = 3$ $n = 14$ $n = 3$	0.4% 0.4% 1.7% 0.4%	$n = 31$ $n = 12$ $n = 96$ $n = 17$	0.4% 0.2% 1.2% 0.2%	IRR[c] IRR[c] IRR[c] IRR[c]	1.09 (0.21-3.51) 2.84 (0.51-10.53) 1.63 (0.86-2.87) 2.01 (0.38-6.95)
Malhotra et al. (2022)	378 TW	Range 18-65+	Cross-sectional	Unknown	n/a	Any CVD	$n = 55$	14.6%				
Mullins et al. (2021)	182 TW	18 (16-20)	Retrospective	Estradiol: oral, transdermal or injections. ± spironolactone and GnRHa	Median 554 (283-1037) days	VTE	$n = 0$	0.0%				
Nota et al. (2019)	2517 TW	Median 30	Retrospective	Oestrogens (± anti-androgens)	Total: 22 830 person-years Median: 5.95 years	Stroke MI VTE	$n = 29$ $n = 30$ $n = 73$	1.2% 1.2% 2.9%	EC = 16.08 EC = 38.03 EC = 16.04	0.6% 1.5% 0.6%	SIR SIR SIR	1.80 (1.23-2.56) 0.79 (0.54-1.11) 4.55 (3.59-5.69)

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Table 1. Continued

Study	Population	Age (years)[a]	Study design	Hormone treatment	Follow-up duration	Outcome measure	Trans women		Cis men		Effect estimator	Effect (95% CI)
Ott et al. (2010)	162 TW	36.6 ± 10.9	Retrospective	Transdermal estradiol 100 mcg/24h twice a week + oral CPA 50 mg/day + oral finasteride 5 mg every other day. After gonadectomy only estradiol.	Mean: 52.5 ± 37.8 months	VTE	$n = 0$	0.0%				
Poteat et al. (2021)	70 TW 447 CM	Mean 55.6	Cross-sectional	Approximately 40% used HT	n/a	VTE Any CVD	$n = 5$ $n = 30$	6.8% 42.3%	$n = 20$ $n = 244$	4.4% 54.5%	AOR AOR	1.90 (0.53-6.81) 0.76 (0.37-1.55)
Pyra et al. (2020)	2509 TW	Median 30 Range 20-70	Retrospective	99% ever used estradiol, 94.2% ever used anti-androgens or finasteride, 29.8% ever used progestin	Unknown	VTE	$n = 19$	0.8%				
Quinn et al. (2017)	3475 TW 34 380 CM	Range 3-55+	Retrospective	58% used HT, eg, estradiol, spironolactone	Unknown	Stroke MI VTE	$n = 88$ $n = 61$ $n = 86$	2.5% 1.8% 2.5%	$n = 943$ $n = 664$ $n = 670$	2.7% 1.9% 1.9%	OR[c] OR[c] OR[c]	0.92 (0.74-1.15) 0.91 (0.70-1.18) 1.28 (1.02-1.60)
Schlatterer et al. (1998)	46 TW	Mostly 21-40 at start of HT (range <20 to >40)	Longitudinal	IM estradiol + oral CPA if needed based on testosterone levels (6.5% did not use HT anymore at time of study)	Unknown	VTE	$n = 0$	0.0%				
Wierckx et al. (2012)	50 TW	43 ± 10.4	Cross-sectional	HT initiated with 50-100 mg CPA for max. 1 year, then addition of oral or transdermal estradiol. After gonadectomy only estradiol.	Total: 473 person-years Mean: 9.2 years	Stroke MI DVT	$n = 3$ $n = 1$ $n = 1$	6.0% 2.0% 2.0%				
Wierckx et al. (2013)	214 TW 640 CM	43.7 ± 12.6	Cross-sectional	Oral or transdermal estradiol ($n = 10$ no longer on hormones, $n = 5$ oral contraceptive ethinylestradiol 30-50 mcg)	Mean: 7.7 years Range: 3 months to 35 years	Stroke MI VTE	$n = 4$ $n = 3$ $n = 11$	1.9% 1.4% 5.1%	$n = 6$ $n = 8$ Unknown	0.9% 1.3%	OR[c] OR[c]	2.01 (0.60-6.71) 1.12 (0.32-3.94)

Abbreviations: AHR, adjusted hazard ratio; AOR, adjusted odds ratio; CM, cis men; CPA, cyproterone acetate; CVD, cardiovascular disease; EC, expected cases; GnRHa, gonadotropin-releasing hormone agonist; HR, hazard ratio; HT, hormone therapy; IM, intramuscular; IRR, incidence rate ratio; MI, myocardial infarction; n/a, not applicable; OR, odds ratio; SIR, standardized incidence ratio; SMR, standardized mortality ratio; TW, trans women; VTE, venous thromboembolism.

[a]At time of study, unless otherwise specified.

[b]Adjusted for hormone use.

[c]Effect size was calculated based on observed cases in both study arms.

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Table 2. Summary of study characteristics of included studies on trans men.

Study	Population	Age (years)[a]	Study design	Hormone treatment	Follow-up duration	Outcome measure	Trans men		Cis women		Effect estimator	Effect (95% CI)
Caceres et al. (2019)	829 TM 368 220 CW	Range 18-65+	Cross-sectional	Unknown	n/a	Stroke MI Any CVD					AOR AOR AOR	1.80 (0.74-4.36) 2.26 (0.98-5.22) 1.60 (0.87-2.93)
De Blok et al. (2021)	1641 TM	23 (20-32)	Retrospective	Testosterone; IM, gel or oral	Total: 17 285 person-years Median: 5 years	Death due to any CVD	$n < 10$	<0.6%			SMR	1.6 (0.5-3.2)
Dhejne et al. (2011)	133 TM 1330 CW	33.3 ± 8.7 at moment of gonadectomy	Retrospective	Not specified, but expected since all participants had gonadectomy	Median: 9.1 years Counted from gonadectomy	Death due to any CVD	$n = 3$	2.3%			HR	3.2 (0.9-11.9)
Gava et al. (2018)	50 TM	Range 21-42	Prospective	IM testosterone	Total: 250 person-years 5 years per person	Stroke MI VTE	$n = 0$ $n = 0$ $n = 0$	0.0% 0.0% 0.0%				
Getahun et al. (2018)	2118 TM 20 807 CW	Range 18-55+	Retrospective	Masculinizing drugs (such as testosterone)	Mean: 3.6 ± 2.7 years	Stroke MI VTE	$n = 16$ $n = 9$ $n = 23$	0.8% 0.4% 1.1%			AHR AHR AHR	1.3 (0.7-2.5) 1.3 (0.5-3.9) 1.1 (0.6-2.1)
Glintborg et al. (2022)	1238 TM 6091 CM	22 (18-29)	Retrospective	$n > 445$ used HT	Mean: 4.5 ± 4.2 years	Any CVD					AHR[b]	1.21 (0.87-1.69)
James et al. (2020)	31 TM	Median 24 Range 5-74	Retrospective	48.4% used hormones. Adolescents: GnRHa or progestins. Adults: testosterone	Median: 40.5 months Range: 1-506 months	Stroke MI VTE	$n = 1$ $n = 1$ $n = 0$	3.2% 3.2% 0.0%				
Karalexi et al. (2022)	932 TM 8772 CW	26 ± 8.4	Retrospective	IM or transdermal testosterone	Differs per outcome measure; around 1080 person-years	Stroke VTE Any CVD Death due to any CVD	$n = 0$ $n = 0$ $n = 4$ $n = 0$	0.0% 0.0% 0.4% 0.0%	$n = 5$ $n = 10$ $n = 44$ $n = 0$	0.1% 0.1% 0.5% 0.0%	RR[c] RR[c] IRR[d] RR[c]	0.2 (0.0-89.9) 0.1 (0.0-47.6) 2.0 (0.5-5.5) 1.0 (0.0-774.0)
Korpaisarn et al. (2021)	39 TM	27.8 ± 6	Retrospective	IM testosterone	Mean: 25.2 ± 12.9 months	Stroke MI VTE	$n = 0$ $n = 0$ $n = 0$	0.0% 0.0% 0.0%				
Malhotra et al. (2022)	394 TM	Range 18-65+	Cross-sectional	Unknown	n/a	Any CVD	$n = 53$	13.5%				
Mullins et al. (2021)	429 TM	17 (16-19)	Retrospective	Testosterone: IM, gel, or patch	Median 577 (283-923) days	VTE	$n = 0$	0.0%				
Nota et al. (2019)	1358 TM	Median 23	Retrospective	Testosterone	Total: 11 003 person-years Median: 4.1 years	Stroke MI VTE	$n = 6$ $n = 11$ $n = 2$	0.4% 0.8% 0.1%	EC = 3.49 EC = 2.98 EC = 4.84	0.3% 0.2% 0.4%	SIR SIR SIR	1.72 (0.70-3.58) 3.69 (1.94-6.42) 0.41 (0.07-1.37)
Oakes et al. (2021)	519 TM	Mean 29	Retrospective	Testosterone, 90% in the form of injections	Unknown	Stroke VTE	$n = 1$ $n = 4$	0.19% 0.77%				
Ott et al. (2010)	89 TM	26.9 ± 7.3	Retrospective	IM testosterone undecanoate 1000 mg every 12 w + oral lynestrenol 5 mg/day. After gonadectomy only testosterone	Mean: 47.3 ± 31.5 months	VTE	$n = 0$	0.0%				
Poteat et al. (2021)	25 TM 517 CW	Mean 50.6	Cross-sectional	Approximately 40% used HT	n/a	VTE Any CVD	$n = 1$ $n = 7$	2.1% 29.3%	$n = 10$ $n = 250$	2.0% 48.4%	AOR AOR	1.60 (0.32-7.95) 0.61 (0.16-2.26)
Pyra et al. (2020)	1893 TM	Median 26 Range 20-67	Retrospective	99.6% ever used testosterone	Unknown	VTE	$n = 3$					

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Table 2. Continued

Study	Population	Age (years)[a]	Study design	Hormone treatment	Follow-up duration	Outcome measure	Trans men	Cis women		Effect estimator	Effect (95% CI)
Quinn et al. (2017)	2892 TM 28 549 CM	Range 3-55+	Retrospective	52% used testosterone	Unknown	Stroke	$n = 42$	1.5%	$n = 360$	1.3%	OR[d]	1.15 (0.84-1.59)
						MI	$n = 17$	0.6%	$n = 210$	0.7%	OR[d]	0.80 (0.49-1.30)
						VTE	$n = 45$	1.6%	$n = 266$	0.9%	OR[d]	1.68 (1.22-2.31)
Schlatterer et al. (1998)	42 TM	Mostly 21-30 at start of HT (range <20 to 40)	Longitudinal	IM testosterone 250 mg every 2-3 weeks (19.04% did not use HT anymore at time of study)	Unknown	VTE	$n = 0$	0.0%				
Wierckx et al. (2012)	50 TM	37 ± 8.2	Cross-sectional	Mostly IM testosterone, less often testosterone gel	Total: 496 person-years Mean: ± 10 years	Stroke	$n = 0$	0.0%				
						MI	$n = 0$	0.0%				
						DVT	$n = 0$	0.0%				
Wierckx et al. (2013)	138 TM 414 CW	37.5 ± 11	Cross-sectional	Mostly IM, very few used transdermal or oral testosterone	Mean: 9.4 years Range: 3 months to 49 years	Stroke	$n = 0$	0.0%	$n = 3$	0.7%	RR[c]	0.2 (0.0-11.4)
						MI	$n = 0$	0.0%	$n = 0$	0.0%	RR[c]	1.0 (0.0-92.0)
						VTE	$n = 0$	0.0%	Unknown			

Abbreviations: AHR, adjusted hazard ratio; AOR, adjusted odds ratio; CVD, cardiovascular disease; CW, cis women; EC, expected cases; GnRHa, gonadotropin-releasing hormone agonist; HR, hazard ratio; HT, hormone therapy; IM, intramuscular; IRR, incidence rate ratio; MI, myocardial infarction; OR, odds ratio; n/a, not applicable; RR, relative risk; SIR, standardized incidence ratio; SMR, standardized mortality ratio; TM, trans men; VTE, venous thromboembolism.
[a]At time of study, unless otherwise specified.
[b]Adjusted for hormone use.
[c]Relative risk was calculated after correction for zero events in one or both arms.
[d]Effect size was calculated based on observed cases in both study arms.

studies, not all participants used hormone therapy. Tables 1 and 2 provide information on hormone use per study.

Summary of study results

A summary of study characteristics and results is given in Table 1 for trans women and Table 2 for trans men.

Incidence proportions (events/population) of stroke, MI, and VTE for trans women were 1.8% (183/9994), 1.2% (145/12 074), and 1.6% (265/16 626), respectively. Any CVD occurred in 7.6% (99/1295) and death due to any CVD in 1.5% (59/3965) of trans women.

Incidence proportions in trans men were substantially lower: 0.8% (66/8127), 0.6% (38/6676), and 0.7% (78/10 605) for stroke, MI, and VTE, respectively. Incidence proportions of any CVD and death due to any CVD were also lower: 4.7% (64/1351) and 0.3% (3/1065).

Meta-analysis

Studies with a control group consisting of cisgender people of the same birth sex were included in the meta-analysis. Ten out of the 22 studies were included, with a total number of 15 781 trans women and 11 304 trans men.

Trans women

Of the 6 studies that evaluated stroke ($n = 11\,268$ trans women), 5 found a higher incidence of stroke in transgender women compared with cisgender men. The pooled relative risk was 1.3 (95% CI, 1.0-1.8). A higher incidence of MI was found in 2 of the 5 studies on MI ($n = 10\,421$ trans women), with a pooled relative risk of 1.0 (95% CI, 0.8-1.2). For VTE, a higher incidence in trans women was found in all 5 studies on VTE ($n = 9751$ trans women), leading to a pooled relative risk of 2.2 (95% CI, 1.1-4.5). The pooled relative risk for stroke, MI, and thrombosis combined was 1.4 (95% CI, 1.0-1.9) (Figure 2).

Four studies evaluated the outcome "any CVD." The pooled relative risk was 1.2 (95% CI, 0.9-1.5) compared with cis men. Three studies reported death due to any CVD, with a pooled relative risk of 1.5 (95% CI, 1.1-2.0) compared with cis men.

Trans men

Four out of 6 studies on stroke ($n = 8267$ trans men) found a higher incidence in trans men compared with cis women. The pooled relative risk was 1.3 (95% CI, 1.0-1.6). A higher incidence of MI was found in 3 out of 5 studies ($n = 7335$ trans men), with a pooled relative risk of 1.7 (95% CI, 0.8-3.6). A higher VTE incidence in transgender men was found in 3 of the 5 studies ($n = 7325$ trans men), with a pooled relative risk of 1.4 (95% CI, 1.0-2.0). The pooled relative risk for all 3 outcomes combined was 1.4 (95% CI, 1.1-1.8) (Figure 3).

Three out of 4 studies evaluating "any CVD" found an increased risk for trans men, which led to a pooled relative risk of 1.3 (95% CI, 1.0-1.7). Three studies estimated the risk of death due to any CVD for trans men, with a pooled relative risk of 2.2 (95% CI, 0.9-5.1).

Sensitivity analysis

The studies by Caceres et al. (2020) and Poteat et al. (2021) were omitted in the sensitivity analyses. The study by Getahun et al. (2018) was not, because a hazard ratio adjusted

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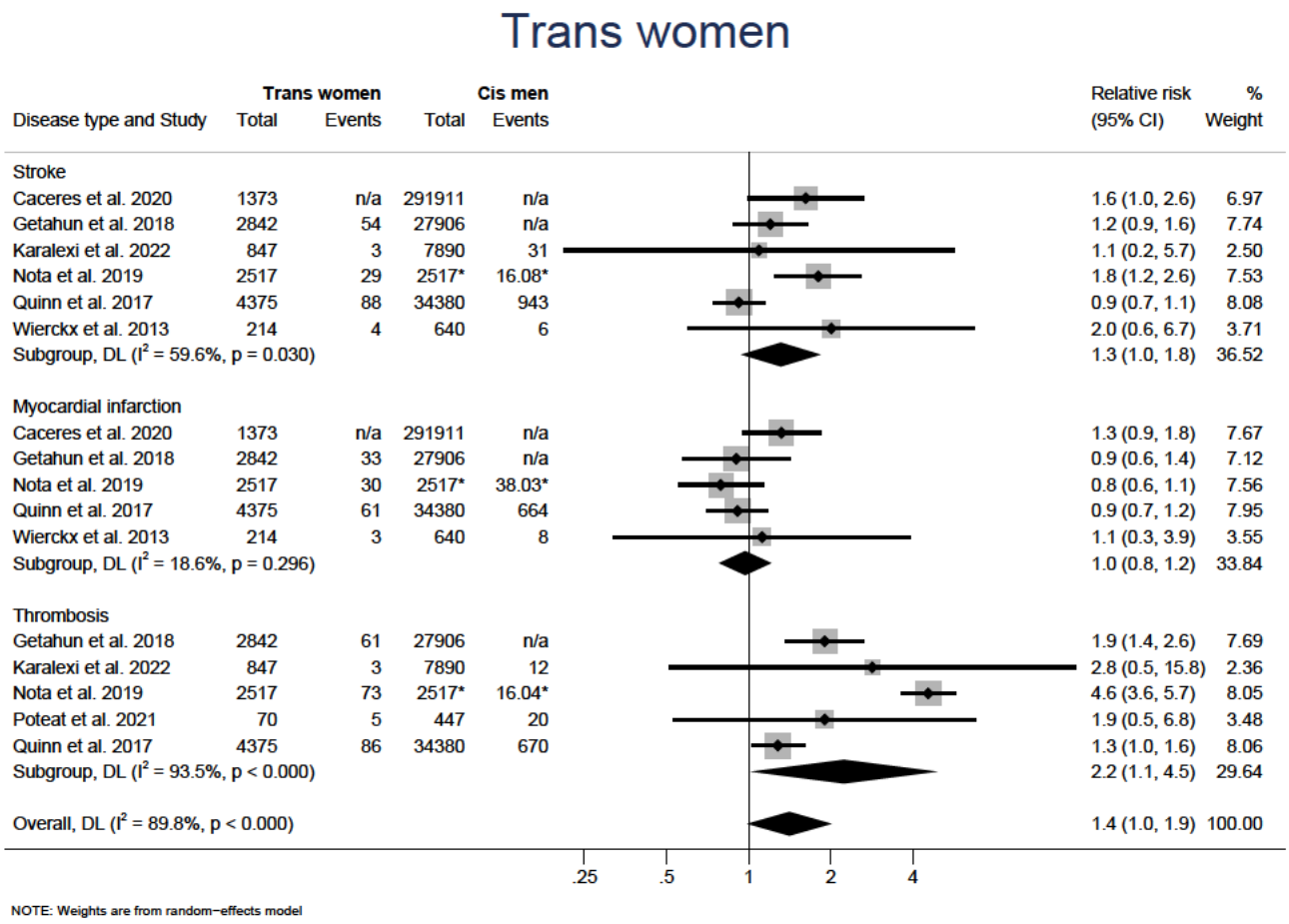

Figure 2. Forest plot of stroke, myocardial infarction, and thrombosis in trans women. *Expected events based on general population risk. CI, confidence interval; n/a, not available.

for hormone use was reported. Omitting these studies from the meta-analysis did not affect the results for either group. The new pooled relative risks for trans women were as follows: stroke 1.3 (95% CI, 0.9-1.8), MI 0.9 (95% CI, 0.7-1.1), VTE 2.3 (95% CI, 1.1-4.9), and any CVD 1.2 (95% CI, 0.7-1.9). For trans men, the new pooled relative risks were 1.2 (95% CI, 0.9-1.6) for stroke, 1.5 (95% CI, 0.6-4.2) for MI, 1.3 (95% CI, 0.8-2.1) for thrombosis, and 1.3 (95% CI, 0.9-1.7) for any CVD. For the outcome "death due to any CVD," no studies were excluded.

Risk of bias and heterogeneity

A detailed risk of bias assessment according to the ROBINS-I tool and JBI checklist is provided in Supplemental Materials S3 and S4, respectively. Most of the 10 studies that were included in the meta-analysis exhibited a serious overall risk of bias according to ROBINS-I, with the potential for confounding as the primary factor. The risk of bias due to deviations from intended interventions was moderately present in most as well. In the majority of the 12 studies without a control group, a risk of bias was present for at least 2 of the 9 JBI checklist items, inadequate sample size being the most frequently observed factor.

Significant heterogeneity was observed for the outcomes stroke and VTE for trans women. The study by Quinn et al. (2017) reported a non-significant smaller risk of stroke in trans women compared with cis men, with only 58% of trans women using hormones. All studies that evaluated VTE in trans women observed an increased risk for trans women. The study of Quinn et al. is the one with the smallest effect of 1.28 (95% CI, 1.02-1.60). The largest effect of 4.55 (95% CI, 3.61-5.73) was found by Nota et al. (2019), where all trans women used hormones. The large CIs in the studies by Karalexi et al. (2022) and Poteat et al. (2021) could also have contributed to the degree of heterogeneity.

For trans men, heterogeneity was only significant for MI. Again, only the study of Quinn et al. deviated from the others, reporting a smaller risk estimate for trans men. Only 52% of the trans men included in this study used testosterone.

Discussion

We conducted a systematic review and meta-analysis on the incidence of several major CVDs in the transgender population: stroke, MI, and VTE. Secondary outcomes were the occurrence of any CVD and death due to any CVD.

Primary outcome measures

For trans women compared with cis men, the risk of thrombosis is higher than for trans men compared with cis women. This aligns with our expectations based on evidence that cis women who use estradiol-containing contraceptives or

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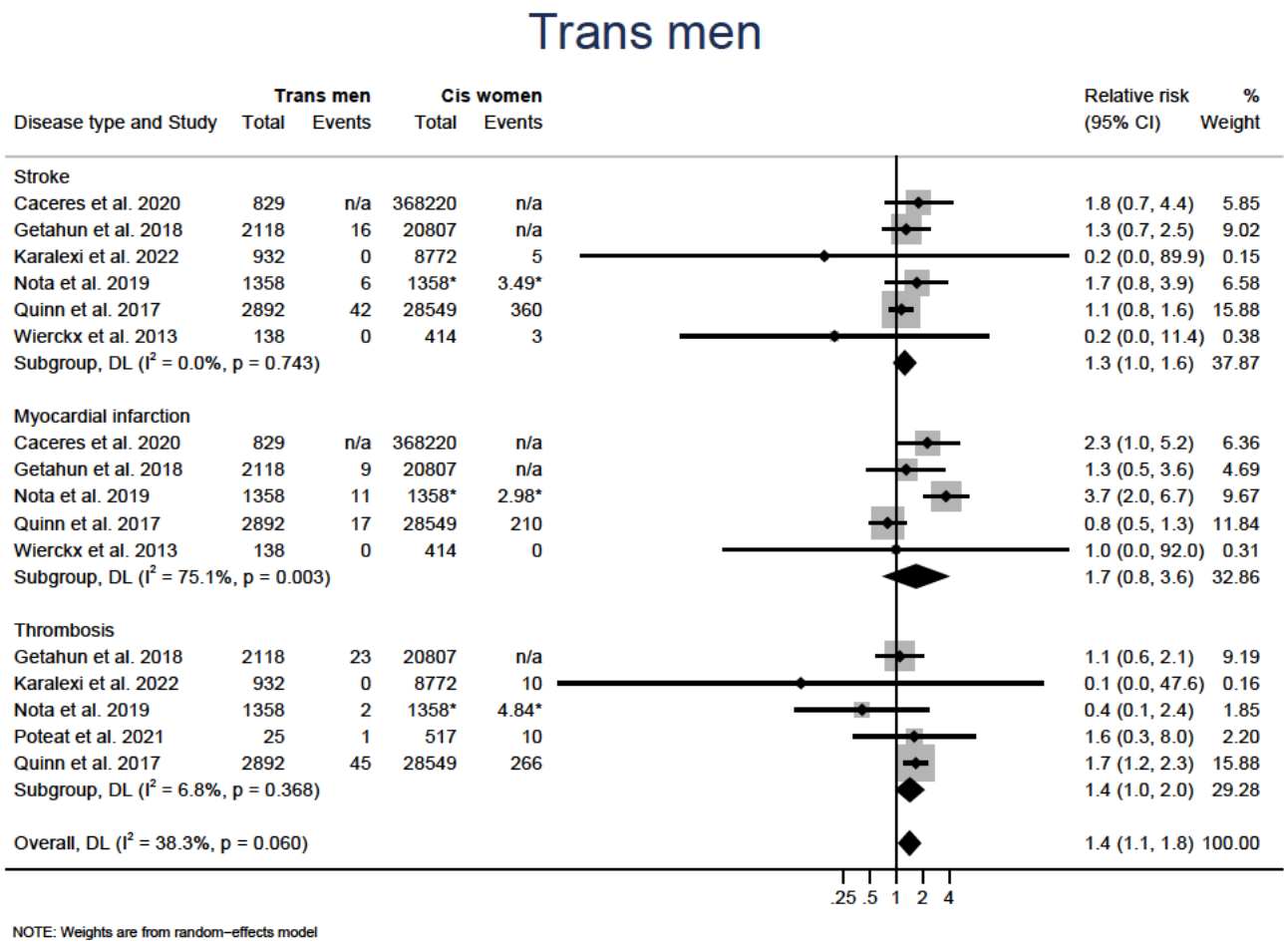

Figure 3. Forest plot of stroke, myocardial infarction, and thrombosis in trans men. *Expected events based on general population risk. CI, confidence interval; n/a, not available.

hormonal replacement therapy have an increased thrombosis risk.[11,55] The increased risk of thromboembolism in both transgender groups may be partially attributed to surgeries involved in the transition process for many transgender individuals, as it is known that major surgery and immobilization are risk factors for venous thrombosis.[56]

It is interesting that between trans women and men, there seems to be a disparity in the risk of thrombosis, but not stroke and MI. Generally, secondary haemostasis is involved in the process of venous thrombosis through activation of pro-coagulant factors, while ischaemic stroke and MI develop via primary haemostasis,[17] which makes the pro-coagulant effect of oestrogens a plausible factor in thrombosis development in trans women. Another explanation is the generally higher risk of thrombosis in cis women compared with cis men. As a result, the risk of thrombosis for trans men compared with cis women is relatively smaller, while the risk for trans women compared with cis men is relatively larger.

The comparable risk of arterial CVD in trans women and men suggests a limited involvement of hormonal factors, as most studies show a beneficial effect of oestrogens and a more detrimental effect of testosterone on classical cardiovascular risk factors. Instead, socio-economic factors and minority stress are hypothesized to contribute to CVD development in transgender people.[27] Previous studies established an association between psychological stress and stroke and MI.[57] The relationship between socio-economic factors and cardiovascular mortality was also established in the earlier mentioned Danish study on people with Klinefelter syndrome,[22] which underlines the effect of socio-economic status on health and disease. It is evident that lifestyle factors such as smoking, diet, and exercise can also largely affect CVD risk. However, the impact of these factors has not yet been studied in transgender people.

Secondary outcome measures

We hypothesized that both hormone use and socio-economic factors together could lead to a higher CVD risk in trans people and, therefore, did not expect to observe that the risk of "any CVD" is increased in trans men, but not trans women. However, the evaluation of "any CVD" was limited to only 4 studies, each employing different definitions; "any CVD" was defined as the occurrence of any major CVD in some, but in others, atrial fibrillation or vasculitis also qualified. For our outcome "death due to any CVD," we observed a higher risk for both trans women and trans men, which emphasizes the severity of the CVD in this population.

Risk of bias and heterogeneity

In studies with a control group, the failure to control for factors such as minority stress, socio-economic status, and

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lifestyle (eg, tobacco use) led to a serious risk of bias due to confounding. As mentioned before, these factors could contribute to the higher risk of cardiovascular events in transgender people.[23-27] Two reasons were involved with the risk of bias due to deviations from intended interventions: Firstly, not all transgender people used hormones. This could have caused an underestimation of CVD risk in transgender people, assuming that hormone use is a risk factor. The second reason is the possibility that transgender people underwent sex-reassignment surgery, which was not specified in most studies. Surgery and immobilization could have increased the observed cases of VTE and subsequently affected the overall risk of CVD. In studies without a control group, the risk of bias was mostly present due to inadequate sample sizes. When outcomes are relatively rare, which appears to be true in this population of relatively young and healthy transgender people, larger sample sizes are needed to detect the outcome.[58]

The studies by Quinn et al. (2017) and Nota et al. (2019) were mostly involved in the observed heterogeneity between studies. They frequently exhibited opposite effects from each other or compared with the other studies. The most notable distinction between these studies is that Quinn et al. reported hormone usage in only 58% of trans women and 52% of trans men, whereas all transgender people in the study by Nota et al. used hormones. With Quinn et al. reporting a smaller overall risk of cardiovascular events, this suggests that hormone use may contribute to the development of CVD. Notably, the cohort of Quinn et al. is from the USA, while the cohort of Nota et al. is from the Netherlands, which means that also the discrepancy in the types of used hormones may have influenced the effects.

Strengths and limitations

A major strength of this systematic review and meta-analysis is the elaborate search strategy that was used and the fact that articles were searched for in 4 different databases. Furthermore, studies on multiple different cardiovascular outcomes in both trans women and trans men were included, which makes our study the most extensive literature study on this subject yet. We were able to include less than half of the total number of studies in our meta-analysis; however, together, they consist of around 75% of the transgender participants in the 22 included studies.

Our study also has several limitations. Most important is the fact that the included studies used different types of risk assessment; some compared lifetime risks while others took the follow-up duration into account and based their risk estimate on person-years. With the information given in the articles, we were unable to calculate one and the same effect size for all studies. So, to still be able to perform the statistical analysis, we combined all effects into the meta-analysis model. While this provides an imprecise estimate of the actual effect, our results demonstrate that the risk is increased. Another important limitation is the heterogeneity between studies, since in different countries, different types of hormones are prescribed. Furthermore, in some studies, trans people used hormone types that are currently no longer prescribed in some countries due to new research and insights in this field of medicine. The studies included in this review did not address the comparative risk of cardiovascular events between oral and transdermal oestrogen users or between users and non-users of CPA. The absence of such comparisons is another noteworthy gap in the existing literature. Another limitation is the fact that control subjects were often matched for age, but not for other characteristics. Because of this, we were unable to investigate the exact influence of hormone use on CVD. Lastly, most studies only assessed the risk of CVD for transgender people compared with cisgender people with the same birth sex. The risk of CVD for transgender people compared with the risk for people with the same gender identity therefore remains a knowledge gap. Knowing this relative risk would be valuable in terms of patient counselling and preventive interventions.

Clinical implications and future research

Our systematic review and meta-analysis provides evidence for an elevated risk of CVD among transgender people relative to cisgender people of the same birth sex. The underlying causes for this increased risk are not yet fully understood. However, given the potential implications for the long-term health outcomes of this population, aiming to minimize cardiovascular risk by implementing lifestyle interventions and cardiovascular risk management in transgender healthcare is imperative.

We are well aware of the fact that we were unable to give information on causality or clear associations. Therefore, future research with long periods of follow-up is needed to evaluate the cardiovascular risk of the currently used hormone types and administration forms as described in the current Standards of Care for the Health of Transgender and Gender Diverse people.[2] Furthermore, another important knowledge gap remains regarding the influence of socioeconomic and lifestyle factors in the transgender population. In order to accurately determine the impact of hormone therapy on cardiovascular risk in transgender people, future research should aim to identify and account for the potential confounding effects of these factors. Only with this information, we will be able to gain better understanding of the cardiovascular risk for transgender people in relation to situational and behavioural factors as well as hormone use.

Supplementary material

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Authors' contributions

Lieve van Zijverden (Conceptualization [supporting], Data curation [lead], Formal analysis [lead], Investigation [lead], Project administration [lead], Validation [supporting], Visualization [lead], and Writing—original draft [lead]), Chantal Wiepjes (Conceptualization [supporting], Data curation [supporting], Formal analysis [supporting], Investigation [supporting], Project administration [supporting], Supervision [equal], Validation [equal], and Writing—review & editing [equal]), Jeske van Diemen (Conceptualization [supporting], Data curation [supporting], Investigation

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Ethical approval

This study was conducted according to the Declaration of Helsinki. Ethical approval was not required since all analyses were based on previously published data.

Data availability

The data underlying this article are publicly available and can be found in the research articles of the included studies, as well as within this article. The software code will be shared on reasonable request to the corresponding author.

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REVIEW ARTICLE Open Access

A Systematic Review of the Effects of Hormone Therapy on Psychological Functioning and Quality of Life in Transgender Individuals

Jaclyn M. White Hughto[1,2,*] and Sari L. Reisner[1,3,4]

Abstract

Objectives: To review evidence from prospective cohort studies of the relationship between hormone therapy and changes in psychological functioning and quality of life in transgender individuals accessing hormone therapy over time.

Data Sources: MEDLINE, PsycINFO, and PubMed were searched for relevant studies from inception to November 2014. Reference lists of included studies were hand searched.

Results: Three uncontrolled prospective cohort studies, enrolling 247 transgender adults (180 male-to-female [MTF], 67 female-to-male [FTM]) initiating hormone therapy for the treatment of gender identity disorder (prior diagnostic term for gender dysphoria), were identified. The studies measured exposure to hormone therapy and subsequent changes in mental health (e.g., depression, anxiety) and quality of life outcomes at follow-up. Two studies showed a significant improvement in psychological functioning at 3 6 months and 12 months compared with baseline after initiating hormone therapy. The third study showed improvements in quality of life outcomes 12 months after initiating hormone therapy for FTM and MTF participants; however, only MTF participants showed a *statistically* significant increase in general quality of life after initiating hormone therapy.

Conclusions: Hormone therapy interventions to improve the mental health and quality of life in transgender people with gender dysphoria have not been evaluated in controlled trials. Low quality evidence suggests that hormone therapy may lead to improvements in psychological functioning. Prospective controlled trials are needed to investigate the effects of hormone therapy on the mental health of transgender people.

Key words: clinical care; gender dysphoria; gender transition; mental health; transgender

Introduction

Transgender people have a gender identity or expression that differs from their sex assigned at birth. Research documents high prevalence of depression, anxiety, and suicidal ideation among transgender individuals relative to the general population.[1–3] Many transgender people experience psychological distress related to the discrepancy between their birth sex and felt a sense of being male, female, or otherwise gender nonconforming.[4] Some individuals experience gender-related psychological distress at such an extreme level that their distress meets criteria for a formal psychiatric diagnosis—*Gender Dysphoria*.[4] The critical element of gender dysphoria is the presence of clinically significant distress associated with the strong and persistent difference between one's expressed/experienced gender and one's sex assigned at birth.[5] The World Professional Association of Transgender Health's Standards of

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Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (Version 7) lists social transition (living full or part-time in one's gender identity), psychotherapy, surgery, and hormone therapy as treatment options for individuals with gender dysphoria.[6] While each person's treatment plan is individualized, and may include one or multiple interventions, hormone therapy is generally the first medical intervention accessed by individuals with gender dysphoria who seek to masculinize or feminize their body to be consistent with their gender identity.[6]

Feminizing or masculinizing hormone therapy is the administration of exogenous endocrine agents to induce changes in physical appearance.[6] Since hormone therapy is inexpensive relative to surgery and highly effective in the development of secondary sex characteristics (e.g., facial and body hair in female-to-male [FTM] individuals or breast tissue in male-to-females [MTFs]), hormone therapy is often the first, and sometimes only, medical gender affirmation intervention accessed by transgender individuals looking to develop masculine or feminine characteristics consistent with their gender identity. In some cases, hormone therapy may be required before surgical interventions can be conducted.[6]

Changing one's physical characteristics through hormone therapy is considered medically necessary for many transgender individuals and may relieve the psychological distress associated with gender dysphoria, reduce psychiatric comorbidities, and improve patients' quality of life.[6] The efficacy of hormone therapy in relieving psychiatric distress related to gender dysphoria has largely been inferred through clinical practice and low quality evidence.[7] In 2008, the first systematic review exploring the relationship between hormone therapy and the mental health of transgender individuals was conducted.[7] Published in 2010, the review found that hormone therapy in individuals with gender identity disorder (the DSM-IV diagnostic name for gender dysphoria) *likely* improves gender dysphoria, psychological function, comorbidities (e.g., depression, anxiety, and suicidality), sexual functioning, and overall quality of life.[7] However, the quality of the empirical evidence was very low. All of the reviewed studies pertaining to psychological functioning were nonrandomized and largely cross-sectional designs. Moreover, the majority of the studies evaluated hormone therapy in concert with sex reassignment surgery and so an evaluation of the specific relationship between hormone therapy and the psychological functioning of transgender individuals independent of surgical interventions was not possible. Since 2008, several higher quality studies exploring the relationship between hormone therapy and psychological functioning in transgender individuals have been published, thus an updated systematic evaluation of the research literature is warranted.

The primary objectives of this review were to locate and describe studies examining the relationship between hormone therapy and the psychological functioning of transgender individuals; determine the risk of experiencing psychiatric distress in transgender individuals receiving hormone therapy compared with those not receiving hormone therapy or the general population; examine whether transgender individuals with poor mental health experience an improvement in their mental health status after the initiation of a hormone regimen; and assess whether any differences in the strength and direction of the association between hormone therapy and psychological functioning exist by gender identity (i.e., for MTF vs. FTM subjects). Additionally, the review aimed to assess the strength of evidence showing a relationship between hormone therapy and healthy psychological functioning in transgender individuals and identify future research and clinical practice needs.

Methods

PRISMA[8] reporting guidelines were used in the development of this protocol-driven report. The protocol was not published, but is available upon request.

Eligibility criteria

Studies were eligible for this review if they enrolled transgender or transsexual (or another term used to describe individuals with a gender identity different from their assigned sex at birth) individuals who were seeking hormone therapy to masculinize or feminize the body. All participants had been diagnosed with having gender identity disorder (prior diagnostic name for gender dysphoria).

Because the goal was to assess changes in psychological functioning and quality of life after initiating hormone therapy, only studies with a longitudinal design were included in the review. No randomized controlled trials were identified. All included studies were nonrandomized (observational) and uncontrolled, prospective cohort studies. One-time cross-sectional studies, single case reports, case series, review articles, commentaries, letters, and studies that did not contain original data were excluded. Studies were included regardless of sample size. Only English language publications

were included in the search. Studies following participants for less than 3 months were excluded.

Interventions were limited to the administration of feminizing or masculinizing hormone therapy. Due to the wide variation of doses and types of hormones, all forms of hormone administration (e.g., self or provider injection, oral pill, intramuscular, transdermal patch or gel, or subcutaneous implant), dosing levels, dose frequency, and types (e.g., estrogen, androgen-reducing medications, progestins, testosterone, bioidentical, and compounded hormones) were included. Psychiatric disorders (DSM diagnosis or clinically significant symptomology), general psychological functioning, and general quality of life outcomes were assessed.

Study identification

The first author consulted an expert reference librarian to design and conduct the electronic search strategy with input from the second author and collaborators with expertise in conducting systematic reviews. To identify eligible studies, electronic databases (Ovid MEDLINE, Ovid PsycInfo, and PubMed) were searched from inception to November 2014. Controlled vocabulary supplemented with keywords was used to define the concept areas (transgender/transsexual, hormone therapy, psychiatric disorder, psychological functioning, and quality of life). A hand search of the bibliographies of retrieved articles was also conducted. A detailed list of subject headings and text words is available upon request.

The first author examined abstracts and titles from the initial search to identify studies that appeared to meet the inclusion criteria. Abstracts were screened twice for inclusion. The full article was then obtained for all studies appearing to meet inclusion criteria or in instances where there was insufficient information from the title, keywords, and abstract to make a clear decision. The studies meeting the inclusion criteria were checked for validity assessment (see the Quality assessment section) and data extraction.

Data collection

Data were extracted for the studies that met inclusion criteria, and then entered into RevMan5. Data were extracted using specially developed data extraction forms to ensure standardization, which included the following headings:

Participant characteristics. Age, birth sex, gender identity, income, education, and psychiatric comorbidities (all at baseline).

Study characteristics. Recruitment method, inclusion/exclusion criteria, setting, allocation procedure, sample size analyzed, study design features, and follow-up period.

Intervention. Description of intervention, mode and frequency of delivery, number, and explanation for any dropouts.

Outcomes. Description of measures used, continuous/dichotomous nature, and validated or unvalidated method of administration.

Statistical results. Adjusted and unadjusted effect estimates (if available) and measures of variability, frequency counts for dichotomous variables, and number of patients.

Confounding. Specific confounders included the following factors, which could impact the mental health of participants independently of hormone therapy: receiving psychotherapy in addition to hormone therapy; accessing other medical gender affirmation technologies (i.e., silicon injections, surgeries, electrolysis) in addition to hormone therapy; possessing any underlying treated or untreated comorbid psychiatric conditions; relationship factors and social support (positive or negative relationships with family, friends, sexual partners); discrimination experiences (in employment, housing, etc.); barriers and facilitators to healthcare access (insurance coverage for hormones or surgeries; feasibility in accessing trained and competent providers, etc.); prior or concurrent use of street-based hormones; and patient characteristics (age, income, level of education).

Quality assessment (risk of bias)

In consultation with an expert in systematic reviews, the first author assessed the risk of bias for each study and reported the bias in the Risk of Bias table according to the Cochrane Handbook for Systematic Reviews of Interventions.[9] Specifically, sequence generation, allocation sequence concealment, blinding, incomplete outcome data, selective outcome reporting, and other potential sources of bias were assessed. Items were assessed by first providing a description of what occurred in the study and then providing a judgment on the adequacy of the study as it relates to each item. When assessing bias, studies were scored as low risk of bias, high risk of bias, and unclear for studies with unclear or unknown risk of bias. Since this tool

was developed specifically for RCTs, items from the Downs and Black instrument[10] and the Newcastle-Ottawa Scale[11] were included in the assessment. The authors intended to explore selective outcome reporting through sensitivity analyses in cases where missing data were likely to introduce serious bias; however, none of these factors were reported in the included studies.

Measures of treatment effect

For prospective cohort studies, statistically significant ($p < 0.05$) within-group pre–post changes (%) were analyzed. The summary measure was the weighted mean difference (standardized mean difference [SMD]) in change in mental health from baseline to follow-up among transgender individuals initiating hormone therapy. For outcomes based on a single study, mean change scores were reported.

The Cochrane Collaboration statistical guidelines were followed for data synthesis.[9] Data were collated into evidence tables and grouped according to each outcome. The reported primary and secondary outcome variables were grouped as follows: Primary: psychological functioning, depression, anxiety, somatization, interpersonal sensitivity, hostility, phobic anxiety; and Secondary: quality of life.

Data analysis

Data were analyzed using RevMan software and reported according to Cochrane Collaboration criteria.[9] A summary statistic for each study was created where possible. A generic inverse variance method was used to create a weighted average for each study according to the amount of information in each study and a fixed-effects model was employed. For continuous data, pooled outcomes were expressed as SMDs with associated 95% confidence intervals (CIs) when outcomes used different scales or different versions of the same scale. When outcomes used the same scale, the weighted mean difference was used and 95% CIs reported.

To avoid a unit of analysis error, several different outcomes based on different periods of follow-up were defined and not combined in a meta-analysis. When missing data were found, the data were assumed to be missing at random. Only available data were analyzed and missing data were ignored.

Inconsistency in treatment effects across studies was quantified using the I^2 statistic, which represents the proportion of variability across trials that is not attributable to random error or chance.[9] Assessment of heterogeneity was made based on the following levels: none <25%, low = 25–49%, moderate = 50–74%, and high = 75% + .[8] Since study outcomes and measurement were too heterogeneous, a narrative synthesis was performed.

Results

Figure 1 depicts the study selection process. Three studies that met inclusion criteria were identified.[12–14] Of the three studies, data were available for a total of 154 participants (two studies) for the primary psychological functioning outcomes;[12,14] one study reported on secondary quality of life outcomes ($n = 83$).[13] Lack of data and variation in follow-up period of assessment time points precluded meta-analysis for the reviewed studies.

Study characteristics

In all three studies, a cohort of transgender patients initiating hormone therapy was followed longitudinally after initiating hormone therapy at baseline. The timing of follow-up for these studies ranged from 3 to 6 months and 12 months after baseline. One study used a 3–6-month follow-up[14] and two used a 12-month follow-up.[12,13] One study[14] followed participants beyond 12 months after completion of gender affirmation surgery; however, this time point was not included in the analyses as per the protocol. All studies lacked a control group.

The three studies enrolled 247 participants (180 MTF, 67 FTM). Only two studies reported the age of participants,[12,13] and the mean age for MTF individuals across studies was similar to FTM individuals (mean age 31 and 30, respectively). All three of the included studies originated in Europe (two in Italy; one in Belgium) and were published in English.

Participants were all recruited from specialty gender identity clinics serving patients diagnosed with having gender identity disorder (prior DSM diagnosis for gender dysphoria). Patients were recruited into the study during a routine visit and all were seeking surgical gender affirmation surgery (i.e., sex reassignment surgery).

All three studies administered hormone therapy following diagnosis of gender identity disorder. All participants lived full-time in their gender role (socially transitioned) and were receiving concurrent psychotherapy. Specific details of the hormone regimen were reported by two studies, which used similar regimens. Both studies administered either transdermal or oral estrogen and antiandrogens to MTF patients, although dosing varied.[12,13] For FTM patients, both studies used intramuscular injections of testosterone, although dosing

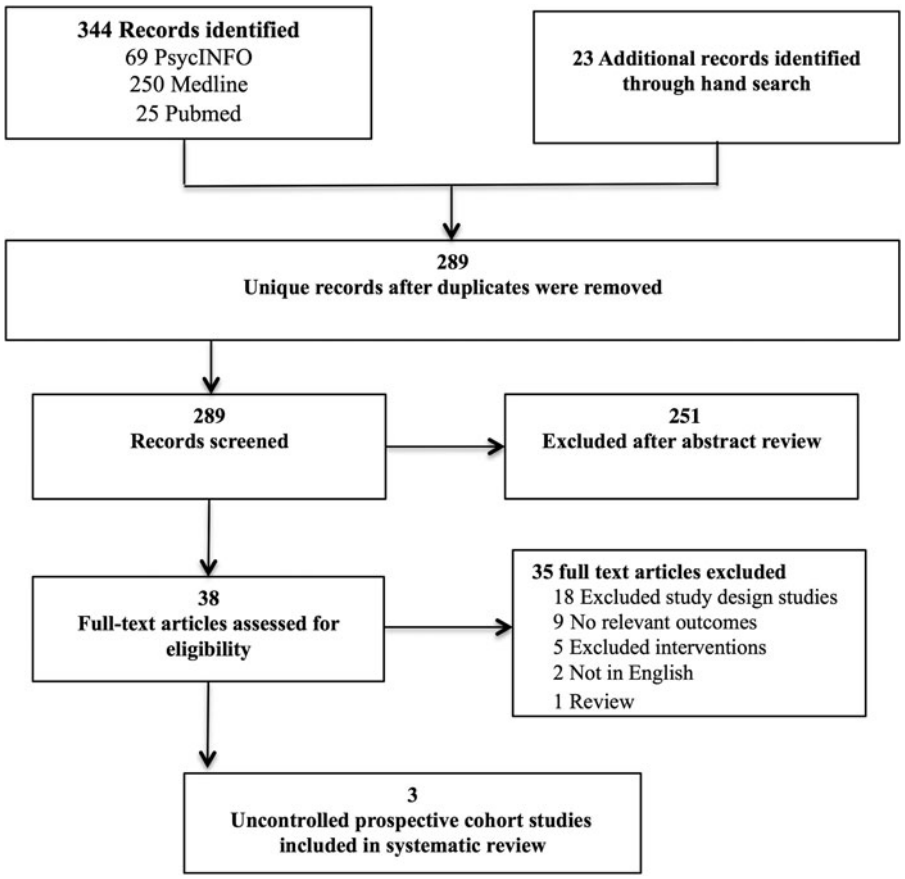

FIG. 1. Flow diagram of study inclusion for systematic review of masculinizing and feminizing hormone therapy and psychological functioning and quality of life in transgender patients.

quantity and frequency differed and one study provided daily low-dose transdermal gel testosterone at the beginning of the treatment period (10–15 days).[13]

The outcomes were ascertained by a self-reported questionnaire in all three studies. Two studies administered assessments in the clinic and one mailed the questionnaire to the participants at follow-up, resulting in missing data. Two studies used the Symptom Checklist-90 (SCL-90) to assess psychological functioning.[12,14] However, one study[12] used the Italian revised version (SCL-90-R)[15] and the other study[14] used the traditional Dutch-adapted version.[16] Two studies assessed anxiety;[12,14] however, only one[12] used a validated scale (Zung Self-Reported Anxiety Scale).[17] One study[12] also measured depression using a second validated depression measure (Zung Depression Scale).[18] Only one study assessed quality of life as a secondary outcome[13] and used the World Health Organization Quality of Life-100 (WHOQOL-100) questionnaire.[19]

Outcomes

Table 1 describes the summary of findings for reported outcomes in included studies.

Psychological functioning. Two studies ($n = 154$) assessed psychological functioning and both used continuous outcomes as measured by the SCL-90.[12,14] Two studies used different versions of the SCL-90 (revised version, Italian version;[12] Dutch-adapted SCL-90[14]), with one study assessing outcomes at 3–6 months posthormone initiation[14] and the other assessing outcomes at 12 months posthormone initiation.[12] One study[12] used additional measures for anxiety and depression (Zung scale), the outcomes of which are reported below. All psychological functioning outcomes were measured continuously with mean change scores reported for the SCL-90 and for the Zung depression and anxiety scales (see summary of findings: Table 1).

Table 1. Hormone Therapy at Follow-Up Compared to No Hormone Therapy at Baseline for Improving Psychological Functioning and Quality of Life in Transgender Patients

Outcomes	Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence	Comments
Psychological functioning: global psychiatric distress (SCL-90)				
SCL-90-Dutch[14]				
Overall psychoneurotic distress standardized mean difference 3–6 months	SMD = 0.88 (1.29, 0.48)	154 (2 studies)	Low ⊕⊕⊕⊖	Two uncontrolled prospective cohort studies investigated hormone therapy and found that global psychiatric distress scores were significantly lower after treatment.
SCL-90-R Italian[12]				
GSI Standardized mean difference 12 months	SMD = 0.52 (0.79, 0.25)			
Psychological functioning: depression (SCL-90)				
SCL-90-Dutch[14]				
Standardized mean difference 3–6 months	SMD = 0.89 (1.30, 0.48)	154 (2 studies)	Low ⊕⊕⊕⊖	Two uncontrolled prospective cohort studies investigated hormone therapy and found that depression scores were significantly lower after treatment.
SCL-90-R Italian[12]				
Standardized mean difference 12 months	SMD = 0.51 (0.78, 0.24)			
Psychological functioning: anxiety (SCL-90)				
SCL-90-Dutch[14]				
Standardized mean difference 3–6 months	SMD = 0.78 (1.18, 0.38)	154 (2 studies)	Low ⊕⊕⊕⊖	Two uncontrolled prospective cohort studies investigated hormone therapy and found that anxiety scores were significantly lower after treatment.
SCL-90-R Italian[12]				
Standardized mean difference 12 months	SMD = 0.66 (0.93, 0.38)			
Psychological functioning: somatization (SCL-90)				
SCL-90-Dutch[14]				
Standardized mean difference 3–6 months	SMD = 0.64 (1.04, 0.24)	154 (2 studies)	Low ⊕⊕⊕⊖	Two uncontrolled prospective cohort studies investigated hormone therapy and found that somatization scores were significantly lower after treatment.
SCL-90-R Italian[12]				
Standardized mean difference 12 months	SMD = 0.38 (0.65, 0.10)			
Psychological functioning: interpersonal sensitivity (SCL-90)				
SCL-90-Dutch[14]				
Standardized mean difference 3–6 months	SMD = 0.70 (1.10, 0.30)	154 (2 studies)	Low ⊕⊕⊕⊖	Two uncontrolled prospective cohort studies investigated hormone therapy and found that interpersonal sensitivity scores were significantly lower after treatment.
SCL-90-R Italian[12]				
Standardized mean difference 12 months	SMD = 0.47 (0.75, 0.20)			
Psychological functioning: hostility (SCL-90)				
SCL-90-Dutch[14]				
Standardized mean difference 3–6 months	SMD = 0.31 (0.70, 0.08)	154 (2 studies)	Low ⊕⊕⊕⊖	Two uncontrolled prospective cohort studies investigated hormone therapy and found that hostility scores were lower after treatment, although only one reached statistical significance.
SCL-90-R Italian[12]				
Standardized mean difference 12 months	SMD = 0.34 (0.61, 0.07)			

(*continued*)

Table 1. (Continued)

Outcomes	Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence	Comments
Psychological functioning: phobic anxiety (Agoraphobia) (SCL-90)				
SCL-90-Dutch[14]				
Standardized mean difference 3–6 months	SMD = 0.42 (0.81, 0.03)	154 (2 studies)	Low ⊕⊕⊕⊖	Two uncontrolled prospective cohort studies investigated hormone therapy and found that phobic anxiety scores were significantly lower after treatment.
SCL-90-R Italian[12]				
Standardized mean difference 12 months	SMD = 0.37 (0.64, 0.10)			
Psychological functioning: depression (Zung Scale)				
Zung depression[12]				
Mean difference 12-month follow-up	8.06 (10.91, 5.21)	107 (1 study)	Moderate ⊕⊕⊕⊖	One study assessed changes in mean anxiety scores and found significant reductions in anxiety at 12-month follow-up, with scores now in the normal range.
Psychological functioning: anxiety (Zung Scale)				
Zung anxiety[12]				
Mean difference 12-month follow-up	7.01 (9.50, 4.52)	107 (1 study)	Moderate ⊕⊕⊕⊖	One study assessed changes in mean depression scores and found significant reductions in depression at 12-month follow-up, with scores now in the normal range.
Quality of Life (WHOQOL-100)				
WHOQOL-100[13]				
Mean difference 12-month follow-up full sample, MTF, FTM	8.3, 9.7, 5.5 (N/A)	107 (1 study)	Very low ⊕⊖⊖⊖	One study assessed mean changes in quality of life by subgroup; however, lack of reported standard deviation and *p*-values meant that CIs for full sample could not be calculated. Only MTF participants had a statistically significant increase ($p < 0.05$) in overall quality of life at 12-month follow-up.

Patient or population, transgender individuals with Gender Dysphoria; settings, European gender identity clinic; intervention, hormone therapy; comparison, no hormone therapy at baseline. Due to heterogeneity in the length of follow-up for all outcomes, the overall effect estimates are not presented. Formal GRADE[20] evaluation was not conducted; however, quality was ranked using GRADE terminology: high quality, further research is very unlikely to change our confidence in the estimate of effect; moderate quality, further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate; low quality, further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate; very low quality, we are very uncertain about the estimate.

CI, confidence interval; FTM, female-to-male; GSI, Global Severity Index; MTF, male-to-female; SCL-90, Symptom Checklist-90; SMD, standardized mean difference; WHOQOL-100, World Health Organization Quality of Life-100.

Global score of psychological functioning. The SCL-90-R Italian version provides a global score of psychological functioning (Global Severity Index), while the SCL-90 Dutch version provides an overall psychoneurotic distress score, which are similar, but scored differently. Both studies measuring overall psychiatric distress saw a significant change in global distress scores at follow-up: SMD = −0.52 [95% CI: −0.79, −0.25] (12 months of follow-up)[12] and −0.88 [95% CI: −1.29, −0.48] (3–6 months of follow-up).[14]

Depression. Participants in both studies had depression scores in the normal range at baseline as indicated by the SCL-90-R Italian version depression subscale, Zung Depression Scale,[12] and SCL-90 Dutch depression subscale.[14] Nonetheless, the SCL-90-R Italian version[12] and SCL-90 Dutch version each showed statistically significant reductions in depression post-hormone therapy across the two studies with an SMD of −0.51 [95% CI: −0.78, −0.24] (12-month follow-up)[12] and −0.89 [95% CI: −1.30, −0.48] (3–6 months of follow-up).[14] One study also assessed depression scores using the Zung Depression Scale and saw a similar statistically significant reduction at 12-month follow-up (mean difference = −8.06 (95% CI: −10.91, −5.21).[12] Meta-analysis of these two studies was precluded due to statistical heterogeneity ($I^2 = 0\%$) and disparate follow-up periods.

Anxiety. Two studies measured changes in anxiety scores from baseline to 3–6-month[14] and 12-month[12] posthormone therapy initiation using the SCL-90 anxiety subscale (SCL-90-R Italian version;[12] SCL-90 Dutch version[14]). One study also used an additional validated continuous measure of anxiety (Zung Anxiety Scale).[12]

The SCL-90 anxiety subscales showed higher than normal anxiety for participants in both studies at baseline (mean = 1.05, SD = 0.94; normal <1.0;[12] mean = 17.0, SD = 6.4; general population mean = 12.8, SD = 4.4).[14] At follow-up, both studies saw a statistically significant reduction in anxiety with scores in the normal range at 3–6-month follow-up (mean = 12.4, SD = 5.1)[14] and 12-month follow-up (mean = 0.54, SD = 0.56),[12] as well as significant standardized mean change scores (–0.66 [95% CI: –0.93, –0.38];[12] –0.78 [95% CI: –1.18, –0.38][14]).

One study also showed a reduction in anxiety using a different continuous measure (Zung Anxiety) from above the normal range at baseline (mean = 44.91, SD = 9.59; normal = 24–44) to within the normal range at 12-month follow-up (mean = 37.90, SD = 8.97)[12] and this change was highly significant (mean difference = −7.01 [95% CI: –9.50, –4.52]).

Somatization. Two studies assess somatization as a subscale measure in the SCL-90 (SCL-90-R Italian version;[12] SCL-90 Dutch version[14]). One study had somatization scores within the normal range at baseline (mean = 0.54, SD = 0.59; normal <1.0).[12] The other study had significantly higher baseline somatization scores compared with the general population at baseline (mean = 18.6, SD = 6.7; general population mean = 16.7, SD = 5.3);[14] however, scores remained significantly higher than the general population even at 3–6-month follow-up (mean = 15.2, SD = 2.7). Nonetheless, both studies saw a significant reduction in somatization scores posthormone therapy initiation as measured by mean change scores at 3–6-month follow-up (–0.64 [95% CI: –1.04, –0.24])[14] and 12-month follow-up (–0.38 [95% CI: –0.65, –0.10]).[12]

Interpersonal sensitivity. Two studies assessed interpersonal sensitivity using the SCL-90 (SCL-90-R Italian version;[12] SCL-90 Dutch version[14]). Participants in one study had significantly higher scores than the general population at baseline (mean = 31.8, SD = 11.7; general population mean = 24.1, SD = 7.6).[14] The other study had normal interpersonal sensitivity scores at baseline (mean = 0.97, SD = 0.82; normal <1.0).[12] Participants in both studies evinced a significant reduction in standardized mean change scores posthormone initiation at 3–6-month follow-up (SMD = −0.70 [95% CI: –1.10, –0.30])[14] and 12-month follow-up (SMD = −0.47 [95% CI: –0.75, –0.20]).[12] One study showed a reduction in interpersonal sensitivity scores that no longer differed significantly from those of the general population at 3–6-month follow-up (mean = 16.6, SD = 7.0; general population mean = 24.6, SD = 7.9).[14] While both studies[12,14] lacked statistical heterogeneity ($I^2 = 0\%$), the interpersonal sensitivity outcomes were measured at different time points (12 months;[12] 3–6 months[14]), making meta-analysis inappropriate.

Hostility. Using the SCL-90, two studies assessed hostility (SCL-90-R Italian version;[12] SCL-90 Dutch version).[14] Participants in both studies had hostility scores in the normal range, consistent with that of the general population (mean = 0.57, SD = 0.69; normal <1.0;[12] mean = 8.2, SD = 3.0; general population mean = 7.2, SD = 2.1).[14] Nonetheless, both studies showed a reduction in hostility scores posthormone therapy initiation, although the reduction was not statistically significant at 3–6 month follow-up (SMD = −0.31 [95% CI: –0.70, –0.08])[14] and the other was statistically significant at 12-month follow-up (SMD = −0.34 [95% CI: –0.61, –0.07]).[12] One study demonstrated a reduction in scores to a similar level as the general population at 3–6 month follow-up (mean = 7.4, SD = 2.0; general population mean = 7.2, SD = 2.1).[14]

Phobic anxiety. Two studies assessed phobic anxiety using the SCL-90 (SCL-90-R Italian version;[12] SCL-90 Dutch version).[14] Participants in one study had phobic anxiety scores in the normal range before initiating hormone therapy (mean = 0.53, SD = 0.61; normal <1.0).[12] The other study had phobic anxiety called agoraphobia in the SCL-90 Dutch version[14] scores that were significantly higher than the general population at baseline (mean = 9.5, SD = 4.2; general population mean = 7.9, SD = 2.3).[14]

Both studies saw a statistically significant change in phobic anxiety scores from baseline to follow-up (SMD = −0.37 [95% CI: –0.64, –0.10];[12] SMD = −0.42 [95% CI: –0.81, –0.03]),[14] with one study showing a reduction in phobic anxiety in scores to a level that was similar to those of the general population (mean = 8.1, SD = 1.8; general population mean = 7.9, SD = 2.3).[14]

Quality of life. Only one study ($n = 83$) assessed quality of life using the validated WHOQOL-100 questionnaire.

Mean baseline scores and 12-month postintervention follow-up scores are reported overall and by subgroup (MTF/FTM). The study reported data for subgroups (MTF/FTM) and the mean follow-up scores were calculated for the full sample. The mean standard deviations for both subgroups were not reported and the *p*-value from the paired *t*-tests was only reported for the MTF subgroup, thus it was not possible to calculate a standard deviation for the full sample and compare pre/post means. Thus, findings must be considered in light of lack of reported data. See summary of findings (Table 1).

One study reported on general quality of life.[13] At baseline, general quality of life, as measured through the WHOQOL-100, was in the normal/good range (i.e., ≥50) at 62.74. At follow-up, the quality of life score increased to 71.08 (max = 100); however, the significance of this increase cannot be determined. Among MTF participants, paired t-tests showed a significant increase in overall quality of life from 62.5 to 72.2 ($p < 0.05$) at 12-month follow-up. For FTM participants, increases were observed (63.25 [baseline]; 68.75 [follow-up]); however, the increase in overall quality of life was not significant.[13] Given that only one study reported on quality of life outcomes, meta-analysis was not possible.

Methodological quality

See summary of findings (Table 1) and risk of bias (Fig. 2). The overall quality of evidence is low. While the studies used a prospective design, which is better quality than one-time cross-sectional studies, all studies lacked a control group. No studies used a randomized design. Moreover, all outcomes were based on self-report, which is subject to bias. However, all the measures used were based on psychometrically valid and reliable scales.

One confounding factor is that all studies provided psychotherapy to patients as part of standard of care for their clinic and all patients socially transitioned while accessing hormone therapy. While concurrent psychotherapy is often accessed by transgender patients on hormone therapy, and transgender patients have generally socially transitioned before initiating hormones, the effects of psychotherapy and social transition on mental health outcomes could have masked the true effects of hormone therapy on the mental health of patients. The studies were careful, however, to exclude participants with serious untreated psychiatric comorbidities (e.g., schizophrenia, substance abuse, and personality disorder).

Many studies failed to assess important confounders such as access to other medical gender affirmation technologies (e.g., surgeries) and none of the studies adjusted for confounders in their results such as the use of psychotropic medications.

Discussion

Although the studies differ with regard to outcome measures and most studies have methodological shortcomings, the three prospective cohort studies reviewed here offer provisional conclusions about the effects of hormone therapy on the psychological functioning of transgender individuals accessing it. Two studies[12,14] reported on psychological functioning and found a statistically significant reduction in depression, somatization, interpersonal sensitivity, anxiety, hostility, and phobic anxiety/agoraphobia after initiating hormone therapy, with one study observing significant results 3–6 months posthormone initiation and the other 12 months posthormone initiation. There is insufficient

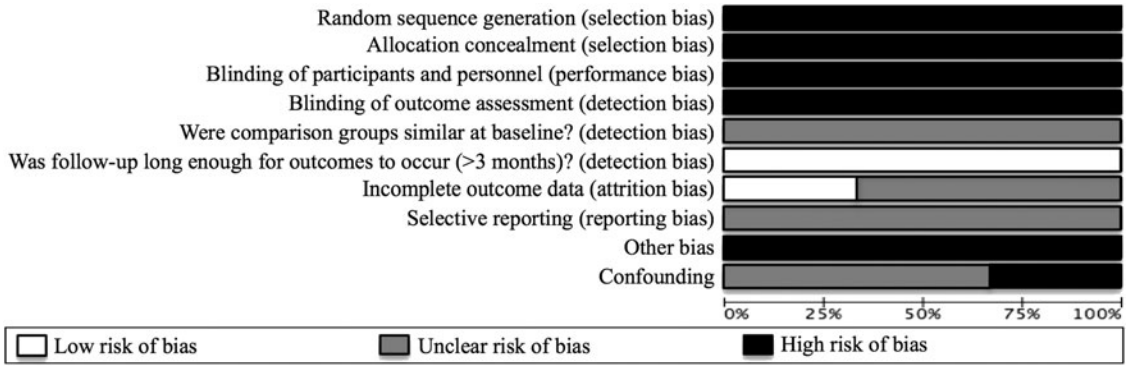

FIG. 2. Risk of bias: Assessment of each risk of bias item presented as percentages across all included studies.

evidence about whether changes in quality of life occur for FTM individuals who initiate hormone therapy. However, low quality evidence suggests that quality of life may be improved for MTF individuals accessing hormone therapy.

Findings support and extend the findings of another review,[7] which provided very low quality evidence that hormone therapy may improve the mental health of transgender people. However, the prior systematic review, which included 28 studies, assessed the effects of hormone therapy together *with* sex reassignment surgery on mental health, psychological functioning, sexual functioning, and quality of life and thus was unable to parse out the effects of hormone therapy separately from surgical interventions.

Given that many transgender people may never access sex reassignment surgery, it was important to study the effects of hormones alone with regard to mental health and quality of life outcomes. Moreover, the majority of studies included in the prior review were cross-sectional and none of the studies assessing mental health or psychological functioning used prospective study designs with a follow-up period of 3 months or more. Furthermore, the only studies that included a control group in the prior review assessed sex reassignment surgery and hormone therapy together, without comparing hormone therapy with an untreated control. Nonetheless, the prior review did find that the studies assessing sex reassignment surgery together with hormone therapy were strongly associated with improved psychological functioning,[7] thus findings from the current review extend these results.

Like the previous systematic review,[7] results of this review demonstrate low quality evidence (previous review demonstrated *very* low quality evidence), suggesting that hormonal therapies given to individuals diagnosed with having gender identity disorder (i.e., gender dysphoria) improve psychological functioning. However, unlike the previous review, this review is unable to offer conclusive evidence regarding the effects of hormone therapy on quality of life for transgender individuals overall.

Contrary to the prior review,[7] which found that MTF transgender people may have worse outcomes than FTM individuals, the study reviewed here found that MTF individuals had statistically significant improvements in quality of life 12 months after initiating hormone therapy, while FTM individuals did not experience increases that reached statistical significance, which was likely due to the small sample size.[13] Additional research is needed to confirm quality of life results overall and by gender subgroups.

Limitations regarding potential sources of bias in the review process should be noted. Three databases were used to identify studies for inclusion in this review and the search was limited to studies published in English. These search limitations may have resulted in the loss of relevant studies and influenced the results of the review. However, the electronic search was supplemented by checking references and citations of other articles, which yielded additional studies. Moreover, while the field of transgender health is truly global, English represents the predominant scientific publication language, thus significant findings, using less biased observational results, would have been likely to be published in English.

Nonstatistically significant findings may not have been published in English (i.e., publication bias). Nonetheless, it is feasible that all relevant studies have been identified. Additionally, study identification was completed by a single reviewer (the first author) in consultation with an expert reference librarian and researchers with expertise in systematic reviews. While the reviewer thoroughly conducted the search and review process, it is possible that studies that met inclusion criteria were not included in the review or were subject to a single reviewer's biases.

The restriction to prospective cohort studies also meant that the reviewer was unable to consider data from other types of evaluations of hormone therapy interventions such as one-time cross-sectional studies or qualitative evaluations. Although prospective cohorts are a stronger design than cross-sectional studies due to temporal ordering of exposure and outcomes, the cohort studies in this review were subject to a number of biases and other limitations (see the risk of bias section above and Fig. 2).

Uncontrolled prospective cohort studies suggest that hormonal therapies given to individuals diagnosed with having gender identity disorder (i.e., gender dysphoria) likely improve psychological functioning 3–12 months after initiating hormone therapy. Findings from the review support current clinical care guidelines such as the WPATH Standards of Care,[6] which recommend the use of hormone therapy as a treatment option to reduce gender dysphoria. Future research should assess the effects of hormone therapy on the mental health of transgender individuals using more robust study designs, including those which utilize clinician-delivered mental health outcome measures, longitudinal designs with control groups, and those examining U.S.-based transgender people over time.

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Abbreviations Used

CI = confidence interval
FTM = female-to-male
MTF = male-to-female
SCL-90 = Symptom Checklist-90
SMD = standardized mean difference
WHOQOL-100 = World Health Organization Quality of Life-100

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SELF-DIRECTED VIOLENCE SURVEILLANCE

UNIFORM DEFINITIONS AND RECOMMENDED DATA ELEMENTS

National Center for Injury Prevention and Control
Division of Violence Prevention

CS214119

AR-002924

Self-directed Violence Surveillance: Uniform Definitions and Recommended Data Elements

Version 1.0

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February 2011

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BACKGROUND

Background

Introduction

Self-directed violence (SDV) is an important cause of mortality and morbidity in the United States and worldwide. Though numerous organizations collect information on fatal and non-fatal SDV, there is considerable confusion about how to define the phenomenon. To address the current lack of uniform definitions, the Centers for Disease Control and Prevention (CDC) proposes the following surveillance* definitions for SDV. Use of consistent terminology with standardized definitions will improve communication among researchers, clinicians, and others working in this important area.

**In this document, the term "surveillance" is used in the public health sense and is defined as the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health.*[1]

Public Health Burden

The World Health Organization defines violence as: "The intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community, that either results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment or deprivation."[2] The definition should be understood to include consequences such as psychological and social problems as well as physical problems, all of which are of concern to communities and place considerable burdens on the health, social and justice systems. This definition recognizes that the outcomes of violence are broader than physical injury, disability or death. Injuries and deaths resulting from self-directed violent behaviors represent a substantial drain on the economic, social, and health resources of the nation.

Self-directed violence (SDV) encompasses a range of violent behaviors, including acts of fatal and nonfatal suicidal behavior, and non-suicidal intentional self-harm (i.e., behaviors where the intention is not to kill oneself, as in self-mutilation). Though not a behavior, we have chosen to include suicidal ideation (i.e., thinking about, considering, or planning for suicide) in this document due to its association with self-directed violent behavior.[3] The National Center for Injury Prevention and Control (NCIPC) has adopted the public health approach to systematically address the problem of self-directed violence. The public health approach involves the following: defining and describing the nature of the problem; studying the factors that increase or lower risk; developing and evaluating ways to prevent the problem; and implementing interventions and disseminating information.[2]

Injury from self-directed violence is a major public health problem throughout the United States and the rest of the world.[2,4-6] In 2007 in the United States, suicide, one form of SDV, was the 11th leading cause of death overall, resulting in 34,598 deaths[7]; it was the third leading cause of death among persons aged 15–24 years, fourth among persons aged 25–44 years, and eighth among those aged 45–64 years.[8] Although suicide continues to be problematic throughout the life span, rates for males are highest among those aged 85+ years, while among females the rates are highest among those aged 45–49 years. Suicides reflect only a minor portion of the total impact of suicidal behavior which itself is a component of SDV. Substantially more persons are hospitalized as a result of nonfatal suicidal behavior than are fatally injured, and an even greater number are either treated in ambulatory settings or not treated at all.[9,10] There were an estimated average of 533,000 visits to U.S. hospital emergency departments for self-directed violence, the majority of which are suicide attempts, which occurred during 2005 and 2006.[11,12] Other research indicates that >50% of persons who engage in suicidal behavior never seek health services.[13] Consequently, prevalence figures based on health records substantially underestimate the societal burden of suicidal behavior and of SDV.

Comparative descriptions of suicidal ideation or behavior demonstrate certain key differences among population groups. For example, rates of suicide are higher among males than among females, while the reverse is found in studies of suicidal thoughts and nonfatal suicidal behavior.[14] Age-group specific suicide rates have traditionally been highest

among older adults aged >65 years compared to adolescents and young adults, but rates on nonfatal suicidal behavior are highest among the younger age groups and relatively low among older adults.[4] Certain US populations such as American Indians/Alaska Natives and African-Americans have their highest suicide rates among adolescents and young adults whereas other groups such as Asian-Americans and Hispanics have their highest rates among older adults.[15]

Total lifetime costs associated with nonfatal injuries and deaths caused by self-directed violence in 2000 were approximately $33 billion, including $1 billion for medical treatment and $32 billion for lost productivity.[16] Compounding these costs is the incalculable impact of loss of life and the emotional trauma experienced by surviving family, friends, and communities that are affected by each person's fatal or nonfatal suicidal behavior.[17]

Need for Better Data

Despite the large volume of data on certain types of SDV, the utility and reproducibility of the resulting information is sometimes questionable. Mortality data are problematic for several reasons: geographical differences in the definition of suicide and how equivocal cases are classified; jurisdictional differences in the requirements for the office of coroner or medical examiner affecting the standard of proof required to classify a death as a suicide; and differences in terms of the extent to which potential suicides are investigated to accurately determine cause of death.[18] The quality of the data on nonfatal suicidal behavior is even more problematic than that of suicides. The concerns about discrepancies in nomenclature[19-23] and accurate reporting[11,24] apply here even more than with suicides. Also, except for rare exceptions there is neither systematic nor mandatory reporting of nonfatal suicidal behavior in the United States at the state or local level, nor is there routine systematic collection of non-suicidal intentional self harm data.

These "system" problems with data collection have been discussed for more than a generation. Over 35 years ago, the National Institute of Mental Health (NIMH) convened a conference on suicide prevention at which a committee was charged with recommending a system for defining and communicating about suicidal behaviors.[25] More recently, two scientific reviews that addressed the state of suicide-related research also remarked on the need for consistent definitions. The Institute of Medicine issued a report entitled *Reducing Suicide: A National Imperative*.[4] This report states "Research on suicide is plagued by many methodological problems… definitions lack uniformity,…reporting of suicide is inaccurate.""There is a need for researchers and clinicians in suicidology to use a common language or set of terms in describing suicidal phenomena."The World Health Organization issued the *World Report on Violence and Health*.[2] In the chapter addressing self-directed violence the authors note "Data on suicide and attempted suicide should be valid and up to date. There should be a set of uniform criteria and definitions and – once established – these should be consistently applied and continually reviewed."

There are also "non-system" barriers to obtaining reliable SDV surveillance information. For example, the repetitive nature of some types of SDV, make it important to separate counts of the number of *individuals* affected from the number of *incidents* of SDV. This difficulty is compounded by the varying procedures used by different data collection sources. Health care organizations may file and treat each event separately, or they may record repeated incidents in the same patient file. In addition, there are social barriers to obtaining accurate SDV surveillance data. These barriers include the stigma associated with the topic; the guilt and shame that inhibit a patient's admission that act was intentional; and the lack of training and other concerns that inhibit health care personnel's capacity to elicit and record accurate accounts of SDV in official records. Furthermore, it appears only a minority of individuals engaging in SDV behavior ever seek help from the health care system.[13]

For example, to address just the suicide-related component of SDV as a public health problem would require the sustained and systematic collection, analysis and dissemination of accurate information on the incidence, prevalence and characteristics of fatal and nonfatal suicidal behavior. Surveillance is a cornerstone of public health, allowing realistic priority setting, facilitating the design of prevention programs, and the ability to evaluate such programs.[26] Official suicide rates have been used to chart trends in suicide; monitor the impact of change in legislation, treatment policies, and social change; and to compare suicides across regions, both within and across countries. In addition, suicide rates afford a method by which to assess population-based risk and protective factors for geographical areas (counties, states and countries). However, there exist serious inadequacies in the availability and quality of mortality data. The sources of data that are currently available remain "'thin' ... with no connection to other relevant data...".[27]

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The need for improved and expanded surveillance systems is highlighted as one of the central goals of the National Strategy for Suicide Prevention.[14]

Inconsistent reporting of SDV has significant consequences for public health and application in problem description, assessment of risk and protective factors, understanding the longitudinal course and outcome of SDV processes, and the development and evaluation of effective preventive and treatment intervention strategies. Differential underreporting for certain groups means that our understanding of that population's risk and protective factors for SDV may contain significant inaccuracies. This could result in inattention to an at-risk population: if the true rates of SDV are higher than the official statistics indicate, not only is SDV likely to be viewed as a less important problem among this population, but the SDV risk factors identified by researchers might more accurately reflect the SDV process for some other group. When these faulty conclusions become the basis for developing SDV prevention programs, such programs might miss opportunities to address the factors more consequential for the targeted population. To correct this process, we need accurate data on each group.

CDC has initiated several activities with the goal of improving classification of certain forms of SDV. CDC developed national practice guidelines for determining suicide for coroners and medical examiners.[28] In addition, CDC has included an objective to examine surveillance methods for SDV in the National Center for Injury Prevention and Control's research agenda.[29] As a co-sponsor of the National Strategy for Suicide Prevention (NSSP), CDC supported the inclusion of items specifically addressing expansion and improvement of data systems including surveillance.[14] CDC's previous efforts developing uniform definitions and recommended data elements in the separate areas of intimate partner violence, sexual violence and child maltreatment have informed the process of developing the definitions for SDV.[30-32] CDC has also supported the development of SDV surveillance. For example, CDC has developed a module to assess self-directed violence in the National Electronic Injury Surveillance System-All Injury Program (NEISS-AIP) which includes data on hospital emergency department visits for nonfatal self-directed violence.[33] The module supplements information from the general NEISS-AIP by collecting additional information on the characteristics of persons presenting to hospital emergency departments (EDs) for self-directed violence; identifying specific substances used in the event; and acting as an early warning system on emerging problems in regard to self-inflicted injury.[34]

Recognizing the need to improve the quality of SDV data, the CDC's National Center for Injury Prevention and Control (NCIPC) initiated a process to address some of the conceptual difficulties inherent in the task. CDC decided to concentrate its new efforts on developing uniform definitions and data elements for SDV surveillance. The process involved a consultative procedure to address some of the scientific issues related to definitions and potential data elements that might be appropriate to collect as part of surveillance activities.

The SDV Consultative Process

- The history of CDC work on SDV surveillance definitions and recommended data elements, spans several years:
- In 2003, CDC commissioned an extensive review of the scientific literature that addressed self-directed violence (SDV) surveillance definitions. The information gathered from this review was synthesized in a report.
- CDC recruited a panel of scientists and practitioners representing multiple disciplines (e.g., medicine, psychology, epidemiology, sociology), various affiliations (e.g., government, academic institutions), and diverse areas of interest (e.g., suicidal behavior, public health surveillance, injury prevention). This panel was convened for a discussion of SDV surveillance definitions.
- The report from the literature review, select publications on suicide-related nomenclature, and other documents on public health and injury-specific surveillance were compiled as background material and distributed to the panel.
- The panel was convened in April 2004 to develop draft SDV definitions, data elements, and items for a glossary.
- The panel discussion was recorded and transcribed and the resulting meeting notes were compiled and distributed to panel members for review and commentary.
- The draft definitions were reviewed and discussed at an October 2005 meeting with suicide prevention leaders representing the U.S Army, Navy, Air Force, Marines and Coast Guard.

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- The meeting notes and draft definitions were distributed to external reviewers nominated by the panel. Written feedback from the external reviewers on the definitions and glossary was compiled and added to the meeting notes. The meeting notes along with the external panel comments and suggestions were distributed to the original panel.
- The original 2004 panel was reconvened in April 2007 (with two substitutions) to examine comments from the external reviewers, discuss advances in the field since the last meeting and revise the definitions document.
- At the April 2007 meeting, the panel was charged with three main tasks: 1) finalizing the definitions to be used in the document; 2) revising the list of glossary terms, and 3) identifying a set of data elements that were considered essential for SDV surveillance. During the panel discussion, however, it became evident that there were no clearly identifiable criteria or procedures for determining which data elements could plausibly be collected in the diverse nature of national, state and local surveillance systems, or which ones were the highest priority. The data elements presented in this report are those identified by the panel as useful, acknowledging that some institutions participating in a surveillance system may be able to collect only a subset of the recommended elements. The panel also developed conceptual definitions of terms to be used in conjunction with the data elements. It became evident that these definitions might need to be operationalized (i.e., made measurable) in different ways, depending on the source of the data.
- The discussion at the April 2007 meeting was recorded, transcribed and distributed to panel members. CDC staff summarized the recommendations from the April 2007 meeting, and incorporated changes recommended by the panel members. CDC staff also researched definitions for the glossary terms, developed descriptions and criteria for the data elements and produced a document containing all of this information.
- A draft of the document using the 2007 meeting notes, glossary, data elements, and vignettes was sent to the panel, and other external reviewers nominated by the panel. Drafts of the definitions-only were also distributed to individuals representing the Department of Defense, Department of Veterans Affairs and Coast Guard for comments and suggestions.
- A summary of the draft definitions and recommended data elements was presented at several national suicide prevention conferences during 2008 and 2009 and comments were solicited from audience members.
- Selected comments from the various groups were incorporated into the document.
- Revisions were made to definitions and key terms to make them consistent with Department of Veterans Affairs' SDV classification system clinical tool.

Purpose and Scope

Self-directed Violence Surveillance: Uniform Definitions and Recommended Data Elements, is intended for use by individuals and organizations interested in gathering surveillance data on self-directed violence. The document is not meant as a mandate, but rather is intended to promote and improve consistency of SDV surveillance. If the recommended data elements can be uniformly recorded and the data made available to numerous users, then better estimates of SDV incidence and prevalence can be obtained and problems such as data incompatibility and high costs of collecting, linking, and using data can be substantially reduced.

The recommended data elements are designed to collect information of value for public health surveillance of SDV and to serve as a technical reference for automation of surveillance data. The 35 data elements are organized into 2 major sections: Identifying Information for the SDV Surveillance System and the Individual's Demographics; and Characteristics associated with the Individual's SDV behavior. A structured format, modified from the Data Elements for Emergency Department Systems (DEEDS), Release 1.0[35], is used to document each data element as follows: a Description/Definition of the data element; a description of its Uses; a Discussion of conceptual or operational issues; specification of the Data Type (and maximum allowed Field Length); an indication of when data element repetition may be necessary to include all answers that may apply; Field Values/Coding Instructions that designate recommended coding specification and valid data entries; and, where applicable, reference to one or more data standards or guidelines used to define the data element and its field values, and other references considered in developing the data element.[35] Data types and field lengths conform to specifications in Health Level 7 (HL7), a widely used protocol for electronic data exchange, and ASTM's (formerly known as the American Society for Testing and Materials) E1238-94: Standard Specification for Transferring Clinical Observations Between Independent Computer Systems.[36,37]

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Notes on the Use of *Self-directed Violence Surveillance: Uniform Definitions and Recommended Data Elements,* Version 1.0

The "definitions" proposed here are likely to be valuable for a wide range of policymakers, researchers, public health practitioners, service providers, and media professionals seeking to clarify discussions about SDV. However, most terms in the "Uniform Definitions" are defined in only a general sense, and researchers and other users may need to further refine them. Other terms, such as "victim-precipitated" and "self-inflicted" are included in the key terms section. However, this document could not be exhaustive regarding terminology so users are referred to other documents such as the IOM report on suicidal behavior or the NSSP. Issues needing further clarification could be addressed in subsequent versions of the "definitions". It should be noted that the definitions proposed here are consistent with others which have undergone empirical testing and demonstrated good reliability.[38]

As you use the "Recommended Data Elements," consider the following points:

- Ethical and safety issues are foremost in any effort to examine self-directed violence. No data should be collected or stored in a manner that could jeopardize an individual's safety or privacy. Those interested in developing a surveillance system for SDV must be particularly conscious of the need to preserve confidentiality. The issue of confidentiality must be balanced with the need for data linkage across multiple data sources, perhaps through mechanisms such as encryption of unique identifiers.
- Concurrent with progress toward more uniform and accessible data, existing methods of protecting the confidentiality of data must be strengthened. Guaranteeing confidentiality will serve multiple purposes. First, it may protect individuals who engage in SDV from potential discrimination. Second, it may encourage those individuals to report SDV.
- Each data element is numbered for convenience of presentation and for easy identification. In addition, literature sources for the background section (i.e., public health burden, need for better data, SDV consultative process, purpose and scope, and next steps) are listed separately from the references for the data elements to ease use. The data elements are not meant to be "administered" as a survey or a questionnaire, but instead are presented as information to be gathered from appropriate data sources in the jurisdictions conducting SDV surveillance. Thus, the elements can be gathered in any order and can be obtained from one or more data sources for individuals engaging in self-directed violence. Each data element includes a code set that specifies recommended coding values and instructions for what to do when the data element is not applicable for a particular victim. Obviously, the accuracy and completeness of data collected on SDV events depends upon what is documented by the agency providing the information.
- Currently the "Recommended Data Elements" contains 35 items, however the list may be modified in the future. Persons implementing a surveillance system using this list may find that one or more variables need to be added, removed, or enhanced.[36] Further, the list should not discourage individuals who operate systems from collecting information that is not included in the recommended elements. Rather, the suggested elements will comprise a core set of data that should, if possible, be systematically be collected by all surveillance systems. Desirable data elements that are not feasible to collect as part of a surveillance system will need to be collected in other ways.
- The goals of SDV surveillance are to obtain an estimate of the number of people who are affected by self-directed violence and to describe the characteristics of people affected, the number and types of SDV episodes, the associated injuries, and other consequences. Counting injuries as part of a surveillance system is a common proxy for estimating the number of people affected. However, the large number of cases in which multiple forms of violence co-occur and the repetitive nature of SDV mean that such a proxy may be less accurate than is desired. To obtain more accurate estimates of the number of people affected by SDV, ultimately we will need to develop some mechanism for linking data, both within and across different data sources.[39, 40] For further discussion and information on setting up an injury surveillance system, please see the WHO's document Injury Surveillance Guidelines.[41]
- No single data source is likely to collect all of the components of SDV. As a consequence, it is likely that anyone setting up a surveillance system will need to integrate data from multiple sources (e.g., death certificates, hospital records, emergency medical system records, surveys, health care records and law enforcement records) to develop a comprehensive picture of SDV in their community.[42, 43]

- It is recognized that categorizing SDV behavior into suicidal and non-suicidal categories can be difficult. This is due to several considerations, first that the behavior is multi-dimensional rather that unitary and second that if information is collected from patients' self-reports, that the way the individual perceives his/her intent can change within a few hours. Nevertheless, due to the essential nature of this information to clinical and public health decision-making, it is critical to try to obtain it.[44]
- Vignettes are included after the data elements to provide the reader with an opportunity to make an assessment about SDV categorization in the situations described. Their purpose is to provide an opportunity for the reader to gauge his/her understanding of the material.

Next Steps

As with the CDC guidelines for recommended data elements for other forms of violence (*Intimate Partner Violence Surveillance: Uniform Definitions and Recommended Data Elements, Version 1.0,* 2002; *Sexual Violence Surveillance: Uniform Definitions and Recommended Data Elements, Version 1.0,* 2002; and *Child Maltreatment Surveillance: Uniform Definitions for Public Health and Recommended Data Elements, Version 1.0.,* 2008), this initial release of *Self-directed Violence Surveillance: Uniform Definitions and Recommended Data Elements, Version 1.0* is intended to serve as a starting point.[30-32] Many data element definitions and coding specifications are new, and field testing is necessary to evaluate them. Systematic field studies or pilot tests are needed to gauge the usefulness of Version 1.0 for SDV surveillance, to identify optimal methods of data collection, and to specify resource requirements for implementation. This testing will help to identify unforeseen problems with the data elements and adaptations needed for various settings, and to ensure that categories are mutually exclusive. Along with testing, evaluation of any surveillance system using these definitions is essential.[43]

These definitions can be applied in a variety of communities or settings where surveillance systems are either in-place or planned such as states, counties, or health clinics, emergency departments, hospitals, and institutions responsible for completing death certificates. Though the proposed definitions are not directly translatable to household or community survey application, the concepts of the definitions could be converted into data items for reliability and validity testing. Prospective users of Version 1.0 are invited to contact CDC to discuss their plans for evaluating or using some or all of the recommended data elements. Lessons learned through field testing and evaluation will be a valuable source of input for subsequent revisions, but all comments and suggestions for improving this document are welcome.

We hope that many organizations will try these definitions and data elements and provide feedback to CDC. Exploration of surveillance methods and assessments of the feasibility and utility of collecting this information will improve future versions of this document. We plan to use information obtained from trials of the initial version to refine the definitions and the number of recommended data elements in future versions.

Please send questions or suggestions for improving *Self-directed Violence Surveillance: Uniform Definitions and Recommended Data Elements, Version 1.0* to:

Etiology and Surveillance Branch
Division of Violence Prevention
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway, NE, MS F63
Atlanta, GA 30341
www.cdc.gov/violenceprevention

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UNIFORM DEFINITIONS

Uniform Definitions

Definitions

Self-directed violence (analogous to self-injurious behavior)

Behavior that is self-directed and deliberately results in injury or the potential for injury to oneself.

This does not include behaviors such as parachuting, gambling, substance abuse, tobacco use or other risk taking activities, such as excessive speeding in motor vehicles. These are complex behaviors some of which are risk factors for SDV but are defined as behavior that while likely to be life-threatening is not recognized by the individual as behavior intended to destroy or injure the self. (Farberow, N. L. (Ed.) (1980). The Many Faces of Suicide. New York: McGraw-Hill Book Company). These behaviors may have a high probability of injury or death as an outcome but the injury or death is usually considered unintentional. Hanzlick R, Hunsaker JC, Davis GJ. *Guide for Manner of Death Classification.* National Association of Medical Examiners. Available at: http://www.charlydmiller.com/LIB03/2002NAMEmannerofdeath.pdf. Accessed 1 Sept 2009.

Self-directed violence is categorized into the following:

Non-suicidal (as defined below)

Suicidal (as defined below).

Non-suicidal self-directed violence

Behavior that is self-directed and deliberately results in injury or the potential for injury to oneself.

There is no evidence, whether implicit or explicit, of suicidal intent. Please see appendix for definition of implicit and explicit.

Suicidal self-directed violence

Behavior that is self-directed and deliberately results in injury or the potential for injury to oneself.

There is evidence, whether implicit or explicit, of suicidal intent.

Undetermined self-directed violence

Behavior that is self-directed and deliberately results in injury or the potential for injury to oneself.

Suicidal intent is unclear based on the available evidence.

Suicide attempt

A non-fatal self-directed potentially injurious behavior with any intent to die as a result of the behavior.

A suicide attempt may or may not result in injury.

Interrupted self-directed violence – by self or by other

By other - A person takes steps to injure self but is stopped by another person prior to fatal injury. The interruption can occur at any point during the act such as after the initial thought or after onset of behavior.

By self (in other documents may be termed "aborted" suicidal behavior) - A person takes steps to injure self but is stopped by self prior to fatal injury.

Source: Posner K, Oquendo MA, Gould M, Stanley B, Davies M. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. Am J Psychiatry. 2007; 164:1035-1043. http://cssrs.columbia.edu/

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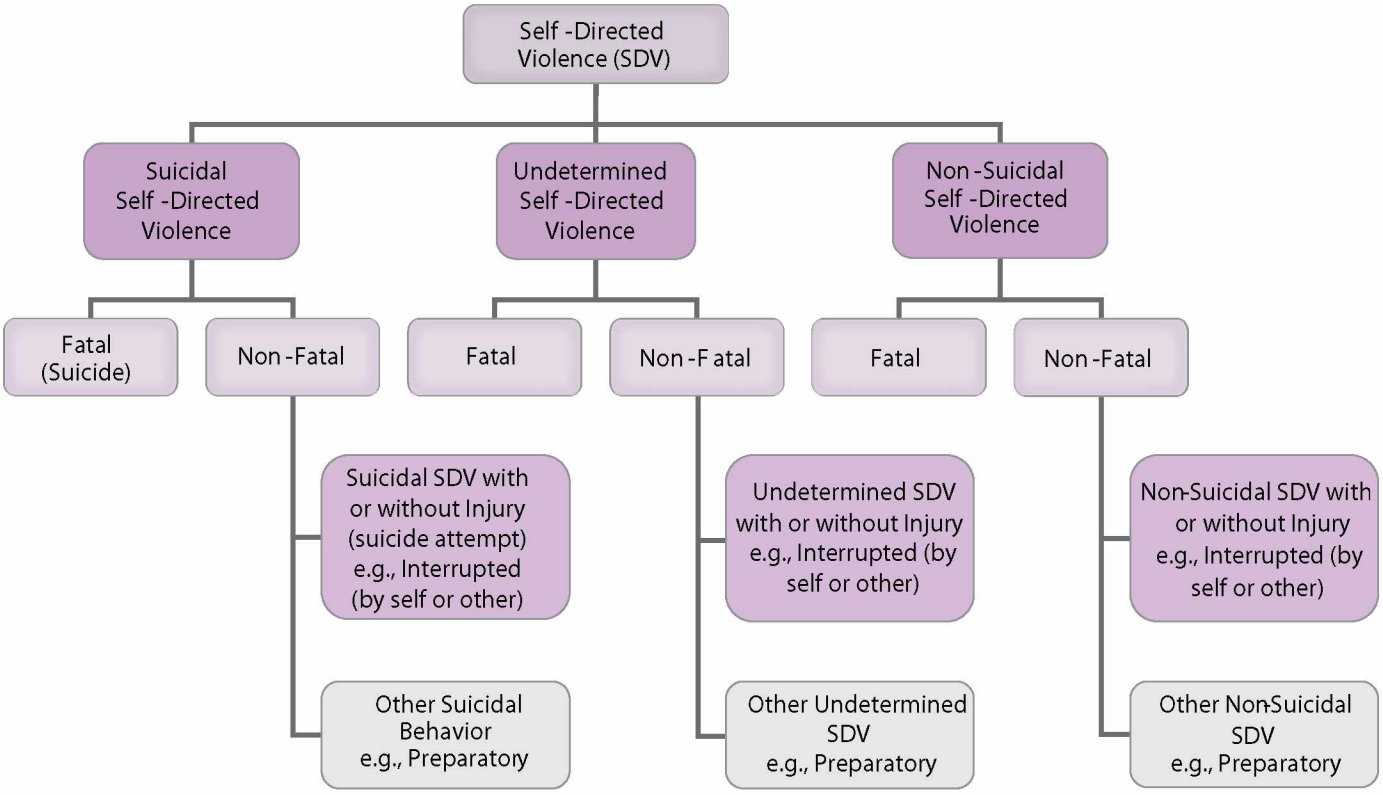
Flowchart for Surveillance Definitions for Self-Directed Violence



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Other suicidal behavior including preparatory acts

Acts or preparation towards making a suicide attempt, but before potential for harm has begun. This can include anything beyond a verbalization or thought, such as assembling a method (e.g., buying a gun, collecting pills) or preparing for one's death by suicide (e.g., writing a suicide note, giving things away). Posner et al, 2007.

Suicide

Death caused by self-directed injurious behavior with any intent to die as a result of the behavior.

Unacceptable Terms

The panel felt the following terms are unacceptable for describing self-directed violence:

- Completed suicide - This terminology implies achieving a desired outcome whereas those involved in the mission of "reducing disease, premature death, and discomfort and disability" (J. Last, Dictionary of Epidemiology 1988) would view this event as undesirable. Alternate term: suicide
- Failed attempt - This terminology gives a negative impression of the person's action, implying an unsuccessful effort aimed at achieving death. Alternate terms: suicide attempt or suicidal self-directed violence.
- Nonfatal suicide – This terminology portrays a contradiction. "Suicide" indicates a death while "nonfatal" indicates that no death occurred. Alternate term: suicide attempt
- Parasuicide – Formally used to refer to a person's self-directed violence whether or not the individual had an intent to die. However, the World Health Organization is now favoring the term suicide attempt. Alternate terms: non-suicidal self-directed violence or suicidal self-directed violence.
- Successful suicide – This term also implies achieving a desired outcome whereas those involved in the mission of "reducing disease, premature death, and discomfort and disability" would view this event as undesirable. Alternate term: suicide.
- Suicidality - This terminology is often used to refer simultaneously to suicidal thoughts and suicidal behavior. These phenomena are vastly different in occurrence, associated factors, consequences and interventions so should be addressed separately. Alternate terms: suicidal thoughts and suicidal behavior.
- Suicide gesture, Manipulative act, and Suicide threat – Each of these terms gives a value judgment with a pejorative or negative impression of the person's intent. They are usually used to describe an episode of nonfatal, self-directed violence. A more objective description of the event is preferable such as non-suicidal self-directed violence or suicidal self-directed violence.

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RECOMMENDED DATA ELEMENTS

Recommended Data Elements

Introduction

Each of the sections to follow describes specific recommended data elements that can be included in a surveillance system designed to collect information on suicide. The order of the data elements as they appear in this document is not intended to suggest a hierarchy, users may choose the order of data elements that best fits their surveillance system.

For each data element some, or all, of the following categories of information are listed:

- Name of the data element;
- Description or Definition of the data element;
- Uses of the data element;
- Discussion of relevant conceptual or operational issues;
- Data Standards or Guidelines used to define the data elements and its field values;
- Multiple Response Option or Repetition, an indication of where it is appropriate to include more than one response, e.g. appropriate to code all answers or response options that apply;
- Other References consulted in developing the data elements.

Depending on the relevance of the information for a specific data element some of the previous categories (e.g., uses, discussion, etc) may be marked as not applicable.

Data elements

Identifying Information

1 Case ID

2 Data Source

Individual Sociodemographics

3 Sex

4 Age, Birth Date of person

5 Race

6 Ethnicity

7 Marital status

8 Person's Residence (City, State, and County)

Socioeconomic status

9 Education

10 Occupation

11 Economic activity

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Event information

12 Manner of injury
13 Place of occurrence
14 Date and Time of injury
15 Nature of injury
16 Mechanism (firearm, cutting/piercing, etc)
17 Activity
18 Alcohol use
19 Drug use
20 Injury severity
21 Disposition
22 Medical care
23 Self-directed violence category
24 Suicidal thoughts at time of injury
25 Risk-Rescue rating

Individual and family history

Previous medical history

26 Somatic
27 Mental
28 Previous suicidal behavior
29 Previous suicidal thoughts
30 Family medical/psychiatric history
31 Sexual orientation
32 Military service

Associated factors

33 Proximal factors (Include precipitating events such as recent history of personal crisis)
34 Protective factors
35 Incident summary

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1. Case ID

Definition: This data element is substituted for confidential identifying information in datasets. It is unique to each case and is intended for properly merging data on individuals from multiple sources and avoiding double-counting. It may be assigned by the facility/agency responsible for surveillance or it may be a generic unique identifier that belongs to the presenting case e.g. national ID with a date suffixed to distinguish between visits and incidents. Alternatively, secure in-house datasets may use a medical record number as the identifier.

Uses: The facility's internal identifier allows appropriate data exchange between approved parties while health care is being delivered and ensures that accessed, entered, or altered records correspond with the proper person. It also facilitates data linkage for administrative and research purposes.

Discussion: Until a universal person identifier is established, a locally assigned identifier is needed. To protect personal privacy and confidentiality, access to this data element must be limited to authorized personnel.

Repetition: No

Data Standards or Guidelines: *Health Level 7, Version 2.3* (HL7, 1996).

Other References: None.

2. Data Source

Definition: Agency or source from which SDV surveillance information is abstracted.

Uses: Identifies the agency or organization that supplied data for this person. It will enable linkage of multiple agency contacts for the same individual.

Code	Description
01	Hospital in-patient
02	Hospital emergency department
02	Other hospital department
03	Other ambulatory health care, including mental health
04	Police/Sheriff/Law enforcement
05	Prosecutor/District attorney
06	Social service agency
07	Telephone hotline for crisis services
08	Other social service agencies
09	Coroner or medical examiner

10	Vital statistics office within state health department
11	Other agency or data source

Discussion: This variable is essential in order to be able to distinguish the source of the information and the differences in definition from various sources such as police reports, coroner's investigative reports, hospital documents, etc. No single agency is likely to collect all of the data elements recommended. As a consequence, it is likely that anyone setting up a surveillance system will need to combine data from a number of sources (e.g., health care records and police records) using a relational database. This will allow information on data elements to be gathered from each data source used.

A unique identifier is the preferred tool for linking documents across all data sources. This identifier may or may not be identical to the data element Case ID.

Repetition: No

Data Standards or Guidelines: None

Other References: None.

3. Sex

Definition: Sex of person.

Uses: The person's sex is standard demographic and identifying information used in clinical care and for multiple additional purposes. Rates of suicide are higher among males than among females, while the reverse is found in studies of suicidal thoughts and nonfatal suicidal behavior.

Code	Description
M	Male
F	Female
O	Other (e.g. Hermaphrodite, Transsexual)
U	Unknown

Discussion: None.

Repetition: No

Data Standards or Guidelines: *E1384-96* (American Society for Testing and Materials, 1996) and *Health Level 7, Version 2.3* (HL7, 1996).

Other References: None

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4. Date of birth

Definition: The calendar date on which the person was born.

Uses: Date of birth can be used to calculate the person's age. Year, month, and day of birth are entered in the format YYYYMMDD. For example, a birth date of August 12, 1946, would be encoded as 19460812. Date and time of birth are entered in the format YYYYMMDDHHMM which uses the 24 hour clock in the time component. For example, a birth at 10:30 pm on June 1, 1997, would be encoded as 199706012230. If age itself is recorded it is strongly recommended that the actual age be collected and if needed later collapsed into groups on analysis. If actual age is unknown, estimate to the nearest 10 years, whenever possible. Age-group specific suicide rates show important differences in suicidal behavior. Suicide rates are highest among older adults aged >65 years compared to adolescents and young adults, but rates on nonfatal suicidal behavior are highest among the younger age groups and relatively low among older adults.

Discussion: None.

Repetition: No

Data Standards or Guidelines: *E1384-96* (American Society for Testing and Materials, 1996) and *Health Level 7, Version 2.3* (HL7, 1996).

Other References: None.

5. Race

Definition: Race is a concept used to differentiate population groups largely on the basis of physical characteristics transmitted by descent. Racial categories are neither precise nor mutually exclusive, and the concept of race lacks clear scientific definition. The common use of race in the United States draws upon differences not only in physical attributes, but also in ancestry and geographic origins. Since 1977, the federal government has sought to standardize data on race and ethnicity among its agencies through the Office of Management and Budget's (OMB) Statistical Policy Directive Number 15: Race and Ethnic Standards for Federal Statistics and Administrative Reporting (OMB, 1978). Directive Number 15 standards were developed to meet federal legislative and program requirements, and they are used widely in the public and private sectors. The directive provides five basic racial categories but states that the collection of race data need not be limited to these categories. However, any additional reporting that uses more detail must be organized in such a way that the additional categories can be aggregated into the five basic groups. Although the directive does not specify a method of determining an individual's race, OMB prefers self-identification to identification by an observer whenever possible. The directive states that persons of multiple racial origins should be coded using multiple categories, and not a multiracial category.

Uses: Data on a person's race are used as a marker, proxy for a related factor such as socio-economic status, in public health surveillance, and epidemiologic, clinical, and health services research. Patterns of suicidal behavior differ among certain US populations. For example using the traditional race categories, American Indians/Alaska Natives and

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African-Americans have their highest suicide rates among adolescents and young adults whereas other groups such as Asian-Americans have their highest rates among older adults.

Code	Description
1	American Indian or Alaskan Native. A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.
2	Asian. A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands, Thailand, or Vietnam.
3	Native Hawaiian/Other Pacific Islander. A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
4	Black. A person having origins in any of the black racial groups of Africa.
5	White. A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.
9	Unknown.

Discussion: Although the biological significance of race has been scientifically questioned, data on race retain use, albeit limited, in public health surveillance and epidemiologic, clinical, and health services research.

Repetition: Yes

Data Standards or Guidelines: *Statistical Policy Directive Number 15: Race and Ethnic Standards for Federal Statistics and Administrative Reporting (OMB, 1978), Standards for the Classification of Federal Data on Race and Ethnicity (OMB, 1995), and E1633-96* (American Society for Testing and Materials, 1996).

Other References: *Core Health Data Elements* (National Committee on Vital and Health Statistics, 1996).

6. Ethnicity

Definition: Ethnicity is a concept used to differentiate population groups on the basis of shared cultural characteristics or geographic origins. A variety of cultural attributes contribute to ethnic differentiation, including language, patterns of social interaction, religion, and styles of dress. However, ethnic differentiation is imprecise and fluid. It is contingent on a sense of group identity that can change over time and that involves subjective and attitudinal influences. Since 1977, the federal government has sought to standardize data on race and ethnicity among its agencies through the Office of Management and Budget's (OMB) *Statistical Policy Directive Number 15: Race and Ethnic Standards for Federal Statistics and Administrative Reporting* (OMB, 1978). *Directive Number 15* standards were developed to meet federal legislative and program requirements, and they are used widely in the public and private sectors. The directive provides two basic ethnic categories — *Hispanic* and *Not of Hispanic Origin* — but states that collection of ethnicity data need not be limited to these categories. However, any additional reporting that uses more detail must be organized in such a way

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that the additional categories can be aggregated into the two basic groups. OMB prefers that data on race and ethnicity be collected separately. The use of the Hispanic category in a combined race/ethnicity data element makes it impossible to distribute persons of Hispanic ethnicity by race and, therefore, reduces the utility of the four basic racial categories by excluding from them persons who would otherwise be included. Although the directive does not specify a method of determining an individual's ethnicity, OMB prefers self-identification to identification by an observer whenever possible. The directive states that persons of mixed ethnicity should use the single category that most closely reflects the individual's recognition in his or her community.

Uses: Data on a person's ethnicity are used in person care, public health surveillance, and epidemiologic, clinical, and health services research. For example, differential risks for SDV, have been attributed at least partly to cultural acceptance of suicidal behavior which differs across ethnic groups.

Code	Description
1	Hispanic. A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race.
2	Not of Hispanic Origin. Anyone with a known ethnicity not fitting the definition of Hispanic.
9	Unknown.

Discussion: Personal self-identification of ethnicity is preferable to observer-identification. Enter 9 if neither method yields an identification of ethnicity.

Repetition: No.

Data Standards or Guidelines: *Statistical Policy Directive Number 15: Race and Ethnic Standards for Federal Statistics and Administrative Reporting* (OMB, 1978), *Standards for the Classification of Federal Data on Race and Ethnicity* (OMB, 1995), *E1633-96* (American Society for Testing and Materials, 1996), and *Core Health Data Elements* (National Committee on Vital Health Statistics, 1996).

Other References: None.

7. Marital status

Definition: Legal marital status of the person at the time when the incident occurred

Uses: Risk of SDV has been shown to vary by legal marital status.

Code	Description
1	Separated. A person legally separated.
2	Divorced. A person divorced and not remarried.
3	Married. A person currently married (includes living together and not living together). Classify common-law marriage as married.

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4	Single/Never married. A person who has never been married or whose only marriages have been annulled.
5	Widowed. A person widowed and not remarried.
9	Unknown/not stated.
Discussion:	Some unmarried partners may be cohabiting. In some states this may qualify as common-law marriage.
Repetition:	No.
Data Standards or Guidelines:	CDC HISSB Common Data Elements Implementation Guide.
Other References:	None

8. Residence or address

Definition: Injured person's normal place of residence

Uses: The address is useful for patient follow-up and billing. It also is used to determine the agency responsible for potential public health interventions and to link patient-specific data with census data so that incidence rates can be calculated. Some components of this element such as street address may not be necessary to collect, however in some jurisdictions suicide attempts are classified as a reportable condition to the health department which may warrant collecting information which enables the health authorities to locate the individual. To protect an individual's privacy and confidentiality access to this data element must be limited to authorized personnel.

The following order is the model:

Component 1 is the street address.

Component 2 is the second line of the address (e.g., apartment number).

Component 3 is the city.

Component 4 is the state or province.

Component 5 is the zip or postal code.

Component 6 is the country.

Component 7 is the type of address (e.g., mailing).

Component 8 is another geographic designation (e.g., catchment area ID).

Component 9 is the county/parish code.

Component 10 is the census tract

Discussion: This information probably is available from registration and billing record systems, in which addresses are routinely entered and stored. The naming convention used will be determined by the application area. It may be a region, state, village, community, or some appropriately defined physical area.

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Repetition: Yes, if the patient has more than one address.

Data Standards or Guidelines: *Health Level 7, Version 2.3* (HL7, 1996).

Other References: None.

9. Education

Definition: The highest level of education within a formal system that a person has completed measured in years.

Uses: Socioeconomic factors (such as education level, income, and occupation) are strong predictors of morbidity and mortality in the United States and many other countries, including those engaging in SDV. These data can be used to describe the relationship between socioeconomic factors and self-directed violence.

"What is the highest grade of school the subject has completed, or the highest degree this person has received?"

Code	Description
0	Less than 1st grade
1-4	1st-4th grade
5-8	5th-8th grade
9	9th grade
10	10th grade
11	11th grade
12	12th grade or high school graduate
13-15	Some college or associate's degree
16	Bachelor's degree
>16	More advanced than bachelor's degree

Discussion: This standard should be consistent with standards from the Bureau of the Census. Education should be coded in a standard format to improve compatibility between systems and datasets. Individuals with foreign educations will map into this standard according to the UNESCO ISCED (International Standard Classification of Education) referenced in this document.

Years of schooling - Highest grade of schooling completed by the person. For children under the age of 18, the individual's status and the mother's highest grade of schooling completed should be obtained.

Repetition: No.

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Data Standards or Guidelines: *Core Health Data Elements* (National Committee on Vital Health Statistics, 1996).

Other References: Bureau of the Census *Current Population Survey;* Bureau of the Census *Census 2000;* National Center for Education Statistics (NCES) http://nces.ed.gov/pubs/eiip/eiip.html; United Nations Educational, Scientific, and Cultural Organization (UNESCO); *International Standard Classification of Education (ISCED)* http://unescostat.unesco.org/Documents/isced.asp; National Center for Health Statistics (NCHS); *E1384-96* (American Society for Testing and Materials, 1996) and *Health Level 7, Version 2.3* (HL7, 1996).

10. Occupation

Definition: Description of person's current work.

Uses: Routine screening information concerning the person's current job activity is used in clinical evaluation and management, and it is needed to assess the person's eligibility for workers' compensation benefits. Data on occupation and industry also are useful for public health surveillance and epidemiologic research. Some studies have shown that suicide rates differ by occupation but these studies often lack comparison groups. Occupation and industry together serve as a surrogate for a person's socioeconomic status.

Each occupation in the Standard Occupational Classification (SOC) system is placed within one of these 23 major groups:

11-0000	Management Occupations
13-0000	Business and Financial Operations Occupations
15-0000	Computer and Mathematical Occupations
17-0000	Architecture and Engineering Occupations
19-0000	Life, Physical, and Social Science Occupations
21-0000	Community and Social Services Occupations
23-0000	Legal Occupations
25-0000	Education, Training, and Library Occupations
27-0000	Arts, Design, Entertainment, Sports, and Media Occupations
29-0000	Healthcare Practitioners and Technical Occupations
31-0000	Healthcare Support Occupations
33-0000	Protective Service Occupations
35-0000	Food Preparation and Serving Related Occupations
37-0000	Building and Grounds Cleaning and Maintenance Occupations
39-0000	Personal Care and Service Occupations
41-0000	Sales and Related Occupations

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43-0000	Office and Administrative Support Occupations
45-0000	Farming, Fishing, and Forestry Occupations
47-0000	Construction and Extraction Occupations
49-0000	Installation, Maintenance, and Repair Occupations
51-0000	Production Occupations
53-0000	Transportation and Material Moving Occupations
55-0000	Military Specific Occupations
98	Other Specified Occupation
99	Unspecified Occupation

Discussion: A succinct description of the person's work can be used to encode occupation (or job title) and industry. Incorporating information about both occupation and industry is important, because similar occupations confer different health risks depending on the industry. For example, a painter in a shipyard is subject to different exposures than a painter in a residential setting. Occupation, combined with industry, is used frequently as an indicator of socioeconomic status. However, its use for this purpose requires linkage between specific occupation groups and socioeconomic status. The codes shown above illustrate only the major categories. More detailed codes exist within each major code. By comparison, the person's educational level is a simple-to-use indicator of socioeconomic status, but occupation and industry are more routinely collected in Emergency Departments because of their clinical relevance. The 2000 Standard Occupational Classification (SOC) system is used by Federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data. All workers are classified into one of over 820 occupations according to their occupational definition. To facilitate classification, occupations are combined to form 23 major groups, 96 minor groups, and 449 broad occupations. Each broad occupation includes detailed occupation(s) requiring similar job duties, skills, education, or experience. For detailed information, coding instructions, and inclusions and exclusions, refer to http://stats.bls.gov/soc/soc_majo.htm.

Repetition: Yes; multiple entries in this field are appropriate if the person has more than one job.

Data Standards or Guidelines: U.S. Department of Labor, Bureau of Labor Statistics, Revising the Standard Occupational Classification System, June 1999, Report 929 http://stats.bls.gov/soc/socrpt929.pdf

Other References: None.

11. Industry or Economic activity

Definition: The type of industry or business in which the injured person was working at the time of injury.

Uses: Knowing the type of industry or business the injured person was working in can help employers and practitioners develop interventions that address work-related factors associated with SDV. For example, certain occupations may have access to highly lethal means for suicide which could be modified. For all injuries related to paid work, select the code that best describes the industry or business in which the injured person was involved.

Economic Activity: Overview of Codes

11	Agriculture, Forestry, Fishing and Hunting
21	Mining, Quarrying, and Oil and Gas Extraction
22	Utilities
23	Construction
31-33	Manufacturing
42	Wholesale Trade
44-45	Retail Trade
48-49	Transportation and Warehousing
51	Information
52	Finance and Insurance
53	Real Estate and Rental and Leasing
54	Professional, Scientific, and Technical Services
55	Management of Companies and Enterprises
56	Administrative and Support and Waste Management and Remediation Services
61	Educational Services
62	Health Care and Social Assistance
71	Arts, Entertainment, and Recreation
72	Accommodation and Food Services
81	Other Services (except Public Administration)
92	Public Administration

Discussion: A summary description of the person's work, identifying both occupation (or job title) and industry can be used to encode both occupation and industry. Incorporating information about both occupation and industry is important, because similar occupations confer different health risks depending on the industry. For example, a painter in a shipyard

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is subject to different exposures than a painter in a residential setting. The Office of Management and Budget (OMB) and the U.S. Bureau of the Census have developed systems for encoding industry (OMB, 1987; U.S. Bureau of the Census, 1992). The National Institute for Occupational Safety and Health is developing and evaluating personal computer software to encode text entries for occupation and industry.

Some existing economic activity codes are based on the International Standard Industrial Classification of All Economic Activities (ISIC), Revision 3 (United Nations, 1990). The North American Industry Classification System (NAICS) is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. NAICS was developed under the auspices of the Office of Management and Budget (OMB), and adopted in 1997 to replace the Standard Industrial Classification (SIC) system. It was developed jointly by the U.S. Economic Classification Policy Committee (ECPC), Statistics Canada and Mexico's Instituto Nacional de Estadistica, Geografia e Informatica

Repetition: Yes; multiple entries in this field are appropriate if the person works in more than one industry.

Data Standards or Guidelines: U.S. Office of Management and Budget's (OMB) North American Industry Classification System (NAICS, pronounced Nakes) - 1997 North American Industry Classification System-1987 Standard Industrial Classification Replacement; Notice. Vol. 62, No. 68, April 9, 1997

Other References: None.

12. Manner of injury

Definition: The role of human intent in the occurrence of the injury incident

Uses: Data describing the injury intent are used in immediate patient care and to arrange appropriate consultations and follow-up. For example, recognizing that an injured patient's wounds were deliberately self-inflicted allows emergency physicians and nurses to take actions that prevent further self-destructive behavior, and establishing that a patient's injury resulted from an assault can be instrumental in protecting the patient from future harm. Cumulative injury intent data are useful for public health surveillance, health care planning and administration, and clinical, health services, and epidemiologic research.

Data Values:

Code	Description
1	*Unintentional (*sometimes called "accidental" injuries*)* injury or poisoning that is not inflicted by deliberate means with the intent to harm and includes those injuries and poisonings described as an "accident," regardless of whether the injury was inflicted by oneself or by another person. Includes person hitting wall with fist when angry with no intent to harm oneself.
2	*Self-directed violence* (Includes fatal and non-fatal suicidal behavior and nonsuicidal behavior. Please see glossary for definition of intentional self-harm)

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2a	*Suicidal self-directed violence* *Includes Interrupted by self and Interrupted by other*
2b	*Non-suicidal self-directed violence*
3	*Assault* (Interpersonal violence, assaults, victim-precipitated assault, etc) Injury from an act of fatal or nonfatal violence where physical force by one or more persons is used with the intent of causing harm, injury, or death to another person; or an intentional poisoning by another person. Includes perpetrators, and intended and unintended (e.g., innocent bystanders) victims of violent acts.
4	*Undetermined* Available information is insufficient to make a distinction between unintentional injury event, self-directed violence, assault or other violence.
8	*Other* This may include:
8a	*Legal interventions Injury or poisoning caused by police or other legal authorities during law enforcement activities and includes injuries and poisonings inflicted during legal action or execution, or while attempting to enforce the law, such as an arrest or restraint of arrested person.*
8b	*Operations of war and civil insurrection*
8c	*Euthanasia*
9	*Unspecified* Injury resulting from unknown incident

Discussion:

Injuries are the acute physical conditions which are listed in Chapter XIX of the Tenth Revision of the International Statistical Classification of Diseases and Health-related Conditions (ICD-10) and which result from the external causes listed in Chapter XX (WHO, 1994). External cause of injury codes are also found in the *International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM)* external cause-of-injury codes.

Further description of certain manners of injury may be included in the incident summary such as the circumstances of a victim-precipitated assault. This description should allow for better rationale for the use of a specific manner.

Repetition:

Yes, if two or more unrelated events cause separate injuries.

Data Standards or Guidelines:

World Health Organization. *International Classification for External Causes of Injuries (ICECI): Guidelines for counting and classifying external causes of injuries for prevention and control.* Consumer Safety Institute: Netherlands; 1998.

Holder Y, Peden M, Krug E et al (Eds). *Injury surveillance guidelines.* Geneva, World Health Organization, 2001.

Other References:

None.

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13. Place of occurrence

Definition: Type of place where the injury event occurred.

Uses: Data on the type of place where an injury occurred help to describe the injury-producing event and are valuable for planning and evaluating injury prevention programs. Place of occurrence data help group injuries by areas of responsibility and may help injury prevention practitioners better target interventions and use resources more effectively. This information can also provide insight into injury etiology. For example, a grouping of SDV events occurring at a bridge may initiate an examination of environmental modifications that reduce risk of injury.

Code	Description
10	Home
20	Residential institution
30	School, other institution, and public administrative area
40	Sports and athletic area
50	Street and highway
60	Trade and service area
70	Industrial and construction area
80	Farm
88	Other specified place
99	Unspecified place

Discussion: Each broad location code shown above includes several more specific location descriptions. Place of occurrence usually has two coding levels, the second level being more detailed. Not all places, however, have a second coding level. NOTE: The codes represent where the injured person was when the injury event began, not when the injury event ended. For detailed information and coding instructions, refer to http://www.rivm.nl/who-fic/ICECI/ICECI_1-2_2004July.pdf

Repetition: Yes, if two or more unrelated events cause separate injuries at separate locations.

Data Standards or Guidelines: *International Statistical Classification of Diseases and Related Health Problems, 10th Revision* (World Health Organization, 1992).

Other References: ICECI Coordination and Maintenance Group (2004). International Classification of External Causes of Injuries (ICECI) version 1.2. Consumer Safety Institute, Amsterdam and AIHW National Injury Surveillance Unit, Adelaide.

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14. Date/time of Injury Onset

Definition: Onset date and time of acute injury resulting from this incident. Date that injury event occurred. Code according to date format conventions of environment Example: YYYY/MM/DD Time of the day that injury event occurred. If resources permit, capture actual time of injury event and use the 2400 hour clock.

Uses: Data that specify when an individual's symptoms or complaints began are used by practitioners to triage, evaluate, and make diagnoses during a clinical encounter. This may be critical for an event of SDV poisoning for which an antidote may need to be administered within a certain time to be effective. In aggregate form, these data also support clinical, epidemiologic, and health services research by allowing for variation in risk by time of day, day of the week, season, etc..

Data values:

1	0000(Midnight) – 0059
2	0100 – 0159
3	0200 – 0259
4	0300 – 0359
5	0400 – 0459
6	0500 – 0559
7	0600 -- 0659
8	0700 – 0759
9	0800 – 0859
10	0900 – 0959
11	1000 – 1059
12	1100 – 1159
13	1200 -- 1259
14	1300 – 1359
15	1400 – 1459
16	1500 – 1559
17	1600 – 1659
18	1700 – 1759
19	1800 -- 1859
20	1900 – 1959
21	2000 – 2059

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22	2100 – 2159
23	2200 – 2259
24	2300 – 2359

Discussion: Since some individuals delay seeking care, it is important to record as accurately as possible the actual time that the acute illness or injury occurred.

Repetition: No.

Data Standards or Guidelines: None.

Other References: *E1744-95* (American Society for Testing and Materials, 1995).

Holder Y, Peden M, Krug E et al (Eds). *Injury surveillance guidelines*. Geneva, World Health Organization, 2001.

15. Nature of injury

Definition: The injury, real or suspected, which brought the injured person to the service. If more than one, select the most serious. Nature-of-injury codes are grouped according to the type of injury, e.g., fractures, intracranial injury, and open wound.

Uses: These categories allow for standardized retrieval of injury cases for epidemiological, clinical, and management oriented analyses. They can be used to characterize the patterns of injury using clinically meaningful diagnostic categories and may assist in determining the severity of the injury.

Data Values:

1	Fracture
2	Dislocation
3	Internal organ injury
4	Open wounds
5	Amputations
6	Blood vessels
7	Contusions/superficial
8	Crush
9	Burn
10	Effect of foreign bodies entering orifice
11	Other effects of external causes
12	Poisoning

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13	Toxic effects
14	Multiple injuries
15	Other specified injury
16	Unspecified injury

Discussion: This element can be used for retrieval of injury events for epidemiologic analyses. It could be used to: characterize the patterns of injury resulting from diverse circumstances; serve as a standard for incident comparison across time and place; and, simplify the process of classifying injuries.

Repetition: No.

Data Standards or Guidelines: L.A. Fingerhut and M. Warner, The ICD-10 Injury Mortality Diagnosis Matrix, Injury Prevention, 2006;12;24-29. Available at http://www.cdc.gov/nchs/data/ice/10_diamatrix.pdf

International Statistical Classification of Diseases and Related Health Problems, 10th Revision (World Health Organization, 1992).

Centers for Disease Control and Prevention. Recommended framework for presenting injury mortality data. MMWR 1997;46(No.RR-14):1-30.

CDC. Clinical modification, (ICD-9-CM). In: International classification of diseases. 6th ed. 9th rev. Hyattsville, MD: US Department of Health and Human Services, CDC; 2007. Available at http://www.cdc.gov/nchs/datawh/ftpserv/ftpicd9/ftpicd9.htm.

Other References: Miniño AM, Anderson RN, Fingerhut LA, Boudreault MA, Warner M. Deaths: Injuries, 2002. National vital statistics reports; vol 54 no 10. Hyattsville, Maryland: National Center for Health Statistics. 2006.

Proceedings of the International Collaborative Effort (ICE) on Injury Statistics, Volume I. (PHS) 95-1252. March 1995 (Edited by LA Fingerhut).

16. Mechanism of injury

Definition: How the injury was inflicted i.e. how the person was hurt. If more than one mechanism, record the most serious injury. If able to record more than one injury, place the injuries in order from most serious to least.

Uses: The classification by mechanism characterizes the external agents or particular activities that caused the injury (e.g., motor vehicle, firearm, submersion, fall, and poisoning). The mechanisms of injury are important because evaluation research indicates that "passive protection" through modification of products and environments can be effective in reducing injury—regardless of intent. For example, interventions for pesticide poisoning-related suicidal behavior in certain regions have been shown to reduce the behavior.

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Data Values:

1	Cut/Pierce
2	Drowning
3	Falls
4	Fire/burn, hot object/substance
5	Firearm
6	Machinery
7	All transportation (e.g., MV traffic, Pedal cyclist, Pedestrian, etc)
8	Natural/ environmental (e.g, Bites/stings)
9	Overexertion
10	Poisoning
11	Struck by, against
12	Suffocation, strangulation, asphyxiation
13	Other
14	Unspecified
15	Adverse effects
99	Unknown

Discussion: Injuries are often the result of a sequence of events. Three types of objects/substances may be involved in the injury event:

- Underlying object/substance—the object/substance involved at the start of the injury event

- Direct object/substance—the object/substance producing the actual physical harm

- Intermediate objects/substances—other objects/substances involved in the injury event

Repetition: No.

Data Standards or Guidelines: *International Statistical Classification of Diseases and Related Health Problems, 10th Revision* (World Health Organization, 1992).

Centers for Disease Control and Prevention. Recommended framework for presenting injury mortality data. MMWR 1997;46(No.RR-14):1-30.

Other References: Proceedings of the International Collaborative Effort (ICE) on Injury Statistics, Volume I. (PHS) 95-1252. March 1995 (Edited by LA Fingerhut).

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17. Activity

Definition: What the injured person was doing at time of incident.

Uses: The type of activity at the time of injury helps to describe the circumstances of the injury-producing event and identify possible opportunities for prevention programs, policies, or strategies. Identification of work-related injuries serves multiple purposes. Better understanding of SDV that occurs while a person is on the job is needed.

Data Values:

Code	Description
10	*Sports.* Comprises exercises with functional purpose (e.g., golf, jogging, riding, school sports and athletics, skiing, swimming, hiking, waterskiing). Includes activities described as a ball game, but excludes those described as play with ball.
20	*Leisure.* Comprises activities with the purpose of entertainment or recreation (e.g., performing hobby activities or going to the theater, a dance, or a party). Includes activities described as play with ball, but excludes activities described as a ball game.
30	*Paid work.* Comprises manual or professional work for salary, bonus, or other income. Includes: — apprentice and vocational activities — rest breaks on employer premises (in hallway, rest room, cafeteria, storage area) — work on, arrival at, or departure from employer parking lot — work for pay or compensation at home — work in family business, including family farm (activity should be clearly related to profit-oriented business) — traveling on business, including to and from customer/business contacts and work activities in which a vehicle is considered the work environment Excludes: — recreational activities on employer-controlled facilities — visits for non-work purposes, when not on official business — domestic activities by a homemaker — nonprofit work for oneself (e.g., mowing lawn, repairing roof, or performing hobby or recreational activities) — school activities by a student — vehicle use (personal or commercial) for non-work purposes — commute to or from work site — illicit work (e.g., drug trafficking)

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40	*Unpaid work.* Comprises duties for which one would not normally gain an income. Includes volunteer work and domestic duties (e.g., caring for children and relatives, cleaning, cooking, gardening, and maintaining a household). Excludes learning activities (e.g., attending school or university).
50	*Educational activity.* Comprises learning activities (e.g., attending school or university). Excludes apprenticeship.
60	*Vital activity.* Comprises resting, sleeping, eating, or engaging in other vital activities.
88	*Other specified activity*
99	*Unknown activity*

Discussion: None.

Repetition: Yes, if a single injury cannot be described adequately with one activity code (e.g., police officer ingests overdose of non-prescription medication) or if injuries occur during separate activities (e.g., forearm laceration from non-suicidal SDV and head injury from crash on the way to hospital).

Data Standards or Guidelines: *Classifying Deaths as on the Job* (Harshbarger and Stout, 1995), *Draft: International Classification for External Cause of Injuries* (World Health Organization Working Group on Injury Surveillance Methodology Development, 1995), and *NOMESCO Classification of External Causes of Injury* (Nordic Medico-Statistical Committee, 1996).

Other References: None.

18. Alcohol use

Definition: Suspicion or evidence of alcohol use preceding the injury event by the injured person and/or other persons involved in the injury event.

Uses: Alcohol use is a known risk factor for injuries including SDV. Therefore, it is important to collect information about the involvement of alcohol use in injury events. In some cases, quantitative biological information about alcohol use (e.g., blood or breath alcohol level) is available. In other cases, one may merely suspect alcohol use (e.g., if the patient smells of alcohol). This data element indicates whether there is either suspicion or evidence of alcohol use. No distinction is made between suspicion and evidence because criteria for each category are too difficult to define.

Alcohol Use:

1	Suspected (by report or observation) or confirmed by biological evidence
2	No information available

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Discussion: Code this item for each injury case, regardless of the severity of injury, age of the injured person, or intent of the injury event. If more information is available (e.g., type of suspicion or evidence, characterization of others involved in the injury event), this detail can be added to the narrative summary. If possible include objective measure such as blood alcohol concentration.

Repetition: No.

Data Standards or Guidelines: Holder Y, Peden M, Krug E et al (Eds). *Injury surveillance guidelines.* Geneva, World Health Organization, 2001.

Other References: ICECI Coordination and Maintenance Group (2004). International Classification of External Causes of Injuries (ICECI) version 1.2. Consumer Safety Institute, Amsterdam and AIHW National Injury Surveillance Unit, Adelaide.

World Health Organization. *International Classification for External Causes of Injuries (ICECI): Guidelines for counting and classifying external causes of injuries for prevention and control.* Consumer Safety Institute: Netherlands; 1998.

19. Other drug or psychoactive substance use

Definition: Suspicion or evidence of psychoactive drug use (e.g., opiates, cocaine, amphetamines, cannabinoids, sedatives, hypnotics) or other psychoactive substance use (eg., hair spray, gasoline, glue) preceding the injury event by the injured person and/or other persons involved in the injury event.

Uses: Use of psychoactive drugs or other substances is a known risk factor for injuries including SDV. Therefore, it is important to collect information about the involvement of drug use and other substance use in injury events. In some cases, biological quantitative information about drug or substance use (e.g., blood/urine drug level) is available. In other cases, one may merely suspect drug or substance use (e.g., because of the patient's current behavior or history). This data element indicates whether there is either suspicion or evidence of alcohol use. No distinction is made between suspicion and evidence because criteria for each category are too difficult to define.

Psychoactive Drug or Substance Use:

1 Suspected (by report or observation) or confirmed by biological evidence

2 No information available

Discussion: Code this item for each injury case, regardless of the severity of injury, age of the injured person, or intent of the injury event. If more information is available (e.g., type of suspicion or evidence, characterization of others involved in the injury event), this detail can be added to the narrative summary. If possible include objective measure such as blood or body fluid concentration.

Repetition: No.

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Data Standards or Guidelines:

ICECI Coordination and Maintenance Group (2004). International Classification of External Causes of Injuries (ICECI) version 1.2. Consumer Safety Institute, Amsterdam and AIHW National Injury Surveillance Unit, Adelaide.

Other References:

World Health Organization. *International Classification for External Causes of Injuries (ICECI): Guidelines for counting and classifying external causes of injuries for prevention and control.* Consumer Safety Institute: Netherlands; 1998.

20. Injury severity

Definition:

State the clinical evaluation of the injury. Injury severity generally describes the impact of an injury in terms of the extent of tissue damage and/or the physiologic response of the body to that damage.

Uses:

These data are designed to quantify the type and severity of the injuries in a standard fashion, which allow providers to communicate in common terms. These data are used widely in injury research and in health care quality improvement processes. An assessment of severity based on the cumulative injuries suffered by the individual is preferred.

Data values:

1	No apparent injury
2	Minor, i.e. superficial injuries e.g. bruises, minor cuts
3	Moderate, requiring some skilled treatment e.g. fractures, sutures
4	Severe, requiring intensive medical/surgical management e.g. internal hemorrhage, punctured organs, severed blood vessels

Discussion:

There are a number and variety of injury severity scales reflecting recognition that severity classification is critical for surveillance, epidemiological investigations and evaluations of programs and policies aimed at mitigating the impact of injury at both the individual and societal levels.

Repetition:

No.

Data Standards or Guidelines:

None

Other References:

Baker SP, O'Neill B, et al. (1974). "The injury severity score: a method for describing patients with multiple injuries and evaluating emergency care." J Trauma 14(3): 187-96.

Gennarelli T, Wodzin E. (2005). The Abbreviated Injury Scale- 2005. Des Plaines, Il, Association for the Advancement of Automotive Medicine.

Beck, AT, Beck R, Kovacs M. (1975). Classification of suicidal behaviors: I.

Quantifying intent and medical lethality. American Journal of Psychiatry, 132(3), 285-287.

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21. Disposition

Definition: Action or status after attendance at facility or person's anticipated location or status following medical encounter usually outpatient visit.

Uses: Data on the disposition can be compared on demographics, various diagnostic categories or with data from steps in the person's medical encounter to determine factors associated with the health outcome or serve as a proxy to describe the severity of the health problem. Disposition data are used in identifying and tracking trends. The following codes are recommended for encoding the disposition:

Code	Description
10	Discharged to home or self-care (routine discharge)
20	Transferred/discharged to another short-term general hospital for inpatient care
30	Transferred/discharged to skilled nursing facility
40	Transferred/discharged to intermediate care facility
50	Transferred/discharged to another type of institution for inpatient care or referred for outpatient services to another institution
60	Transferred/discharged to home under care of a home IV drug therapy provider
70	Transferred/discharged to home under care of certified home care provider/program
80	Left without receiving medical advice against leaving (includes left without being seen, eloped)
90	Left after receiving medical advice against leaving (i.e., left AMA)
100	Placed in designated observation unit (not considered an in-person hospital admission)
110	Admitted to hospital floor bed
120	Admitted to intermediate care/telemetry unit
130	Admitted to intensive care unit
140	Admitted to operating room
150	Died
888	Other
999	Unknown

Users may expand this table to meet local needs for more detailed data. For example, disposition category 130 could be expanded as follows:

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Code	Description
131	Admitted to medical intensive care unit
132	Admitted to cardiac care unit
133	Admitted to surgical intensive care unit
134	Admitted to burn unit
135	Admitted to neonatal intensive care unit
136	Admitted to pediatric intensive care unit

Discussion : None.

Repetition: No.

Data Standards or Guidelines: None.

Other References: Uniform Bill-92 (National Uniform Billing Committee, 1996) and E1744-95 (American Society for Testing and Materials, 1995).

22. Medical care received by individual

Definition The medical health care received by the individual following the most recent SDV episode.

Uses Documents the medical health care received by the individual. May be useful in documenting the effect of SDV events on the medical care system and the range of services that individuals receive for their incidents.

Code	Description
0	The individual was known not to have received any medical health care following the most recent SDV episode.
1	The individual received outpatient medical treatment (e.g., emergency room or physician office visit), not followed by inpatient medical health care, after the most recent SDV episode.
2	The individual received outpatient medical treatment (e.g., emergency room or physician office visit), followed by inpatient medical health care, after the most recent SDV episode.
3	The individual received outpatient medical treatment (e.g., emergency room or physician office visit), unknown if followed by inpatient medical health care, after the most recent SDV episode .
4	The individual received no outpatient medical health care (e.g., emergency room or physician office visit), but did receive inpatient medical health care, after the most recent SDV episode.
5	Unknown if the individual received outpatient medical health care (e.g., emergency room or physician office visit), but did receive inpatient medical health care, after the most recent SDV episode.

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9	Unknown if the individual received any medical health care following the most recent SDV episode.

Discussion: In addition to documenting the individual's medical care, this data element can be used as a proxy for injury severity, but it must be used in conjunction with other data elements.

Repetition: No.

If the individual died as a result of the SDV event then this data element should be used to indicate any medical care related to the most recent SDV prior to death.

Data Standards or Guidelines: None.

Other References: None.

23. Self-directed violence category

Definition: Assessment of the self-directed behavior

Uses: Self-directed violence (SDV) is behavior that deliberately results in injury or the potential for injury to oneself irrespective of suicidal intent. SDV encompasses a range of violent behaviors, including acts of fatal and nonfatal suicidal behavior, and non-suicidal intentional self-injury (i.e., behaviors where the intention is not to kill oneself, as in self-mutilation). The assessment of which type of SDV a particular event represents is a crucial issue, which has implications on decisions for the individual, his/her family, and society regarding prevention and treatment. The data from this element can help practitioners identify unique circumstances that put individuals at risk for the various types of SDV and guide development of appropriate prevention strategies. The data are also useful for public health surveillance, health care planning and administration, and clinical, health services, and epidemiologic research. Research that definitively characterizes specific categories of SDV is needed to establish the utility of potential interventions.

Data Values:

Code	Description
1	*Non-suicidal self-directed violence* (Other terms include self-harm, self mutilation, self cutting, self battery)
1a	*Non-fatal non-suicidal SDV (sucide attempt)* Including interrupted by self and interrupted by other
1b	*Fatal non-suicidal SDV*
2	*Suicidal self-directed violence.* (Includes fatal and non-fatal suicidal SDV)
2a	*Non-fatal suicidal SDV* Including interrupted by self and interrupted by another and suicide attempt
2b	*Fatal suicidal SDV (sucide)*

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3	Undetermined self-directed violence (SDV with suicidal intent undetermined) *(Includes fatal and non-fatal undetermined SDV)*
3a	*Non-fatal undetermined SDV* Including interrupted by self and interrupted by another
3b	*Fatal undetermined SDV*

Discussion:

The assessment in this element is based on the best available evidence to the recorder of the victim's behavior.

Certain types of SDV events are more difficult to categorize. For example, poisoning events may be suicidal or undetermined. In some settings, such as hospital emergency departments, the priority may be treating the injury and not collecting information on the events leading up to the incident. Though ideally the information should be elicited from the person who sustained the injury, data collectors may need to solicit information from other sources such as family members or acquaintances of the injured person or other organizations like law enforcement or social service agencies.

Sensitivity, and confidentiality must be exercised in collecting information from persons who have already undergone trauma from a violent event. Persons who gather injury information must be empathetic and well-trained.

Further description of certain manners of injury may be included in the incident summary such as the circumstances of a victim-precipitated assault. This description should allow for better rationale for the use of a specific manner.

Repetition:

Yes, if two or more unrelated events cause separate injuries.

Data Standards or Guidelines:

None.

Other References:

De Leo D, Burgis S, Bertolote JM, Kerkhof AJFM, Bille-Brahe U. Definitions of suicidal behavior: Lessons learned from the WHO/EURO Multicentre Study. Crisis: The Journal of Crisis Intervention and Suicide Prevention. 2006; 27:4-15.

Posner K, Oquendo MA, Gould M, Stanley B, Davies M. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. Am J Psychiatry. 2007; 164:1035-1043.

AR-002978

24. Suicidal thoughts at time of injury

Definition: Record individual's acknowledgment of his/her perception of outcome as a result of their behavior.

Uses: Detecting and measuring the existence, or intensity of an individuals' specific attitudes, behaviors, and plans to commit suicide may influence the intervention strategy. This information is necessary to distinguish a suicide attempt from non-suicidal self-directed violence.

How did the patient describe his/her intent to the staff, other people, or in a (suicide) note?

Code	Description
	*(Please indicate the **most severe intent,** e.g. intent to die before intent to injure oneself. Using the coding scheme below 1>2>3>4>5 or 6 [5=6])*
1	"Intent to die" described
2	"Intent to injure oneself but not die" described
3	"Intent to escape" described
4	Other intent described (e.g. intent to attract attention) Please specify: _____
5	Intent unclear
9	Unknown or no information

Discussion: Suicidal thoughts can be a risk factor for subsequent fatal and nonfatal suicidal behavior and are sometimes associated with other disorders. In general suicidal thoughts do not focus upon the actual suicide process. Suicidal planning involves a much higher complex cognitive process. Those who actually engage in suicide planning that may require more extensive evaluation and/or intervention.

Repetition: No.

Data Standards or Guidelines: None

Other References: None

25. Risk-Rescue rating

Definition: A term used in assessing a suicide act that indicates the degree to which the situation allowed for the possibility of intervention by others to prevent death.

Uses: This scale is a descriptive and quantitative method of assessing the lethality of SDV. There are five risk and five rescue factors which are defined, weighted and scored. Documentation of the circumstances surrounding an incident may assist in developing and evaluating preventive interventions.

AR-002979

Risk factors (numbers = scoring points)

A. Risk mechanism:

1. Ingestion, cutting, stabbing
2. Drowning, asphyxiation, strangulation
3. Jumping, shooting

B. Risk impaired consciousness:

1. None in evidence
2. Confusion, semicoma
3. Coma, deep coma

C. Risk lesions/toxicity:

1. Mild
2. Moderate
3. Severe

D. Risk reversibility:

1. Good, complete recovery expected
2. Fair, recovery expected with time
3. Poor, residual expected, if recovery

E. Risk treatment required:

1. First aid, outpatient

   Includes hospital emergency dept
2. Hospital admission, routine in-patient care
3. Intensive care, special treatment

Total risk points _____

Risk score

High risk:	13-15 risk points
High moderate:	11-12 risk points
Moderate:	9-10 risk points
Low moderate:	7-8 risk points
Low risk:	5-6 risk points

Rescue factors (numbers = scoring points)

A. Rescue location:

3. Familiar

2. Non-familiar, non remote

1. Remote

B. Rescue person initiating rescue:

3. Key person (knows or is known by the subject)

2. Professional

1. Passerby

C. Rescue probability of discovery by any rescuer

3. High, almost certain

2. Uncertain discovery

1. Accidental discovery

D. Rescue accessability to rescue:

3. Asks for help

2. Drops clues

1. Does not ask for help

E. Rescue delay until discovery:

3. Immediate <1 hour

2. > 1hour but < 4 hours

1. > 4 hours

Total rescue points _____

Rescue score*

Least rescuable:	5-7 rescue points
Low moderate:	8-9 rescue points
Moderate:	10-11 rescue points
High moderate:	12-13 rescue points
Most rescuable:	14-15 rescue points

Self rescue automatically yields a rescue score of 5

The risk-rescue rating is determined by the formula risk score/risk score + rescue score. Scores range from 17 to 83. Low= 17-39, Moderate=40-59, High=60-83.

AR-002981

Discussion: A description of the lethality characteristics of self-directed violence can help clinicians and researchers communicate efficiently about the similarities and differences of the behaviors under study. There are various ways of defining lethality. However a complete appraisal of lethality should only partially be based on any kind of rating or scale, a more comprehensive assessment of the physical, psychological, and social characteristics of the individual and his or her environment is required.

Repetition: No.

Data Standards or Guidelines: None.

Other References: Weissman, A. D., & Worden, J. W. (1972). Risk-rescue rating and suicide assessment. Archives of General Psychiatry. 1972; 26: 553–560.

26. Medical/Somatic history

Definition: Has individual ever experienced or been diagnosed by a health care professional with a somatic or physical illness or injury.

Uses: There is limited information on the association of non-mental health diseases or injuries with SDV. Collection of this variable would be helpful in documenting whether certain conditions are associated with an increase or reduction in risk for SDV especially chronic diseases or conditions and traumatic injuries. These data are also needed for continuity of care, and they are useful for quality-of-care monitoring, public health surveillance, and clinical, health services, and epidemiologic research.

Code	Description
0	No
1	Yes, if yes, record actual illness(es)
8	Not applicable
9	Unknown/not stated

Can describe specific illness within the following organ system categories:

- Cardiovascular
- Nervous
- Respiratory
- Digestive
- Endocrine
- Reproductive
- Urinary
- Musculoskeletal
- Dermatological
- Infectious disease
- Immunological

AR-002982

Discussion: A clinician's reported diagnosis is the basis for diagnostic coding and classification. In most instances, a clinical description will provide more detail than a diagnostic code and its associated rubric. Practitioners and other authorized data users may need to read unaltered text or search it electronically for words or phrases of interest.

Repetition: Yes

Data Standards or Guidelines: Uniform Hospital Discharge Data Set (UHDDS).

Other References: Office of the Secretary, Department of Health and Human Services: Health Information Policy Council: 1984 Revision of the Uniform Hospital Discharge Data Set. Federal Register, Volume 50, No. 147. July 31, 1985.

27. Psychiatric history

Definition: Has individual ever been diagnosed by a health care professional with a mental health condition and/or has a current diagnosis.

Uses: Biological, psychological, social, and cultural factors all have a major impact on the risk of suicidal behavior. Studies have estimated that a large percentage of suicide decedents have symptoms or a diagnosis consistent with mental illness and/or alcohol and substance misuse disorder.

Code	Description
0	No
1	Yes, if yes, record actual diagnosis(es) and whether individual is under current treatment
8	Not applicable
9	Unknown/not stated
	Can use the following categories though this list is not comprehensive - Depression - Bipolar disorder - Schizophrenia - Anxiety disorder - Post-traumatic stress disorder - Alcohol or substance abuse disorder - Other (specify)

AR-002983

Discussion: Estimates of lifetime risk of suicide for mental illness show that a majority of people with mental illness don't die of suicide. This confirms that suicidal behavior results from an interaction of factors not just mental illness so other categories of factors should also be collected. Current diagnosis should also be included in this category.

Repetition: Yes

Data Standards or Guidelines: Uniform Hospital Discharge Data Set (UHDDS).

Other References: Office of the Secretary, Department of Health and Human Services: Health Information Policy Council: 1984 Revision of the Uniform Hospital Discharge Data Set. Federal Register, Volume 50, No. 147. July 31, 1985.

28. Previous nonfatal self-directed violence

Definition: Record actual number of previous events of suicidal or non-suicidal self-directed violence. This applies to events where an action occurred, not thoughts only.

Uses: Number of events may be used to estimate the human and economic cost of this behavior.

Code	Description
0	Individual has engaged in 0 events of SDV
1	Individual has engaged in 1-2 events of SDV ever.
2	Individual has engaged in 3-5 events of SDV ever.
3	Individual has engaged in 6-10 events of SDV ever.
4	Individual has engaged in 10 or more events of SDV ever.
9	Unknown how many events of SDV have occurred.
	If there has been more than one SDV event, the code should reflect the total of all events.

Discussion: A history of one or more incidents of self-directed violence is a risk factor for subsequent fatal and nonfatal suicidal behavior.

Repetition: No.

Data Standards or Guidelines: None

Other References: None

AR-002984

29. Past suicidal thoughts or ideation

Definition: Record individual's acknowledgment of previous suicidal ideation.

Uses: Detecting and measuring the existence, or intensity of an individuals' specific attitudes, behaviors, and plans to commit suicide may influence the intervention strategy.

Code	Description
Yes	If yes, could record its chronological proximity to the most recent self-directed violent behavior, include whether the person made a specific plan for carrying out the self-harm act.
	Chronological proximity:
	1 within past 24 hours
	2 > 24 hrs less than 7 days
	3 7 days – 13 days
	4 14 days – 27 days
	5 28 days – 180 days (approximately 1 month to 6 months)
	6 >180 days – 364 days (just over 6 months to slightly less that 1 year)
	7 365+ (greater that 1 year)
	Plan:
	1 The individual reports outlining a plan to methodically take his or her life.
	2 No reported plan
No	No known history
Unknown	Unknown

Discussion: Suicidal thoughts can be a risk factor for subsequent fatal and nonfatal suicidal behavior and are sometimes associated with other disorders. In general suicidal thoughts do not focus upon the actual suicide process. Suicidal planning involves a much higher complex cognitive process. Those who actually engage in suicide planning that may require more extensive evaluation and/or intervention.

Repetition: No.

Data Standards or Guidelines: None

Other References: None

AR-002985

30. Family history

Definition: Have family members ever been diagnosed by a health care professional with a somatic or psychiatric condition or suicidal behavior. Emphasis of documentation should be on immediate family. Immediate family includes spouse, parents and grand parents, children and grand children, brothers and sisters, mother-in-law and father-in-law, brothers-in-law and sisters-in-law, daughters-in-law and sons-in-law. Adopted and step members are also included in immediate family.

Uses: Research has established associations between parental psychopathology and their offspring's suicidal behavior. There is also limited evidence to suggest that a family history of suicidal behavior is associated with increased risks of suicidal behavior among a variety of relatives. This element can be used to identify factors connected to self-directed violence risk.

Code	Description
0	No
1	Yes (If yes, record actual illness(es) and the relationship.)
8	Not applicable
9	Unknown/not stated

The following categories can be used for family members:

Adopted Son	Great Grandfather	Stepfather
Adopted Daughter	Great Grandmother	Stepmother
Aunt	Half-brother	Stepsister
Brother	Half-sister	Stepson
Brother-In-Law	Husband	Uncle
Cousin	Mother - Adoptive	Unrelated, Friend
Daughter	Mother - Biological	Ward
Daughter-In-Law	Mother-In-Law	Wife
Father - Adoptive	Nephew	Other (specify)
Father - Biological	Niece	
Father-In-Law	Sister	
Foster Child	Sister-In-Law	
Granddaughter	Son	
Grandfather	Son-In-Law	
Grandmother	Stepbrother	
Grandson	Stepdaughter	

Discussion: Health conditions that exist in an individual's family could indicate a predisposition for the same or similar conditions in the person.

Repetition: Yes

Data Standards or Guidelines: Relationship categories - ASTM E1633 (American Society for Testing and Materials), X12 (American National Standards Institute Accredited Standards Committee X12), NCVHS

(National Committee on Vital and Health Statistics), Bureau of the Census - *Current Population Survey*

Other References: None

31. Sexual Orientation

Definition: The sexual preference of the individual.

Uses: Adding these questions will help identify and monitor progress toward reducing disparities. Sexual orientation can be an important factor in health outcomes. Studies have shown that people who identify themselves within certain categories of sexual orientation tend to have different socialization, expectations, and lifestyles. Certain groups as a result of identifying their orientation are differentially exposed to stigma, discrimination, and other factors that affect and interact with health. Studies of nonfatal suicidal behavior have found an increased occurrence of this behavior among those who identify as homosexual, bisexual or transgender.

Data Values Do you consider yourself to be?

Code	Description
1	Heterosexual
2	Homosexual
3	Bisexual
4	Transgender
5	Or something else? Specify _____
9	Unknown/not stated.

Discussion: Sexual orientation has been discussed as two definitional components: the psychological component and the behavioral component. Definitions of the psychological component may include the terms "sexual attraction", "sexual interest", or "sexual preference."

Definitions of the behavioral component are often described with terms such as "sexual intercourse" or "sexual contact". Each one of these presents challenges for those collecting data. For example, how should each of these terms be defined and how should they be operationalized for measurement?

AR-002987

The data element listed above addresses the issue of sexual identity but not behavior. Personal self-identification of sexual orientation is preferable to observer-identification. Enter 9 if neither method yields an identification of sexual orientation.

Repetition: No.

Data Standards or Guidelines: CDC, National Center for Health Statistics, National Health and Nutrition Examination Survey (NHANES)

Other References: Sell RL, Becker JB. Sexual Orientation Data: Inclusion in Health Information Systems Used to Monitor HP2010. American Journal of Public Health. 2001;91(6):876-82.

National Survey of Family Growth (NSFG) as described in: Citation: Mosher WD, Chandra A, Jones J. Sexual behavior and selected health measures: Men and women 15-44 years of age, United States, 2002 . Advance data from vital and health statistics; no 362. Hyattsville, MD: National Center for Health Statistics. 2005.

Behavioral Risk Factor Surveillance System (BRFSS), CDC as described in San Francisco Department of Public Health AIDS Office. San Francisco HIV Behavioral Risk Factor Telephone Survey. 1998. Accessed on 7 November 2008 from http://www.dph.sf.ca.us/PHP/RptsHIVAIDS/new_brfs.pdf.

Youth Risk Behavior Surveillance System as described in Garofalo R, Wolf RC, Kessel S, Palfrey J, DuRant R. The Association Between Health Risk Behaviors and Sexual Orientation Among a School-based Sample of Adolescents. *Pediatrics.* 1998:101(5), 895-902

32. Military service

Definition: A person who has served or is currently serving in the armed forces. If resources permit, capture specific information about military service such as actual length of time served, which branch (e.g., Army, Navy, Air Force, Marines), and experiences (e.g., combat, international travel).

Uses: Military service can have an influence on an individual's health through recruitment, training, tours of duty, exposure to combat and adjustment to military culture. Military service can also affect the health of the military person's family through economic and social means. Veteran status, including the period of military service, can be used to measure the needs of veterans and to evaluate the impact of military service on health care needs. These data are needed to conduct policy analysis, program planning, and budgeting for federal veterans' programs and for reports to Congress on state projections of veterans' facilities and services.

AR-002988

Data values:

A. Has this person ever served on active duty in the U.S. Armed Forces, military Reserves, or National Guard? Active duty does not include training for the Reserves or National Guard, but DOES include activation, for example, for the Persian Gulf War.

1 Yes, now on active duty

2 Yes, on active duty in past, but not now

3 No, training for Reserves or National Guard only

4 No, never served in the military

B. When did this person serve on active duty in the U.S. Armed Forces? Mark for *EACH period in which this person served.*

1 April 1995 or later

2 August 1990 to March 1995 (including Persian Gulf War)

3 September 1980 to July 1990

4 May 1975 to August 1980

5 Vietnam era (August 1964—April 1975)

6 February 1955 to July 1964

7 Korean conflict (June 1950—January 1955)

8 World War II (September 1940—July 1947)

9 Some other time (please specify)

C. In total, how many years of active-duty military service has this person had?

1 Less than 2 years

2 2 years or more (if possible specify the exact number of years)

Discussion: This standard should be consistent with standards from the Bureau of the Census. At state and county levels, veteran status is used for budgeting and program planning for medical services for veterans. Veteran status is used as one factor to determine the segments of the population who may not be receiving needed medical services.

Repetition: No.

Data Standards or Guidelines: U.S. Census Bureau, Census 2000 questionnaire. http://nces.ed.gov/pubs/eiip/eiip.html;http://www.census.gov/prod/2003pubs/c2kbr-22.pdf, and www.census.gov/prod/cen2000/doc/sf3.pdf

Other References: Bureau of the Census. Current Population Survey, September 2003: Veterans Supplement, Technical Documentation CPS-03 (Census Bureau, 2004);

Department of Veterans Affairs (VA) National Survey of Veterans (NSV) http://www1.va.gov/vetdata/docs/survey_final.htm. US Census American Community Survey Veteran status and period of military service asked 1840, 1890, 1910, since 1930). http://www.census.gov/acs/www/SBasics/SQuest/QbyQfact/veteran.pdf

AR-002989

33. Proximal risk factors

Definition: Data element that describes the most recent crises that led to the self-harm incident. Summarizes external circumstances believed to have played a role in precipitating the suicidal behavior. Select all that apply and indicate the one which is most closely connected to the event.

Uses: Documentation of the circumstances surrounding an incident may assist in developing and evaluating preventive interventions. Identification of suicidal behaviors that follow an acute life crisis (such as a suicide committed immediately after an arrest) may indicate some level of impulsivity in the suicide act.

Data values:

Code	Description
1	Physical health problem (e.g. terminal disease, debilitating condition)
2	Intimate partner problem (e.g. divorce, breakup, discord)
3	Other relationship problem (e.g. family argument)
4	Job problem (e.g. layoff, problems at work, job pressure)
5	School problem (e.g. failure, academic pressure, bullying)
6	Financial problem (e.g. bankruptcy, debts, foreclosure)
7	Recent suicide of friend or family member
8	Other death of friend or family member
9	Criminal legal problem (e.g. recent or impending arrest, police pursuit, recently committed crime, currently in jail, impending criminal court date)
10	Other or unspecified legal problems (e.g. custody dispute, civil lawsuit)
11	Perpetrator of interpersonal violence (specify type such as intimate partner, child maltreatment, sexual violence, etc.)
12	Victim of interpersonal violence (specify type such as intimate partner, child maltreatment, sexual violence, etc.)
13	Crisis within two weeks of injury
14	Other: Specify_____
15	Unknown

AR-002990

Discussion: Medical examiners' and coroners' reports and police incident reports often include detail on the circumstances that contributed to self directed violence. While this information is not consistently documented, the data element is being treated as an important one to underline the need for coroners, medical examiners, and police to document this information.

Repetition: Yes.

Data Standards or Guidelines: ICECI Coordination and Maintenance Group (2004). International Classification of External Causes of Injuries (ICECI) version 1.2. Consumer Safety Institute, Amsterdam and AIHW National Injury Surveillance Unit, Adelaide.

Other References: Centers for Disease Control and Prevention. National Violent Death Reporting System (NVDRS) Coding Manual [Online].(2003). National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (producer). Available from: http:// www.cdc.gov/injury

34. Protective factors

Definition: Summarizes internal or external factors that interact with a risk factor to reduce or nullify its effect among at-risk individuals or populations. Select all that apply.

Uses: Research has found that many successful interventions both reduce risk factors and promote protective factors. Focusing on promoting protective factors is a more productive approach than reducing risk factors alone due to the following: protective factors are positive attributes that strengthen all families, not just those at risk; these factors are usually attributes that individuals and families themselves want to improve which often provides more motivation to participate.

Based on the best information available, describe the contextual factors. This axis can be coded multiple times in order to fully describe the contextual factors that may have prevented self-directed violence. Record the factors listed as present, absent, or unknown.

Categories and sub-types:

A. Personal resources such as:

1	Positive/resilient temperament
2	Social competency and problem-solving skills
3	Perception of social support from adults and peers
4	Positive expectations/optimism for the future

AR-002991

B. Community resources or relationships such as:

5	Bonding or connectedness to family
6	Bonding or connectedness to school (attachment to teachers, belief, commitment)
7	Presence and involvement of caring, supportive adults (for adolescents)
8	Integration into social networks
9	Cultural and religious beliefs that discourage suicide and support self preservation
10	Quality and access to social services and health care

C. Other: Specify_____

Discussion: This classification is an exploratory classification among the data elements. Less is known about the relationship between self-directed violence some of the factors listed in the classification. Therefore, data collected by using this classification may contribute to generate hypotheses to elucidate these relationships.

Protective factors are believed to operate in three ways: buffering risk factors so that they provide a cushion against negative effects; by interrupting the processes through which risk factors operate; or by preventing the initial occurrence of a risk factor. Fewer studies have been done on protective factors than on risk factors, so many have not been identified making this information somewhat harder to collect.

Personal self report by the subject for this element is preferred. However, the information may need to collected from a proxy of the subject if the subject is unable to respond.

Repetition: Yes. If person has one or more protective factor, record all that apply and specify which type.

Data Standards or Guidelines: None.

Other References:

Risk and Protective Factors for Suicide and Suicidal Behaviour: a Literature Review. Joanne McLean, Margaret Maxwell, Stephen Platt, Fiona Harris, Ruth Jepson.Scottish Government Social Research. Edinborough. 2008. Accessed on 10 December 2008 at http://www.scotland.gov.uk/Publications/2008/11/28141444/0

Beautrais AL, Collings SCD, Ehrhardt P, et al. 2005. Suicide Prevention: A review of evidence of risk and protective factors, and points of effective intervention. Wellington: New Zealand Ministry of Health.

AR-002992

35. Incident summary

Definition:

Brief description of injury incident that precipitated the current event. A free text field that describes the circumstances surrounding the incident. It should capture information not collected under the other elements. For example, it should answer questions like the following:

"What were you doing at the time of the incident?"

"What were you feeling emotionally at the time of the incident?"

"What were you expecting to happen as a result of your action?"

"How did it happen?"

"How did you hurt yourself?"

"Who discovered what happened?"

"How did you get help?"

Uses:

Data describing the cause of injury are used in evaluating and treating individual patients, and these data are useful for public health surveillance and clinical and epidemiologic research. This element should be a concise text description of the injury-producing event or circumstance, including the mechanism by which bodily harm was produced and what the patient was doing when injured. Specify the agent or class of agents in poisonings, toxic exposures, and adverse drug reactions.

Examples:

Individual ties a rope around his neck and attempts to hang self while incarcerated after arrest for intoxicated driving. Feeling despondent due to possible loss of job and did not want to live. Was discovered by corrections officer.

Person ingests more than recommended dosage of medication. Had argued with boyfriend that afternoon. After taking pills called boyfriend and told him about ingestion. He notified emergency medical services.

Motor vehicle driver crashes into bridge support. Found unconscious by passing motorist who called police.

Discussion:

This data element is intended for use in describing the injury that led to the clinical encounter, and its intended use encompasses initial treatments, treatments of injury sequelae (late effects), patient transfers from other health care facilities, and referrals from elsewhere within the hospital. This information is not intended for use in a scheduled return visit following initial treatment (e.g., suture removal). Researchers can use the injury incident description in two ways: 1) they can read unaltered text or search it electronically for words or phrases of interest; 2) they can apply injury coding and classification systems to existing text entries.

AR-002993

Repetition: No.

Data Standards or Guidelines: None.

Other References: None.

References (general surveillance or injury surveillance)

ASTM. *E1384-96: Standard Guide for Content and Structure of the Computer-Based Patient Record.* West Conshohocken, Pennsylvania: ASTM, 1996.

ASTM. *E1633-96: Standard Specification for Coded Values Used in the Computer-Based Patient Record.* West Conshohocken, Pennsylvania: ASTM, 1996.

ASTM. *E1744-95: Standard Guide for View of Emergency Medical Care in the Computerized Patient Record.* West Conshohocken, Pennsylvania: ASTM, 1995.

Holder Y, Peden M, Krug E et al (Eds). ***Injury surveillance guidelines***. Geneva, World HealthOrganization, 2001.

International Organization for Standardization (ISO). *ISO 2995-83 Information Processing — Representation of SI and Other Units in Systems with Limited Character Sets.* Geneva, Switzerland: ISO, 1983.

National Center for Injury Prevention and Control. Data elements for emergency department systems, release 1.0. Atlanta, GA: Centers for Disease Control and Prevention, 1997.

World Health Organization. *International Classification for External Causes of Injuries (ICECI): Guidelines for counting and classifying external causes of injuries for prevention and control.* Consumer Safety Institute: Netherlands; 1998.

Other resources on data elements

Duke University Medical Center Information Center Home Page

http://www.mcis.duke.edu/

Logical Observation Identifier Names and Codes(LOINC)

http://www.mcis.duke.edu/standards/HL7/termcode/loinclab/loinc.html

Health Care Financing Administration (HCFA)

http://www.mcis.duke.edu/standards/government-organizations/hcfa.htm

ANSI X12

http://www.mcis.duke.edu/standards/X12N/x12.htm

Health Level 7 (HL7)

http://www.hl7.org

National Standards Systems Network (NSSN) - Search for standards

http://www.nssn.org/

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National Committee on Vital and Health Statistics (NCVHS)

http://aspe.os.dhhs.gov/NCVHS/

X12 Implementaton Guides

http://www.wpc-edi.com/pubs.cfm?pub=001

U.S. Census

http://www.census.gov/

American National Standards Institute(ANSI)

http://www.ansi.org/

Data Interchange Standards Association (DISA) - X12

http://www.disa.org/

International Organization for Standardization (ISO) ISO Standard 3166 - Countries

http://www.hike.te.chiba-u.ac.jp/ikeda/ISO/home.html

American Medical Informatics Association (AMIA)

http://www.amia.org/

Medical Records Institute (MRI)

http://www.medrecinst.com/

Systematized Nomenclature of Human and Veterinary Medicine (SNOMED)

http://snomed.org/

AR-002995

VIGNETTES

002998

Vignettes

Vignettes

Vignettes are brief descriptions of events or situations to which the reader is asked to react. The descriptions, which can either be fictitious or based on fact, are structured to elicit information about the reader's perceptions, opinion, attitudes, or knowledge about some phenomenon. The following vignettes are descriptions of hypothetical persons in a particular situation which the reader is asked to evaluate to determine which SDV term fits best.

The purpose of these vignettes is multifaceted, for example they can provide an opportunity for the reader to engage in self-assessment on understanding of the material, compare responses to the writers, or generate questions about how a solution was determined. Further, the vignettes can help contextualize the definitions to which the situation is linked.

These vignettes are adapted from training materials developed by Drs. Morton Silverman and Lisa Brenner for the Department of Veterans Affairs' project for developing a Suicide and Self-Harm Classification System Clinical Tool and materials developed by Dr. Kelly Posner for the Columbia Classification Algorithm of Suicide Assessment (C-CASA) and used by permission of the authors.

Vignette		Terms (please circle the correct term)
1.	After being diagnosed with breast cancer, a client goes to meet with the oncology nurse regarding her chemotherapy regime. Seeing that she is tearful and seemingly depressed, the nurse inquires whether or not she has been feeling suicidal. The client indicates that she has had thoughts, but before she can fully respond to the question, she begins crying uncontrollably.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined
2.	The patient stated that she experienced heartbreak over the "loss of a guy" a week before the interview. She stated that she took four clonazepam, called a girlfriend, and talked/cried it out while on the phone. She was dismissive of the seriousness of the attempt, but indicated that she wanted to die at the time she took the overdose.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined

Vignette		Terms (please circle the correct term)
3.	The patient was feeling extremely guilty and felt he deserved to die. He held a gun to his head. Just before he pulled the trigger, his wife came in the room and pulled the gun from his hand.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined
4.	After months of expressing the desire to end her own life, a client maneuvered around barriers and jumped to her death from a very tall building.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined
5.	After a long argument with his wife, a client with previous suicidal behaviors left the house and went to a bar where he drank heavily. He then got in his car, drove erratically, and broke the speed limit. He called his wife on the way home, and they shouted at each other briefly before he hung up. Shortly thereafter, his car hit a pole. He was taken by ambulance to the hospital where he was unconscious and could not answer questions about what happened and why.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined

AR-003001

Vignette		Terms (please circle the correct term)
6.	The patient wanted to escape from her mother's home. She researched lethal doses of ibuprofen. She took six ibuprofen pills and said she felt certain from her research that this amount was not enough to kill her. She stated she did not want to die, only to escape from her mother's home. She was taken to the emergency room where her stomach was pumped and she was admitted to a psychiatric ward.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined
7.	A former Navy pilot has bipolar disorder and is delusional in the midst of a mixed episode. Friends report that he has been rambling about themes of religious self-sacrifice, and the need to atone for the sins of the world. The client is found dead after falling to his death from the roof of his apartment building.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined
8.	During pill count on the hospital ward, the staff discovered that six tablets were missing. Upon questioning, the patient admitted that she was saving them up so she could take them all together at a later time in order to kill herself.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined

AR-003002

Vignette		Terms (please circle the correct term)
9.	A patient is receiving inpatient rehabilitation after a lower limb amputation. His Rehabilitation Psychologist has noted that he has become decreasingly engaged in therapies and asked about his current level of suicidality. He responds that he has been thinking about hanging himself with his bed sheets.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined
10.	A man was feeling very depressed, and he wanted to die. He went to the roof to jump off. He changed his mind about wanting to die once he got to the roof, and he came down.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined
11.	The patient was feeling ignored. She went to the kitchen where her mom and sister were talking, took a knife out of the drawer, and made a cut on her arm. She denied that she wanted to die at all. She said she just wanted them to pay attention to her.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined

AR-003003

Vignette		Terms (please circle the correct term)
12.	As the level of conflict between a client and his girlfriend escalated, he said, "Maybe you'd be better off if I shot myself." When she asked him what he meant or what he might do, he paused and then said "I don't know, but I want us to stop fighting."	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined
13.	A client is drinking to excess near a lake with a group of friends on Labor Day. He and a buddy decide to "swim it off" (something that has "worked" before) so that he can drive home sober. He gets disoriented and exhausted and drowns.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined
14.	A very intoxicated client is brought to the emergency room by the police who found him walking beside a busy road. When asked about whether or not he was feeling suicidal, the client mumbled, "I am so tired of everything." He then passed out.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined

AR-003004

Vignette		Terms (please circle the correct term)
15.	A man put a gun to his head because he wanted to kill himself. He pulled the trigger, and the gun failed to fire.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined
16.	A patient had a big fight with her ex-husband. She took 15-20 imipramine tablets and went to sleep. She woke many hours later unable to walk. She called EMS, was taken to the ER and given charcoal, and was admitted to the hospital. The patient was unable to verbalize her intent but stated she was well-aware of the dangers of TCA overdose and the potential for death.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined
17.	The patient was unconscious when he was admitted to the ER after taking 300 prescription pills. He woke up later in the ICU and denied any intention to die.	A. Suicidal ideation B. Suicide attempt C. Suicide D. Non-suicidal self-directed violence E. Suicide attempt interrupted by self F. Suicide attempt interrupted by other G. Other suicidal behaviors H. Unintentional injury I. Not enough information/undetermined

AR-003005

Answers and explanations for vignettes:

1. Answer: A. Suicidal ideation. Based on the information stated in the vignette, the patient has only endorsed suicidal thoughts and the description did not indicate any behavior. It is possible that she has engaged in suicidal behaviors as well, but at this point, that information is not available and only suicidal ideation was endorsed.

2. Answer: B. Suicide attempt. The patient engaged in a behavior where the potential for injury has occurred (ingested at least one pill) with the intent to die as a result of the act (the reason she took the pills was to end her life/e.g. the method to kill herself). As soon as one pill is ingested, even if they change their mind shortly thereafter and it couldn't have been lethal yet, it has become a suicide attempt at that point.

3. Answer: F. Suicide attempt interrupted by other. The patient began to take steps towards making a suicide attempt but was stopped by external circumstances before starting the potentially self-injurious act. Behavior was engaged in, but it could not have hurt him at that point (potential for harm). If the trigger had been pulled, it would be a suicide attempt. If not for this interruption, an actual attempt would have occurred.

4. Answer: C. Suicide. The patient died as a result of self-inflicted behavior engaged in order to end her life. It's clear that she jumped because she wanted to die (no other feasible intent).

5. Answer: I. Not enough information. Based on the vignette, it is unclear whether the man intentionally hit the pole with his car or that he wanted to kill himself. There is also nothing that indicated he had any suicidal thoughts. We know from the vignette that he was engaged in reckless behavior, but it is unclear whether hitting the pole was accidental or intentional. In this example, neither the intent nor the behavioral piece of the definition is clear.

6. Answer: D. Non-suicidal self-directed violence. The patient makes it clear that she did not want to die as a result of taking the ibuprofen and she did not believe the amount taken would kill her. She actually did research to make sure she took an amount that wouldn't harm her, because she ONLY wanted to escape from her mother's home. Her intention was not to die but entirely to make people believe she had made a suicide attempt in order to get out of the house

7. Answer: I. Not enough information/undetermined. Based on the available information, it is unclear whether he intended to jump off the roof, or if it was accidental. It is possible that there was some suicidal ideation and content (themes about self-sacrifice) but it is not clear this was related to his falling from the building. If he had expressed command hallucinations about jumping or killing himself, or there was no logical reason why he was on the roof, there would be more compelling information to infer suicidal intent.

8. Answer: G. Other suicidal behavior. As the patient states, she began making preparations towards an imminent suicide attempt. She indicated that she engaged in a behavior (collecting pills) associated with suicidal intent, so it has gone beyond suicidal thoughts.

9. Answer: A. Suicidal ideation. The patient endorsed thoughts of killing himself (active suicidal thoughts) with thoughts of a method (not formulated enough to call it a plan yet), but has not engaged in any behavior.

10. Answer: E. Suicide attempt interrupted by self. The man took steps towards making a suicide attempt (walked up to the roof) but stopped himself/changed his mind before the potential for harm had begun.

11. Answer: D. Non-suicidal self-directed violence. This is non-suicidal self-directed violence because she ONLY wanted to get attention and that's why she cut herself, not at all because she wanted to kill herself. The behavior was intentional but the suicidal intent component of the definition of attempt is not indicated.

12. Answer: I. Not enough information. This example does not clearly indicate suicidal ideation. If he had said he wanted to die or shoot himself it would reflect suicidal thoughts, but it is not clear. Alternatively, if he had said he said it only to get them to stop fighting but did not actually have thoughts of wanting to be dead or killing myself, then it would be clear there was NO suicidal ideation.

13. Answer: H. Unintentional injury death. Based on the available information, this person's death is more likely an unintentional injury than a suicide as there was no indication of suicidal intent . His intention was clearly for another reason ('to swim it off").

14. Answer: I. Not enough information. It is possible that this man is alluding to suicidal ideation by his statement and may have been considering a suicide attempt by walking in the busy road, but there is not enough information to support making such assumptions. Thus, it is not clear there is suicidal ideation or behavior.

15. Answer: B. Suicide attempt. This is a suicide attempt because the patient indicated he was trying to kill himself and as soon as he pulled the trigger he could have been injured (the potential for harm), which fulfills both the components of the definition of suicide attempt (behavior and intent).It is important to note that there does not have to be injury or harm for it to be called a suicide attempt, so even though the gun failed to fire and there was no injury, as soon as the trigger was pulled it became an attempt.

16. Answer B. Suicide attempt. Even though her stated/explicit intent is unclear, intent can be inferred (implicit) because she thought it could have killed her.

17. Answer B. Suicide attempt. Even though he denied having tried to kill himself on purpose (explicit), intent can be inferred form the clinical circumstances. It was such a highly lethal act, no other intent but suicide can be inferred (implicit).

AR-003007

APPENDIX

Appendix

Key terms

Additional terms that the reader is likely to encounter in other documents discussing self-directed violence are included and defined here. In addition, some of the data standards or guidelines mentioned in this document may use terms which are not part of the definitions derived by this process but may be important for the reader to be familiar with when using the document.

Term	Definition	Source
Act	The performance of any function or the bringing about of any effect Example - A suicidal act may result in death (suicide), injuries, or no injuries	Dorland's Illustrated Medical dictionary, W. B. Saunders Company, Philadelphia, 1974
Death of undetermined intent	A death whose manner is unclear when all available information is considered.	CDC. Medical Examiners' and Coroners' Handbook on Death Registration and Fetal Death Reporting. Washington, D.C.: U.S. Department of Health and Human Services; 2003 publication # 2003-1110
Direct	Pertaining to an association between a factor and a condition where the factor occurs prior to the condition, the change in the factor is correlated with a change in the condition and the correlation is not itself the consequence of the factor and the condition being correlated with some prior factor	Mausner & Bahn *Epidemiology: An introductory text*. W.B. Saunders, Philadelphia, 1985
Distal risk factor	The underlying vulnerability that potentiates a characteristic, variable, or hazard which increases the likelihood of development of an adverse outcome which is measurable and precedes the outcome	Mościcki EK. Epidemiology of completed and attempted suicide: Toward a framework for prevention. Clinical Neuroscience Research. 2001; 1:310-323.
Episode	A developed situation that is integral to but separate from a continuous narrative	ICECI version 1.2, WHO, 2004
Explicit	Fully revealed or expressed without vagueness, implication, or ambiguity; leaving no question as to meaning or intent	Rosenberg ML, Davidson LE, Smith JC, Berman AL, Buzbee H, Gantner G, Gay GA, Moore-Lewis B, Mills DH, Murray D, O'Carroll PW, Jobes D. Operational criteria for the determination of suicide. Journal of Forensic Science. 1988; 33(6):1445-56.

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Fatal	Causing death	Dorland's Illustrated Medical dictionary, W. B. Saunders Company, Philadelphia, 1974
Immediate cause of death	The final disease, injury, or complication directly causing death	CDC. Medical Examiners' and Coroners' Handbook on Death Registration and Fetal Death Reporting.
Implicit	Being without doubt or reserve, implied though not directly expressed; inherent in the nature of something	Rosenberg et al, 1988.
Impulsivity	Cognitive Impulsivity -The intellectual or mental process which results in an act performed without delay, reflection, voluntary direction or obvious control in response to a stimulus Behavioral Impulsivity - An act performed without delay, reflection, voluntary direction or obvious control in response to a stimulus	Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision, American Psychiatric Association, American Psychiatric Association, Arlington, VA, 2000.
Indirect	Pertaining to an association between a factor and a condition because both are related to some common underlying condition	Mausner, 1985
Inferred	To derive as a conclusion from facts or premises	International Epidemiological Association. Dictionary of Epidemiology, fourth edition. Last JM, editor. New York: Oxford; 2001.
Injury	A (suspected) bodily lesion resulting from acute overexposure to energy (this can be mechanical, thermal, electrical, chemical or radiant) interacting with the body in amounts or rates that exceed the threshold of physiological tolerance. In some case an injury results from an insufficiency of vital elements, such as oxygen. Acute poisonings and toxic effects, including overdoses of substances and wrong substances given or taken in error are included, as are adverse effects and complications of therapeutic, surgical and medical care. Psychological harm is excluded in this context.	World Health Organization. International statistical classification of diseases and related health problems, tenth revision. 2nd edition. Geneva, Switzerland. 2004. chapter XIX (19)

AR-003013

Institution	An established organization or corporation, such as a hospital/urgent care center (emergency facility), mental health facility, clinic	ICECI Coordination and Maintenance Group (2004). International Classification of External Causes of Injuries (ICECI) version 1.2. Consumer Safety Institute, Amsterdam and AIHW National Injury Surveillance Unit, Adelaide.
Intentional self-harm	Purposely self-inflicted poisoning or injury	World Health Organization. International statistical classification of diseases and related health problems, tenth revision. 2nd edition. Geneva, Switzerland. 2004.
Non-fatal	Not causing death	Dorland's Illustrated Medical dictionary, W. B. Saunders Company, Philadelphia, 1974
Physical Injury	A (suspected) bodily lesion resulting from acute overexposure to energy (this can be mechanical, thermal, electrical, chemical or radiant) interacting with the body in amounts or rates that exceed the threshold of physiological tolerance. In some case an injury results from an insufficiency of vital elements, such as oxygen. Acute poisonings and toxic effects, including overdoses of substances and wrong substances given or taken in error are included, as are adverse effects and complications of therapeutic, surgical and medical care. Psychological harm is excluded in this context.	ICECI Coordination and Maintenance Group (2004). International Classification of External Causes of Injuries (ICECI) version 1.2. Consumer Safety Institute, Amsterdam and AIHW National Injury Surveillance Unit, Adelaide.
Precipitating event	Factors associated with the definitive onset of a disease, illness, accident, behavioral response, or course of action. Examples include exposure to specific disease; circumstance, condition, or agent	International Epidemiological Association. Dictionary of Epidemiology, fourth edition. Last JM, editor. New York: Oxford; 2001.
Proximal risk factor	A measurable characteristic, variable, or hazard that increases the likelihood of development of an adverse outcome and is more immediately antecedent to the outcome, acting as a precipitant	Mościcki, 2001

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Rescueability	A term used in assessing a suicide act that indicates that the situation allowed for the possibility of intervention by others to prevent death	Weissman, A. D., & Worden, J. W. (1972). Risk-rescue rating and suicide assessment. Archives of General Psychiatry. 1972; 26: 553–560.
Self Harm Behavior/self-inflicted/ self Injurious	The act of injuring oneself intentionally by various methods such as self-laceration, self-battering, taking overdoses or exhibiting deliberate recklessness but with no intent to die	U.S. Public Health Service. *National Strategy for Suicide Prevention: Goals and Objectives for Action*. Washington, DC: U.S. Department of Health and Human Services, 2001.
Self harm ideation	Any thought of or communication regarding a person's desire to engage in self-inflicted potentially injurious behavior. There is no evidence of intent to die.	Silverman MM, Berman AL, Sanddal ND, O'Carroll PW, Joiner TE. Rebuilding the Tower of Babel: a revised nomenclature for the study of suicide and suicidal behaviors. Part 2: suicide-related ideations, communications, and behaviors. Suicide Life Threat Behav 2007;37:264–277.
Suicidal ideation	Thoughts of engaging in suicide-related behavior	National Strategy for Suicide Prevention: Goals and Objectives for Action.
Suicidal intent	There is evidence (explicit and/or implicit) that at the time of injury the individual intended to kill self or wished to die and that the individual understood the probable consequences of his or her actions	World Health Organization. International Classification of External Causes of Injuries (ICECI) version 1.2, WHO, 2004 . Available at: http://www.iceci.org. Accessed November 21, 2007.
Suicidal plan	A thought regarding a self-initiated action that facilitates self-harm behavior or a suicide attempt this will often include an organized manner of engaging in suicidal behavior such as a description of a time frame and method.	Silverman MM et al, 2007.

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Types of suicide	Categories of suicides within a broad social context. Based on the work of Durkheim, they include egoistic, altruistic, anomic, and fatalistic. Egoistic suicide - This is the type of suicide that occurs where the degree of social integration is low and there is a sense of meaninglessness among individuals. Altruistic suicide - This is the type of suicide that occurs when integration is too great. The person feels deeply committed to group norms and goals and see their own lives as unimportant, they die for a "cause". Anomic suicide - This type of suicide occurs when there is social instability resulting from breakdown of standards and values, regulation is too low. To individuals, life seems aimless. Fatalistic suicide - When regulation is too strong, the individual sees no hope of change against the oppressive discipline of the society.	Durkheim, Emile. Suicide: A Study in Sociology (1897). New York. The Free Press reprint 1997.
Underlying cause of death	The disease, injury, or complication, if any, that gave rise to the immediate cause of death	CDC. Medical Examiners' and Coroners' Handbook on Death Registration and Fetal Death Reporting. Washington, D.C.: U.S. Department of Health and Human Services; 2003 publication # 2003-1110
Undetermined injury incident	Events where available information is insufficient to enable a medical or legal authority to make a distinction between unintentional, self-directed and assault.	World Health Organization. International Statistical Classification of Diseases and Related Health Problems, 10th Revision Version for 2007, Available at: http://apps.who.int/classifications/apps/icd/icd10online/ Accessed October 11, 2009.
Victim-precipitated assault or homicide	An act in which a person engages in actual or apparent danger to others in an attempt to get oneself killed or injured.	Sheehan DC, Warren JI, editors. Suicide and law enforcement: A compilation of papers from the 1999 Suicide and Law Enforcement Conference, Published 2001, U.S. Dept. of Justice, Federal Bureau of Investigation (Washington, D.C)

AR-003016

For more information, please contact
The Centers for Disease Control and Prevention:
4770 Buford Highway, MS F-64, Atlanta, GA 30341
Telephone: 1-800-CDC-INFO (232-4636)/TTY:1-888-232-6348
Email: cdcinfo@cdc.gov Web: www.cdc.gov/violenceprevention



National Center for Injury Prevention and Control
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Correctional Policy and Attempted Suicide Among Transgender Individuals

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Abstract

Little research has examined the link between incarceration and suicide among transgender individuals. Transgender inmates face unique circumstances within the correctional setting that expose them to potentially harmful conditions, including correctional policies that limit access to proper medical care and expose them to threats of harassment and violence. Using data from the 2011 National Transgender Discrimination Survey, this article examines the link between incarceration and suicide among transgender individuals by focusing on the link between correctional policies and attempted suicide among transgender individuals who have been incarcerated. Multivariate results suggest that correctional policies regarding health care and housing may deleteriously impact transgender inmates.

Keywords

suicide, transgender, mental health, policy, incarceration

Introduction

Researchers have begun to focus on the relationship between incarceration and suicide (Binswanger, Blatchford, Lindsay, & Stern, 2011; Binswanger et al., 2007; Fazel, Cartwright, Norman-Mott, & Hawton, 2008; Rosen, Schoenbach, & Wohl, 2008; Yu, Sung, Mellow, & Shlosberg, 2014). While many of these studies focus on the overall population of previously incarcerated individuals, certain populations of inmates face unique circumstances in the correctional system that may negatively impact their well-being. Transgender inmates in particular are likely to experience circumstances detrimental to their well-being (Tarzwell, 2006). Although the transgender status complicates the placement of transgender inmates into gender-segregated facilities, few quantitative studies have offered insight into the plight of transgender inmates, a point likely arising from the difficulties inherent in sampling this population (Melendez, Bonem, & Sember, 2006). Given the disproportionate risk of incarceration experienced by transgender individuals (G. Brown & McDuffie, 2009; Tarzwell, 2006), it

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is important to understand the mental impact of their incarceration experiences, particularly how these experiences are impacted by correctional policy.

Correctional policies may detrimentally impact transgender inmates by limiting access to transgender-related medical care and exposing transgender inmates to elevated levels of gender-based victimization (G. Brown & McDuffie, 2009; Sumner & Jenness, 2014; Tarzwell, 2006). This article addresses the gap in the literature regarding the mental impacts of incarceration among transgender individuals by examining the link between correctional policy and lifetime suicide attempt among transgender individuals who have been incarcerated. The results offer evidence of relationships among medical care, gender-based victimization, and lifetime suicide attempt, suggesting that correctional policies may negatively impact transgender inmates.

The status of correctional facilities as "total institutions" comprising the entirety of inmates' social worlds necessitates comprehensive management of inmates' daily lives (Goffman, 2007). Policies enacted in support of facility management standardize social life, and help ensure efficient operation of penal facilities, although they may complicate matters regarding certain inmates. This is a concern that applies to transgender inmates, who are frequently inadequately accounted for by correctional policies (Sumner & Jenness, 2014), which exposes them to marginalization, potentially magnifying the distresses broadly associated with incarceration (Goff, Rose, Rose, & Purves, 2007; Haney, 2003b; Massoglia, 2008; Turney, Wildeman, & Schnittker, 2012). Correctional policy frequently fails to address transgender inmates across two domains: provision of transgender-related medical care and the housing of transgender inmates (G. Brown & McDuffie, 2009; Sumner & Jenness, 2014; Tarzwell, 2006).

A review of state correctional system policies regarding transgender-related medical care indicated that adequate care is infrequently provided to transgender inmates (G. Brown & McDuffie, 2009). While many states have failed to enact policies managing the health care of transgender inmates, those that have are frequently inconsistent in providing a level of care conducive to alleviating the distresses associated with gender dysphoria. Problems in transgender-related medical care with state correctional systems include difficulties in attaining care by experienced personnel, initiating hormones, and obtaining sexual reassignment surgery, although the continuation of hormone usage predating incarceration is relatively common among those states that have established policies managing transgender inmates (G. Brown & McDuffie, 2009). Proper medical care is particularly salient to the mental well-being of transgender individuals and is associated with decreased levels of depression, anxiety, stress, and suicide ideation, as well as improved overall quality of life (Colton Meier, Fitzgerald, Pardo, & Babcock, 2011; Murad et al., 2010; Wilson, Chen, Arayasirikul, Wenzel, & Raymond, 2015). In sum, adequate medical care remains vital to the well-being of transgender individuals, suggesting that the denial of adequate medical care in correctional facilities offers potential implications for the mental health of transgender inmates.

Additionally, transgender inmates are impacted by policies governing their assignment to correctional facilities. Even though many states have failed to enact coherent policies governing the housing of transgender inmates, of those that do, assignment on the basis of external genitalia is nearly universal (G. Brown & McDuffie, 2009; Sumner & Jenness, 2014; Tarzwell, 2006). As a result, many preoperative transgender individuals end up in facilities that house inmates of their sex assigned at birth rather than that consistent with their gender identity, exposing them to heightened levels of physical and sexual assaults at the hands of inmates and correctional staff (Jenness, Maxson, Matsueda, & Sumner, 2007; Sexton, Jenness, & Sumner, 2010; Sumner & Jenness, 2014). Due to themes of masculinity and dominance recurrent in male correctional facilities (Sabo, Kupers, & London, 2001; Tarzwell, 2006), transgender women housed in male prisons are subjected to highly pronounced levels of physical and sexual violence as evidenced by the prevalence of rape experiences among such inmates. Several studies have noted that fewer than 5% of male inmates report sexual assault (Jenness et al., 2007; Wolff & Shi, 2009), a level greatly eclipsed by

transgender inmates. In a study of sexual assault in California prisons, 60% of transgender inmates reported being sexually assaulted (Jenness et al., 2007), a rate at least 12 times that reported by cisgender men.

Victims of sexual assault in correctional facilities report increased psychological distress including fear, shock, difficulty sleeping, crying, flashbacks, depression, and nightmares (Wolff & Shi, 2009). For transgender individuals, these forms of victimization present potentially profound effects on their mental psyche. One study in Virginia found that gender-based victimization increased the odds of attempting suicide among transgender individuals by a factor of approximately four (Goldblum et al., 2012). Additional research has provided further evidence in support of the link between gender-based victimization and suicide attempts by uncovering positive relationships between suicide attempts and verbal, physical, and sexual assaults and harassment (Clements-Nolle, Marx, & Katz, 2006; Grossman & D'Augelli, 2007), suggesting that policies managing the housing of transgender inmates may impact them due to increased risks of harassment and violence.

While the literature regarding incarceration and gender-based victimization of transgender inmates has provided understanding of the conditions and potential mental health effects of incarceration among these individuals, little empirical evidence exists indicating how their mental health is impacted by incarceration. The aim of the present study is to address this gap in the literature by examining suicide attempts among transgender individuals who have been incarcerated, with emphasis on the role of correctional system policies. This study is guided by two hypotheses: (1) Given the importance of medical care to the well-being of transgender individuals, it is expected that greater access to medical care by state correctional systems will be inversely related with the odds of attempting suicide; and (2) given the increased risks of gender-based victimization resulting from housing policies, along with the link between such victimization and suicide, it is expected that higher levels of gender-based victimization will be associated with increased odds of attempting suicide.

Methods

Data

Data for this study come from the 2008/2009 wave of the National Transgender Discrimination Survey (NTDS). NTDS used a variety of convenience sampling techniques including recruitment through community-based organizations and online communities and within social service settings in attempting to recruit respondents. While most surveys were collected online, more than 2,000 paper surveys were distributed through service organizations in an effort to target hard-to-reach populations, resulting in the inclusion of 500 paper surveys in the final sample of 6,450 valid respondents, which closely parallels the geographic distribution of the U.S. population (Grant et al., 2011). NTDS included a series of questions regarding incarceration. The first of these questions asked whether respondents "have ever been sent to jail or prison for any reason." A subsample of 1,007 cases was retained based on respondents answering yes to this question.

Variables

NTDS respondents were asked whether they had ever attempted suicide. This question was used to create an outcome variable indicating whether the respondent had attempted suicide (1 *yes*). Respondents were asked about their experiences regarding five forms of victimization while incarcerated: harassment, physical assaults, sexual assaults, denial of hormones, and denial of regular medical care. These questions were asked in two installments: one concerning victimization from correctional staff and the other pertaining to victimization from inmates. The results of these questions were used to create two binary variables indicating staff victimization and inmate

victimization (1 *did experience*). Incarceration length was controlled through a dichotomous indicator (1 *more than 1 year*).

A variable indicating policies granting access to transgender-related medical care in state-level correctional systems was created based on the results of G. Brown and McDuffie (2009) across five domains of transgender health care: psychological evaluations, consultation with an experienced provider, continuation of hormones, freeze-frame hormone dosages, and initiation of hormones. The level of transgender-related care provided was dichotomized into an indicator of high care access (1 *multiple services offered*) according to the respondents' state of residence.

In addition to the key variables outlined, covariates were included to control relevant factors. Binary indicators were incorporated for minority racial status, mental disability, homelessness, and being in a partnered relationship. Gender was assessed categorically (male-to-female, female-to-male, and other gender nonconforming), while 5-point measures accounted for age (18 to 24, 24 to 44, 45 to 54, 55 to 64, and 65+) as well as class variables such as education (no high school, high school degree, some college, college degree, and graduate degree) and income (less than $10,000, $10,000 to 20,000, $20,000 to 50,000, $50,000 to 100,000, and $100,000 and up). Finally, covariates were added for substance use using a 3-point measure (no substance use, previous substance use, and current substance use). Descriptive statistics for all variables are presented in Table 1.

Analytic Strategy

Variable nonresponse was low, with almost all variables having less than 3.5% of cases missing. The sole exception was age, with approximately 8% of cases missing. In an effort to preserve cases, a variable indicating that age was missing was added to the analyses. Binary logistic regression was then used to estimate separate models predicting the effects of access to care and gender-based victimization on the odds of reporting lifetime suicide attempts. To ease interpretability, coefficients were exponentiated into odds ratios (*OR*s). In the estimation of models predicting attempted suicide relative to correctional system access to medical care, an interaction term was included to account for the likelihood that only respondents reporting long-term access would be subject to the included state-level policies. Researchers have reported difficulties in the testing of differences between groups in logit regression models due to unobserved heterogeneity between groups (Allison, 1999). Models estimated by the ordinal generalized linear models module for Stata 13.1 (Williams, 2010) produced similar results, indicating that unobserved heterogeneity between groups does not appear to be a concern.

Results

Binary logistic regression models were used to estimate the effect of access to transgender-related medical care in state correctional facilities on lifetime suicide attempt. As shown in the base model (Table 2), there is not a significant effect with respect to the level of care provided. However, part of the sample reported short-term incarceration, which is more likely to occur in local jails outside of the purview of state correctional systems. To account for this, a model was then estimated that included an interaction term between level of care and long-term incarceration. The interaction term was found to be statistically significant ($p < .05$), indicating that changes in reports of lifetime suicide attempt with respect to different levels of medical care varies according to the incarceration term. For respondents who reported short-term incarceration, the coefficient for the interaction is canceled out since the long-term indicator has a value of 0. As such, residence in states that provide higher levels of transgender-related medical care in their correctional systems is associated with a negligible and insignificant change in the odds of reporting attempted suicide.

Table 1. Descriptive Statistics.

Covariates	Mean/Percentage
Gender	
Male-to-female	62.89
Female-to-male	17.91
Other gender nonconforming	19.20
Non-White	30.19
Age	
Missing	7.94
18–24	17.48
25–44	49.45
45–54	14.80
55–64	9.14
65+	1.19
Education	
Less than high school	8.95
High school graduate	12.68
Some college	48.19
College degree	17.00
Graduate degree	13.18
Income	
>$10,000	24.20
$10,000–$19,999	14.42
$20,000–$49,999	33.06
$50,000–$99,999	21.32
$100,000+	7.00
Has partner	46.56
Homeless	5.00
Mental disability	23.44
Substance use	
None	58.66
Prior use	27.56
Current use	13.78
Long-term incarceration	11.47
Multiple health services	58.64
Inmate victimization	38.93
Staff victimization	45.28
Has attempted suicide	52.62

Respondents reporting long-term incarceration in states with low levels of medical care are estimated as having odds of reporting attempted suicide 3 times that of short-term incarcerated respondents. For respondents who reported long-term incarceration and lived in states providing high levels of transgender medical care, the estimated effects for long-term incarceration, level of medical care, and interaction term act in concert. The combining of *OR*s is multiplicative; thus, the estimated effect of providing higher levels of medical care to transgender inmates incarcerated long-term results in an *OR* of 0.812, an expected decrease of 18.8% in the odds of reporting suicide relative to respondents who were incarcerated short term.

To facilitate understanding of this relationship, the predicted effects are presented graphically (Figure 1). Consistent with the results presented in Table 2, Figure 1 illustrates that state-level correctional care is associated with insignificant changes in the odds of reporting suicide attempts among respondents who reported short-term incarceration. Respondents reporting long-term

Table 2. Logit Models Predicting Attempted Suicide Relative to Medical Care.

	Without Interaction Term		With Interaction Term	
	Odds Ratio	Std. Error	Odds Ratio	Std. Error
Gender[a]				
Female-to-male	1.268	.257	1.270	.258
Other nonconforming	0.702	.141	0.693	.139
Non-White	0.910	.170	0.961	.181
Age[b]				
25–44	1.149	.236	1.156	.238
45–54	0.872	.236	0.873	.237
55–64	1.272	.391	1.284	.396
65+	0.147	.160	0.158	.172
Missing	0.900	.322	0.913	.329
Education[c]				
High school graduate	0.892	.306	0.892	.306
Some college	1.115	.338	1.116	.340
College degree	0.685	.236	0.686	.237
Graduate degree	0.807	.289	0.790	.284
Income (thousands)[d]				
$10–$20	1.509	.380	1.538	.390
$20–$50	0.988	.202	0.993	.204
$50–$100	1.196	.284	1.190	.284
$100+	1.028	.354	1.044	.359
Has partner	1.193	.182	1.219	.187
Homeless	1.560	.655	1.588	.669
Mental disability	3.231***	.605	3.244***	.609
Substance use[e]				
Prior use	2.042***	.342	2.078***	.349
Current use	2.291***	.516	2.364***	.534
Long-term incarceration	1.336	.325	3.293*	1.565
Level of medical care	0.805	.122	0.884	.138
Long Term × Medical Care	—	—	0.279*	.154
Constant	0.609	.226	0.557	.208

Note. $N = 913$.
Level of significance: *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.
[a]Male-to-female. [b]18–24 Years old. [c]Less than high school graduate. [d]≥$10,000. [e]No substance use.

incarceration are expected to experience a sizable decrease (36.2%) in the probability of reporting suicide attempts relative to level of care provided. The net result of this change is that transgender individuals experiencing long-term incarceration in correctional environments where higher levels of transgender-related health care are provided are expected to report that they have attempted suicide at rates similar to transgender individuals experiencing short-term incarceration.

The analyses then focused on the effect of gender-based victimization on lifetime suicide attempts. Due to concerns of multicollinearity arising from the high correlation between these two forms of victimization (r .661), their effects were estimated separately. The results (Table 3) provide evidence of a statistically significant relationship ($p < .05$) between gender-based victimization and suicide attempts. The estimated effects of both forms of victimization are similar, with inmate-induced victimization associated with a 41.7% increase in the odds of reporting attempted suicide, while victimization occurring at the hands of correctional staff is associated with an expected increase of 47.6% in the odds of reporting suicide attempts. The predicted

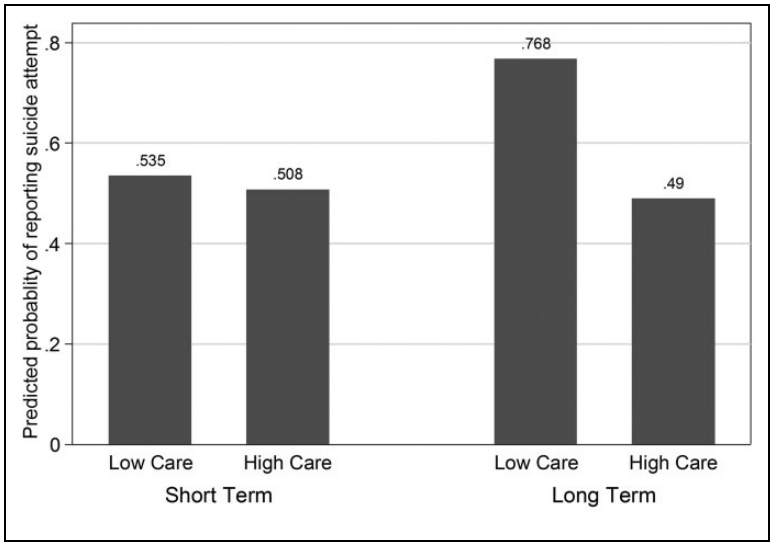

Figure 1. Attempted suicide by level of care and incarceration term.

probabilities of reporting attempted suicide relative to experiences of incarceration-related gender-based victimization are presented in Figure 2. Respondents reporting victimization, regardless of form, were predicted to have a .571 probability of reporting having attempted suicide. In the instance of inmate-induced victimization, respondents reporting no victimization were predicted to have a .495 probability of having attempted suicide, a decrease of 15.4%. Similarly, respondents reporting no staff-induced victimization are expected to have a .486 probability of attempting suicide.

Models with an interaction term between victimization and long-term incarceration were estimated in order to assess whether these differences vary according to the incarceration length, which may be an indicator of the differences between incarceration in jails and prisons. The results of these models (not shown) find no evidence that differences in suicide attempts relative to gender-based victimization vary by incarceration term. Thus, it appears that the relationship between victimization experienced in correctional facilities and suicide attempts among transgender individuals may be consistent whether such victimization occurs in jails or prisons.

Discussion and Conclusion

Although prior research has yielded evidence of a relationship between incarceration and suicide among the general population (Binswanger et al., 2007, 2011; Fazel et al., 2008; Rosen et al., 2008; Yu et al., 2014), few researchers have studied the link between incarceration and suicide among transgender individuals. The current study addresses this gap in the literature by focusing on the possible role of correctional policies on attempted suicide among transgender individuals who have been incarcerated. Two key findings arise out of the analyses: (1) transgender individuals reporting long-term incarceration and residing in states providing high levels of transgender-related medical services were significantly less likely to report attempting suicide and (2) transgender individuals who experienced gender-based victimization while incarcerated were more likely to report lifetime suicide attempts. These results contribute to the literature by illustrating a link between incarceration and suicide among transgender individuals that may be impacted by commonly enacted correctional policies regarding the incarceration of transgender inmates.

Table 3. Logit Models Predicting Attempted Suicide Relative to Victimization.

	Inmate Induced		Staff Induced	
	Odds Ratio	Std. Error	Odds Ratio	Std. Error
Gender[a]				
Female-to-male	1.415	.284	1.337	.268
Other nonconforming	0.796	.157	0.794	.157
Non-White	0.821	.151	0.817	.150
Age[b]				
25–44	1.138	.230	1.125	.228
45–54	0.900	.242	0.897	.242
55–64	1.365	.416	1.357	.413
65+	0.180	.195	0.184	.199
Missing	0.914	.307	0.947	.319
Education[c]				
High school graduate	0.946	.311	0.910	.298
Some college	1.243	.360	1.219	.352
College degree	0.777	.258	0.758	.251
Graduate degree	0.839	.288	0.790	.271
Income (thousands)[d]				
$10–$20	1.182	.368	1.489	.371
$20–$50	0.990	.200	0.991	.201
$50–$100	1.192	.278	1.255	.294
$100+	0.988	.336	1.023	.349
Has partner	1.242	.188	1.216	.183
Homeless	1.855	.761	1.845	.757
Mental disability	3.274***	.607	3.372***	.628
Substance use[e]				
Prior use	1.911***	.320	1.935***	.322
Current use	2.093***	.467	2.096**	.466
Long-term incarceration	1.178	.291	1.186	.292
Victimization	1.417*	.229	1.476*	.228
Constant	0.429***	.154	0.425***	.151

Note. $N = 942$.
Level of significance: *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.
[a]Male-to-female. [b]18–24 Years old. [c]Less than high school graduate. [d]≥$10,000. [e]No substance use.

In models predicting suicide attempts relative to level of transgender-related medical care provided by state correctional systems, among respondents who reported long-term incarceration, those who resided in states that provided higher levels of care were less likely to report having attempted suicide. This suggests that the effect of access to medical care is constrained to the individuals who were most likely to be incarcerated pursuant to state-level policies. While these results suggest that increased access to transgender-related health care may help reduce the likelihood of attempting suicide among inmates incarcerated in state institutions, they provide little indication of the relationship between suicide attempts and medical care provided in local jails. Given that inmates in local jails may be incarcerated for shorter terms, access to transgender-related medical care in the correctional facility may not have as pronounced of an effect on the probability of attempting suicide among these inmates. In this vein, the mental health effects of providing adequate medical care to transgender inmates in such facilities may be more limited in scope. Further research will be necessary to determine how the mental impacts of providing transgender-related health care differ between local jails and state prisons.

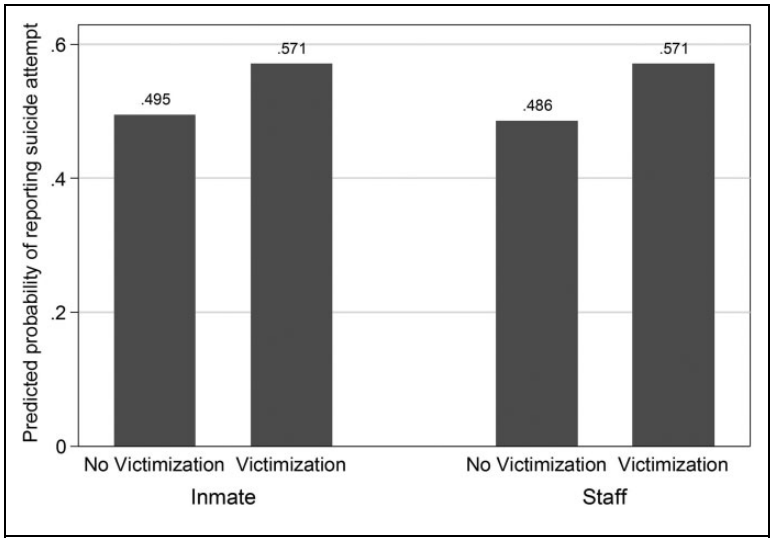

Figure 2. Attempted suicide by gender-based victimization.

The inverse association between transgender-related medical services provided and attempted suicide is not altogether unexpected. Transgender-related medical care has consistently been shown to be associated with increased quality of life and mental well-being (Colton Meier et al., 2011; Murad et al., 2010; Wilson et al., 2015). The results presented by the present study suggest that the benefits of transgender-related medical care may extend into correctional institutions. Considering that many correctional systems provide low levels of such care, increasing the care available to transgender inmates presents the potential of greatly enhancing their well-being, which may help alleviate incarceration-related stress.

Additionally, the results indicated that transgender individuals experiencing victimization as part of their incarceration were more likely to report having attempted suicide. Many correctional systems in the United States have policies that place transgender inmates into facilities inconsistent with their gender identity (G. Brown & McDuffie, 2009; Sumner & Jenness, 2014; Tarzwell, 2006), heightening their risk of gender-based victimization, a point evidenced by the disparity in sexual assaults reported by transgender women and cisgender men in male prisons (Jenness et al., 2007). There is strong evidence of a relationship between gender-based victimization, including rape, discrimination, and verbal and physical abuse, and suicide among transgender individuals (Clements-Nolle et al., 2006; Goldblum et al., 2012; Grossman & D'Augelli, 2007; Mustanski & Liu, 2013). The results presented here add further evidence of an association between gender-based victimization and suicide among transgender individuals and extend the literature by showing that this relationship extends to victimization occurring in correctional facilities.

Higher odds of attempted suicide among respondents reporting victimization while incarcerated highlight the need for correctional policy to evolve concerning the housing of transgender inmates. Current policies commonly assign inmates to facilities on the basis of genitalia, placing transgender inmates at risk of victimization. Protective custody is commonly used to help minimize victimization of transgender inmates (Sumner & Jenness, 2014), a process that is likewise problematic for the mental well-being of inmates (Haney, 2003a). Enactment of identity-based housing policies presents its own challenges, particularly in ensuring the safety of other inmates (Sumner & Jenness, 2014). Cognizant of the difficulties inherent in "one-size-fits-all" policies that rigidly assign housing, several jails, including the Denver (J. Brown, 2015) and Cook County jails (Lu, 2011), have

introduced policies managing transgender inmates on a case-by-case basis. Under these policies, a committee determines the appropriate course of action based upon the particulars of each case. The effectiveness of this policy in ensuring a safe environment for all inmates is currently unknown and will need to be assessed by future research.

This study is limited in several ways. Chief among these is the use of lifetime suicide attempt, which impacts the ability to draw conclusions regarding the direction of causality in the links between incarceration and suicide attempts uncovered by the analysis. It is entirely possible that these results arise due to endogeneity, that is, the factors that place respondents at risk of attempting suicide are related to factors that expose them to negative incarceration experiences. This is a concern primarily regarding models predicting suicide attempts relative to gender-based victimization. While the factors underlying attempting suicide may make individuals more likely to experience incarceration, they do little to predict the level of transgender-related medical care provided by correctional systems. Thus, it is less likely that the models predicting suicide attempts relative to medical care are affected by this issue, particularly considering that the effect was constrained to those respondents reporting long-term incarceration, which likely provide a more valid assessment. Furthermore, there are concerns regarding the representability of the sample. Transgender individuals comprise a minute portion of the overall national population (Flores, Herman, Gates, & Brown, 2016), and thus random sampling is unlikely to result in a sufficient sample. Even with these limitations, these novel results are significant enough to contribute to the discussion of correctional policies for managing transgender inmates, and the results presented herein warrant more attention on the part of researchers.

In conclusion, while incarceration is a stressful experience for most inmates, it presents particularly harmful risks for transgender individuals. Policies enacted by many correctional systems fail to adequately manage the incarceration of transgender inmates, leading to harassment, while preventing inmates from accessing adequate medical care. The results presented here suggest that the shortcomings of current correctional policy offer potentially harmful impacts. Changes in the current policy could potentially improve the mental health outcomes of transgender inmates.

Author's Note

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PLoS one

Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden

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Abstract

Context: The treatment for transsexualism is sex reassignment, including hormonal treatment and surgery aimed at making the person's body as congruent with the opposite sex as possible. There is a dearth of long term, follow-up studies after sex reassignment.

Objective: To estimate mortality, morbidity, and criminal rate after surgical sex reassignment of transsexual persons.

Design: A population-based matched cohort study.

Setting: Sweden, 1973-2003.

Participants: All 324 sex-reassigned persons (191 male-to-females, 133 female-to-males) in Sweden, 1973–2003. Random population controls (10:1) were matched by birth year and birth sex or reassigned (final) sex, respectively.

Main Outcome Measures: Hazard ratios (HR) with 95% confidence intervals (CI) for mortality and psychiatric morbidity were obtained with Cox regression models, which were adjusted for immigrant status and psychiatric morbidity prior to sex reassignment (adjusted HR [aHR]).

Results: The overall mortality for sex-reassigned persons was higher during follow-up (aHR 2.8; 95% CI 1.8–4.3) than for controls of the same birth sex, particularly death from suicide (aHR 19.1; 95% CI 5.8–62.9). Sex-reassigned persons also had an increased risk for suicide attempts (aHR 4.9; 95% CI 2.9–8.5) and psychiatric inpatient care (aHR 2.8; 95% CI 2.0–3.9). Comparisons with controls matched on reassigned sex yielded similar results. Female-to-males, but not male-to-females, had a higher risk for criminal convictions than their respective birth sex controls.

Conclusions: Persons with transsexualism, after sex reassignment, have considerably higher risks for mortality, suicidal behaviour, and psychiatric morbidity than the general population. Our findings suggest that sex reassignment, although alleviating gender dysphoria, may not suffice as treatment for transsexualism, and should inspire improved psychiatric and somatic care after sex reassignment for this patient group.

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Introduction

Transsexualism (ICD-10),[1] or gender identity disorder (DSM-IV),[2] is a condition in which a person's gender identity - the sense of being a man or a woman - contradicts his or her bodily sex characteristics. The individual experiences gender dysphoria and desires to live and be accepted as a member of the opposite sex.

The treatment for transsexualism includes removal of body hair, vocal training, and cross-sex hormonal treatment aimed at making the person's body as congruent with the opposite sex as possible to alleviate the gender dysphoria. Sex reassignment also involves the surgical removal of body parts to make external sexual characteristics resemble those of the opposite sex, so called sex reassignment/confirmation surgery (SRS). This is a unique

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intervention not only in psychiatry but in all of medicine. The present form of sex reassignment has been practised for more than half a century and is the internationally recognized treatment to ease gender dysphoria in transsexual persons.[3,4]

Despite the long history of this treatment, however, outcome data regarding mortality and psychiatric morbidity are scant. With respect to suicide and deaths from other causes after sex reassignment, an early Swedish study followed 24 transsexual persons for an average of six years and reported one suicide.[5] A subsequent Swedish study recorded three suicides after sex reassignment surgery of 175 patients.[6] A recent Swedish follow-up study reported no suicides in 60 transsexual patients, but one death due to complications after the sex reassignment surgery.[7] A Danish study reported death by suicide in 3 out of 29 operated male-to-female transsexual persons followed for an average of six years.[8] By contrast, a Belgian study of 107 transsexual persons followed for 4–6 years found no suicides or deaths from other causes.[9] A large Dutch single-centre study (N = 1,109), focusing on adverse events following hormonal treatment, compared the outcome after cross-sex hormone treatment with national Dutch standardized mortality and morbidity rates and found no increased mortality, with the exception of death from suicide and AIDS in male-to-females 25–39 years of age.[10] The same research group concluded in a recent report that treatment with cross-sex hormones seems acceptably safe, but with the reservation that solid clinical data are missing.[11] A limitation with respect to the Dutch cohort is that the proportion of patients treated with cross-sex hormones who also had surgical sex-reassignment is not accounted for.[10]

Data is inconsistent with respect to psychiatric morbidity post sex reassignment. Although many studies have reported psychiatric and psychological improvement after hormonal and/or surgical treatment,[7,12,13,14,15,16] other have reported on regrets,[17] psychiatric morbidity, and suicide attempts after SRS.[9,18] A recent systematic review and meta-analysis concluded that approximately 80% reported subjective improvement in terms of gender dysphoria, quality of life, and psychological symptoms, but also that there are studies reporting high psychiatric morbidity and suicide rates after sex reassignment.[19] The authors concluded though that the evidence base for sex reassignment "is of very low quality due to the serious methodological limitations of included studies."

The methodological shortcomings have many reasons. First, the nature of sex reassignment precludes double blind randomized controlled studies of the result. Second, transsexualism is rare [20] and many follow-ups are hampered by small numbers of subjects.[5,8,21,22,23,24,25,26,27,28] Third, many sex reassigned persons decline to participate in follow-up studies, or relocate after surgery, resulting in high drop-out rates and consequent selection bias.[6,9,12,21,24,28,29,30] Forth, several follow-up studies are hampered by limited follow-up periods.[7,9,21,22,26,30] Taken together, these limitations preclude solid and generalisable conclusions. A long-term population-based controlled study is one way to address these methodological shortcomings.

Here, we assessed mortality, psychiatric morbidity, and psychosocial integration expressed in criminal behaviour after sex reassignment in transsexual persons, in a total population cohort study with long-term follow-up information obtained from Swedish registers. The cohort was compared with randomly selected population controls matched for age and gender. We adjusted for premorbid differences regarding psychiatric morbidity and immigrant status. This study design sheds new light on transsexual persons' health after sex reassignment. It does not, however, address whether sex reassignment is an effective treatment or not.

Methods

National registers

The study population was identified by the linkage of several Swedish national registers, which contained a total of 13.8 million unique individuals. The Hospital Discharge Register (HDR, held by the National Board of Health and Welfare) contains discharge diagnoses, up to seven contributory diagnoses, external causes of morbidity or mortality, surgical procedure codes, and discharge date. Discharge diagnoses are coded according to the 8th (1969-1986), 9th (1987–1996), and 10th editions (1997-) of the International Classification of Diseases (ICD). The register covers virtually all psychiatric inpatient episodes in Sweden since 1973. Discharges that occurred up to 31 December 2003 were included. Surgical procedure codes could not be used for this study due to the lack of a specific code for sex reassignment surgery. The Total Population Register (TPR, held by Statistics Sweden) is comprised of data about the entire Swedish population. Through linkage with the Total Population Register it was possible to identify birth date and birth gender for all study subjects. The register is updated every year and gender information was available up to 2004/2005. The Medical Birth Register (MBR) was established in 1973 and contains birth data, including gender of the child at birth. National censuses based on mandatory self-report questionnaires completed by all adult citizens in 1960, 1970, 1980, and 1990 provided information on individuals, households, and dwellings, including gender, living area, and highest educational level. Complete migration data, including country of birth for immigrants for 1969–2003, were obtained from the TPR. In addition to educational information from the censuses, we also obtained highest educational level data for 1990 and 2000 from the Register of Education. The Cause of Death Register (CDR, Statistics Sweden) records all deaths in Sweden since 1952 and provided information on date of death and causes of death. Death events occurring up to 31 December 2003 are included in the study. The Crime Register (held by the National Council of Crime Prevention) provided information regarding crime type and date on all criminal convictions in Sweden during the period 1973–2004. Attempted and aggravated forms of all offences were also included. All crimes in Sweden are registered regardless of insanity at the time of perpetration; for example, for individuals who suffered from psychosis at the time of the offence. Moreover, conviction data include individuals who received custodial or non-custodial sentences and cases where the prosecutor decided to caution or fine without court proceedings. Finally, Sweden does not differ considerably from other members of the European Union regarding rates of violent crime and their resolution.[31]

Study population, identification of sex-reassigned persons (exposure assessment)

The study was designed as a population-based matched cohort study. We used the individual national registration number, assigned to all Swedish residents, including immigrants on arrival, as the primary key through all linkages. The registration number consists of 10 digits; the first six provide information of the birth date, whereas the ninth digit indicates the gender. In Sweden, a person presenting with gender dysphoria is referred to one of six specialised gender teams that evaluate and treat patients principally according to international consensus guidelines: Standards of Care.[3] With a medical certificate, the person applies to the National Board of Health and Welfare to receive permission for sex reassignment surgery and a change of legal sex status. A new national registration number signifying the new gender is assigned after sex reassignment surgery. The National

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Board of Health and Welfare maintains a link between old and new national registration numbers, making it possible to follow individuals undergoing sex reassignment across registers and over time. Hence, sex reassignment surgery in Sweden requires (i) a transsexualism diagnosis and (ii) permission from the National Board of Health and Welfare.

A person was defined as exposed to sex reassignment surgery if two criteria were met: (i) at least one inpatient diagnosis of gender identity disorder diagnosis without concomitant psychiatric diagnoses in the Hospital Discharge Register, and (ii) at least one discrepancy between gender variables in the Medical Birth Register (from 1973 and onwards) or the National Censuses from 1960, 1970, 1980, or 1990 and the latest gender designation in the Total Population Register. The first criterion was employed to capture the hospitalization for sex reassignment surgery that serves to secure the diagnosis and provide a time point for sex reassignment surgery; the plastic surgeons namely record the reason for sex reassignment surgery, i.e., transsexualism, but not any co-occurring psychiatric morbidity. The second criterion was used to ensure that the person went through all steps in sex-reassignment and also changed sex legally.

The date of sex reassignment (start of follow-up) was defined as the first occurrence of a gender identity disorder diagnosis, without any other concomitant psychiatric disorder, in the Hospital Discharge Register after the patient changed sex status (any discordance in sex designation across the Censuses, Medical Birth, and Total Population registers). If this information was missing, we used instead the closest date in the Hospital Discharge Register on which the patient was diagnosed with gender identity disorder without concomitant psychiatric disorder prior to change in sex status. The reason for prioritizing the use of a gender identity disorder diagnosis *after* changed sex status over *before* was to avoid overestimating person-years at risk of sex-reassigned person.

Using these criteria, a total of 804 patients with gender identity disorder were identified, whereof 324 displayed a shift in the gender variable during the period 1973–2003. The 480 persons that did not shift gender variable comprise persons who either did not apply, or were not approved, for sex reassignment surgery. Moreover, the ICD 9 code 302 is a non specific code for sexual disorders. Hence, this group might also comprise persons that were hospitalized for sexual disorders other than transsexualism. Therefore, they were omitted from further analyses. Of the remaining 324 persons, 288 were identified with the gender identity diagnosis *after* and 36 *before* change of sex status. Out of the 288 persons identified *after* changed sex status, 185 could also be identified *before* change in sex status. The median time lag between the hospitalization *before* and *after* sex change for these 185 persons was 0.96 years (mean 2.2 years, SD 3.3).

Gender identity disorder was coded according to ICD-8: 302.3 (transsexualism) and 302.9 (sexual deviation NOS); ICD-9: 302 (overall code for sexual deviations and disorders, more specific codes were not available in ICD-9); and ICD-10: F64.0 (transsexualism), F64.1 (dual-role transvestism), F64.8 (other gender identity disorder), and F64.9 (gender identity disorder NOS). Other psychiatric disorders were coded as ICD-8: 290-301 and 303-315; ICD-9: 290-301 and 303-319; and ICD-10: F00-F63 as well as F65-F99.

Identification of population-based controls (unexposed group)

For each exposed person (N = 324), we randomly selected 10 unexposed controls. A person was defined as unexposed if there were no discrepancies in sex designation across the Censuses, Medical Birth, and Total Population registers *and* no gender identity disorder diagnosis according to the Hospital Discharge Register. Control persons were matched by sex and birth year and had to be alive and residing in Sweden at the estimated sex reassignment date of the case person. To study possible gender-specific effects on outcomes of interest, we used two different control groups: one with the same sex as the case individual at birth (birth sex matching) and the other with the sex that the case individual had been reassigned to (final sex matching).

Outcome measures

We studied mortality, psychiatric morbidity, accidents, and crime following sex reassignment. More specifically, we investigated: (1) all-cause mortality, (2) death by definite/uncertain suicide, (3) death by cardiovascular disease, and (4) death by tumour. Morbidity included (5) any psychiatric disorder (gender identity disorders excluded), (6) alcohol/drug misuse and dependence, (7) definite/uncertain suicide attempt, and (8) accidents. Finally, we addressed court convictions for (9) any criminal offence and (10) any violent offence. Each individual could contribute with several outcomes, but only one event per outcome. Causes of death (Cause of Death Registry from 1952 and onwards) were defined according to ICD as suicide (ICD-8 and ICD-9 codes E950-E959 and E980-E989, ICD-10 codes X60-X84 and Y10-Y34); cardiovascular disease (ICD-8 codes 390-458, ICD-9 codes 390-459, ICD-10 codes I00-I99); neoplasms (ICD-8 and ICD-9 codes 140-239, ICD-10 codes C00-D48), any psychiatric disorder (gender identity disorders excluded); (ICD-8 codes 290-301 and 303-315, ICD-9 codes 290-301 and 303-319, ICD-10 codes F00-F63 and F65-F99); alcohol/drug abuse and dependence (ICD-8 codes 303-304, ICD-9 codes 303-305 (tobacco use disorder excluded), ICD-10 codes F10-F16 and F18-F19 (x5 excluded); and accidents (ICD-8 and ICD-9 codes E800-E929, ICD-10 codes V01-X59).

Any criminal conviction during follow-up was counted; specifically, violent crime was defined as homicide and attempted homicide, aggravated assault and assault, robbery, threatening behaviour, harassment, arson, or any sexual offense.[32]

Covariates

Severe psychiatric morbidity was defined as inpatient care according to ICD-8 codes 291, 295-301, 303-304, and 307; ICD-9 codes 291-292, 295-298, 300-301, 303-305 (tobacco use disorder excluded), 307.1, 307.5, 308-309, and 311; ICD-10 codes F10-F16, F18-F25, F28-F45, F48, F50, and F60-F62. Immigrant status, defined as individuals born abroad, was obtained from the Total Population Register. All outcome/covariate variables were dichotomized (i.e., affected or unaffected) and without missing values.

Statistical analyses

Each individual contributed person-time from study entry (for exposed: date of sex reassignment; for unexposed: date of sex reassignment of matched case) until date of outcome event, death, emigration, or end of study period (31 December 2003), whichever came first. The association between exposure (sex reassignment) and outcome (mortality, morbidity, crime) was measured by hazard ratios (HR) with 95% CIs, taking follow-up time into account. HRs were estimated from Cox proportional hazard regression models, stratified on matched sets (1:10) to account for the matching by sex, age, and calendar time (birth year). We present crude HRs (though adjusted for sex and age through matching) and confounder-adjusted HRs [aHRs] for all outcomes. The two potential confounders, immigrant status (yes/no) and history of severe psychiatric morbidity (yes/no) prior to sex

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reassignment, were chosen based on previous research[18,33] and different prevalence across cases and controls (Table 1).

Gender-separated analyses were performed and a Kaplan-Meier survival plot graphically illustrates the survival of the sex reassigned cohort and matched controls (all-cause mortality) over time. The significance level was set at 0.05 (all tests were two-sided). All outcome/covariate variables were without missing values, since they are generated from register data, which are either present (affected) or missing (unaffected). The data were analysed using SAS version 9.1 (SAS Institute Inc., Cary, NC, USA).

Ethics

The data linking of national registers required for this study was approved by the IRB at Karolinska Institutet, Stockholm. All data were analyzed anonymously; therefore, informed consent for each individual was neither necessary nor possible.

Results

We identified 324 transsexual persons (exposed cohort) who underwent sex reassignment surgery and were assigned a new legal sex between 1973 and 2003. These constituted the sex-reassigned (exposed) group. Fifty-nine percent (N = 191) of sex-reassigned persons were male-to-females and 41% (N = 133) female-to-males, yielding a sex ratio of 1.4:1 (Table 1).

The average follow-up time for all-cause mortality was 11.4 (median 9.1) years. The average follow-up time for the risk of being hospitalized for any psychiatric disorder was 10.4 (median 8.1).

Characteristics prior to sex reassignment

Table 1 displays demographic characteristics of sex-reassigned and control persons prior to study entry (sex reassignment). There were no substantial differences between female-to-males and male-to-females regarding measured baseline characteristics. Immigrant status was twice as common among transsexual individuals compared to controls, living in an urban area somewhat more common, and higher education about equally prevalent. Transsexual individuals had been hospitalized for psychiatric morbidity other than gender identity disorder prior to sex reassignment about four times more often than controls. To adjust for these baseline discrepancies, hazard ratios adjusted for immigrant status and psychiatric morbidity prior to baseline are presented for all outcomes [aHRs].

Mortality

Table 2 describes the risks for selected outcomes during follow-up among sex-reassigned persons, compared to same-age controls of the same birth sex. Sex-reassigned transsexual persons of both genders had approximately a three times higher risk of all-cause mortality than controls, also after adjustment for covariates. Table 2

Table 1. Baseline characteristics among sex-reassigned subjects in Sweden (N = 324) and population controls matched for birth year and sex.

Characteristic at baseline	Sex-reassigned subjects (N = 324)	Birth-sex matched controls (N = 3,240)	Final-sex matched controls (N = 3,240)
Gender			
Female at birth, male after sex change	133 (41%)	1,330 (41%)	1,330 (41%)
Male at birth, female after sex change	191 (59%)	1,910 (59%)	1,910 (59%)
Average age at study entry [years] (SD, min-max)			
Female at birth, male after sex change	33.3 (8.7, 20–62)	33.3 (8.7, 20–62)	33.3 (8.7, 20–62)
Male at birth, female after sex change	36.3 (10.1, 21–69)	36.3 (10.1, 21–69)	36.3 (10.1, 21–69)
Both genders	35.1 (9.7, 20–69)	35.1 (9.7, 20–69)	35.1 (9.7, 20–69)
Immigrant status			
Female at birth, male after sex change	28 (21%)	118 (9%)	100 (8%)
Male at birth, female after sex change	42 (22%)	176 (9%)	164 (9%)
Both genders	70 (22%)	294 (9%)	264 (8%)
Less than 10 years of schooling prior to entry vs. 10 years or more			
Females at birth, males after sex change	49 (44%); 62 (56%)	414 (37%); 714 (63%)	407 (36%); 713 (64%)
Males at birth, females after sex change	61 (41%); 89 (59%)	665 (40%); 1,011 (60%)	595 (35%); 1,091 (65%)
All individuals with data	110 (42%); 151 (58%)	1,079 (38%); 1,725 (62%)	1,002 (36%); 1,804 (64%)
Psychiatric morbidity* prior to study entry			
Female at birth, male after sex change	22 (17%)	47 (4%)	42 (3%)
Male at birth, female after sex change	36 (19%)	76 (4%)	72 (4%)
Both genders	58 (18%)	123 (4%)	114 (4%)
Rural [vs. urban] living area prior to entry			
Female at birth, male after sex change	13 (10%)	180 (14%)	195 (15%)
Male at birth, female after sex change	20 (10%)	319 (17%)	272 (14%)
Both genders	33 (10%)	499 (15%)	467 (14%)

Note:
*Hospitalizations for gender identity disorder were not included.
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Table 2. Risk of various outcomes among sex-reassigned subjects in Sweden (N = 324) compared to population controls matched for birth year and birth sex.

	Number of events cases/ controls 1973–2003	Outcome incidence rate per 1000 person-years 1973–2003 (95% CI)		Crude hazard ratio (95% CI) 1973–2003	Adjusted* hazard ratio (95% CI) 1973–2003	Adjusted* hazard ratio (95% CI) 1973–1988	Adjusted* hazard ratio (95% CI) 1989–2003
		Cases	Controls				
Any death	27/99	7.3 (5.0–10.6)	2.5 (2.0–3.0)	2.9 (1.9–4.5)	2.8 (1.8–4.3)	3.1 (1.9–5.0)	1.9 (0.7–5.0)
Death by suicide	10/5	2.7 (1.5–5.0)	0.1 (0.1–0.3)	19.1 (6.5–55.9)	19.1 (5.8–62.9)	N/A	N/A
Death by cardiovascular disease	9/42	2.4 (1.3–4.7)	1.1 (0.8–1.4)	2.6 (1.2–5.4)	2.5 (1.2–5.3)	N/A	N/A
Death by neoplasm	8/38	2.2 (1.1–4.3)	1.0 (0.7–1.3)	2.1 (1.0–4.6)	2.1 (1.0–4.6)	N/A	N/A
Any psychiatric hospitalisation‡	64/173	19.0 (14.8–24.2)	4.2 (3.6–4.9)	4.2 (3.1–5.6)	2.8 (2.0–3.9)	3.0 (1.9–4.6)	2.5 (1.4–4.2)
Substance misuse	22/78	5.9 (3.9–8.9)	1.8 (1.5–2.3)	3.0 (1.9–4.9)	1.7 (1.0–3.1)	N/A	N/A
Suicide attempt	29/44	7.9 (5.5–11.4)	1.0 (0.8–1.4)	7.6 (4.7–12.4)	4.9 (2.9–8.5)	7.9 (4.1–15.3)	2.0 (0.7–5.3)
Any accident	32/233	9.0 (6.3–12.7)	5.7 (5.0–6.5)	1.6 (1.1–2.3)	1.4 (1.0–2.1)	1.6 (1.0–2.5)	1.1 (0.5–2.2)
Any crime	60/350	18.5 (14.3–23.8)	9.0 (8.1–10.0)	1.9 (1.4–2.5)	1.3 (1.0–1.8)	1.6 (1.1–2.4)	0.9 (0.6–1.5)
Violent crime	14/61	3.6 (2.1–6.1)	1.4 (1.1–1.8)	2.7 (1.5–4.9)	1.5 (0.8–3.0)	N/A	N/A

Notes:
*Adjusted for psychiatric morbidity prior to baseline and immigrant status.
‡Hospitalisations for gender identity disorder were excluded.
N/A Not applicable due to sparse data.
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separately lists the outcomes depending on when sex reassignment was performed: during the period 1973-1988 or 1989–2003. Even though the overall mortality was increased across both time periods, it did not reach statistical significance for the period 1989–2003. The Kaplan-Meier curve (Figure 1) suggests that survival of transsexual persons started to diverge from that of matched controls after about 10 years of follow-up. The cause-specific mortality from suicide was much higher in sex-reassigned persons, compared to matched controls. Mortality due to cardiovascular disease was moderately increased among the sex-reassigned, whereas the numerically increased risk for malignancies was borderline statistically significant. The malignancies were lung cancer (N = 3), tongue cancer (N = 1), pharyngeal cancer (N = 1), pancreas cancer (N = 1), liver cancer (N = 1), and unknown origin (N = 1).

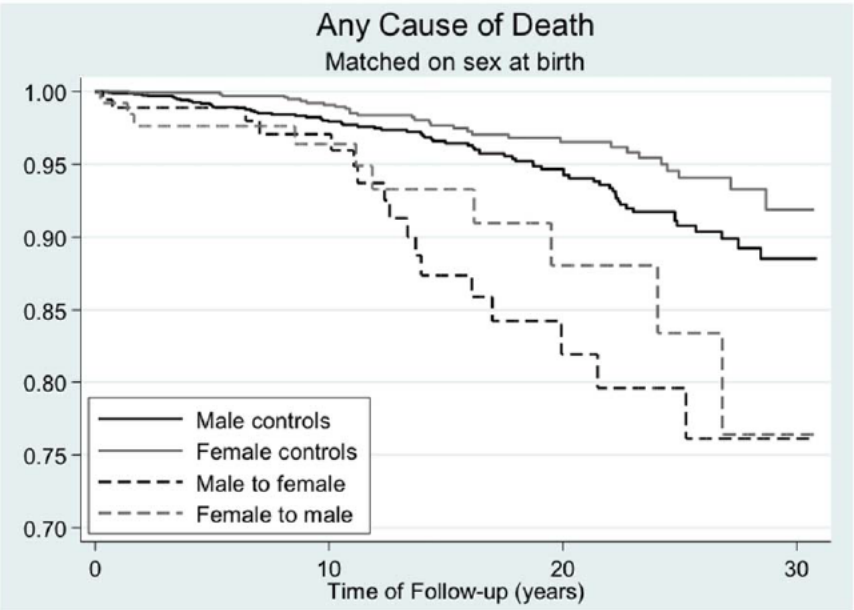

Figure 1. Death from any cause as a function of time after sex reassignment among 324 transsexual persons in Sweden (male-to-female: N = 191, female-to-male: N = 133), and population controls matched on birth year.
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Psychiatric morbidity, substance misuse, and accidents

Sex-reassigned persons had a higher risk of inpatient care for a psychiatric disorder other than gender identity disorder than controls matched on birth year and birth sex (Table 2). This held after adjustment for prior psychiatric morbidity, and was true regardless of whether sex reassignment occurred before or after 1989. In line with the increased mortality from suicide, sex-reassigned individuals were also at a higher risk for suicide attempts, though this was not statistically significant for the time period 1989–2003. The risks of being hospitalised for substance misuse or accidents were not significantly increased after adjusting for covariates (Table 2).

Crime rate

Transsexual individuals were at increased risk of being convicted for any crime or violent crime after sex reassignment (Table 2); this was, however, only significant in the group who underwent sex reassignment before 1989.

Gender differences

Comparisons of female-to-males and male-to-females, although hampered by low statistical power and associated wide confidence intervals, suggested mostly similar risks for adverse outcomes (Tables S1 and S2). However, violence against self (suicidal behaviour) and others ([violent] crime) constituted important exceptions. First, male-to-females had significantly increased risks for suicide attempts compared to both female (aHR 9.3; 95% CI 4.4–19.9) and male (aHR 10.4; 95% CI 4.9–22.1) controls. By contrast, female-to-males had significantly increased risk of suicide attempts only compared to male controls (aHR 6.8; 95% CI 2.1–21.6) but not compared to female controls (aHR 1.9; 95% CI 0.7–4.8). This suggests that male-to-females are at higher risk for suicide attempts after sex reassignment, whereas female-to-males maintain a female pattern of suicide attempts after sex reassignment (Tables S1 and S2).

Second, regarding any crime, male-to-females had a significantly increased risk for crime compared to female controls (aHR 6.6; 95% CI 4.1–10.8) but not compared to males (aHR 0.8; 95% CI 0.5–1.2). This indicates that they retained a male pattern regarding criminality. The same was true regarding violent crime. By contrast, female-to-males had higher crime rates than female controls (aHR 4.1; 95% CI 2.5–6.9) but did not differ from male controls. This indicates a shift to a male pattern regarding criminality and that sex reassignment is coupled to increased crime rate in female-to-males. The same was true regarding violent crime.

Discussion

Principal findings and comparison with previous research

We report on the first nationwide population-based, long-term follow-up of sex-reassigned transsexual persons. We compared our cohort with randomly selected population controls matched for age and gender. The most striking result was the high mortality rate in both male-to-females and female-to males, compared to the general population. This contrasts with previous reports (with one exception[8]) that did not find an increased mortality rate after sex reassignment, or only noted an increased risk in certain subgroups.[7,9,10,11] Previous clinical studies might have been biased since people who regard their sex reassignment as a failure are more likely to be lost to follow-up. Likewise, it is cumbersome to track deceased persons in clinical follow-up studies. Hence, population-based register studies like the present are needed to improve representativity.[19,34]

The poorer outcome in the present study might also be explained by longer follow-up period (median >10 years) compared to previous studies. In support of this notion, the survival curve (Figure 1) suggests increased mortality from ten years after sex reassignment and onwards. In accordance, the overall mortality rate was only significantly increased for the group operated before 1989. However, the latter might also be explained by improved health care for transsexual persons during 1990s, along with altered societal attitudes towards persons with different gender expressions.[35]

Mortality due to cardiovascular disease was significantly increased among sex reassigned individuals, albeit these results should be interpreted with caution due to the low number of events. This contrasts, however, a Dutch follow-up study that reported no increased risk for cardiovascular events.[10,11] A recent meta-analysis concluded, however, that data on cardiovascular outcome after cross-sex steroid use are sparse, inconclusive, and of very low quality.[34]

With respect to neoplasms, prolonged hormonal treatment might increase the risk for malignancies,[36] but no previous study has tested this possibility. Our data suggested that the cause-specific risk of death from neoplasms was increased about twice (borderline statistical significance). These malignancies (see Results), however, are unlikely to be related to cross-hormonal treatment.

There might be other explanations to increased cardiovascular death and malignancies. Smoking was in one study reported in almost 50% by the male-to females and almost 20% by female-to-males.[9] It is also possible that transsexual persons avoid the health care system due to a presumed risk of being discriminated.

Mortality from suicide was strikingly high among sex-reassigned persons, also after adjustment for prior psychiatric morbidity. In line with this, sex-reassigned persons were at increased risk for suicide attempts. Previous reports [6,8,10,11] suggest that transsexualism is a strong risk factor for suicide, also after sex reassignment, and our long-term findings support the need for continued psychiatric follow-up for persons at risk to prevent this.

Inpatient care for psychiatric disorders was significantly more common among sex-reassigned persons than among matched controls, both before and after sex reassignment. It is generally accepted that transsexuals have more psychiatric ill-health than the general population prior to the sex reassignment.[18,21,22,33] It should therefore come as no surprise that studies have found high rates of depression,[9] and low quality of life[16,25] also after sex reassignment. Notably, however, in this study the increased risk for psychiatric hospitalisation persisted even after adjusting for psychiatric hospitalisation prior to sex reassignment. This suggests that even though sex reassignment alleviates gender dysphoria, there is a need to identify and treat co-occurring psychiatric morbidity in transsexual persons not only before but also after sex reassignment.

Criminal activity, particularly violent crime, is much more common among men than women in the general population. A previous study of all applications for sex reassignment in Sweden up to 1992 found that 9.7% of male-to-female and 6.1% of female-to-male applicants had been prosecuted for a crime.[33] Crime after sex reassignment, however, has not previously been studied. In this study, male-to-female individuals had a higher risk for criminal convictions compared to female controls but not compared to male controls. This suggests that the sex reassignment procedure neither increased nor decreased the risk for criminal offending in male-to-females. By contrast, female-to-males were at a higher risk for criminal convictions compared to female controls and did not differ from male controls, which suggests increased crime proneness in female-to-males after sex reassignment.

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Strengths and limitations of the study

Strengths of this study include nationwide representativity over more than 30 years, extensive follow-up time, and minimal loss to follow-up. Many previous studies suffer from low outcome ascertainment,[6,9,21,29] whereas this study has captured almost the entire population of sex-reassigned transsexual individuals in Sweden from 1973–2003. Moreover, previous outcome studies have mixed pre-operative and post-operative transsexual persons,[22,37] while we included only post-operative transsexual persons that also legally changed sex. Finally, whereas previous studies either lack a control group or use standardised mortality rates or standardised incidence rates as comparisons,[9,10,11] we selected random population controls matched by birth year, and either birth or final sex.

Given the nature of sex reassignment, a double blind randomized controlled study of the result after sex reassignment is not feasible. We therefore have to rely on other study designs. For the purpose of evaluating whether sex reassignment is an effective treatment for gender dysphoria, it is reasonable to compare reported gender dysphoria pre and post treatment. Such studies have been conducted either prospectively[7,12] or retrospectively,[5,6,9,22,25,26,29,38] and suggest that sex reassignment of transsexual persons improves quality of life and gender dysphoria. The limitation is of course that the treatment has not been assigned randomly and has not been carried out blindly.

For the purpose of evaluating the safety of sex reassignment in terms of morbidity and mortality, however, it is reasonable to compare sex reassigned persons with matched population controls. The caveat with this design is that transsexual persons before sex reassignment might differ from healthy controls (although this bias can be statistically corrected for by adjusting for baseline differences). It is therefore important to note that the current study is only informative with respect to transsexuals persons health after sex reassignment; no inferences can be drawn as to the effectiveness of sex reassignment as a treatment for transsexualism. In other words, the results should not be interpreted such as sex reassignment *per se* increases morbidity and mortality. Things might have been even worse without sex reassignment. As an analogy, similar studies have found increased somatic morbidity, suicide rate, and overall mortality for patients treated for bipolar disorder and schizophrenia.[39,40] This is important information, but it does not follow that mood stabilizing treatment or antipsychotic treatment is the culprit.

Other facets to consider are first that this study reflects the outcome of psychiatric and somatic treatment for transsexualism provided in Sweden during the 1970s and 1980s. Since then, treatment has evolved with improved sex reassignment surgery, refined hormonal treatment,[11,41] and more attention to psychosocial care that might have improved the outcome. Second, transsexualism is a rare condition and Sweden is a small country (9.2 million inhabitants in 2008). Hence, despite being based on a comparatively large national cohort and long-term follow-up, the statistical power was limited. Third, regarding psychiatric morbidity after sex reassignment, we assessed inpatient psychiatric care. Since most psychiatric care is provided in outpatient settings (for which no reliable data were available), underestimation of the *absolute* prevalences was inevitable. However, there is no reason to believe that this would change the *relative risks* for psychiatric morbidity unless sex-reassigned transsexual individuals were more likely than matched controls to be admitted to hospital for any given psychiatric condition.

Finally, to estimate start of follow-up, we prioritized using the date of a gender identity disorder diagnosis *after* changed sex status over *before* changed sex status, in order to avoid overestimating person-years at risk after sex-reassignment. This means that adverse outcomes might have been underestimated. However, given that the median time lag between the hospitalization before and after change of sex status was less than a year (see Methods), this maneuver is unlikely to have influenced the results significantly. Moreover, all deaths will be recorded regardless of this exercise and mortality hence correctly estimated.

Conclusion

This study found substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts, and psychiatric hospitalisations in sex-reassigned transsexual individuals compared to a healthy control population. This highlights that post surgical transsexuals are a risk group that need long-term psychiatric and somatic follow-up. Even though surgery and hormonal therapy alleviates gender dysphoria, it is apparently not sufficient to remedy the high rates of morbidity and mortality found among transsexual persons. Improved care for the transsexual group after the sex reassignment should therefore be considered.

Supporting Information

Table S1 Risk of various outcomes in sex-reassigned persons in Sweden compared to population controls matched for birth year and *birth sex*.
(DOCX)

Table S2 Risk of various outcomes in sex-reassigned persons in Sweden compared to controls matched for birth year and *final sex*.
(DOCX)

Author Contributions

Conceived and designed the experiments: CD PL AJ NL ML. Performed the experiments: MB AJ. Analyzed the data: CD PL MB AJ NL ML. Contributed reagents/materials/analysis tools: PL NL AJ. Wrote the paper: CD PL MB AJ NL ML.

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CCHCS / DHCS Care Guide: Gender Dysphoria

SUMMARY | **DECISION SUPPORT** | **PATIENT EDUCATION / SELF MANAGEMENT**

GOALS

- ✓ **Ensure accurate diagnosis of Gender Dysphoria (GD)**
- ✓ **Maintain psychological well being and functioning**
- ✓ **Maintain sex hormone levels that are safe and appropriate for the desired gender when hormones are prescribed**

ALERTS

- ♦ Co-occurrence of mental health disorders (e.g., borderline personality disorder, psychosis, factitious disorder, malingering)
- ♦ Self-harm behaviors (often associated with co-occurring borderline personality disorder)
- ♦ Suicidal ideation, gestures, and attempts (often associated with co-occurring borderline personality disorder or depression)
- ♦ Risk of sexual assault, threatened or actual
- ♦ Medical conditions exacerbated by transgender hormone therapy

DIAGNOSTIC CRITERIA / EVALUATION

DIAGNOSIS—According to the APA, the name change to Gender Dysphoria, rather than Gender Identity Disorder "remove(s) the connotation that the patient is 'disordered'." The change… "offer(s) a diagnostic name that is more appropriate to the symptoms and behavior…"

DSM V Gender Dysphoria (GD) diagnostic criteria include:

A. A marked incongruence between one's expressed gender and one's primary and assigned gender of at least 6 months duration as manifested by at least 2 of the following:
- a marked incongruence between one's experienced/expressed gender and one's physical sex characteristics
- a strong desire to be rid of one's sex characteristics because of the incongruence with one's experienced/expressed gender
- a strong desire for the primary and/or secondary sex characteristics of the other gender
- a strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
- a strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)
- a strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

EVALUATION OF GD IN CCHCS / DHCS

- Mental Health rules out co-occurring mental health disorders (MHDs) or MHD's that may complicate treatment and rules out mimics of gender dysphoria, including factitious disorder, borderline personality disorder, malingering, and psychosis.
- Medicine rules out medical mimics of gender dysphoria including adrenalizing syndromes, chromosomal abnormalities, and conditions that preclude hormone treatment.
- Medical and mental health treatment team case conference to establish GD diagnosis.

DEFINITIONS

TRANSGENDER: Transgender is the state of one's "gender identity" (self-identification as a woman, a man, neither or both) not matching one's physically "assigned sex" (identification by others as male, female or intersex, based on physical/genetic sex).

TRANSSEXUAL: A person who establishes, or wishes to establish, a permanent identity with the gender opposite their birth sex utilizing some type of medical treatment

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TREATMENT

PSYCHOLOGICAL
- Patient education
- Psychotherapy when indicated
- Group therapy when indicated

MEDICAL
- Patient education
- Hormone therapy (pages 4-5)

SOCIAL / ENVIRONMENTAL
- Appropriate housing
- Medical Classification Chrono (CDCR 128-C3) indicating GD status
- Gender appropriate clothing shall be provided by custody staff upon request to inmates identified as transgender on the CDCR 128-C3 per the Department Operations Manual (DOM).

DOM, Ch 6, Section 62080.14, Transgendered Inmates

OTHER

Requests from patients for surgical treatment for gender dysphoria (GD) shall be referred by providers to the Institution Utilization Management Committee (IUMC) using a Request for Services (RFS).

The treating clinicians and the IUMC will provide requested medical, mental health, and custody information to the Headquarters Utilization Management Committee (HQUMC) but will defer approval/disapproval of the requests to the HQUMC.

Information contained in the Care Guide is not a substitute for a health care professional's clinical judgment. Evaluation and treatment should be tailored to the individual patient and the clinical circumstances. Furthermore, using this information will not guarantee a specific outcome for each patient. Refer to "Disclaimer Regarding Care Guides" for further clarification.

CCHCS / DHCS Care Guide: Gender Dysphoria

GENDER DYSPHORIA EVALUATION AND MANAGEMENT

PATIENT REQUESTS GD TREATMENT*

MEDICAL PROVIDER ASSESSMENT

Medical provider refers patient for mental health Gender Dysphoria assessment

For patients currently receiving hormone therapy (or with a clear, well-documented history of recent therapy *prescribed by a clinician),*

Initial temporary hormone therapy may be prescribed by the PCP *after:*

- Informed consent is obtained (patient must be aware of benefits and risks of hormone therapy).
- Patient is informed that a mental health evaluation will be performed before a decision is made by the treatment team about continuing hormone therapy and that this therapy may be discontinued upon review of patient's case by the treatment teams.
- Ensure there are no medical contraindications to hormone therapy.
- Obtain baseline lab work (page 6).

For all patients (previously treated with hormones or never previously treated with hormones), the medical provider will assess patient for:

- Medical disorders causing or contributing to gender dysphoria symptoms (chromosomal or hormonal conditions).
- Medical conditions which may preclude or complicate medical treatment of GD.
- Prior history of GD treatment or work-up.
- Patient's understanding of medical effects and adverse effects of GD therapy (what it will and will not do).
- Likelihood of patient's adherence with therapy.
- Any contraindications to therapy.

MENTAL HEALTH PROVIDER ASSESSMENT

Mental health provider will determine:

- Patient's history of mental health disorders (past and present).
- Presence of mental health disorders that mimic GD.
- Relevant background information on GD counseling or medical therapy.
- Abuse and neglect history.
- Substance use history past and present.
- Psychological conditions which may preclude medical treatment of GD
  - self-injurious behaviors
  - suicidal behaviors [including ideation, gestures, or attempts],
  - potential sexual violence or related violent behaviors,
  - any other condition that may negatively impact GD medical treatment
- Patient's understanding of effects of GD therapy (what it will and will not do).
- Likelihood of patient's adherence with therapy.
- Safety and housing assessment.
- Recommendation for MHSDS placement if indicated.

Case conference scheduled by medical provider with mental health and primary care treatment teams to establish a diagnosis of GD (or to establish absence of GD)

GD Diagnosis confirmed?

YES

Refer to medical provider (who may be the PCP) for assessment and for a recommended treatment plan.

NO

- Inform patient of decision to discontinue or not to start GD therapy.
- Discontinue hormones if already prescribed.

Upon completion of designated medical clinician's treatment plan, the PCP shall:

- Review the plan and ensure there are no contraindications to the proposed therapy.
- Obtain informed consent from the patient (page 8).
- Obtain baseline labs, if not already collected.
- Prescribe hormone therapy per treatment plan after reviewing results of baseline labs.
- Schedule routine PCP follow-up to initiate, monitor, or adjust therapy.
- Obtain consultation when clinically indicated.

*Evaluation and treatment of Reception Center patients who desire hormone therapy and have not been previously treated will be deferred in most cases until transfer to a mainline institution.

Note: Individuals with GD may be sexually attracted to males, females, both or neither. Some carefully diagnosed persons spontaneously change their aspirations and some accommodate their gender identities without medical intervention.

EVALUATION FOR HORMONE THERAPY

ELIGIBILITY FOR HORMONE THERAPY

- Fulfills DSM V criteria for GD or transsexualism per designated mental health provider.
- Lack of mental health diagnosis, physical diagnosis, or needed treatment that would contraindicate or greatly increase risk of hormone therapy.
- Able to demonstrate knowledge and understanding of the expected outcomes of hormone treatment and the medical and social risks and benefits.
- No medical contraindications to therapy.

POTENTIAL MEDICAL CONTRAINDICATIONS TO HORMONE THERAPY

MALE TO FEMALE	FEMALE TO MALE
Very high risk of adverse effects • History of thromboembolic disease **Moderate to high risk of adverse effects** • History of prolactinoma • Significant liver disease (transaminases > 3 times upper limit of normal) • History of breast cancer • Coronary artery disease • Cerebrovascular disease • Severe migraine headaches	**Very high risk of adverse effects** • History of breast or uterine cancer • erythrocytosis (Hct > 50%) **Moderate to high risk of adverse effects** • Significant liver disease (transaminases > 3 times upper limit of normal)

EFFECTS OF HORMONE THERAPY

MALE TO FEMALE	FEMALE TO MALE
Feminizing effects: *Note: maximal physical effects may not be evident until ≥ 2 years of therapy. The degree of change varies from person to person, is limited by heredity, and cannot be overcome by increased doses.* Treatment with estrogen and antiandrogens can result in: • Breast enlargement • Body fat redistribution to approximate a female body habitus • Decreased upper body strength • Softening of the skin • Decreased body hair • Slowing the loss of scalp hair • Decreased testicular size • Decreased libido • Decreased frequency and firmness of erections • Decreased spontaneous erections • Decreased sperm production	**Masculinizing effects:** *Note: maximal physical effects may not be evident until ≥ 2 years of therapy. The degree of change varies from person to person, is limited by heredity, and cannot be overcome by increased doses.* Treatment with testosterone can cause: • Deepening of the voice • Increased oiliness of skin, acne • Clitoral enlargement • Increased libido • Mild breast atrophy • Increased facial and body hair • Male pattern baldness • Increased upper body strength • Weight gain • Increased sexual interest • Decreased hip fat

POTENTIAL ADVERSE EFFECTS OF HORMONE THERAPY*

MALE TO FEMALE	FEMALE TO MALE
• Increased emotional lability/depression • Increased risk of: ◦ Thromboembolic disease ◦ Pituitary prolactinoma ◦ High blood pressure ◦ Diabetes mellitus ◦ Liver disease ◦ Gallstones ◦ Breast cancer ◦ Cardiovascular disease	• Increased risk of: ◦ Cardiovascular or cerebrovascular disease ◦ Hypertension ◦ Liver disease and increased LFTs ◦ Diabetes mellitus ◦ Breast or uterine cancer ◦ Thromboembolic disease • Increased aggression or depression • Adverse changes in lipid profile

*For complete list of possible adverse effects see manufacturers' medication prescribing information.

HORMONE THERAPY FOR MALE TO FEMALE TRANSSEXUAL PERSONS

GOALS OF HORMONE THERAPY

Initial:
- Suppress endogenous hormone production of gender at birth
- Induce secondary sex characteristics of new gender

Maintenance:
- Maintain sex hormone levels in the normal physiologic range for the designated gender

Note: maximal physical effects may not be evident until ≥ 2 years of therapy. The degree of change varies from person to person, is limited by heredity, and cannot be overcome by increased doses.

MEDICATION CLASS	MEDICATION*	COMMENTS	EFFECTS / ADVERSE EFFECTS / DRUG INTERACTIONS
ESTROGEN			
Parenteral $$	**estradiol valerate** 5 - 20 mg IM every two weeks	➢ **Parenteral (IM) administration <u>is preferred</u> in CCHCS** • Consider adding aspirin 81 - 325 mg for all patients who do not have contraindications, especially if cigarette smoker, obese, > 40 years old, cardiac risk factors • Stop all estrogens two weeks prior to major surgery/immobilizing event, resume when normal mobility restored • Response to treatment is highly variable • Test hormone level midway between injections. Titrate estrogen dose to result in a physiologic range for young healthy females, not to exceed 200 pg/ml	• Estrogen effects and adverse effects, see page 7 • Drug interactions, see page 7
$$	estradiol cypionate 2 - 10 mg IM (only) every two weeks		
Oral $	**estradiol** 2 - 6 mg daily		
Transdermal $$	estradiol patch 0.1 - 0.4 mg twice weekly		
ANDROGEN SUPPRESSANTS			
$	**spironolactone** 100 - 200 mg by mouth twice daily	• Contraindicated with renal insufficiency and/or potassium > 5.5 mEq/dl • Avoid use in patients who are receiving digoxin, ACE inhibitors, potassium sparing diuretics	• Hyperkalemia • Dehydration • Hyponatremia
	finasteride (Proscar®/Propecia®) 5 - 10 mg by mouth daily		

***Bold**=Formulary

SUMMARY	DECISION SUPPORT	PATIENT EDUCATION/SELF MANAGEMENT

HORMONE THERAPY FOR FEMALE TO MALE TRANSSEXUAL PERSONS

MEDICATION CLASS	MEDICATION*	COMMENTS	EFFECTS / ADVERSE EFFECTS / DRUG INTERACTIONS
TESTOSTERONE			
Parenteral $	Testosterone cypionate 50 - 200 mg IM (only) every two weeks	➢ **Parenteral (IM) administration <u>is preferred</u> in CCHCS** • During the first three to nine months of testosterone treatments total testosterone levels may be high although free testosterone levels are normal due to high sex hormone binding globulin levels in some biological women • 15% of patients on testosterone will experience transient elevations in liver enzymes • Do not use cypionate and enanthate interchangeably due to differences in duration of action • Test hormone level midway between injections. Titrate the testosterone dose to result in a serum testosterone level between 350 to 750 ng/dl	• Testosterone effects and adverse effects, see page 7 • Drug interactions, see page 7
$	Testosterone enanthate 50 - 200 mg IM (only) every two weeks		
Topical $$	testosterone gel 1% 20 - 100 mg testosterone/day		
$$$	testosterone patch 24 hr (daily) 2.5 - 7.5 mg/day		

***Bold**=Formulary

MONITORING HORMONE THERAPY

MALE TO FEMALE	PROVIDER AND LAB FOLLOW-UP	LABS	LAB GOAL	PREVENTIVE SERVICES
BASELINE	N/A	• CBC, serum creatinine and potassium • Liver function tests (LFTs) • Fasting lipid panel • Fasting glucose (if family history of DM) • A1C (if diabetic) • Thyroid stimulating hormone • Testosterone level • Prolactin level • Estradiol level		➢ Routine Cancer Screening • Mammography per CCHCS IMSP&P Vol. 4, Ch. 7, Preventive Clinical Services Policy, Appendix A; Preventive Clinical Services: Screening Guidelines • Fecal occult blood (FOB) testing per CCHCS preventive services screening guidelines • Prostate cancer screening per CCHCS preventive services screening guidelines • Consider bone density testing at baseline if risk factors for osteoporosis are present, (e.g., previous fracture, family history of osteoporosis, significant corticosteroid use, prolonged hypogonadism) otherwise screen at age 60
HORMONE THERAPY < 1 YEAR	EVERY TWO TO THREE MONTHS	• Serum testosterone • Serum estradiol • CBC, LFTs • Serum creatinine and potassium for those on spironolactone therapy	Testosterone: < 55 ng/ml Estrogen: Normal physiologic range for young healthy females, not to exceed 200 pg/ml	
HORMONE THERAPY > 1 YEAR	EVERY SIX TO TWELVE MONTHS	• Serum testosterone • Serum estradiol • CBC, LFTs • Serum creatinine and potassium for those on spironolactone therapy • Serum prolactin yearly for two years, then every two years thereafter	Testosterone: < 55 ng/ml Estrogen: Normal physiologic range for young healthy females, not to exceed 200 pg/ml	
FEMALE TO MALE	**PROVIDER AND LAB FOLLOW-UP**	**LABS**	**LAB GOAL**	**PREVENTIVE SERVICES**
BASELINE	N/A	• CBC, serum creatinine, and potassium • Liver function tests (LFTs) • Fasting lipid panel • Fasting glucose (if family history of DM) • A1C (if diabetic) • Testosterone level • Estradiol level		➢ Routine Cancer Screening • Mammography per CCHCS IMSP&P Vol. 4, Ch. 7, Preventive Clinical Services Policy, Appendix A; Preventive Clinical Services: Screening Guidelines • Fecal occult blood (FOB) testing per CCHCS preventive services screening guidelines • PAP smear per CCHCS preventive services screening guidelines • Consider bone density testing at baseline if risk factors for osteoporosis are present, (e.g., previous fracture, family history of osteoporosis, significant corticosteroid use, prolonged hypogonadism) otherwise screen at age 60
HORMONE THERAPY < 1 YEAR	Every two to three months	• Serum testosterone • Serum estradiol every three months for the first six months or until no uterine bleeding for six months • CBC, LFTs • Fasting lipid panel	Testosterone: Normal physiologic range between 350 to 750 ng/dl Estrogen: < 50 pg/ml	
HORMONE THERAPY > 1 YEAR	Every six to twelve months	• Serum testosterone • Serum estradiol as needed • CBC, LFTs • Fasting lipid panel • Fasting glucose (if family history of DM) • A1C (if diabetic) • Monitor weight	Testosterone: Normal physiologic range between 350 to 750 ng/dl Estrogen: < 50 pg/ml	

Adapted from Endocrine Society Guidelines: Endocrine Treatment for Transsexual Persons 2009

POTENTIAL DRUG INTERACTIONS WITH SEX HORMONE THERAPY

ESTROGENS

Estrogens are partially metabolized by CYP3A4 and interactions may occur with agents that inhibit or induce CYP3A4. [See full prescribing information for more details about potential drug interactions]

Estrogens may **reduce** levels or effects of:	Estrogens may **increase** levels or effects of:	Estrogen levels or effects may be **increased** by:	Estrogen levels or effects may be **decreased** by:
• Warfarin • Hypoglycemic agents • Fosamprenavir • Levothyroxine	No significant interactions reported	• Erythromycin, clarithromycin • Azole antifungals • Calcium channel blockers: ◦ verapamil ◦ diltiazem • Isoniazid • Vitamin C • Fluoxetine, fluvoxamine, paroxetine, nefazodone, sertraline • Some HIV medications: ◦ efavirenz ◦ indinavir ◦ saquinavir ◦ atazanavir ◦ etravirine	• Anticonvulsants: ◦ carbamazepine ◦ oxcarbazepine ◦ phenytoin ◦ phenobarbital ◦ topiramate • Rifampin, rifapentine • Cimetidine • Dexamethasone • Some HIV medications: ◦ lopinavir/ritonavir ◦ ritonavir ◦ tipranavir ◦ darunavir ◦ nelfinavir ◦ nevirapine

TESTOSTERONE

Testosterone Reduces levels or effects of:	**Testosterone Increases** levels or effects of:	Testosterone levels or effects may be **increased** by:	Testosterone levels or effects may be **decreased** by:
No significant effects reported	• Warfarin • Cyclosporine	No significant interactions reported	No significant interactions reported

STATE OF CALIFORNIA
HORMONE ADMINISTRATION CONSENT
CDCR 7528 (09/13)

DEPARTMENT OF CORRECTIONS AND REHABILITATION

Form: Page 1 of 1

Initial Each Box:

Patient Initials: ☐ I have received and read all patient education/staff management materials.

Patient Initials: ☐ I agree that all my questions and concerns have been adequately addressed and I understand the information provided.

Patient Initials: ☐ I have been given the opportunity to discuss the effects, risks, and possible adverse reactions of the use of hormones.

Initial the Appropriate Box:

Male to Female	Female to Male
I voluntarily give my informed consent to use hormones (estrogen and possibly progesterone) along with the anti-testosterone drug spironolactone for the purpose of transition to the female gender. Patient Initials: ☐	I voluntarily give my informed consent to use male hormones (testosterone) for the purpose of transition to the male gender. Patient Initials: ☐

Initial Each Box:

Patient Initials: ☐ I agree to have regular physical examinations and laboratory testing as required by my provider. I understand that these are required to continue hormone therapy.

Patient Initials: ☐ I agree to take my hormone therapy as prescribed by my provider. I will inform my provider of any problems with my treatment. I agree not to change hormone dosages without consultation with my provider and I realize that in doing so may result in my discontinuation in the gender change program.

Patient Initials: ☐ I understand that I can choose to stop hormone therapy at any time. I also understand that my provider can discontinue treatment for medical reasons. I agree to follow a prescribed reduction plan if either of these situations occurs to reduce potentially harmful side effects that may happen if I suddenly stop hormone therapy.

Patient Signature: _____ Patient Name (Print): _____ Date: _____

Witness Signature: _____ Witness Name and Title (Print): _____ Date: _____

1. Disability Code:	2. Accommodation:	3. Effective Communication:	
☐ TABE score ≤ 4.0	☐ Additional time	☐ P/I asked questions	CDCR #:
☐ DPH ☐ DPV ☐ LD	☐ Equipment ☐ SLI	☐ P/I summed information	Last Name:
☐ DPS ☐ DNH	☐ Louder ☐ Slower	**Please check one:**	First Name: MI:
☐ DNS ☐ DDP	☑ Basic ☐ Transcribe	☐ Not reached* ☐ Reached	DOB:
☐ Not Applicable	☐ Other*	*See chrono/notes	
4.Comments:			

Unauthorized collection, creation, use, disclosure, modification or destruction of personally identifiable information and/or protected health information may subject individuals to civil liability under applicable federal and state laws.

SAMPLE

CCHCS/DHCS Care Guide: Gender Dysphoria

SUMMARY | DECISION SUPPORT | PATIENT EDUCATION/SELF MANAGEMENT

HORMONE THERAPY: MALE TO FEMALE

- Changing your gender is a serious and possibly dangerous process.
- The normal process of going through puberty is gradual and transforming to another gender also takes time. This transformation can be very hard on your body.
- There are many things you can do to get the safest and best results for your body and mind like:
  - Not smoking
  - Not drinking alcohol or taking illegal drugs
  - Maintaining a healthy weight
  - Getting regular exercise






- You should only trust information you get from your medical and mental health providers.

WHAT YOU NEED TO KNOW ABOUT ESTROGEN THERAPY

- The feminizing effects of estrogen can take many months to be noticed and several years to be complete.
- Some changes to your body will be permanent, even if you stop taking estrogen, including:
  - Breast development
    - You will need to learn to do monthly breast self-examinations, have an annual medical exam, and you will need to have mammograms after age 50.
  - Changes in fertility and sperm production
    - Estrogen can cause sperm to stop maturing and may cause infertility. Even if estrogen is stopped, the ability to make healthy sperm may or may not come back.
- Taking estrogen will not protect you from sexually transmitted diseases.
- Estrogen may cause migraine headaches.
- Estrogen is a very strong medication with possibly serious side effects. It must be used carefully and must be monitored regularly. Take estrogen only as directed by your health care provider. The correct dosage for you may not be the same as someone else. Dangerous side effects can include:
  - Blood clots
  - Breast cancer
  - Clinical depression
  - Stroke
  - Heart Disease
  - Liver disease
- Estrogen may raise your risk of heart disease, just like smoking cigarettes. Smoking is not allowed within the California Department of Corrections and Rehabilitation. If you choose to smoke, your health care provider may not prescribe estrogen or may prescribe lower doses. It is important to reduce other risk factors for heart disease, like high cholesterol and being overweight.
- You can choose to stop taking estrogen at any time. Your health care provider can also stop your treatment for medical reasons. If you stop taking estrogen, you must follow a plan to reduce the dose gradually to avoid harmful side effects.

WHAT YOU NEED TO DO

- Tell your health care provider if you are taking any dietary supplements, herbs, *drugs (legal or illegal) obtained in prison, other than those prescribed for you* or other medications.
- Alcohol, smoking, and drug abuse must be controlled before estrogen therapy is started.
- If you are in the mental health services delivery system, continue care with your mental health provider . If you feel you need mental health services submit a CDCR 7362 request or notify a staff member.
- You will be asked to sign an informed consent form before starting estrogen therapy.

If you have any questions, talk to your health care or mental health provider

HORMONE THERAPY: FEMALE TO MALE

- Changing your gender is a serious and possibly dangerous process.
- The normal process of going through puberty is gradual and transforming to another gender also takes time. This transformation can be very hard on your body.
- There are many things you can do to get the safest and best results for your body and mind like:
  - Not smoking
  - Not drinking alcohol or taking illegal drugs
  - Maintaining a healthy weight
  - Getting regular exercise






- You should only trust information you get from your medical and mental health providers.

WHAT YOU NEED TO KNOW ABOUT TESTOSTERONE THERAPY

- The masculinizing effects of testosterone can take many months to be noticed and many years to be complete.
- Some changes to your body will be permanent, even if you stop taking testosterone, including:
  - Hair loss
  - Facial hair growth and increased body hair
  - Deepening of your voice
- Taking testosterone will not protect you from sexually transmitted diseases or from becoming pregnant.
- Testosterone may effect fertility. If you take testosterone for a long time, you may not be able to get pregnant in the future, even if you stop taking testosterone.
- Testosterone is a very strong medication with possibly serious side effects. It must be used carefully and must be monitored regularly. Take testosterone only as directed by your health care provider. The correct dosage for you may not be the same as someone else. Dangerous side effects can include:
  - Blood clots
  - High blood pressure
  - Liver disease
  - Clinical depression
  - Breast and/or uterine cancer
  - Aggressive behavior/hostility
  - Heart Disease
  - Stroke
- Testosterone may raise your risk of getting diabetes in the future.
- Testosterone may raise your risk of heart disease, just like smoking cigarettes. Smoking is not allowed within the California Department of Corrections and Rehabilitation. If you choose to smoke, your health care provider may not prescribe testosterone or may prescribe lower doses. It is important to reduce other risk factors for heart disease, like high cholesterol and being overweight.
- You can choose to stop taking testosterone at any time. Your health care provider can also stop your treatment for medical reasons. If you stop taking testosterone, you must follow a plan to reduce the dose slowly to avoid harmful side effects.

WHAT YOU NEED TO DO

- Tell your health care provider if you are taking any dietary supplements, herbs, *drugs (legal or illegal) obtained in prison, other than those prescribed for you* or other medications
- Alcohol, smoking, and drug abuse must be controlled before testosterone therapy is started.
- If you are in the mental health services delivery system, continue care with your mental health provider . If you feel you need mental health services submit a CDCR 7362 request or notify a staff member.
- You will be asked to sign an informed consent form before starting testosterone therapy.

If you have any questions, talk to your health care or mental health provider

TERAPIA HORMONAL: DE HOMBRE A MUJER



- Cambiar de género es un proceso serio y posiblemente peligroso.
- El proceso normal de la pubertad es gradual y transformarse hacia otro género también toma su tiempo. Es una trasformación que puede ser muy severa para el cuerpo.
- Existen muchas cosas que puede hacer para obtener resultados más seguros y mejores para mente y cuerpo:
  - No fumar
  - No ingerir alcohol ni tomar drogas ilegales
  - Mantener un peso sano
  - Ejercitarse regularmente







- Debe confiar únicamente en la información que le suministren su médico y proveedores de salud mental.

Lo que necesita saber sobre la terapia de estrógenos

- Los efectos de la feminización por estrógenos pueden tomar muchos meses antes de comenzar a notarse y varios años para completarse.
- Algunos cambios en su cuerpo serán permanentes, aun si deja de tomar estrógenos, tales como:
  - Desarrollo de senos
    - Debe aprender a autoexaminarse los senos de forma mensual, hacerse un control médico anual y debe hacerse mamografías a partir de los 50 años de edad.
  - Cambios en la fertilidad y en la producción de esperma
    - Los estrógenos pueden causar que el esperma deje de madurar y puede causar infertilidad. Incluso si se deja de tomar estrógenos, la habilidad de producir esperma sana podría volver o no volver.
- Tomar estrógenos no le protegerá de contraer enfermedades de transmisión sexual.
- Los estrógenos pueden ocasionar migrañas.
- Los estrógenos son un medicamento muy poderoso con posibles efectos secundarios graves. Debe administrarse con cuidado y bajo monitoreo médico regular. Tome estrógenos solo como se lo indica su médico. La dosis adecuada para usted podría no ser la misma para otra persona. Algunos efectos secundarios peligrosos son:
  - Coágulos de sangre
  - Cáncer de seno
  - Depresión clínica
  - Infarto
  - Enfermedad cardíaca
  - Enfermedad hepática
- Los estrógenos pueden elevar su riesgo de sufrir enfermedades cardíacas, tal como lo hace el fumar cigarillos. El Departamento Correccional y de Rehabilitación de California (*California Department of Corrections and Rehabilitation*) prohíbe fumar. Si decide fumar, su proveedor de cuidados de salud podría no recetar estrógenos o podría recetar una dosis más baja. Es importante reducir otros factores de riesgo de enfermedad cardíaca, como colesterol y sobrepeso.
- Puede decidir dejar de tomar estrógenos en cualquier momento. Su proveedor de salud también podría detener el tratamiento por razones médicas. Si deja de tomar estrógenos, debe seguir un plan de reducción progresiva de la dosis para evitar así efectos secundarios dañinos.

Lo que necesita hacer

- Avise a su proveedor de salud si usted está tomando algún suplemento dietético, hierbas, drogas (legales o ilegales) obtenidos en la cárcel aparte de los que le han sido recetados u otros medicamentos.
- Deberá controlarse el abuso del alcohol, el tabaco y las drogas antes de iniciar la terapia de estrógenos.
- Si está participando en el programa de servicios de salud mental, debe continuar viéndose con un proveedor de salud mental. Si piensa que necesita servicios de salud mental debe llenar y enviar un Formulario 7362 o indíqueselo a cualquier empleado del CDCR.
- Se le pedirá que firme un formulario de consentimiento informado antes de iniciar su terapia de estrógenos.

Si tiene alguna pregunta, converse con su médico o proveedor de salud mental antes de comenzar su terapia de estrógenos

TERAPIA HORMONAL: DE MUJER A HOMBRE



- Cambiar de género es un proceso serio y posiblemente peligroso.
- El proceso normal de la pubertad es gradual y transformarse hacia otro género también toma su tiempo. Es una trasformación que puede ser muy severa para el cuerpo.
- Existen muchas cosas que puede hacer para obtener resultados más seguros y mejores para mente y cuerpo:
  - No fumar
  - No ingerir alcohol ni tomar drogas ilegales
  - Mantener un peso sano
  - Ejercitarse regularmente







- Debe confiar únicamente en la información que le suministren su médico y proveedores de salud mental.

Lo que necesita saber sobre la terapia de testosterona

- Los efectos de la masculinización por testosterona pueden tomar muchos meses antes de comenzar a notarse y varios años para completarse.
- Algunos cambios en su cuerpo serán permanentes, aun si deja de tomar testosterona, tales como:
  - Pérdida de cabello
  - Crecimiento de vello facial y aumento de vello corporal
  - Intensificación de la voz
- Tomar testosterona no le protegerá de contraer enfermedades de transmisión sexual ni de quedar embarazada.
- La testosterona podría afectar la fertilidad. Si toma testosterona por un largo período de tiempo, podría quedar infértil a futuro, incluso si deja de tomar testosterona.
- La testosterona es un medicamento muy poderoso con posibles efectos secundarios graves. Debe administrarse con cuidado y bajo monitoreo médico regular. Tome testosterona solo como se lo indica su médico. La dosis adecuada para usted podría no ser la misma para otra persona. Algunos efectos secundarios peligrosos son:
  - Coágulos de sangre
  - Presión arterial alta
  - Enfermedad hepática
  - Depresión clínica
  - Cáncer de seno/ o uterino
  - Comportamiento agresivo/hostilidad
  - Enfermedades cardíacas
  - Ataques cardíacos
- La testosterona podría elevar su riesgo de sufrir diabetes a futuro.
- La testosterona puede elevar su riesgo de sufrir enfermedades cardíacas, tal como lo hace el fumar cigarillos. El Departamento Correccional y de Rehabilitación de California (*California Department of Corrections and Rehabilitation*) prohíbe fumar. Si decide fumar, su proveedor de cuidados de salud podría no recetar testosterona o podría recetar una dosis más baja. Es importante reducir otros factores de riesgo de enfermedad cardíaca, como colesterol y sobrepeso.
- Puede decidir dejar de tomar testosterona en cualquier momento. Su proveedor de salud también podría detener el tratamiento por razones médicas. Si deja de tomar testosterona, debe seguir un plan de reducción progresiva de la dosis para evitar así efectos secundarios dañinos.

Lo que necesita hacer

- Avise a su proveedor de salud si usted está tomando algún suplemento dietético, hierbas, drogas (legales o ilegales) obtenidos en la cárcel aparte de los que le han sido recetados u otros medicamentos.
- Deberá controlarse el abuso del alcohol, el tabaco y las drogas antes de iniciar la terapia de testosterona.
- Si está participando en el programa de servicios de salud mental, debe continuar viéndose con un proveedor de salud mental. Si piensa que necesita servicios de salud mental debe llenar y enviar un Formulario 7362 o indíqueselo a cualquier empleado del CDCR.
- Se le pedirá que firme un formulario de consentimiento informado antes de iniciar su terapia de testosterona.

Si tiene alguna pregunta, converse con su médico o proveedor de salud mental antes de comenzar su terapia de testosterona

GOALS

- ✓ Provide gender affirming care.
- ✓ Assess transgender patients for Gender Dysphoria (GD).
- ✓ Monitor patient's psychological well-being and functioning.
- ✓ Maintain gender affirming hormone levels that are safe and appropriate for the patient's individualized gender goals when gender affirming hormone therapy (GAHT) is prescribed for GD.

ALERTS

- ♦ Be aware of potential for gender related victimization and discrimination that increases risk for death by suicide.
- ♦ Risk of sexual coercion or assault threatened or actual.
- ♦ Evaluate for comorbid medical conditions when on GAHT.
- ♦ Refer to Mental Health (MH) as appropriate.
- ♦ Refer to PREA Compliance Manager (PCM) as appropriate.

DIAGNOSTIC CRITERIA[1] For definitions see page 3.

Introduction: The term "transgender" is generally used to describe a diverse group of individuals whose gender identity differs from their sex assigned at birth.[2] Gender dysphoria refers to discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth.[3] **Not all transgender individuals will have GD.[4] DSM-5 GD diagnostic criteria include**:

A. A marked incongruence between one's experienced/expressed gender and assigned (natal) gender of at least six months duration as manifested by at least two of the following:
   - A marked incongruence between one's experienced/expressed gender and primary (1°) and/or secondary (2°) sex characteristics.
   - A strong desire to be rid of one's 1° and/or 2° sex characteristics b/c of a marked incongruence w/one's experienced/expressed gender.
   - A strong desire for the 1° and/or 2° sex characteristics of the other gender.
   - A strong desire to be of the other gender (or some alternative gender different from one's designated gender).
   - A strong desire to be treated as the other gender (or some alternative gender different from one's designated gender).
   - A strong conviction one has typical feelings/reactions of the other gender (or alternative gender different from one's designated gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

EVALUATION

MENTAL HEALTH

- Assess self-identified transgender patients for GD (Pg. 4); enter the GD diagnosis on the Problem List.
- Assess for MH disorders.
- If the patient desires GAHT refer to the primary care provider (PCP), if evaluation not previously completed.
- Encourage the patient to join a transgender support group, if available.

MEDICAL

- Perform history - focus on past medical history and history of GD hormones/surgery, include review of MH assessment (Pg. 4-5).
- Physical exam when indicated (Pg. 5).
- Order baseline labs to include human immunodeficiency virus (HIV), hepatitis C virus (HCV), hepatitis B virus (HBV), and sexually transmitted infections (STIs) screening (Pg. 6).
- Assess and manage acute and chronic care conditions.
- Ensure the World Professional Association for Transgender Health (WPATH) criteria are met to be eligible for GAHT (Pg. 6).

TREATMENT

PRE-HORMONE THERAPY (for patients who request hormones)

- Discuss realistic goals and expectations of GAHT (Transwoman Pg. 7, Transman Pg. 15).
- Review baseline labs (Transwoman Pg. 7, Transman Pg. 15).
- Evaluate for contraindications to GAHT (Transwoman Pg.8,Transman Pg. 16).
- Inform the patient of the risks/benefits of GAHT (Transwoman Pg. 8, Transman Pg.16) and obtain informed consent using a CDCR 7528 (Transwoman) or CDCR 7528-1 (Transman).

SOCIAL/ENVIRONMENTAL/HOUSING

- As indicated, refer patient to submit a CDCR Form 22 to the PCM and/or a Correctional Counselor for housing and/or gender appropriate allowable clothing and personal property (Transwoman Pg. 9, Transman Pg. 16).

HORMONE MEDICATIONS

- **Transwoman**: Estrogen/Androgen blockers (Feminizing) (Pg.9).
- **Transman**: Testosterone (Masculinizing) (Pg. 17).

GENDER AFFIRMING SURGERY (GAS)

- Upon patient request, submit RFS(s) (Pg. 21)

MONITORING

MENTAL HEALTH

- Assess as clinically indicated for MH conditions.

MEDICAL

- Monitor labs as indicated (Transwoman Pg.12, Transman Pg. 18).
- Ask patients about hormone effects, sexual activity, mental health, lifestyle, psychosocial issues, etc. (Transwoman Pg.12, Transman Pg. 19).
- Ensure routine preventive screening as needed for the patient's anatomy (Transwoman Pg.13, Transman Pg. 19).
- Treatment for patients with special circumstances (Transwoman Pg.14, Transman Pg. 20).
- Refer to specialist as clinically indicated (Transwoman Pg.14,Transman Pg. 20).

Information contained in the Care Guide is not a substitute for a health care professional's clinical judgment. Evaluation and treatment should be tailored to the individual patient and the clinical circumstances. Furthermore, using this information will not guarantee a specific outcome for each patient. Refer to "Disclaimer Regarding Care Guides" for further clarification. https://cchcs.ca.gov/clinical-resources/

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Initial Presentation of Patient – Pg. 4

- If the patient newly identifies and wishes to pursue GAHT or the patient arrives on GAHT already prescribed, refer to MH for a GD assessment.
- If the patient arrives at CDCR on GAHT, obtain baseline labs as soon as possible.
- Continue GAHT consistent with CCHCS/DHCS Care Guide.

Initial Evaluation for Hormone Therapy

1 | Pg. 4

MH Assessment

- Assess for GD
- Assess for MH disorders
- Refer the patient to the PCP if the patient has GD and wishes to be on GAHT
- Encourage the patient to join a transgender support group, if available

2A | Pg. 4

Medical Provider History

- Perform History - Focus on past medical history, history of GAHT/surgery, family history, etc.
- Review MH Assessment - GD diagnosis

2B | Pg. 5

Medical Provider Physical Exam

- Unless an immediate medical need, sensitive elements of the exam (breast, pelvic, and rectal) can be delayed until provider-patient rapport has developed
- Perform a focused physical examination if indicated

3 | Pg. 6

Baseline Labs

- Order labs and screen for HIV, HCV, HBV, and STIs
- Identify and manage any acute and chronic care conditions present

4 | Pg. 6

Eligibility For GAHT

- Ensure the patient is eligible for GAHT using WPATH criteria

Treatment and Monitoring

5 | Transwoman Pg. 7 | **5 | Transman Pg. 15**

Goals & Expectations

- Review the realistic goals of GAHT
- Help the patient understand that effects of GAHT are variable

6 | Transwoman Pg. 7 | **6 | Transman Pg. 15**

Labs

- Review labs to determine any current or previous health problems that may pose a risk to GAHT

7 | Transwoman Pg. 8 | **7 | Transman Pg. 16**

Contraindications & Risks

- If any contraindications are present, consult with a Transgender Care Provider (CCHCS or eConsult)
- Review potential GAHT risks with patients and provide educational handout

8 | Transwoman Pg. 9 | **8 | Transman Pg. 16**

Consent

- Obtain consent for GAHT using CDCR 7528 (Feminizing) or CDCR 7528-1 (Masculinizing)

9 | Transwoman Pg. 9 | **9 | Transman Pg. 16**

Social/Environmental

- Offer referral to a MH clinician as needed for support
- Referral to the PCM for housing requests and transgender access card; refer to a Correctional Counselor for personal property items

10 | Transwoman Pg. 9 | **10 | Transman Pg. 17**

Order Medications

- Review recommended approaches and titration of hormones
- Use appropriate Transgender PowerPlans

11 | Transwoman Pg. 12 | **11 | Transman Pg. 18**

Monitoring and Follow-Up

- Monitor labs to follow hormone levels as indicated
- Monitor for progress toward patient's individualized gender expression goals

12 | Transwoman Pg. 13 | **12 | Transman Pg. 19**

Preventive Screening

- Conduct preventive screenings, as clinically indicated for age and anatomy present

Reference Below When Indicated

Transwoman Pg. 14 | **Transman Pg. 20**

Special Circumstances

See recommendations for patients with special circumstances

Transwoman Pg. 14 | **Transman Pg. 20**

Refer to Specialist

Refer patient to a Transgender Care Provider, as clinically indicated

Pg. 21

Referral for GAS

Refer GAS requests to Headquarters for review

Criteria for Hair Removal Procedures

Assess criteria in InterOual

DEFINITIONS	
Sex	**WPATH:** Sex is assigned at birth as male or female, usually based on the appearance of the external genitalia. When the external genitalia are ambiguous, other components of sex (internal genitalia, chromosomal and hormonal sex) are considered in order to assign sex. For most people, gender identity and expression are consistent with their sex assigned at birth; for transsexual, transgender, and gender-nonconforming individuals, gender identity or expression differ from their sex assigned at birth.[3]
Gender Identity Male, Female, Non-Binary	**WPATH:** A person's intrinsic sense of being male (a boy or a man), female (a girl or woman), or non-binary gender.[3] **CDCR Department Operations Manual (DOM):** Distinct from sexual orientation and refers to a person's internal, deeply felt sense of being male or female, or neither.
Gender Expression or Role	**WPATH:** Characteristics in personality, appearance, and behavior that in a given culture and historical period are designated as masculine or feminine (that is, more typical of the male or female social role). While most individuals present socially in clearly male or female gender roles, some people present in a non-binary gender expression. All people tend to incorporate both masculine and feminine characteristics in their gender expression in varying ways and to varying degrees.[3] **CDCR DOM:** A person's expression of [their] gender identity, including appearance, dress, mannerisms, speech, and social interactions.
Gender Non-Conforming	**Not all gender non-conforming people identify as transgender and not all transgender people are gender non-conforming. "**Many people have gender expressions that are not entirely conventional – that fact alone does not make them transgender.**"**[5] **WPATH:** Adjective to describe individuals whose gender identity, role, or expression differs from what is normative for their assigned sex in a given culture and historical period.[3] **CDCR DOM:** Gender characteristics and/or behaviors that do not conform to those typically associated with a person's biological sex.
Transgender (adj.)	**WPATH:** Adjective to describe a diverse group of individuals who cross or transcend culturally-defined categories of gender. The gender identity of transgender people differ to varying degrees from the sex they were assigned at birth.[3] **Health Care Department Operations Manual (HCDOM):** Describing or relating to a person whose gender identity is different from the person's sex assigned at birth.
Transgender man/ transman	A person whose sex assigned at birth was female, but knows oneself to be male.
Transgender woman/ transwoman	A person whose sex assigned at birth was male, but knows oneself to be female.
Transition	**WPATH:** Period of time when individuals change from the gender role associated with their sex assigned at birth to a different gender role. For many people, this involves learning how to live socially in another gender role; for others this means finding a gender role and expression that are most comfortable for them. Transition may or may not include feminization or masculinization of the body through hormones or other medical procedures. The nature and duration of transition are variable and individualized.[3] **Avoid the phrase "sex change"**.
Gender Dysphoria	**WPATH:** Distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or 1° and 2° sex characteristics).[3]
OTHER TERMS YOU MAY SEE	
Cisgender	**Merriam-Webster Dictionary**: Of, relating to, or being a person whose gender identity corresponds with the sex the person had or was identified as having at birth.[6] The prefix "Cis-" is Latin meaning "on the same side as."
Non-binary	**Merriam-Webster Dictionary:** Relating to or being a person who identifies with or expresses a gender identity that is neither entirely male nor entirely female. [6]
Genderqueer	**Merriam-Webster Dictionary:** Of, relating to, or being a person whose gender identity cannot be categorized as solely male or female. [6]
Gender fluid	**Merriam-Webster Dictionary:** Of, relating to, or being a person whose gender identity is not fixed. [6]
Intersex	**CDCR DOM:** An individual born with external genitalia, internal reproductive organs, chromosome patterns, and/or endocrine systems that do not seem to fit typical definitions of male or female. Hermaphrodite is an **outdated** term.

INITIAL PRESENTATION OF PATIENT

Many transgender people may avoid seeking or continuing care due to prior discrimination or disrespect in a clinic setting.[7] As such, it is essential to provide a welcoming clinic environment to ensure CCHCS transgender patients are comfortable seeking care when issues arise and also when returning for scheduled follow-up visits. Often, transgender patients will first present to medical for treatment of GD by requesting hormone therapy.

- PCPs should refer to transgender patients by the name and pronoun that the patient indicates is correct for them (Transwoman: She, her, hers; Transman: He, him, his, etc.; Non-binary gender identity: they, them, theirs, etc.). If unsure, ask the patient, "What pronoun is correct for you?"[5,7]
- Not all individuals identifying as transgender have GD. That said, many clinicians report that most transgender individuals experience some degree of dysphoria in the absence of treatment. Without treatment, this population may experience higher rates of depression, anxiety, and suicidality.[4]
- If a patient newly self-identifies as transgender, an initial referral to MH is done to evaluate for GD, then a referral to the PCP for evaluation for hormone therapy, if desired. The patient's PCP can typically complete the evaluation and order labs and is able to start and manage first line hormone therapy.
- If the patient needs evaluation for increased risk factors or nonresponsiveness to initial GAHT, the patient can be referred to the transgender care central team provider or a contracted specialist via telemedicine.
- For questions please email m_MSDTransgenderSupport@cdcr.ca.gov

STEP 1: MENTAL HEALTH ASSESSMENT[8,9]

The patient should receive a MH assessment for GD before considering starting gender affirming treatment. Typically the following areas are covered:

HISTORY - The MH clinician does a thorough assessment for GD based on current DSM-5 criteria, including evaluating for the presence of co-occurring MH disorders (bio/psych/social assessment).

⇒ Patient's history of MH diagnoses and current stability
⇒ Evaluate for the presence and severity of MH symptoms and/or diagnoses (i.e., gender related delusions, body dysmorphia with fixation on primary and/or secondary sex characteristics) that may confound or complicate GD
⇒ Gender development history, including any steps taken towards achieving gender goals

DIAGNOSIS

⇒ **DSM-5 Gender Dysphoria** diagnostic criteria include[1]:

- A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months in duration, as manifested by at least 2 of the following:
  - ♦ A marked incongruence between one's experienced/expressed gender and 1° and/or 2° sex characteristics
  - ♦ A strong desire to be rid of one's 1° and/or 2° sex characteristics because of a marked incongruence with one's experienced/expressed gender
  - ♦ A strong desire for the 1° and/or 2° sex characteristics of the other gender
  - ♦ A strong desire to be the other gender (or some alternative gender different from one's designated gender)
  - ♦ A strong desire to be treated as other gender (or some alternative gender different from assigned gender)
  - ♦ A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)
- The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

- Following the MH assessment, if the patient is found to have GD and wishes to pursue therapy options, refer the patient to the PCP for evaluation.
- Encourage the patient to join a transgender support group, if available.

STEP 2A: MEDICAL PROVIDER - HISTORY[10]

Below are some targeted history elements that should be obtained for patients seeking GAHT. Transgender patients frequently have challenging experiences attempting to obtain health care and may be understandably hesitant during interactions. It is required by CDCR/CCHCS policy and California state law that staff address patients with their correct name and/or pronouns.

Many patients have experienced trauma in their lives and utilizing the five guiding principles of trauma informed care (safety, choice, collaboration, trustworthiness, and empowerment) can help the patient feel safer in the health care setting and result in a better patient-provider interaction.

History is focused on determining the safety of prescribing or continuing GAHT.

HISTORY– The PCP rules out conditions that preclude hormone therapy. A full history should be taken and specifically include:

- ♦ **Detailed past medical history (PMH),** assessing for coronary artery disease or cerebrovascular disease, arterial or venous thromboembolism (VTE)/pulmonary embolism, liver disease, hypertension, diabetes (DM), breast or uterine cancer, erythrocytosis, pituitary adenomas, HIV testing, and STIs.
- ♦ **Gender-related hormonal and surgical interventions**
  - ⇒ Past hormone use or body modifications:
    - Medically supervised or unsupervised
    - Injectable silicone

INITIAL PRESENTATION OF PATIENT (CONT)

⇒ Current status. Enter all GD-related surgeries in "Procedures" - Electronic Health Record System (EHRS), if not already noted.
⇒ Plans to pursue GAHT or GAS

- **Reproductive/Sexual History**
  - ⇒ Patients who produce sperm/eggs who have sexual intercourse with patients who have ovaries/testicles should be counseled on pregnancy prevention
  - ⇒ Sexual history should include sexual function as GAHT can affect the ability to maintain a functional erection and the ability to achieve orgasm
  - ⇒ Inquire about unprotected consensual or nonconsensual anal receptive intercourse and refer to HIV team as indicated for PrEP treatment
  - ⇒ Offer ongoing opportunities for STI screening
  - ⇒ Inquire about history of biological children and counsel patients regarding GAHT effects on future fertility
- **Social History**
  - ⇒ Substance abuse (nicotine is a risk factor for deep vein thrombosis (DVT)/pulmonary embolism, particularly with exogenous estradiol)
    - Refer to the Integrated Substance Use Disorder Treatment (ISUDT) program for ongoing substance abuse
  - ⇒ Refer to MH for patient identified stressors such as:
    - Social isolation, rejection by family or community of origin
    - Harassment or discrimination; ensure the patient works with custody if there are any safety concerns
  - ⇒ Refer to transgender/LGBTQ+ support group as available
- **Family History**
  - ⇒ Any cancer, cardiovascular disease (CVD), DM, blood clotting disorders, or liver disease
  - ⇒ Known or suspected genetic mutations for cancer should be investigated with regard to the anatomy that is present (e.g., breast, ovarian, testicular)
- **CDCR 7385, Authorization for Release of Protected Health Information (ROI)**
  - ⇒ Ensure continuity of care from the community by obtaining applicable health records, when appropriate.

REVIEW MH EVALUATION

- See MH Evaluation on Page 4.
- **Diagnosis of GD:** Confirm the patient has a diagnosis of GD (if requesting GAHT).

Note: Enter GD diagnosis in the Consolidated Problems section of the EHRS PCP Workflow, if not already done. See page 6 for diagnosis.

INITIAL EVALUATION FOR GAHT

STEP 2B: MEDICAL PROVIDER - PHYSICAL EXAM

PHYSICAL EXAM – Regardless of the gender identity of the patient, exams should be based on the external and internal anatomy present and the patient's presenting symptoms.

- Unless there is an immediate medical need, sensitive elements of the exam (particularly breast, pelvic, and rectal exams) can be delayed until the provider-patient rapport has developed.
- A complete exam is not required for the initiation of GAHT, but screening for health problems and a plan for a future examination/evaluation should be discussed. The exam should always follow a patient-centered approach, keeping in mind that some patients may have extreme discomfort with their bodies and find some elements of an exam traumatic.
- Patients who have undergone GAS should have exams focused to the anatomy present and be evaluated for any potential post-surgical complications.
- In addition to a routine exam, please note the following:

⇒ **Transwoman Special Considerations: Genitourinary:**

- Tucking of testicles and penis - May lead to hernias/other complications at the external inguinal ring or skin breakdown at the perineum. A thorough history and education is recommended for all transwomen.
- Vaginal exams in post-surgical transwomen[7] - The anatomy of a neovagina created in a transwoman differs from a natal vagina in that it is a blind cuff, lacks a cervix or surrounding fornices, and may have a more posterior orientation. As such, using an anoscope may be a more anatomically appropriate approach for a visual examination. The anoscope can be inserted, the trocar removed, and the vaginal walls visualized collapsing around the end of the anoscope as it is withdrawn.

⇒ **Transman Special Considerations: Genitourinary:**

- Conducting a pelvic examination with transmen[7]
  - The pelvic exam can be a traumatic and anxiety inducing procedure for transmen and other trans-masculine persons. Transmen patients are less likely to be up to date on cervical cancer screenings and have a higher rate of inadequate cytologic sampling.
  - Should the patient express distress or concern about the examination, it may be deferred until a later date once a trusting relationship has been developed.
  - Various techniques can be used to make a pelvic examination (including bimanual and/or speculum exam) less uncomfortable such as:
    - Discuss procedures with the patient beforehand including the order in which steps will occur and reminding the patient that

INITIAL EVALUATION FOR GAHT (CONT)

the exam can be stopped at any time at their request.
- If the patient experiences pain during examination, an estradiol vaginal cream can be prescribed for 2 to 3 weeks prior to the examination and discontinued after the examination.

♦ When appropriate and indicated, findings suggestive of intersex conditions (e.g., ambiguous genitalia) should be evaluated by an endocrinologist. Transwoman Page 14, Transman Page 20

STEP 3: ORDER BASELINE LABS

Laboratory tests should evaluate for existing health problems such as liver dysfunction, high cholesterol, or DM. As indicated, these conditions should be managed while considering a patient for GAHT. The values will also provide a useful baseline to help with future monitoring for endocrine changes.

- Screen for HIV. After initial screening of all patients, a repeat screening is based on HIV risk assessment. **Effective risk assessment requires the ability to obtain an accurate sexual history that includes anatomy-specific sexual behavior.**[11]
- Screen for HBV, gonorrhea, chlamydia, and syphilis.
- Screen for the HCV risk factors and do antibody screen per current guidelines.
- Asymptomatic STI screening intervals should be based on risk, and offer screening every three months as indicated for high risk behavior.

Baseline Labs In Addition To Above

All Patients

- CBC
- Serum creatinine and potassium
- Liver function tests (LFTs)
- A1C (if diabetic)
- Fasting glucose (if family history of DM)
- Fasting lipid panel
- Total testosterone level
- Estradiol level

Transwoman Only

- Thyroid Stimulating Hormone (TSH)
- Prolactin level

STEP 4: ELIGIBILITY FOR GAHT[3,4]

Although the decision to implement treatment with hormones for a transgender person is individualized, there are common guidelines. These guidelines are designed to maximize the safety of the patient, fulfill the legal and ethical requirements of the PCP, and reduce the possibility of inappropriate treatment.

WPATH Criteria: Identifies four eligibility criteria for GAHT but also emphasizes the need for individualized treatment plans that may include GAHT in selected cases that do not meet all four criteria. The WPATH criteria are as follows:

1. Gender Dysphoria that is persistent and documented
2. Medical and/or mental health conditions, if present, are reasonably well-controlled
3. Legal age of majority (18 years in California)
4. Informed consent

The presence of coexisting MH concerns does not necessarily preclude access to feminizing/masculinizing hormones; rather, these concerns need to be managed prior to, or concurrent with, treatment of GD.

Ensure the absence of absolute contraindications to GAHT. Transwoman Page 8, Transman Page 16

Diagnoses In EHRS

The primary diagnosis is "Transgender", with the addition of GD when appropriate, and when patient is on GAHT. The following diagnoses can be found in EHRS, however, please refrain from using the first five listed as they are not currently accepted or appropriate terminology.

Term	Code
Endocrine disorder in female-to-male transgender person	61491908
Endocrine disorder in male-to-female transgender person	61491873
Female-to-male transgender person	61491874
Hormonal imbalance in transgender patient	1525569
Male-to-female transgender person	61491875
Transgender	10067958
Transgender with history of sex reassignment surgery	68837711
Transgender, S/P sex reassignment surgery	68837718
Transgender, status post sex reassignment surgery	68837739

Note: In the following pages, the steps for the treatment and monitoring of transgender patients are divided into two sections: Transwoman (Pages 7-14) and Transman (Pages 15-20).

TREATMENT AND MONITORING

STEP 5: GOALS AND EXPECTATIONS OF GAHT

Transwoman: A person whose sex assigned at birth was male, and knows oneself to be female.

The PCP should cover the following topics when discussing GAHT with patients.

- **What are the goals of GAHT?**

  Patients need to have realistic goals of what may be accomplished with GAHT. Some patients have the mistaken belief that changes will occur quickly and have unrealistic expectations of what changes will occur. When disappointed with the timing or degree of changes, some patients want to increase the dose of their GAHT beyond what is considered to be a safe dose range.
- **What is the expected timing of the response?**

  Help the patient understand that changes are individual and will take place over months to years, with most changes being realized by 3 years of treatment.

  Increasing GAHT beyond recommended guidelines is not indicated, will not result in accelerated changes, and may cause harm.

Expected Effects of Feminizing Hormones (Estrogen and Androgen Blockers)

General effects include:

- Suppress endogenous hormone production
- Induce secondary sex characteristics of desired gender expression
  - Breast development (usually to Tanner stage 2 or 3)
  - Redistribution of facial and body subcutaneous fat
  - Reduction of muscle mass
  - Reduction of body hair (and to a lesser extent, facial hair)
  - Change in sweat and odor patterns
  - Arrest and possible reversal of scalp hair loss
  - Changes in emotional and social functioning
- Feminizing hormones do not affect the pitch of the voice

Sexual and gonadal effects include:

- Reduction in erectile function
- Changes in libido
- Reduced or absent sperm count and ejaculatory fluid
- Reduced testicular size
- Although GAHT will likely inhibit production of gametes, persons may retain reproductive potential

Time Needed To See Feminizing Effects Of Medication (Estrogen & Androgen Blockers)[12]

Effect	Onset	Maximum
Redistribution of body fat	3-6 months	2-3 years
Decrease in muscle mass and strength	3-6 months	1-2 years
Softening of skin/decreased oiliness	3-6 months	Unknown
Decreased sexual desire	1-3 months	3-6 months
Decrease spontaneous erections	1-3 months	3-6 months
Breast growth	3-6 months	2-3 years
Decreased testicular volume	3-6 months	2-3 years
Decreased sperm production	Unknown	>3 years
Decreased terminal hair growth	6-12 months	>3 years
Scalp hair	Variable	-----
Voice changes	None	-----

STEP 6: REVIEW BASELINE LABS[13]

Obtain the following baseline labs to determine the patient's current health and identify any health problems that may pose immediate or future risk to estrogen therapy.

CBC	• Estrogens inhibit erythropoiesis; hemoglobin and hematocrit (H&H) may drop after initiating estrogen therapy.
Serum Creatinine and Potassium	• For patients using spironolactone, serum potassium and renal function should be monitored for development of hyperkalemia.
Liver Function Tests (LFTs)	• Estrogen use may be associated with transient liver enzyme elevations and rarely clinical hepatotoxicity. • Seek consultation if increase LFTs ≥ 3x baseline. • Estrogen use increases the risk of cholelithiasis and subsequent cholecystectomy.
A1C (If diabetic) **Fasting Glucose** (If family history of DM)	• The effect of hormone therapy on DM risk/disease course is unclear. • A study of the effects of gender affirming hormones on insulin resistance found that transwomen may experience some increase in markers of insulin resistance. • WPATH Standards of Care recommend that conditions such as DM be "reasonably well controlled" prior to initiating hormone therapy.

TRANSWOMAN

TREATMENT AND MONITORING (CONT)	
Fasting Lipid Panel (Based on USPTF Guidelines)	• Oral estrogen use may markedly increase triglycerides in patients, increasing the risk of pancreatitis and cardiovascular events. • Different routes of administration will have different metabolic effects on levels of HDL cholesterol and LDL cholesterol.
Thyroid Stimulating Hormone	• Estrogen is known to increase serum thyroid-binding globulin concentration which may cause reduction in free thyroxine available for hormone activity. This will lead to an increase in serum TSH.
Testosterone Level (Total)	• Androgen suppression goals are typically to keep testosterone <50 ng/dL, however this may vary based on individualized gender expression goals.
Estradiol Level	• Goal estradiol levels are 100-200 pg/mL, with consideration for gender expression goals. However, estradiol levels should not exceed 250 pg/mL.
Prolactin Level	• Estrogen therapy can increase the growth of pituitary lactotroph cells. • If increased, consult with an endocrinologist or the transgender care central team provider. • If persistently elevated or symptomatic, consider possible pituitary adenoma; obtain a pituitary MRI. • **Note:** Psychotropic meds can frequently increase prolactin.

STEP 7: CONTRAINDICATIONS AND POTENTIAL RISKS OF GAHT[13]

Absolute contraindications:

- Psychiatric conditions which limit the ability to provide informed consent
- Current estrogen sensitive cancer

The following patients are at a very high risk of adverse effects:
Consider referral to the transgender care central team provider or a contracted provider (typically an endocrinologist) via telemedicine.

- Unstable ischemic CVD
- Estrogen-dependent cancer
- End stage chronic liver disease
- Hypersensitivity to one of the components of the hormone formulation
- History of thromboembolic disease
- History of or current hormone-sensitive cancer, such as prostate cancer

The following patients are at a moderate to high risk of adverse effects:
Proceed with caution considering risks versus benefits and utilizing shared decision-making.

- History of prolactinoma
- History of breast cancer (non-estrogen dependent)
- Significant liver disease (transaminases increase > 3 X)
- History of cerebrovascular disease
- History of coronary artery disease
- History of severe migraine headaches

STEP 8: POTENTIAL ADVERSE EFFECTS[13] & INFORMED CONSENT

Estrogen has a more serious risk profile as compared to other medications used in transgender individuals. Although each hormone will have its own specific considerations and precautions, it is worthwhile to address general considerations and precautions with hormone use.

Estrogen should be used with **CAUTION**, after risks/benefits discussion with the patient, if:

- Excess weight
- Nicotine use
- Migraines or seizures
- High cholesterol
- High blood pressure (BP)
- Has a strong family history of breast cancer or other estrogen sensitive cancers
- Heart disease, heart valve problems, or tendency to have blood clots, kidney or liver disease

If any of the above conditions are present consider referral to the transgender care central team provider or a contracted provider (typically an endocrinologist) via telemedicine.

Estrogen can:

- Increase risk of blood clots that can cause heart attacks, strokes, lung/leg blood clots
- Increase fat around internal organs which can increase risk for DM and heart disease
- Increase BP
- Increase risk of getting gallstones or cause nausea and vomiting
- Cause damage to liver
- Cause headaches or migraines
- Increase the risk of prolactinomas
- Cause temporary or permanent loss of fertility

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TREATMENT AND MONITORING (CONT)

PCPs should use the **CDCR 7528, Feminizing Hormone Therapy Consent** form and ensure the patient understands the risks associated with use of estradiol and androgen blockers and all questions are answered.
Hormone therapy is expected to be life changing and may result in some irreversible effects. The process of sharing in the decision-making involves developing a partnership, exchanging information about the available options, deliberating while considering the potential consequences of each one, and making a decision by consensus. The informed consent for hormone therapy is a decision aid that includes the before mentioned information to help patients make a well-informed decision that reflects their values and goals with their PCP.

STEP 9: POSSIBLE SOCIAL/ENVIRONMENTAL CHALLENGES

- During the course of treatment, a patient's housing may be reevaluated and the patient may be transferred to a different facility.
- A request from the patient via Gender Identity Questionnaire (GIQ), Form 22, note, etc., to be housed consistent with their gender identity, will be forwarded to the PCM.
- Advise the patient to work with a Correctional Counselor to obtain gender appropriate accommodations per the CDCR DOM.
- Offer referral to a MH clinician if patient reports social or other challenges due to their gender expression.

In designated male institutions, transwomen are typically allowed personal items, which may vary with custody level and security status or may vary somewhat between institutions.

Please reference the Transgender Inmates Authorized Personal Property Schedule (TIAPPS) for the current property schedule.
https://www.cdcr.ca.gov/wp-content/uploads/sites/171/2019/06/transgender-inmates-authorized-personal-property-schedule.pdf

STEP 10: MEDICATIONS[13]

Prescriber: Prescribing gender affirming hormones is within the scope of practice of PCPs including medical doctors, nurse practitioners, and physician assistants. Most medications used in GAHT are already familiar due to their use in the management of menopause, hirsutism, prostatism, or abnormal uterine bleeding. There have been no evidence based studies to support the use of progesterone in feminizing hormone regimens.

Estrogen

- The primary class of estrogen used for feminizing therapy is 17-beta estradiol (estradiol), which is a "bioidentical" hormone in that it is chemically identical to that from a human ovary.
- The general approach is similar to estrogen replacement in agonadal (i.e., Turner syndrome) or menopausal states, with some dosing modifications.
- Estradiol is most commonly delivered to transwomen via a transdermal patch, oral or sublingual tablet, or injection of a conjugated ester (estradiol valerate or estradiol cypionate). **In CCHCS, oral estradiol is the preferred agent.**

Androgen Blockers – Common Approaches

- Suppression of testosterone production and blocking of its effects contributes to the suppression/minimization of male secondary sexual characteristics. Many of these characteristics are permanent upon completion of natal puberty and are irreversible.
- Androgen blockers allow the use of lower estradiol dosing.
- Spironolactone is the most commonly used androgen blocker in the United States (U.S.). Spironolactone is a potassium sparing diuretic, which has direct anti-androgen receptor activity as well as a suppressive effect on testosterone synthesis.
- Finasteride blocks 5-alpha reductase type 2/3 mediated conversion of testosterone to potent androgen dihydrotestosterone.
    - Finasteride 1 mg daily is FDA-approved for male pattern baldness, while the 5 mg dose is approved for management of prostatic hypertrophy.
    - Since these medications block neither the production nor action of testosterone, their antiandrogen effect is less than that encountered with full blockade.
    - 5-alpha reductase inhibitors may be a good choice for those unable to tolerate, or with contraindications to the use of spironolactone.

Titration

- Titration upwards of dose should be driven by patient goals, clinical response, hormone level monitoring, and safety precautions (See dosing tables on the following pages).
- A general approach for titration would include increasing of both estradiol and antiandrogen dosing until the estradiol level is in the female physiologic range.
    - Once this has been achieved, titration efforts can focus on increasing androgen blockade.
    - Starting dose of estradiol can be maintained for 1-2 months after which a dose increase can be considered upon review of labs and consistent with patient goals.
    - Physical changes related to androgen blockade and estradiol may take months to appear and are generally considered to be complete after 2-3 years on hormone therapy. Patients should be well-educated on expected timeframes for physical changes.
        - Weak evidence suggests that initiation of estradiol therapy at lower doses and titrating up over time may result in enhanced breast development in transwomen.
        - The estrogen receptor agonist activity of spironolactone may play a role in reduced breast development due to premature breast bud fusion.

As such, an escalating regimen beginning with low dose estradiol only, titrating up over several months, and then adding spironolactone may be an alternative approach. Upward titration of spironolactone can also help minimize side effects such as orthostasis or polyuria. It is recommended that PCPs discuss these considerations with patients before initiation of hormones in order to make an informed decision.

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TREATMENT AND MONITORING (CONT)

- To order medication(s), use the Transgender Feminizing Therapy PowerPlan.
- In order to achieve adequate suppression of androgens, estradiol alone would need to be administered in higher doses, with associated increased risks. Thus, the combination of an androgen blocker and estradiol is the preferred approach.
- Note that oral estradiol is preferred.
- For patients over 50 years old who have been on estradiol for several years, doses may be reduced to those administered to post-menopausal cisgender women. For transwomen starting GAHT over 50 years old, treatment with suggested doses used for younger transwomen may be considered following a thorough assessment and discussion of relative risks and benefits. See Page 14 - Special Circumstances.

Medication Class	Medication*	Effects/Adverse Effects/Drug Interactions*	Comments*
Estrogen			
Oral Estradiol (Estrace®) **Tablet:** **0.5 mg, 1 mg, 2 mg** **$-$$**	**Dose:** 2-6 mg orally daily **Initial Dose:** 2-4 mg orally daily **Max Dose:** 4 mg twice daily (8 mg total)	Estrogens are partially metabolized by CYP3A4 and interactions may occur with agents that inhibit or induce CYP3A4. • Estrogens may reduce levels/effects of: *warfarin, hypoglycemic agents, fosamprenavir, levothyroxine* • Estrogen levels/effects may be ↑ by: *Erythromycin, clarithromycin, azole antifungals, calcium channel blockers (verapamil, diltiazem), Isoniazid, vitamin C, fluoxetine, fluvoxamine, paroxetine, nefazodone, sertraline, some HIV medications (efavirenz, indinavir, saquinavir, atazanavir, cimetidine)* • Estrogen levels/effects may be ↓ by: *Anticonvulsants (carbamazepine, oxcarbazepine, phenytoin, phenobarbital, topiramate), rifampin, rifapentine, etravirine, dexamethasone, some HIV medications (lopinavir/ritonavir, ritonavir, tipranavir, darunavir, nelfinavir, nevirapine)* **Adverse Effects**: Abdominal pain, back pain, headache, n/v, diarrhea, fluid retention, pruritus, skin irritation, weight gain, breast pain/ tenderness, URI, DVT, VTE, pulmonary embolism, rash, urticaria.	➢ Oral estradiol is preferred in CCHCS • Consider adding aspirin 81 mg for patients at high risk for VTE who do not have contraindications to ASA therapy, especially if cigarette smoker, obese, > 40 years old, cardiac risk factors • Consider stopping, reducing estrogen dose or changing to transdermal estradiol two weeks prior to major surgery/immobilizing event, resume regular dose when normal mobility restored • Response to therapy is highly variable • Test hormone level midway between injections • Titrate estrogen dose to result in a physiologic range for young healthy females, not to exceed 250 pg/mL • **Contraindications**: Hepatic disease, hepatocellular cancer, history of angioedema, protein C deficiency, protein S deficiency, active or past history of MI, stroke, thromboembolism, thromboembolic disease, thrombophlebitis, hypersensitivity to estradiol or any component of the product • **Caution in the following**: asthma, cardiac disease, renal disease, obesity, coronary artery disease, cerebrovascular disease, migraine, hypertension, seizure disorder, hyperlipidemia **Black Box Warning for Estradiol**: Estrogens increase the risk of endometrial cancer; monitor for abnormal vaginal bleeding. Estrogens with or without progestins should not be used for the prevention of CVD. Increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, deep vein thrombosis in postmenopausal women (50 to 79 years of age) have been reported. An increased risk of developing probable dementia in postmenopausal women 65 years of age or older has also been reported.
Parenteral **Estradiol valerate** (Delestrogen®) **10 mg/mL** **$$$$-$$$$$**	**Estradiol valerate** **Initial Dose:** 5 mg weekly OR 10 mg every 2 weeks **Max Dose:** 8 mg IM weekly OR 15 mg IM every 2 weeks		
Depo-Estradiol® (estradiol cypionate) 5 mg/mL in oil for injection $$$$$	Estradiol cypionate **Initial Dose**: 3 mg IM weekly OR 10 mg IM every 2 weeks **Max Dose:** 5 mg IM weekly OR 12 mg every 2 weeks		
Transdermal Estradiol Weekly Patch: (Climara®) 0.025 mg/24h, 0.0375 mg/24h, 0.05 mg/24h, 0.06 mg/24h, 0.075 mg/24h, 0.1 mg/24h Biweekly Patch: (Alora®, Vivelle dot®, Minivelle®) 0.025 mg/24h, 0.0375 mg/24h, 0.05 mg/24h, 0.075 mg/24h, 0.1 mg/24h $$$$$	**Initial Dose:** 0.1 mg/24h **Initial Dose (low):** 0.05 mg/24h **Maximum Dose:** 0.4 mg/24h Replace patch/patches once or twice weekly. Frequency of patch replacement is brand/ product dependent.		

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Bold = CCHCS Formulary

*See prescribing information for complete description of contraindications/precautions, adverse effects and drug interactions. The cost scale $-$$$$$ represents the relative cost of acquisition of medication only. Frequency and complexity of medication administration (institution workload, effect on adherence) should be considered when determining overall cost-effectiveness of treatment.

TREATMENT AND MONITORING (CONT)

TRANSWOMAN

Medication Class	Medication*	Effects/Adverse Effects/Drug Interactions*	Comments*
Androgen Blockers			
Spironolactone (Aldactone®) **Tablet:** **25 mg, 50 mg, 100 mg** **$$-$$$**	**Dose**: 100-200 mg orally twice daily **Initial Dose:** 50 mg orally twice daily **Standard Dose:** 100 mg orally twice daily **Renal impairment:** CrCl ≥ 10 mL/min: No dosage adjustment needed. Monitor renal function closely as hyperkalemia is more likely to occur in patients with renal impairment. CrCl < 10 mL/min: Avoid use **Heart failure patients:** CrCl 30-49 mL/min: Clinical practice guidelines recommended 12.5 mg orally once daily or every other day for the first 4 weeks followed by 12.5 to 25 mg orally once daily. CrCl < 30 mL/min: Avoid use. **Hepatic impairment**: Per mfg. labeling initiate in the hospital	**Adverse reactions**: gynecomastia, breast pain, diarrhea, fever, nausea, vomiting, GI bleeding, gastritis, gastric ulcer, somnolence, hyperkalemia- may be severe, hyponatremia, hyperuricemia, electrolyte imbalance, metabolic acidosis, gout, lethargy, muscle cramps, headache, abdominal cramps, confusion, dizziness, rash, blood dyscrasias/ agranulocytosis, gastritis, hypersensitivity reactions, anaphylaxis, vasculitis, renal failure, hepatotoxicity, Stevens-Johnson syndrome, SLE, severe dermatologic conditions, dehydration **Drug interactions**: concomitant triamterene, eplerenone and/or amiloride(contraindicated), ACEIs, ARBs, heparin, lithium, NSAIDs, corticosteroids, digoxin, trimethoprim, MAOIs, amikacin, lofexidine, warfarin, chlofarabine	**Black Box Warning**: Shown to be a tumorigen in chronic toxicity animal studies. Avoid unnecessary use **Contraindications**: Acute renal insufficiency and/or potassium > 5.5 mEq/ dl, anuria, Addison's disease, concomitant eplerenone, amiloride, and/or triamterene use, hypersensitivity to spironolactone or any component of the product • Avoid use in patients who are receiving digoxin, ACE inhibitors, potassium sparing diuretics **Use caution**: in patients with cirrhosis, heart failure, renal impairment, adrenal vein catheterization, volume depletion, diabetes, hepatic impairment, gout
Finasteride (Proscar®/ Propecia®) **Tablet:** **5 mg,** 1 mg **$$-$$$**	**Dose:** 1-5 mg orally daily **Initial Dose:** 1 mg orally daily **Max Dose:** 5 mg orally daily **Hepatic Dosing:** Initiate with caution. **Renal Dosing:** Specific guidelines for dosage adjustments are not available. Appears no dosage adjustments are needed.	**Adverse reactions**: gynecomastia, breast pain, neoplasm of male breast, prostate cancer (high- grade), hypotension, orthostatic hypotension, peripheral edema, pruritus, urticaria, rash, constipation, diarrhea, asthenia, dizziness, headache, testicular pain, somnolence, depression **Drug interactions**: Terazosin, Saw palmetto, St. John's wort	**Contraindications**: Hypersensitivity to finasteride or any component of the product **Use caution**: With hepatic impairment, increased risk of high-grade prostate cancer has been reported, serum PSA levels may be decreased, monitoring recommended

Bold = CCHCS Formulary

*See prescribing information for complete description of contraindications/precautions, adverse effects and drug interactions. The cost scale $-$$$$$ represents the relative cost of acquisition of medication only. Frequency and complexity of medication administration (institution workload, effect on adherence) should be considered when determining overall cost-effectiveness of treatment.

TREATMENT AND MONITORING (CONT)

STEP 11: MONITORING AND FOLLOW-UP[13]

Monitoring: Prior to starting GAHT, obtain a baseline estradiol, testosterone, prolactin, and CMP. Standard monitoring of estradiol administration should be done every 3 months for the first year and then twice a year once hormone levels have reached target range. Follow-up visits should include an assessment of the patient's tolerance to medication, progress towards gender expression goals, targeted PE, bloodwork, and health promotion/disease prevention counselling as indicated. The suggested tasks for each of these follow-up visits are summarized and expanded upon below.

- While laboratory monitoring of hormone levels may seem complex, it is of similar difficulty to the monitoring of other complex lab-monitored conditions managed by PCPs, such as thyroid disorders, anticoagulation, or DM.
- Once hormone levels have reached the target range for a specific patient, it is reasonable to monitor levels twice yearly.

Physiologic hormone levels in cisgender people are used as reference ranges.

- Patients should be counseled that specific secondary sex characteristics and specific phenotypical end points (i.e., breast development) are likely multifactorial and particularly dependent on genetics and the age at which GAHT is begun. Supratherapeutic estradiol levels will not lead to more significant development of secondary sex characteristics.

Target Hormone Levels
Serum Estradiol: Should not exceed the peak physiologic range 250 pg/mL (exogenous)
Serum Testosterone: Should be < 50 ng/dL if patient desires full androgen suppression (endogenous)
Prolactin: Should be monitored at least yearly, and more frequently if elevation is noted

	3 MONTHS*	6 MONTHS*	9 MONTHS*	12 MONTHS*	TWICE A YEAR
Assess At Each Visit†	• BP • Weight, Waist and Abdominal Circumference • Hormone Effects		• Mental Health • Social/Environmental • Education/Lifestyle		
BLOODWORK					
BUN/Creatinine/Potassium‡	✓	✓	✓	✓	✓
HbA1C§ or glucoseǁ					✓
Lipids					✓
Testosterone	✓	✓	✓	✓	✓
Estradiol	✓	✓	✓	✓	✓
Prolactin		✓	✓		✓

*In first year of therapy only
† See Page 16 for details
‡ Only if on spironolactone
§ Only if diabetic
ǁ Only if family history DM

Blood Pressure	Estrogen may increase BP, but the effect on incidence of overt hypertension is unknown. Estrogen increases the risk of cardiovascular events in patients over age 50 with underlying cardiovascular risk factors. Spironolactone reduces BP and is recommended for at-risk or hypertensive patients desiring feminization.
Weight, Waist and Abdominal Circumference	Estrogen causes the body to redistribute fat. Fat will begin to collect around the hips and thighs. The muscles in arms and legs will become less defined and have a smoother appearance as the fat just below skin becomes thicker. Estrogen does not have a significant effect on abdominal fat.
Hormone Effects	Although the goal of therapy is to reduce the hormonally induced male secondary sex characteristics, complete elimination is not possible. The initial changes (over the first three to six months) include a possible decrease in sexual desire along with decreased rates of growth of facial and body hair. There will also be some initial growth of breast tissue, a decrease in oiliness of the skin, and early redistribution of fat mass. Monitor the following hormone effects: ✓ **Hair** – Adult male beard growth is very resistant to inhibition by combined hormonal intervention. ✓ **Breast development** – Breast formation starts almost immediately after initiation of estradiol administration and decreased androgen levels; it is typically maximal at two to three years. Some transwomen may report nipple tenderness and discomfort during the period of breast growth.

TRANSWOMAN

TREATMENT AND MONITORING (CONT)	
	✓ **Skin** – Androgen suppression leads to a decrease activity of the sebaceous glands and may result in dry skin. ✓ **Body composition** – Following androgen suppression, there is an increase in subcutaneous fat and a decrease in lean body mass. Body weight usually increases. ✓ **Testes** – Atrophy of the testes occurs over many years. Lacking gonadotropic stimulation, the testes become atrophic and may occasionally enter the inguinal canal, which may cause discomfort. ✓ **Prostate** – Atrophy of the prostate also occurs over many years. ✓ **Voice** – Antiandrogens and estrogens have no effect on the properties of the voice. ✓ **Sexual function** – Feminizing hormone therapy may reduce sexual desire, reduce erectile function, and decrease ejaculation among transwomen. Some transwomen choose to reduce hormone doses to balance the degree of feminization with the level of sexual function, while others may not, depending on their gender expression goals.
Mental Health	• Screen and refer to MH for any new or worsening mental health conditions.
Dental	• Patient on oral hormone therapy should maintain proper oral hygiene and attend regular scheduled dental visits.
Social/Environmental	• Assess housing, relationships, and safety concerns. • Social Supports – Assess the extent of a patient's social supports and suggest or refer additional resources as needed.
Education/Lifestyle/ Counselling	• Educate patient on hormone adherence: missed doses of estradiol impacts bone health if post-orchiectomy, while extra doses may lead to risks associated with supraphysiologic levels of estradiol. • Educate patient on the signs and symptoms of DVT and pulmonary embolism and advise immediate medical attention should these occur. • Adherence with screening recommendations (See below). • Continue current lifestyle modifications to reduce cardiovascular risk, including but not limited to, no nicotine use, avoidance of illicit drugs, maintaining optimal nutrition, and physical activity. • Review risks of taking nonprescribed medications, particularly GAHT.
STEP 12: PREVENTIVE SCREENING[13]	
General Approach to Screening	The appropriate screening of transgender patients should generally follow the recommendations for anatomy present and as age appropriate for all genders.
Breast Cancer	• It is recommended that screening commence in transwomen when they are age ≥50 AND have been on GAHT for a minimum of 5 years. • Once screening commences, continue as per current U.S. Preventive Services Task Force (USPSTF) recommendations. • Breast Cancer: Discuss screening in patients with additional risk factors
Prostate Cancer	• PCPs should remain aware of the possibility of prostate cancer for people who still have a prostate. • Transwomen who have undergone vaginoplasty may have a prostate anterior to the vaginal wall. • It should be noted that when prostate specific antigen testing is performed in patients on 5-alpha reductase inhibitors, it may be appropriate to reduce the upper limit of normal.
Testicular Cancer	• There is no evidence to perform routine testicular screening. • Transwomen adherent to therapeutic doses of estrogen plus an androgen blocker, and with persistent testosterone elevations, should be evaluated for testicular tumors by physical exam, as well as human chorionic gonadotropin (hCG), alpha-fetoprotein (AFP) and lactic dehydrogenase (LDH) levels, and possibly a scrotal ultrasound.
Cardiovascular Disease	• Estrogen use increases the risk of cardiovascular events in patients over age 50 with underlying cardiovascular risk factors. • The risk of DM type II is possibly increased, particularly with the presence of additional risk factors. • While there is minimal impact on LDL and HDL, there is likely a significantly increased risk of hypertriglyceridemia with oral estrogen, so if hypertriglyceridemia is an issue do not use oral estrogen. • It is recommended to manage vascular risk factors prior to and during estrogen administration. • Spironolactone should be used preferentially for androgen blockade in clients whose BP is of concern. • Individuals at high risk for CVD should be offered aspirin as primary prevention.
Osteoporosis	• Transgender people (regardless of birth assigned sex) should begin bone density screening at age 65. • Screening between ages 50 and 64 should be considered for those with established risk factors for osteoporosis. • Transgender people (regardless of birth assigned sex) who have undergone gonadectomy and have a history of at least 5 years without GAHT should also be considered for bone density testing, regardless of age.

TRANSWOMAN

TREATMENT AND MONITORING (CONT)	
STEP 13: SPECIAL CIRCUMSTANCES[13]	
Transwomen ≥ 50 years old	• Older transwomen initiating therapy may have less rapid/degree of changes. • Initiation and/or continuation of GAHT should be based on patient specific goals. • Transwomen who retain their gonads and discontinue GAHT may experience return of virilization., Individualized and shared decision-making is critical.
Pituitary Adenoma	• Increase in prolactin levels are associated with estradiol therapy. • High-dose estrogen use may promote the clinical appearance of preexisting but clinically unapparent prolactinoma.[3] • It should be noted that psychotropic medications may increase serum prolactin, in particular, antipsychotic medications. • With the administration of physiologic doses of estradiol, there is no clear basis for an increased risk of prolactinomas in comparison to the population background rate in cisgender women. • Additionally, Endocrine Society guidelines for the management of incidental prolactinomas are expectant management only, in the absence of suggestive visual or other symptoms (headache/galactorrhea). • It is noted that some transwomen experience a minimal amount of galactorrhea early in their hormone therapy course. The presence of non-bloody minimal galactorrhea from more than one duct and/or bilateral is typically physiologic and would not warrant further evaluation.
Chronic HCV and Hormone Therapy	• Chronic HCV is not a contraindication to hormone therapy. • Both estrogen and testosterone undergo hepatic metabolism, and routine monitoring of hepatic function is recommended. • Non-oral forms of hormone therapy avoid first pass through liver metabolism and may be preferred for patients with liver disease, though there is no specific evidence to support this recommendation.
Perioperative Use of Feminizing Hormones	• Many surgeons insist that patients discontinue GAHT for several weeks before and after any gender affirming procedure. These recommendations may appear as benign to the surgeon; however, to patients undergoing a life and body altering procedure simultaneous with gonadectomy, sudden and prolonged complete withdrawal of estrogens can have a profound impact. • Postoperative depression is a nontrivial concern and may have some basis in the drastic hormone shifts, including cessation of GAHT, experienced in the perioperative period. • There is no evidence to suggest that transwomen who lack specific risk factors (e.g. nicotine use, personal history of coagulopathy) need to cease estrogen therapy before and after surgical procedures. • Possible alternatives include using a lower dose of estradiol, and/or changing to a transdermal route if not already in use.
Venous Thromboembolism	• Several studies have demonstrated an increased risk of VTE in transgender individuals receiving GAHT, particularly estradiol. • Risk factors for VTE include immobilization after surgery, nicotine use, or a hypercoagulable disorder. • In the absence of risk factors, routine VTE prophylaxis with aspirin transgender populations is not recommended. • Routine screening for prothrombotic mutations is not recommended in the absence of risk factors. • It is known that estradiol therapy has increased risk for patients with risk factors for or a personal history of VTE who use nicotine. Regardless of the circumstances, estrogen therapy is very risky in patients with significant risk factors for, or history of, VTE who continue to smoke tobacco. • The incidence of thrombophilias appears to be the same in the transgender population as the general population. Therefore, routine pretreatment screening for thrombophilias is not suggested. • When thrombophilias are detected, it has been suggested that treatment with anticoagulants be administered if estrogen therapy is to be continued. • Consider referral to a specialist if thrombophilia is present.

STEP 14: WHEN TO REFER TO A SPECIALIST

PCPs can care for their transgender patients. Consider referring patients to a transgender care provider (either the transgender care central team provider or specialty contracted provider) using the "Request for Transgender" request for services via telemedicine in the following cases:

1. Patients that are at high risk for adverse effects from GAHT:
   - Unstable ischemic CVD/cerebrovascular disease
   - End stage chronic liver disease
   - Hypersensitivity to one of the components of GAHT
   - Have a history of thromboembolic disease
   - Had or have a hormone-sensitive cancer
2. PCPs are unclear about patient's GAHT goals
3. Patients do not achieve expected clinical response with GAHT

TRANSWOMAN

TREATMENT AND MONITORING (CONT)

STEP 5: GOALS AND EXPECTATIONS OF GAHT

Transman: A person whose sex assigned at birth was female and knows oneself to be male.

The PCP should cover the following topics when discussing GAHT with patients.

- **What are the goals of GAHT?**
  Patients need to have realistic goals of what may be accomplished with GAHT. Some patients have the mistaken belief that changes will occur quickly and have unrealistic expectations of what changes will occur. When disappointed with the timing or degree of changes, some patients want to increase the dose of their GAHT beyond what is considered to be a safe dose range.
- **What is the expected timing of the response?**
  Help the patient understand that changes are individual and will take place over months to years, with most changes being realized by 3 years of treatment. Increasing GAHT beyond recommended guidelines is not indicated, will not result in accelerated changes, and may cause harm.

Expected Effects of Masculinizing Hormones (Testosterone)

General effects include:	Sexual and gonadal effects include:

• Suppress endogenous hormone production
• Induce secondary masculinizing characteristics
  • Development of facial hair
  • Potential deepening of voice
  • Redistribution of facial and body subcutaneous fat
  • Increased muscle mass
  • Increased body hair
  • Change in sweat and odor patterns
  • Frontal and temporal hairline recession
  • Potential male pattern baldness
	• Increase in libido
	• Clitoral growth
	• Vaginal canal dryness
	• Cessation of menses/ovulation (anovulatory state)
	  • Although GAHT will likely inhibit production of gametes, persons may retain reproductive potential
	  • Testosterone use can impact long term fertility, although some men can achieve a pregnancy after stopping GAHT

Time Needed To See Masculinizing Effects Of Medication (Testosterone)[12]

Effect	Onset	Maximum
Skin oiliness/acne	1-6 months	1-2 years
Facial/body hair growth	6-12 months	4-5 years
Scalp hair loss	6-12 months	-----
Increased muscle mass/strength	6-12 months	2-5 years
Fat redistribution	1-6 months	2-5 years
Cessation of menses	1-6 months	-----
Clitoral enlargement	1-6 months	1-2 years
Vaginal atrophy	1-6 months	1-2 years
Deepening of voice	6-12 months	1-2 years

STEP 6: REVIEW BASELINE LABS[13]

Obtain the following baseline labs to determine the patient's current health and identify any health problems that may pose immediate or future risk to testosterone therapy.

CBC	• An expected potential side effect of testosterone treatment is polycythemia. • As high hematocrit levels may increase risk for cardiovascular events, stroke, and VTE, regular monitoring of hematocrit during testosterone therapy is important. • If hematocrit greater than 50 mg/dl, consider referral to the transgender care central team provider or contracted specialist.
Liver Function Tests (LFTs)	• Testosterone is metabolized by the liver. • Transient elevations in liver enzymes may occur with testosterone therapy.
A1C (If diabetic) **Fasting Glucose** (If family history of DM)	• Testosterone can increase risk of diabetes. • WPATH Standards of Care recommends that conditions such as DM be "reasonably well controlled" prior to initiating GAHT.
Fasting Lipid Panel (Based on USPTF Guidelines)	• Testosterone may increase triglycerides in patients, increasing the risk of pancreatitis and cardiovascular events (typically treat if triglycerides > 500) • Testosterone may also lower HDL.
Testosterone Level (Total)	• The goal total testosterone level for transmen is 400-700 ng/dL.
Estradiol Level	• Serum estradiol is checked at baseline and then twice a year. • It is not necessary to check estradiol levels more than twice a year, unless patient has persistent genital bleeding after six months of testosterone therapy.

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TREATMENT AND MONITORING (CONT)

STEP 7: CONTRAINDICATIONS AND POTENTIAL RISKS OF GAHT[13]

Absolute contraindications:

- Pregnancy
- Psychiatric conditions which limit the ability to provide informed consent
- Current androgen sensitive cancer

The following patients are at a very high risk of adverse effects:
Consider referral to the transgender care central team provider or a contracted provider (typically an endocrinologist) via telemedicine.

- Androgen-sensitive cancer
- Unstable ischemic CVD
- Hypersensitivity to one of the components of the formulation
- Polycythemia/Erythrocytosis (Hct > 50%)
- History of breast or uterine/endometrial cancer

The following patients are at a moderate to high risk of adverse effects:
Proceed with caution considering risks versus benefits and utilizing shared decision-making.

- Significant liver disease (transaminases > 3 upper limit of normal)
- History of coronary artery disease or history of cerebrovascular disease

STEP 8: POTENTIAL ADVERSE EFFECTS[13] & INFORMED CONSENT

The medical effects and safety of testosterone are not completely known and there may be long-term risks that are not yet established. As with most medical interventions, a number of health risks have been postulated to be related to testosterone therapy. Several pre-existing medical conditions and risk factors may increase the risks associated with testosterone administration. When these are present, a careful evaluation of risks and benefits should be completed and fully discussed with the patient.

Testosterone can:

- Increase risk of heart disease, which includes:
  - Less good cholesterol (HDL)
  - More bad cholesterol (LDL)
  - Higher BP
  - Increased deposits of fat around internal organs
- Increase risk of liver disease and increased LFTs
- Increase risk of DM
- Expected increases in red blood cells, hemoglobin, and hematocrit to levels consistent with other men; monitor for higher increases that may increase risk for stroke and heart attack
- Especially at supratherapeutic levels, may metabolize to estradiol
- Cause atrophy of cervix and vaginal mucosa can lead to increased risk of STIs
- Increase migraines incidence

PCPs should use the **CDCR 7528-1, Masculinizing Hormone Therapy Consent** form and ensure the patient understands the risks associated with use of estradiol and androgen blockers and all questions are answered.

Hormone therapy is expected to be life changing and may result in some irreversible effects. The process of sharing in the decision-making involves developing a partnership, exchanging information about the available options, deliberating while considering the potential consequences of each one, and making a decision by consensus. The informed consent for hormone therapy is a decision aid that includes the before mentioned information to help patients make a well-informed decision that reflects their values and goals with their PCP.

STEP 9: POSSIBLE SOCIAL/ENVIRONMENTAL CHALLENGES

- During the course of treatment, a patient's housing may be reevaluated and the patient may be transferred to a different facility.
- A request from the patient via GIQ, Form 22, note, etc., to be housed consistent with their gender identity, will be forwarded to the PCM.
- Advise the patient to work with a Correctional Counselor to obtain gender appropriate accommodations per the CDCR DOM.
- Offer referral to a MH clinician if patient reports social or other challenges due to their gender expression.

Transmen are typically allowed personal items, which may vary with custody level and security status or may vary somewhat between institutions.

Please reference the Transgender Inmates Authorized Personal Property Schedule (TIAPPS) for the current property schedule.
https://www.cdcr.ca.gov/wp-content/uploads/sites/171/2019/06/transgender-inmates-authorized-personal-property-schedule.pdf

TREATMENT AND MONITORING (CONT)

STEP 10: MEDICATIONS[13]

Prescriber: Prescribing gender affirming hormones is within the scope of practice of PCPs including medical doctors, nurse practitioners, and physician assistants. The testosterone used in GAHT is already familiar due to its use in treating low testosterone levels in older sex at birth males.

Testosterone

- All testosterone preparations currently used in the U.S. are "bioidentical" meaning they are chemically equivalent to the testosterone secreted from the human testicle.
- Prior use of oral methyltestosterone and other synthetics commonly encountered in bodybuilding communities has resulted in unsubstantiated concerns about negative hepatic effects of testosterone use in transmen.
- Testosterone is available in a number of injected and topical preparations, which have been designed for use in men with low androgen levels. **In CCHCS, parenteral (IM) administration of testosterone cypionate is preferred.**

Titration

- Titration upwards of dose should be driven by patient goals, clinical response, hormone level monitoring, and safety precautions (i.e., H&H).
- Clinical response can be measured objectively by the presence of amenorrhea by 6 months.
- Once total testosterone is greater than the midpoint value in the lab reported reference range, it is unclear if an increase in dose will have any further positive effect on degree of masculinization.
  - Titrate dose upwards based on testosterone levels measured at 3 and 6 months.
  - Once hormone levels have reached the target range for a specific patient, it is reasonable to monitor levels twice yearly (See page with lab monitoring table).

Ordering Medication

- To order medication use the Transgender Masculinizing Therapy PowerPlan.
- Route of injection (intramuscular vs. subcutaneous): While testosterone for injection is labeled for the intramuscular route, many PCPs and patients administer testosterone using the subcutaneous route with good efficacy and patient satisfaction, and without complications. Benefits of subcutaneous administration include a smaller and less painful needle, and may avoid scarring or fibrosis from long term (possibly > 50 years) intramuscular therapy.

Medication Class	Medication*	Effects/Adverse Effects/Drug Interactions*
Testosterone		
Parenteral **Testosterone cypionate in oil for injection** (Depo-Testosterone®) **100 mg/mL;** **200 mg/mL** **$-$$**	**Initial Dose:** 50 mg IM weekly **Standard Dose:** 50-100 mg IM weekly **Hepatic Dosing**: Severe dysfunction: Contraindicated Mild to Moderate dysfunction: Initiate with caution **Renal Dosing**: Specific guidelines for dosage adjustments are not available. Appears no dosage adjustments are needed.	**Adverse reactions**: Injection site reaction, acne, alopecia, dyslipidemia, increased glucose levels, headache, hypertension, edema, DVT, pulmonary embolism, erythrocytosis, cerebrovascular accident (CVA), cholestatic hepatitis, n/v, neoplasm of liver, increased LFTs, MI, unstable angina, paresthesia **Drug interactions**: warfarin, paclitaxel, bupropion, insulin, cyclosporine, corticosteroids, blood glucose lowering agents, edoxaban, carvedilol, dabigatran, dapagliflozin, dronedarone, posaconazole, rivaroxaban, ritonavir, rifaximin
		Comments*
Testosterone enanthate in oil for injection (Delatestryl®) 200 mg/mL $-$$	**Initial Dose:** 50 mg IM weekly **Standard Dose:** 50-100 mg IM weekly **Hepatic Dosing**: Severe dysfunction: Contraindicated Mild to Moderate dysfunction: Initiate with caution. **Renal Dosing**: Specific guidelines for dosage adjustments are not available. Appears no dosage adjustments are needed.	**Parenteral (IM) administration is preferred in CCHCS** • 15% of patients on testosterone will experience transient elevations in liver enzymes (if increase > 3X stop and seek expert consultation, e.g., endocrinologist) • Do not use cypionate and enanthate interchangeably due to differences in duration of action • Test total testosterone midway between injections for every 2 week dosing, and on day 3 post injection for weekly dosing • Titrate the testosterone dose to result in a serum testosterone level between 400-700 ng/dl • Contraindications: Hypersensitivity to testosterone or any component of the product, pregnancy, cypionate—serious cardiac, hepatic or renal disease, enanthate—sesame oil hypersensitivity (potential cross-sensitivity with nut allergy) • Use caution in the following: cardiac disease, coronary artery disease (CAD), hepatic disease, renal disease, hypertension

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		Testosterone Enanthate Black Box Warning: Testosterone enanthate can cause blood pressure increases that can increase the risk of major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non- fatal stroke and cardiovascular death. Before initiating testosterone enanthate, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled. Periodically monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension and reevaluate whether the benefits of testosterone enanthate outweigh its risks in patients who develop cardiovascular risk factors or CVD on treatment. Due to this risk, use testosterone enanthate only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.

Bold = CCHCS Formulary
*See prescribing information for complete description of contraindications/precautions, adverse effects and drug interactions. The cost scale $-$$$$$ represents the relative cost of acquisition of medication only. Frequency and complexity of medication administration (institution workload, effect on adherence) should be considered when determining overall cost-effectiveness of treatment.

STEP 11: MONITORING AND FOLLOW-UP[13]

Monitoring: Standard monitoring of testosterone administration should be done at baseline, 3 months, 6 months, 9 months, 12 months, and then twice a year once hormone levels have reached target range. This should include an assessment of the patient's adjustment to therapy, targeted physical exam, bloodwork, and health promotion/disease prevention counseling as indicated. The suggested tasks for each of these follow-up visits are summarized and expanded upon below.

- While laboratory monitoring of hormone levels may seem complex, it is of similar difficulty to the monitoring of other complex lab-monitored conditions managed by PCPs, such as thyroid disorders, anticoagulation, or DM.
- Once hormone levels have reached the target range for a specific patient, it is reasonable to monitor levels twice yearly.

Physiologic hormone levels in cisgender people are used as reference ranges.
- For transgender care, the Endocrine Society recommends monitoring of the total testosterone level.
- Free testosterone represents the portion of testosterone unbound to serum proteins and depends on levels of Sex Hormone Binding Globulin (SHBG).
- Consensus is lacking on the role of free vs. total testosterone levels; total testosterone levels are reliable and readily available, however they do not describe the actual bioavailable testosterone level.

Target Hormone Levels
- **Total Testosterone:** Target level is 400-700 ng/dL (exogenous)
- **Estradiol:** Should be < 50 pg/mL (endogenous)

	3 MONTHS*	6 MONTHS*	9 MONTHS*	12 MONTHS*	TWICE A YEAR
Assess At Each Visit†	• BP • Weight, Waist and Abdominal Circumference • Hormone Effects		• Mental Health • Social/Environmental • Education/Lifestyle		
BLOODWORK					
Lipids					✓
HbA1C‡ or glucose§					✓
Hemoglobin & Hematocrit	✓	✓	✓	✓	✓
Total Testosterone	✓	✓	✓	✓	✓
Estradiol					✓

*In first year of therapy only
† See Page 26 for details
‡ Only if diabetic
§ Only if family history DM

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TREATMENT AND MONITORING (CONT)	
Blood Pressure	Testosterone therapy at normal physiologic doses may increase BP, but does not appear to increase the risk of significant hypertension. Patients with risk factors for hypertension, such as obesity, family history, or polycystic ovary syndrome (PCOS) may be at increased risk, and BP should be monitored while on testosterone therapy.
Weight, Waist and Abdominal Circumference	Testosterone therapy leads to a reduction in subcutaneous fat but increases in abdominal fat. The increase in lean body mass is on average 4 kg, and the increase in body weight may be greater.
Amenorrhea	Genital bleeding usually stops within a few months of starting testosterone, however, may occasionally continue. The recommended approach is to increase the testosterone dose modestly. Another approach is to add an oral progestin such as medroxyprogesterone acetate (MPA; 5 to 10 mg daily continuously) or treatment with a gonadotropin-releasing hormone (GnRH) agonist to stop the bleeding. (Patients requiring these additional therapies are typically referred for specialty consultation.
Hormone Effects	Testosterone causes male-pattern hair growth and an increase in lean body mass, muscle mass, and fat mass. It also causes growth in midline structures like the larynx and clitoris. Monitor the following hormone effects: ✓ **Hair** – The development of hair follows the pattern observed in pubertal boys: first the upper lip, then chin, then cheeks, etc. The degree of hair growth might be predicted from the pattern in male members of the same family. The same applies to the occurrence of androgenetic alopecia, male-pattern baldness. ✓ **Voice** – Deepening of the voice may occur due to oropharyngeal growth and may be irreversible. ✓ **Acne** – Acne is common, similar to that observed in hypogonadal men starting androgen treatment past the age of normal puberty. Acne will frequently need treatment to prevent cystic lesions and scarring. ✓ **Clitoral enlargement** – Clitoral enlargement is common in varying degrees. ✓ **Sexual desire** – Increased libido is common. ✓ **Breasts** – Androgen administration may cause a decrease in glandular tissue. Stature and hip configuration or width does not change with testosterone therapy.
Mental Health	• Screen and refer to MH for any new or worsening MH conditions.
Dental	• Patient on oral hormone therapy should maintain proper oral hygiene and attend regular scheduled dental visits.
Social/Environmental	• Assess housing, relationships, and safety concerns. • Social Supports – Assess the extent of a patient's social supports and suggest or refer additional resources as needed.
Education/Lifestyle/ Counselling	• Hormone adherence: missed doses of testosterone. • Adherence with screening recommendations (See below). • Continue current lifestyle modifications to reduce cardiovascular risk, including but not limited to, no nicotine use, avoidance of illicit drugs, maintaining optimal nutrition, and physical activity. • Review risks of taking nonprescribed medications.
STEP 12: PREVENTIVE SCREENING[13]	
General Approach to Screening	The appropriate screening of transgender patients should generally follow the recommendations for anatomy present and as age appropriate for all genders.
Breast Cancer	Transmen who have not undergone bilateral mastectomy, or who have only undergone breast reduction, should undergo screening according to current guidelines for cisgender women.
Cervical Cancer	Cervical cancer screening for transmen including interval of screening and age to begin and end screening follows recommendations for cisgender women. Transmen may need special accommodations for cervical cancer screening (such as a pediatric speculum).
Pelvic pain and persistent menses	• The general approach to the workup of pelvic pain in transmen is similar to that for cisgender women. An anatomic approach to history gathering that considers urological, gynecologic, gastrointestinal (GI), musculoskeletal, and psychological components is critical. Specific etiologies may be multifactorial, such as post-op adhesions +/- GI surgery, or endometriosis and/or pelvic floor muscle dysfunction. • Patients with risk factors for endometrial hyperplasia, or pre-existing amenorrhea or oligomenorrhea may require evaluation for endometrial abnormalities prior to or concurrent with testosterone therapy.
Osteoporosis	• Screen all patients > 65 years old • Screen patients age 50-65 years old if off hormones for > 5 years
Hyperlipidemia	On testosterone: Annual lipid screening for all patients and twice yearly for patients at increased risk of CVD.

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TREATMENT AND MONITORING (CONT)	
STEP 13: SPECIAL CIRCUMSTANCES[13]	
Older Transmen	• No upper age limit exists for testosterone replacement in cisgender men. As such, there is no age recommendation for the termination of testosterone therapy in transmen. • Discontinuation of testosterone therapy at any age should involve a thorough discussion with the patient and reviewing their goals for GAHT.
Erythrocytosis/ polycythemia	• H&H values in transmen should be interpreted in the context of the dose of testosterone used and menstruation status. • Transmen with physiologic male testosterone levels and who are amenorrheic would be expected to have H&H values in the cisgender male normal range. • Patients with persistent menses or on lower doses of testosterone should have their H&H interpreted accordingly. Transmen with true polycythemia should first have their testosterone levels checked, including a peak level, and have dose adjusted accordingly. • Changing to a more frequent injection schedule (maintaining the same total amount of testosterone over time) or transdermal preparations may limit the risk of polycythemia. • Phlebotomy or blood donation may be an appropriate short term solution depending on the level of elevation; in all cases other pathologic causes of polycythemia should be excluded. In addition to neoplasms and cardiopulmonary disease, specific conditions of concern in transmen include obesity-related obstructive sleep apnea (OSA), and tobacco use.
Chronic HCV and Hormone Therapy	• Chronic HCV is not a contraindication to hormone therapy. • Both estrogen and testosterone undergo hepatic metabolism, and routine monitoring of hepatic function is recommended. • Monitoring of liver function in patients with chronic HCV infection should proceed as routinely recommended by disease stage and risk factors for progression dictate. • Non-oral forms of hormone therapy avoid first pass through liver metabolism and may be preferred for patients with liver disease, though there is no specific evidence to support this recommendation.
Metabolic syndrome and related conditions (obesity, hyperlipidemia, impaired glucose tolerance, PCOS)	• Cardiovascular and DM considerations are covered elsewhere in these guidelines. • PCOS can manifest with any combination of impaired fasting glucose, dyslipidemias, hirsutism, obesity, and oligo- or amenorrhea with anovulation. • Some of these features (hirsutism, oligo- or amenorrhea) may be welcomed by transmen and present prior to testosterone administration. • Testosterone administration is not contraindicated in the presence of PCOS, but patients should be monitored for hyperlipidemia and DM. • Transmen with amenorrhea in the presence of testosterone are not believed to be at elevated risk of endometrial hyperplasia, due to the atrophic effects of testosterone on the endometrium. It may be prudent to pursue endometrial evaluation prior to initiation of testosterone in transmen with a current history amenorrhea/oligomenorrhea. • Testosterone replacement in cisgender men is associated with an increased risk of OSA. It is unknown whether OSA is increased in transmen after the initiation of testosterone. However, the behavioral health improvements seen with testosterone therapy may result in positive lifestyle changes that reduce obesity, disorders of glucose metabolism, or hyperlipidemia. • In all but the most severe cases (DM out of control, active unstable coronary artery disease), transmen should be informed of risks, and if testosterone therapy continues to be desired, it should be continued with concurrent conventional management of metabolic disorders and their sequelae.

STEP 14: WHEN TO REFER TO A SPECIALIST

PCPs can care for their transgender patients. Consider referring patients to a transgender care provider (either the transgender care central team provider or specialty contracted provider) using the "Request for Transgender" request for services via telemedicine in the following cases:

1. Patients that are at high risk for adverse effects from GAHT:
   - Unstable ischemic CVD/cerebrovascular disease
   - Androgen-sensitive cancer
   - Polycythemia / Erythrocytosis (Hct > 50%)
   - History of breast or uterine cancer
   - Significant liver disease (transaminases > 3 times upper limit of normal)
2. PCPs are unclear about patient's GAHT goals
3. Patients do not achieve expected clinical response with GAHT

CCHCS GENDER AFFIRMING SURGERY

- Everyone's gender journey is individual and may or may not involve surgery. Patient's goals may evolve with treatment and surgery can be considered as appropriate to reach those goals.
- Most individuals seeking gender affirming surgery have been previously treated with GAHT. GAHT is not a requirement to proceed with GAS.
- Each referral is considered on a case-by-case basis.
- Surgery is not required for legal changes in California (e.g., legal gender marker change, birth certificate, name change). Other states and countries may have different requirements.
- The patient should both initiate the request for GAS and demonstrate informed decision making capacity related to its permanence, potential complications, and alternative options.

CRITERIA FOR GENDER AFFIRMING SURGERY[3,8,10]

1. Persistent, well-documented Gender Dysphoria.
2. Legal age of majority (in California, 18 years old).
3. For hysterectomy, salpino-oopherectomy, and orchiectomy: 12 months of continuous gender affirming hormone therapy (unless there is a medical contraindication to such therapy, or the patient is otherwise unable or unwilling to take hormones).
4. For metoidioplasty, phalloplasty, vaginoplasty: Continuous full-time living in the new gender role for 12 months, insofar as reasonable in the prison setting.
5. If significant medical or mental health concerns are present, they should be well controlled.

All gender affirming related procedures should be referred to the GASRC for consideration. Examples of gender affirming procedures that are commonly requested are provided below and in the Patient Education handouts.

Transwoman	**Transman**
Vaginoplasty: Create a vagina	Mastectomy – Remove breasts
Clitoroplasty: Create a clitoris	Reduction mammoplasty – Make breasts smaller
Labioplasty: Construct labia	Vaginectomy – Remove vagina
Vulvoplasty: Construct vulva	Hysterectomy – Remove uterus
Orchiectomy: Remove testicles	Salpingo-oophorectomy - Remove ovaries
Penectomy: Remove penis	Metoidioplasty - Make a penis using genital tissue
Breast Augmentation: Make or enlarge breasts	Phalloplasty - Make a penis using other parts
Facial Surgery: Change face structures	Scrotoplasty – Make a scrotum
Tracheal Shave: Make Adam's Apple smaller	Urethroplasty – Reconstruct or replace urethra
	Placement of testicular prostheses
	Facial Surgery - Change face structures

Referral Process: See Referral for Consideration for Gender Affirming Surgery Guidelines

For questions please contact: CDCRCCHCSGASRC@cdcr.ca.gov

CRITERIA FOR HAIR REMOVAL PROCEDURES

For pre-procedural hair removal, submit referral after approval of relevant procedure and after initial GAS surgical consultation.
Pre-operative hair removal is included in the GASRC approval.
Pre-procedural/Pre-operative hair removal occurs over weeks to months in preparation for gender affirming surgery, typically vaginoplasty and phalloplasty.

For facial and body hair removal that is not pre-operative/pre-procedural, refer to InterQual criteria for institutional review and local approval.

Patients approved for permanent hair removal through InterQual may require transfer to a facility that offers on-site electrolysis. For a list of current institutions that offer on-site electrolysis, please see the Hair Reduction, Restoration, and Growth page of the IGAHP SharePoint site.

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PATIENT EDUCATION

HORMONE THERAPY: TRANSWOMAN

- Transitioning your gender is a life changing process.
- Taking gender affirming hormone therapy can be part of your transition. Your provider will talk to you about the benefits, risks, and alternatives to taking hormones.
- There are many things you can do to get the safest and best results for your body and mind such as:
  - Not smoking anything
  - Not taking illegal or nonprescribed drugs
  - Exercise regularly
  - Not drinking alcohol
  - Keep a healthy weight

WHAT YOU NEED TO KNOW ABOUT ESTROGEN THERAPY

➢ The feminizing effects of estrogen can take months to be noticed and years to be complete.

Time Needed To See Potential Effects of Estrogen & Androgen Blockers[12]

Effect	Starting	Maximum
Less stomach fat/More fat on butt, hips, thighs	3-6 months	2-3 years
Less muscle mass	3-6 months	1-2 years
Softer skin/Less oily skin	3-6 months	Unknown
Less sexual desire	1-3 months	3-6 months
Less spontaneous and desired erections	1-3 months	3-6 months
Less ability to orgasm	Variable	Variable
Breast growth	3-6 months	2-3 years
Smaller testicles	3-6 months	2-3 years
Make less sperm	Unknown	>3 years
Less hair growth on body and face	6-12 months	>3 years

➢ Some changes to your body will be permanent, even if you stop taking estradiol, including:
  - Breast development: You will need to do monthly breast self-examinations, and have an annual medical exam
  - Less sperm production: Even if you stop estradiol, the ability to make healthy sperm may be decreased

➢ Taking estradiol will not protect you from sexually transmitted infection

➢ Some dangerous side effects of taking estradiol can include:
  - Blood clots
  - Feeling depressed
  - Breast cancer
  - Stroke
  - Heart attacks
  - Liver disease

➢ Estradiol may raise your risk of heart disease, just like smoking cigarettes. If you choose to smoke, your doctor may not prescribe estradiol or may prescribe lower doses. It is important to reduce other risk factors for heart disease, like high cholesterol and being overweight.

➢ You can choose to stop taking estradiol at any time. Your doctor can also stop your treatment for medical reasons. If you stop taking estradiol, you should follow a plan to reduce the dose slowly to avoid harmful side effects.

WHAT YOU NEED TO DO

➢ Tell your doctor if you are taking any dietary supplements, herbs, drugs (legal or illegal), or prescription medications not prescribed for you.
➢ If you are in the mental health services delivery system, continue care with your mental health clinician. If you feel you need mental health services submit a CDCR 7362 or notify a staff member.
➢ You will be asked to sign an informed consent form before starting estradiol therapy.

If you have any questions, talk to your medical or mental health provider

PATIENT EDUCATION

Gender Affirming Surgery (Feminizing)

Patient Education

Gender Affirming Surgery is a surgical procedure or procedures that changes a person's physical appearance and/or their sex characteristics to align with their gender identity. There are several different types of gender affirming surgeries. Feminizing gender affirming surgeries make your body look more female

WHAT TO KNOW IF CONSIDERING SURGERY

- Surgery is not needed for legal changes in California (gender change, birth certificate, name change).
- Some changes from surgery are permanent and cannot be reversed.
- Smoking is not good for your body before and after surgery. Discuss any substance use, including nicotine or alcohol, with your doctor.
- Several surgeries and procedures may be needed.
- The entire process can take more than a year including hair removal procedures, surgery or surgeries, and recovery time.
- If you have surgery your doctor will give you instructions to follow. It is important you follow the instructions for your body to heal correctly.
- Your decisions about any surgery should be carefully based on information from your doctor and mental health providers.

WHO CANNOT HAVE SURGERY?

In general, surgery is not recommended for patients:

- Who have a serious medical or mental health condition not under control.
- Who smoke, use drugs and/or alcohol.
- Who have a history of not following medical or mental health interventions.
- Who cannot follow instructions before and after surgery.

WHO IS ELIGIBLE FOR SURGERY?

- Patients who are diagnosed with Gender Dysphoria.
- Patients of legal age (in California, 18 years old).

Patients should also:

- Be able to make their own medical decisions and agree to surgery.
- Be able to understand that some surgeries cannot be reversed and that bad side effects of the surgery (if they happen) can be permanent.
- Have a mental health evaluation to be sure they understand the surgery process and that they can follow up with surgery instructions.
- Have a medical check-up and lab tests to be sure there are no medical conditions that make surgery too dangerous to the patient.

LEARN THE TERMS

Gender Identity: A person's feeling of being male, female, non-binary, or none of these. **Gender Dysphoria**: Distress caused by a difference between a person's gender identity and their sex predicted/ assigned at birth. **Transgender**: A group of people whose gender identity differs from their sex predicted/assigned at birth.
Transman: A person with a masculine gender identity who was predicted/assigned a female sex at birth.
Transwoman: A person with a feminine gender identity who was predicted/assigned a male sex at birth.
Non-binary: A term used by some people who do not identify as either male or female.

PATIENT EDUCATION

Gender Affirming Surgery (Feminizing)

COMMON FEMINIZING SURGERIES INCLUDE:

- Vaginoplasty - Make a functioning vagina
- Vulvoplasty - Make all the parts of a vagina except canal (not a functional vagina)
- Orchiectomy - Remove testicles
- Penetcomy - Remove penis
- Clitoroplasty - Make a clitoris
- Labiaplasty - Make labia
- Breast Augmentation - Make or enlarge breasts
- Facial Surgery - Change face structures
- Trachal Shave - Make Adam's Apple smaller

The type of surgery or procedure performed will be decided between you and your surgeon, after review of your best and safest options.

HOW TO REQUEST GENDER AFFIRMING SURGERY

- Submit a CDCR 7362 Health Care Services Request Form or tell your doctor, mental health clinician, or nurse that you would like to be considered for surgery.
- Your doctor will submit your request for surgery and perform a physical exam.
- Once your request is submitted, you will be interviewed by your mental health clinician.
- Your information including your request for surgery, your doctor's report about your health, and your mental health interview will be sent to a committee of doctors and mental health clinicians.
- This committee, known as the Gender Affirming Surgery Review Committee, will consider many factors when making a decision (especially your health and safety) to either approve or not approve you for surgery.

WILL YOUR HOUSING LOCATION CHANGE?

In some cases, housing may be re-evaluated after gender affirming surgery. Housing changes are based on individual factors, and you may be asked for your input. Your own requests may also be considered.

WHAT ARE THE RISKS AND COMPLICATIONS OF SURGERY?

All surgeries carry risks. The surgeon will explain all potential risks and/or complications and answer any questions patients might have. Some possible risks and complications are listed below.

Possible Complications For Any Surgery Include (but not limited to):

- Bleeding
- Hematoma (blood collection)
- Seroma (fluid collection)
- Infection
- Poor wound healing
- Blood clots

Your surgeon will review complications and risks that relate to your surgery or procedure.

WHAT CAN YOU DO TO BE A GOOD CANDIDATE FOR SURGERY?

- Don't smoke or use drugs or alcohol.
- Go to your doctor/mental health appointments and follow their instructions.
- Consistently take your hormones and other medications (unless your doctor says you shouldn't).
- Be at a healthy weight.
- Have a good understanding of the risks and complications of surgery, the permanent changes from surgery, and the short and long-term treatments after surgery.

KNOW YOUR RESOURCES

1. To obtain clothing/personal property:
   - Submit a Form 22 requesting the item
2. To start hormone therapy or if you want to make changes to your current hormone treatment:
   - Submit a CDCR 7362 Health Care Services Request Form
3. A Transgender Support Group may be available in your prison. Ask your mental health provider.

FOR ANY QUESTIONS OR CONCERNS, TALK TO YOUR MEDICAL OR MENTAL HEALTH PROVIDER

PATIENT EDUCATION

HORMONE THERAPY: TRANSMAN

- Transitioning your gender is a life changing process.
- Taking gender affirming hormone therapy can be part of your transition. Your provider will talk to you about the benefits, risks, and alternatives to taking hormones.
- There are many things you can do to get the safest and best results for your body and mind such as:
  - Not smoking anything
  - Not taking illegal or nonprescribed drugs
  - Exercise regularly
  - Not drinking alcohol
  - Keep a health weight

WHAT YOU NEED TO KNOW ABOUT TESTOSTERONE THERAPY

- The masculinizing effects of testosterone can take months to be noticed and years to be complete.

Time Needed To See Potential Effects of Testosterone[12]

Effect	Starting	Maximum
Skin oiliness/acne	1-6 months	1-2 years
Facial/body hair growth	6-12 months	4-5 years
Scalp hair loss	6-12 months	-----
More muscle and strength	6-12 months	2-5 years
Less fat on butt, hips, thighs	1-6 months	2-5 years
No menstrual periods	1-6 months	-----
Bigger clitoris	1-6 months	1-2 years
Vaginal canal dryness	1-6 months	1-2 years
Deeper voice	6-12 months	1-2 years

- Some changes to your body will be permanent, even if you stop taking testosterone, including:
  - Scalp hair loss
  - Facial hair growth and more body hair
  - Deepening of your voice
- Testosterone will not protect you from sexually transmitted infections or from becoming pregnant
- If you take testosterone for a long time, you may not be able to get pregnant in the future, even if you stop taking testosterone
- Some dangerous side effects of taking testosterone can include:
  - Blood clots
  - Feeling depressed
  - High blood pressure
  - Breast and/or uterine cancer
  - Liver disease
  - Heart attacks
  - Stroke
- Testosterone may raise your risk of heart disease, just like smoking cigarettes. If you choose to smoke, your doctor may not prescribe testosterone or may prescribe lower doses. It is important to reduce other risk factors for heart disease, like high cholesterol and being overweight.
- You can choose to stop taking testosterone at any time. Your doctor can also stop your treatment for medical reasons. If you stop taking testosterone, you should follow a plan to reduce the dose slowly to avoid harmful side effects.

WHAT YOU NEED TO DO

- Tell your doctor if you are taking any dietary supplements, herbs, drugs (legal or illegal), or prescription medications not prescribed for you.
- If you are in the mental health services delivery system, continue care with your mental health clinician. If you feel you need mental health services submit a CDCR 7362 or notify a staff member.
- You will be asked to sign an informed consent form before starting testosterone therapy.

If you have any questions, talk to your medical or mental health provider

PATIENT EDUCATION

Gender Affirming Surgery (Masculinizing)

Patient Education

Gender Affirming Surgery is a surgical procedure or procedures that changes a person's physical appearance and/or their sex characteristics to align with their gender identity. There are several different types of gender affirming surgeries. Masculinizing gender affirming surgeries make your body look more male.

WHAT TO KNOW IF CONSIDERING SURGERY

- Surgery is not needed for legal changes in California (gender change, birth certificate, name change).
- Some changes from surgery are permanent and cannot be reversed.
- Smoking is not good for your body before and after surgery. Discuss any substance use, including nicotine or alcohol, with your doctor.
- Several surgeries and procedures may be needed.
- The entire process can take months to more than a year including surgery or surgeries, and recovery time.
- If you have surgery your doctor will give you instructions to follow. It is important you follow the instructions for your body to heal correctly.
- Your decisions about any surgery should be carefully based on information from your doctor and mental health providers.

WHO CANNOT HAVE SURGERY?

In general, surgery is not recommended for patients:

- Who have a serious medical or mental health condition not under control.
- Who smoke, use drugs and/or alcohol.
- Who have a history of not following medical or mental health interventions.
- Who cannot follow instructions before and after surgery.

WHO IS ELIGIBLE FOR SURGERY?

- Patients who are diagnosed with Gender Dysphoria.
- Patients of legal age (in California, 18 years old).

Patients should also:

- Be able to make their own medical decisions and agree to surgery.
- Be able to understand that some surgeries cannot be reversed and that bad side effects of the surgery (if they happen) can be permanent.
- Have a mental health evaluation to be sure they understand the surgery process and that they can follow up with surgery instructions.
- Have a medical check-up and lab tests to be sure there are no medical conditions that make surgery too dangerous to the patient.

LEARN THE TERMS

Gender Identity: A person's feeling of being male, female, non-binary, or none of these. **Gender Dysphoria**: Distress caused by a difference between a person's gender identity and their sex predicted/ assigned at birth. **Transgender**: A group of people whose gender identity differs from their sex predicted/assigned at birth.
Transman: A person with a masculine gender identity who was predicted/assigned a female sex at birth.
Transwoman: A person with a feminine gender identity who was predicted/assigned a male sex at birth.
Non-binary: A term used by some people who do not identify as either male or female.

PATIENT EDUCATION

Gender Affirming Surgery (Masculinizing)

COMMON MASCULINIZING SURGERIES INCLUDE:

- Mastectomy - Remove breasts
- Reduction mammoplasty - Make breasts smaller
- Vaginectomy - Remove vagina
- Hysterectomy - Remove uterus
- Salpingo-oophorectomy - Remove ovaries
- Metoidioplasty - Make a penis using genital tissue
- Phalloplasty - Make a penis using other parts
- Scrotoplasty - Make a scrotum
- Urethroplasty - Reconstruct or replace urethra
- Placement of testicular prostheses
- Facial Surgery - Change face structures

Removal of uterus and/or ovaries can lead to permanent infertility. Removal of ovaries can lead to early bone thinning and decreased bone strength, which can lead to bones breaking.

The type of surgery or procedure performed will be decided between you and your surgeon, after review of your best and safest options.

HOW TO REQUEST GENDER AFFIRMING SURGERY

- Submit a CDCR 7362 Health Care Services Request Form or tell your doctor, mental health clinician, or nurse that you would like to be considered for surgery.
- Your doctor will submit your request for surgery and perform a physical exam.
- Once your request is submitted, you will be interviewed by your mental health clinician.
- Your information including your request for surgery, your doctor's report about your health, and your mental health interview will be sent to a committee of doctors and mental health clinicians.
- This committee, known as the Gender Affirming Surgery Review Committee, will consider many factors when making a decision (especially your health and safety) to either approve or not approve you for surgery.

WILL YOUR HOUSING LOCATION CHANGE?

In some cases, housing may be re-evaluated after gender affirming surgery. Housing changes are based on individual factors, and you may be asked for your input. Your own requests may also be considered.

WHAT ARE THE RISKS AND COMPLICATIONS OF SURGERY?

All surgeries carry risks. The surgeon will explain all potential risks and/or complications, and answer any questions patients might have. Some possible risks and complications are listed below.

Possible Complications For Any Surgery Include (but not limited to):

- Bleeding
- Hematoma (blood collection)
- Seroma (fluid collection)
- Infection
- Poor wound healing
- Blood clots

Your surgeon will review complications and risks that relate to your surgery or procedure.

WHAT CAN YOU DO TO BE A GOOD CANDIDATE FOR SURGERY?

- Don't smoke or use drugs or alcohol.
- Go to your doctor/mental health appointments and follow their instructions.
- Consistently take your hormones and other medications (unless your doctor says you shouldn't).
- Be at a healthy weight.
- Have a good understanding of the risks and complications of surgery, the permanent changes from surgery, and the short and long-term treatments after surgery.

KNOW YOUR RESOURCES

1. To obtain clothing/personal property:
   - Submit a Form 22 requesting the item
2. To start hormone therapy or if you want to make changes to your current hormone treatment:
   - Submit a CDCR 7362 Health Care Services Request Form
3. A Transgender Support Group may be available in your prison. Ask your mental health provider.

PATIENT EDUCATION

TRANSGENDER HEALTH WHILE INCARCERATED FREQUENTLY ASKED QUESTIONS (FAQS)

WHAT DOES IT MEAN TO BE TRANSGENDER?

⇒ When you were born, your body appeared to be male, female, or intersex (a natural body variation that is not male or female).

⇒ If your gender identity (your personal sense of your gender) is different from your sex assigned at birth, you may identify as transgender.

Examples:

- You were assigned male at birth, and you identify as female (transwoman) or non-binary.
- You were assigned female at birth, and you identify as male (transman) or non-binary.
- You were assigned non-binary at birth, and you identify as male or female.

Note: Intersex newborns have generally been designated male or female at birth. More recently, some intersex newborns have been designated non-binary on their birth certificates, and they are later assigned a different gender if they develop a male or female gender identity as they grow up.

DO I HAVE TO TELL ANYONE THAT I AM TRANSGENDER OR INTERSEX?

⇒ You don't have to tell anyone that you are transgender or intersex unless you want to request medical treatment, mental health treatment, or accommodations (like clothing, property, different housing, separate showers,or search procedures).

⇒ You can ask any staff member to use the pronouns that are correct for you; staff are required to use the pronouns you say are correct for you.

Examples:

- He, him, his
- She, her, hers
- They, them, theirs

⇒ Identifying as transgender does not mean you have a mental health condition, however, it may be helpful to talk to a mental health professional about how you are feeling.

WHAT IF I WANT TO REQUEST ACCOMMODATIONS (LIKE CLOTHING, PROPERTY, DIFFERENT HOUSING, SEPARATE SHOWERS, OR SEARCH PROCEDURES)?

⇒ To be housed consistent with your gender identity, talk to your Correctional Counselor or PREA Compliance Manager about requesting different housing.

⇒ To request accommodations, please see your Correctional Counselor who canassist you in obtaining gender appropriate accommodations per the CDCR Department Operations Manual.

WHAT IF I'M NOT SURE OF MY GENDER IDENTITY?

⇒ If you have thoughts or feelings related to being uncomfortable with your sex assigned at birth, or you are not sure about your gender identity, you can talk to a mental health professional about this. You don't need to be in the Mental Health Program to ask to talk to a mental health professional.

PATIENT EDUCATION

TRANSGENDER HEALTH WHILE INCARCERATED FREQUENTLY ASKED QUESTIONS (FAQS)

What happens once I tell my medical provider that I am transgender, non-binary or intersex?

⇒ Your Correctional Counselor and classification committee will meet to decide the most appropriate housing for you based on individual factors.
⇒ You can request to be issued a Transgender Access Card by submitting a Form 22 to your Correctional Counselor I or the PREA Compliance Manager. Your Transgender Access Card is provided to facilitate receipt of clothing, property, and other accommodations approved for transgender individuals.
⇒ You don't have to have any specific medical or mental health diagnosis to be transferred to a transgender designated facility.
⇒ You will not be automatically included in the Mental Health Program if you are transgender. However, if you would like to talk to a mental health care provider you can submit a CDCR 7362 Healthcare Services Request Form.

Can I be prescribed hormones to change my body to look more male or female?

⇒ You can tell your medical provider that you want to be prescribed hormones for the first time or continue to take hormones previously prescribed.
⇒ Your medical provider will conduct an assessment and discuss your request with you. Your medical provider will also refer you to a mental health provider for an assessment.
⇒ If your medical provider and your mental health provider agree that hormones are a safe treatment for you, you can be prescribed hormones even if you have never taken them before.
⇒ Your medical provider may prescribe hormones or may refer you to a transgender health care specialist to prescribe hormones.
⇒ A patient education handout about hormone treatment is available from your medical provider. You can ask your medical provider to give you this handout.
⇒ You should only take hormones prescribed to you. Some people are not satisfied with their hormone dosage or blood level because they are not seeing the changes they want in their body. More hormones may harm you rather than making the physical changes you want. Your genetics passed down from your biological parents affect how the hormones are used in your body and how much your body will change.
⇒ Discuss any concerns with your medical providers.

Can I get other treatment while prescribed hormones, such as a modified diet or specific vitamins or supplements?

⇒ There are no standardized dietary recommendations for people taking hormones. Decisions about dietary and nutritional needs should be individualized based on each person's medical assessment.

PATIENT EDUCATION

TRANSGENDER HEALTH WHILE INCARCERATED FREQUENTLY ASKED QUESTIONS (FAQS)

CAN I HAVE SURGERY OR PROCEDURES TO CHANGE MY BODY SO IT BETTER MATCHES MY GENDER IDENTITY (ALSO CALLED GENDER AFFIRMING SURGERY)? WHAT ARE SOME COMMONLY AVAILABLE SURGERIES AND PROCEDURES?

⇒ Surgeries and procedures may include feminizing bottom surgery, breast augmentation (implants), facial surgery, and facial hair removal, as examples.
⇒ You can tell your medical provider that you want to have gender affirming surgery, or revision of a prior surgery. Your medical provider will talk to you about your surgical options.
⇒ Your medical provider will complete an electronic referral for services, which will start the process for considering your request for surgery. You can ask your medical provider if they have completed this referral, called an "eRFS."
⇒ A mental health provider will be assigned to complete an evaluation. This should be completed within 90 days of the referral. You do not have to be part of the Mental Health Program to be evaluated for gender affirming surgery.
⇒ The medical and mental health evaluation will be sent to a headquarters committee that includes qualified providers trained to consider requests for gender affirming surgery.
⇒ Once a decision is made, you will be informed by a mental health provider, and you will meet with a medical provider to talk about next steps. You should receive a copy of this decision memo, and you may request a copy from a mental health provider or your medical provider.
⇒ If you are approved for surgery, you will be scheduled for an appointment with a surgeon. Some surgeries require additional evaluation and preparation.
⇒ In some cases, housing may be re-evaluated after gender affirming surgery. Housing changes are based on individual factors, and you may be asked for your input. Your own requests may also be considered.

WHAT IF I REQUEST SURGERY AND I AM NOT APPROVED? WILL I BE TOLD THE REASON?

The headquarters committee follows guidelines set up by the World Professional Association of Transgender Health (WPATH) and CDCR/CCHCS to decide if surgery is medically necessary and safe. Some of the things considered in the decision include but are not limited to:

- Do you have a condition that might worsen if you have surgery?
- Do you have a condition or behavior that might stop you from healing properly after surgery?
- Is surgery likely to improve your health?
- Are you able to understand the risks of surgery and are you able to make independent decisions?
- Is someone else influencing your decision to have surgery or are you making the decision freely?
- If you are prescribed hormones, have you been on them long enough to benefit from them (about one year)? **Note:** If you can't take hormones for a medical reason or don't want to take them, this criteria does not apply.

⇒ Since the headquarters decision takes into account many different medical and mental health factors, the committee is unable to describe for each person the exact reason(s) that led to their surgery not being approved.
⇒ If the headquarters committee decides that you should receive additional information about the decision, the committee may assign a member to contact your treatment team and communicate the information to you.
⇒ If you are not approved for surgery, you can request surgery again one year from the date of the decision memo from headquarters communicating that your surgery was not approved. Your mental health or medical provider will be able to give you this decision memo.

EDUCACIÓN DEL PACIENTE

TERAPIA HORMONAL: MUJER TRANS

- La transición de su género es un proceso que cambia la vida.
- Someterse a la terapia hormonal de afirmación de género puede ser parte de su transición. Su proveedor le hablará sobre los beneficios, riesgos y alternativas a las hormonas.
- Hay muchas cosas que puede hacer para obtener los mejores y más seguros resultados para su cuerpo y mente, tales como:
  - No fumar nada
  - No consumir drogas ilegales o no recetadas
  - Hacer ejercicio regularmente
  - No beber alcohol
  - Mantener un peso saludable

LO QUE DEBE SABER SOBRE LA TERAPIA CON ESTRÓGENOS

➢ Los efectos feminizantes del estrógeno pueden tardar meses en notarse y años en completarse.

Tiempo necesario para ver los efectos potenciales de los bloqueadores de estrógenos y andrógenos[12]

Efecto	Inicio	Máximo
Menos grasa estomacal/más grasa en glúteos, caderas, muslos	3 a 6 meses	2 a 3 años
Menos masa muscular	3 a 6 meses	1 a 2 años
Piel más suave/piel menos grasa	3 a 6 meses	Desconocido
Menos deseo sexual	1 a 3 meses	3 a 6 meses
Menos erecciones espontáneas y deseadas	1 a 3 meses	3 a 6 meses
Menos capacidad para alcanzar el orgasmo	Varía	Varía
Crecimiento de los senos	3 a 6 meses	2 a 3 años
Testículos más pequeños	3 a 6 meses	2 a 3 años
Produce menos esperma	Desconocido	>3 años
Menos crecimiento de vello en el cuerpo y la cara	6 a 12 meses	>3 años

➢ Algunos cambios en su cuerpo serán permanentes, incluso si deja de tomar estradiol, entre estos:
  - Desarrollo de los senos: Deberá realizarse autoexámenes mamarios mensuales y realizarse un examen médico anual
  - Menos producción de esperma: Incluso si suspende el estradiol, la capacidad de producir espermatozoides saludables puede disminuir

➢ Tomar estradiol no lo protegerá de infecciones de transmisión sexual

➢ Algunos efectos secundarios peligrosos de tomar estradiol pueden incluir:
  - Coágulos de sangre
  - Sentirse deprimido
  - Cáncer de mama
  - Accidente cerebrovascular
  - Infartos
  - Enfermedades del hígado

➢ El estradiol puede aumentar su riesgo de enfermedad cardíaca, al igual que fumar cigarrillos. Si elige fumar, es posible que su médico no le recete estradiol o le recete dosis más bajas. Es importante reducir otros factores de riesgo de enfermedades cardíacas, como el colesterol alto y el sobrepeso.

➢ Puede optar por dejar de tomar estradiol en cualquier momento. Su médico también puede interrumpir su tratamiento por motivos médicos. Si deja de tomar estradiol, debe seguir un plan para reducir la dosis lentamente para evitar efectos secundarios perjudiciales.

LO QUE DEBE HACER

➢ Informe a su médico si está tomando suplementos dietéticos, hierbas, drogas (legales o ilegales) o medicamentos prescritos pero que no le hayan sido recetados.

➢ Si está en el sistema de prestación de servicios de salud mental, continúe recibiendo atención con su médico de salud mental. Si cree que necesita servicios de salud mental, envíe un CDCR 7362 o notifique a un miembro del personal.

➢ Se le pedirá que firme un formulario de consentimiento informado antes de comenzar la terapia con estradiol.

Si tiene alguna pregunta, consulte a su médico o proveedor de salud mental

EDUCACIÓN DEL PACIENTE

Cirugía de afirmación de género (feminización)

Educación del paciente

Cirugía de afirmación de género es un procedimiento o procedimientos quirúrgicos que cambian la apariencia física de una persona y/o sus características sexuales para alinearlas con su identidad de género. Hay varios tipos diferentes de cirugías de afirmación de género. Las cirugías de afirmación de género (feminización) hacen que su cuerpo se vea más femenino.

LO QUE DEBE SABER SI CONSIDERA LA CIRUGÍA

- La cirugía no es necesaria para los cambios legales en California (cambio de género, certificado de nacimiento, cambio de nombre).
- Algunos cambios de la cirugía son permanentes e irreversibles.
- Fumar no es conveniente para su cuerpo ni antes, ni después de la cirugía. Consulte con su médico sobre el uso de cualquier sustancia, incluida la nicotina o el alcohol.
- Podría requerirse varias cirugías y procedimientos.
- Todo el proceso puede llevar más de un año, incluidos los procedimientos de depilación, la cirugía o cirugías y el tiempo de recuperación.
- Su médico le dará instrucciones a seguir si decide someterse a la cirugía. Es importante que siga las instrucciones para que su cuerpo sane correctamente.
- Sus decisiones sobre cualquier cirugía deben basarse minuciosamente en la información de su médico y proveedores de salud mental.

¿QUIÉN NO SE PUEDE OPERAR?

En general, la cirugía no se recomienda para pacientes:

- Que tienen una condición médica o de salud mental grave que no está bajo control.
- Que fumen, consuman drogas y/o alcohol.
- Que tienen antecedentes de no seguir las intervenciones médicas o de salud mental.
- Quienes no pueden seguir las instrucciones antes y después de la cirugía.

¿QUIÉN ES ELEGIBLE PARA LA CIRUGÍA?

- Pacientes con diagnóstico de disforia de género.
- Pacientes mayores de edad (18 años, en California).

Los pacientes también deben:

- Ser capaces de tomar sus propias decisiones médicas y estar de acuerdo con la cirugía.
- Ser capaces de comprender que algunas cirugías no se pueden revertir y que los efectos secundarios negativos de la cirugía (si ocurren) pueden ser permanentes.
- Hacerse una evaluación de salud mental para asegurarse que entienden el proceso de la cirugía y pueden seguir las instrucciones de la misma.
- Hacerse una evaluación médica y pruebas de laboratorio para asegurarse que no existan condiciones médicas que conlleven a que la cirugía sea de alto riesgo para el paciente.

APRENDA LOS TÉRMINOS

Identidad de género: El sentimiento de una persona de ser hombre, mujer, no binario o ninguno de estos.
Disforia de género: Angustia causada por una diferencia entre la identidad de género de una persona y su sexo previsto/asignado al nacer.
Transgénero: Grupo de personas cuya identidad de género difiere de su sexo previsto/asignado al nacer.
Hombre trans: Persona con identidad de género masculino a quien se le predijo/asignó un sexo femenino al nacer.
Mujer trans: Persona con identidad de género femenina a la que se le predijo/asignó un sexo masculino al nacer.
No binario: Término utilizado por algunas personas quienes no se identifican como hombre ni mujer.

EDUCACIÓN DEL PACIENTE

Cirugía de afirmación de género (feminización)

LAS CIRUGÍAS FEMINIZANTES COMUNES INCLUYEN:

- Vaginoplastia: construir una vagina funcional
- Vulvoplastia: construir todas las partes de una vagina excepto el canal (no una vagina funcional)
- Orquiectomía: extirpar los testículos
- Penectomía: extirpar el pene
- Clitoroplastía: construir un clítoris
- Labioplastia: construir los labios
- Aumento de mamas: hacer o agrandar las mamas
- Cirugía facial: cambiar las estructuras de la cara
- Afeitado traqueal: reducir la manzana de Adán

El tipo de cirugía o procedimiento realizado se decidirá entre usted y su cirujano, después de revisar las opciones más seguras para usted.

CÓMO SOLICITAR UNA CIRUGÍA DE AFIRMACIÓN DE GÉNERO

- Envíe un formulario de solicitud de servicios de atención médica CDCR 7362 o consulte a su médico, especialista en salud mental o enfermera que le gustaría ser considerado para la cirugía.
- Su médico enviará su solicitud de cirugía y realizará un examen físico.
- Una vez que se envíe su solicitud, su médico de salud mental lo entrevistará.
- Su información, incluida su solicitud de cirugía, el informe de su médico sobre su salud y su entrevista de salud mental, se enviará a un comité de médicos y especialistas de salud mental.
- Este comité, conocido como el Comité de Revisión de Cirugía de Afirmación de Género, considerará muchos factores al tomar una decisión (especialmente su salud y seguridad) para aprobar o no su cirugía.

¿CAMBIARÁ LA UBICACIÓN DE SU VIVIENDA?

En algunos casos, el alojamiento puede reevaluarse después de la cirugía de afirmación de género. Los cambios de alojamiento se basan en factores individuales y es posible que se le solicite su opinión. También se pueden considerar sus propias solicitudes.

¿CUÁLES SON LOS RIESGOS Y LAS COMPLICACIONES DE LA CIRUGÍA?

Todas las cirugías conllevan riesgos. El cirujano explicará todos los riesgos o complicaciones potenciales y responderá cualquier pregunta que puedan tener los pacientes. A continuación, se enumeran algunos posibles riesgos y complicaciones.

Las posibles complicaciones de cualquier cirugía incluyen, entre otras:

- Sangrado
- Hematoma (acumulación de sangre)
- Seroma (acumulación de líquido)
- Infección
- Mala cicatrización de heridas
- Coágulos de sangre

Su cirujano evaluará las complicaciones y los riesgos relacionados con su cirugía o procedimiento.

¿QUÉ HACER PARA SER UN BUEN CANDIDATO A LA CIRUGÍA?

- No fume ni use drogas o alcohol.
- Acuda a sus citas médicas o de salud mental y siga sus instrucciones.
- Sea constante con la ingestión de sus hormonas y otros medicamentos (a menos que su médico le diga que no debe hacerlo).
- Manténgase en un peso saludable.
- Comprenda muy bien los riesgos y complicaciones de la cirugía, los cambios permanentes de la cirugía y los tratamientos a corto y largo plazo después de la cirugía.

CONOZCA SUS RECURSOS

1. Para obtener ropa/propiedad personal:
   - Envíe un Formulario 22 solicitando el artículo
2. Para comenzar la terapia hormonal o si desea hacer cambios en su tratamiento hormonal actual:
   - Envíe un formulario de solicitud de servicios de atención médica CDCR 7362
3. Podría tener disponible algún grupo de apoyo transgénero en su prisión. Pregúntele a su proveedor de salud mental.

PARA CUALQUIER PREGUNTA O INQUIETUD, CONSULTE A SU PROVEEDOR MÉDICO O DE SALUD MENTAL

EDUCACIÓN DEL PACIENTE

TERAPIA HORMONAL: HOMBRE TRANS

- La transición de su género es un proceso que cambia la vida.
- Someterse a la terapia hormonal de afirmación de género puede ser parte de su transición. Su proveedor le hablará sobre los beneficios, riesgos y alternativas a las hormonas.
- Hay muchas cosas que puede hacer para obtener los mejores y más seguros resultados para su cuerpo y mente, tales como:
  - No fumar nada
  - No consumir drogas ilegales o no recetadas
  - Hacer ejercicio regularmente
  - No beber alcohol
  - Mantener un peso saludable

LO QUE DEBE SABER SOBRE LA TERAPIA CON TESTOSTERONA

- Los efectos masculinizantes de la testosterona pueden tardar meses en notarse y años en completarse.

Tiempo necesario para ver los efectos potenciales de la testosterona[12]

Efecto	Inicio	Máximo
Piel grasosa/acné	1 a 6 meses	1 a 2 años
Crecimiento de vello facial/corporal	6 a 12 meses	4 a 5 años
Pérdida de cabello del cuero cabelludo	6 a 12 meses	-----
Más músculo y fuerza	6 a 12 meses	2 a 5 años
Menos grasa en glúteos, caderas, muslos	1 a 6 meses	2 a 5 años
Sin períodos menstruales	1 a 6 meses	-----
Clítoris más grande	1 a 6 meses	1 a 2 años
Sequedad del canal vaginal	1 a 6 meses	1 a 2 años
Voz más profunda	6 a 12 meses	1 a 2 años

- Algunos cambios en su cuerpo serán permanentes, incluso si deja de tomar testosterona, incluyen:
  - Pérdida de cabello del cuero cabelludo
  - Crecimiento de vello facial y más vello corporal
  - Engrosamiento de su voz
- La testosterona no brindará protección ante las infecciones de transmisión sexual o quedar embarazada
- Si toma testosterona por mucho tiempo, es posible que no pueda quedar embarazada en el futuro, incluso si deja de tomar testosterona.
- Algunos efectos secundarios peligrosos de tomar testosterona pueden incluir:
  - Coágulos de sangre
  - Sentirse deprimido
  - Hipertensión arterial
  - Cáncer de mama y/o útero
  - Enfermedades del hígado
  - Infartos
  - Accidente cerebrovascular
- La testosterona puede aumentar su riesgo de enfermedad cardíaca, al igual que fumar cigarrillos. Si elige fumar, es posible que su médico no le recete testosterona o le recete dosis más bajas. Es importante reducir otros factores de riesgo de enfermedades cardíacas, como el colesterol alto y el sobrepeso.
- Puede optar por dejar de tomar testosterona en cualquier momento. Su médico también puede interrumpir su tratamiento por motivos médicos. Si deja de tomar testosterona, debe seguir un plan para reducir la dosis lentamente para evitar efectos secundarios perjudiciales.

LO QUE DEBE HACER

- Informe a su médico si está tomando suplementos dietéticos, hierbas, drogas (legales o ilegales) o medicamentos prescritos pero que no le hayan sido recetados.
- Si está en el sistema de prestación de servicios de salud mental, continúe recibiendo atención con su médico de salud mental. Si cree que necesita servicios de salud mental, envíe un CDCR 7362 o notifique a un miembro del personal.
- Se le pedirá que firme un formulario de consentimiento informado antes de comenzar la terapia con testosterona.

Si tiene alguna pregunta, consulte a su proveedor médico o de salud mental.

EDUCACIÓN DEL PACIENTE

Cirugía de afirmación de género (masculinizante)

Educación del paciente

Cirugía de afirmación de género es un procedimiento o procedimientos quirúrgicos que cambian la apariencia física de una persona y/o sus características sexuales para alinearlas con su identidad de género. Hay varios tipos diferentes de cirugías de afirmación de género. Las cirugías de afirmación de género masculinizantes hacen que su cuerpo se vea más masculino.

LO QUE DEBE SABER SI CONSIDERA LA CIRUGÍA

- La cirugía no es necesaria para los cambios legales en California (cambio de género, certificado de nacimiento, cambio de nombre).
- Algunos cambios de la cirugía son permanentes e irreversibles.
- Fumar no es conveniente para su cuerpo ni antes, ni después de la cirugía. Consulte con su médico sobre el uso de cualquier sustancia, incluida la nicotina o el alcohol.
- Podría requerirse varias cirugías y procedimientos.
- Todo el proceso puede llevar de meses a más de un año, incluida la cirugía o cirugías, y el tiempo de recuperación.
- Su médico le dará instrucciones a seguir si decide someterse a la cirugía. Es importante que siga las instrucciones para que su cuerpo sane correctamente.
- Sus decisiones sobre cualquier cirugía deben basarse minuciosamente en la información de su médico y proveedores de salud mental.

¿QUIÉN NO SE PUEDE OPERAR?

En general, la cirugía no se recomienda para pacientes:

- Que tienen una condición médica o de salud mental grave que no está bajo control.
- Que fumen, consuman drogas y/o alcohol.
- Que tienen antecedentes de no seguir las intervenciones médicas o de salud mental.
- Quienes no pueden seguir las instrucciones antes y después de la cirugía.

¿QUIÉN ES ELEGIBLE PARA LA CIRUGÍA?

- Pacientes con diagnóstico de disforia de género.
- Pacientes mayores de edad (18 años, en California).

Los pacientes también deben:

- Ser capaces de tomar sus propias decisiones médicas y estar de acuerdo con la cirugía.
- Ser capaces de comprender que algunas cirugías no se pueden revertir y que los efectos secundarios negativos de la cirugía (si ocurren) pueden ser permanentes.
- Hacerse una evaluación de salud mental para asegurarse que entienden el proceso de la cirugía y pueden seguir las instrucciones de la misma.
- Hacerse una evaluación médica y pruebas de laboratorio para asegurarse que no existan condiciones médicas que conlleven a que la cirugía sea de alto riesgo para el paciente.

APRENDA LOS TÉRMINOS

Identidad de género: El sentimiento de una persona de ser hombre, mujer, no binario o ninguno de estos.
Disforia de género: Angustia causada por una diferencia entre la identidad de género de una persona y su sexo previsto/asignado al nacer.
Transgénero: Grupo de personas cuya identidad de género difiere de su sexo previsto/asignado al nacer.
Hombre trans: Persona con identidad de género masculino a quien se le predijo/asignó un sexo femenino al nacer.
Mujer trans: Persona con identidad de género femenina a la que se le predijo/asignó un sexo masculino al nacer.
No binario: Término utilizado por algunas personas quienes no se identifican como hombre ni mujer.

Cirugía de afirmación de género (masculinizante)

LAS CIRUGÍAS MASCULINIZANTES COMUNES INCLUYEN:

- Mastectomía: extirpar las mamas
- Mamoplastia de reducción: reducir las mamas
- Vaginectomía: extirpar la vagina
- Histerectomía: extirpar el útero
- Salpingo-ooforectomía: extirpar los ovarios
- Metoidioplastia: construir un pene con tejido genital
- Faloplastia: construir un pene con otras partes
- Escrotoplastia: construir un escroto
- Uretroplastia: Reconstruir o reemplazar la uretra
- Colocación de prótesis testiculares
- Cirugía facial: cambiar las estructuras de la cara

La extirpación del útero y/o los ovarios puede conducir a la infertilidad permanente. La extirpación de los ovarios puede provocar un adelgazamiento temprano de los huesos y una disminución de la resistencia de los huesos, lo que puede provocar la rotura de los huesos.

El tipo de cirugía o procedimiento realizado se decidirá entre usted y su cirujano, después de revisar las opciones más seguras para usted.

CÓMO SOLICITAR UNA CIRUGÍA DE AFIRMACIÓN DE GÉNERO

- Envíe un formulario de solicitud de servicios de atención médica CDCR 7362 o consulte a su médico, especialista en salud mental o enfermera que le gustaría ser considerado para la cirugía.
- Su médico enviará su solicitud de cirugía y realizará un examen físico.
- Una vez que se envíe su solicitud, su médico de salud mental lo entrevistará.
- Su información, incluida su solicitud de cirugía, el informe de su médico sobre su salud y su entrevista de salud mental, se enviará a un comité de médicos y especialistas de salud mental.
- Este comité, conocido como el Comité de Revisión de Cirugía de Afirmación de Género, considerará muchos factores al tomar una decisión (especialmente su salud y seguridad) para aprobar o no su cirugía.

¿CAMBIARÁ LA UBICACIÓN DE SU VIVIENDA?

En algunos casos, el alojamiento puede reevaluarse después de la cirugía de afirmación de género. Los cambios de alojamiento se basan en factores individuales y es posible que se le solicite su opinión. También se pueden considerar sus propias solicitudes.

¿CUÁLES SON LOS RIESGOS Y LAS COMPLICACIONES DE LA CIRUGÍA?

Todas las cirugías conllevan riesgos. El cirujano explicará todos los riesgos o complicaciones potenciales y responderá cualquier pregunta que puedan tener los pacientes. A continuación, se enumeran algunos posibles riesgos y complicaciones.

Las posibles complicaciones de cualquier cirugía incluyen, entre otras:

- Sangrado
- Hematoma (acumulación de sangre)
- Seroma (acumulación de líquido)
- Infección
- Mala cicatrización de heridas
- Coágulos de sangre

Su cirujano evaluará las complicaciones y los riesgos relacionados con su cirugía o procedimiento.

¿QUÉ HACER PARA SER UN BUEN CANDIDATO A LA CIRUGÍA?

- No fume ni use drogas o alcohol.
- Acuda a sus citas médicas o de salud mental y siga sus instrucciones.
- Sea constante con la ingestión de sus hormonas y otros medicamentos (a menos que su médico le diga que no debe hacerlo).
- Manténgase en un peso saludable.
- Comprenda muy bien los riesgos y complicaciones de la cirugía, los cambios permanentes de la cirugía y los tratamientos a corto y largo plazo después de la cirugía.

CONOZCA SUS RECURSOS

1. Para obtener ropa/propiedad personal:
   - Envíe un Formulario 22 solicitando el artículo
2. Para comenzar la terapia hormonal o si desea hacer cambios en su tratamiento hormonal actual:
   - Envíe un formulario de solicitud de servicios de atención médica CDCR 7362
3. Podría tener disponible algún grupo de apoyo transgénero en su prisión. Pregúntele a su proveedor de salud mental.

EDUCACIÓN DEL PACIENTE

PREGUNTAS FRECUENTES (FAQS) SOBRE LA SALUD DE LAS PERSONAS TRANSGÉNERO DURANTE LA ENCARCELACIÓN

¿QUÉ SIGNIFICA SER TRANSGÉNERO?

⇒ Cuando nació, su cuerpo parecía ser masculino, femenino o intersexual (una variación natural del cuerpo que no es masculino ni femenino).

⇒ Si su identidad de género (su sentido personal de su género) es diferente de su sexo asignado al nacer, puede identificarse como transgénero.

Ejemplos:

- Se le asignó varón al nacer y se identifica como mujer (mujer trans) o no binaria.
- Se le asignó mujer al nacer y se identifica como hombre (hombre trans) o no binario.
- Se le asignó no binario al nacer y se identifica como hombre o mujer.

Nota: Los recién nacidos intersexuales generalmente han sido designados como hombres o mujeres al nacer. Últimamente, algunos recién nacidos intersexuales han sido designados como no binarios en sus certificados de nacimiento y, luego, se les asigna un género diferente si desarrollan una identidad de género masculina o femenina a medida que crecen.

¿TENGO QUE DECIRLE A ALGUIEN QUE SOY TRANSGÉNERO O INTERSEXUAL?

⇒ No tiene que decirle a nadie que es transgénero o intersexual a menos que desee solicitar tratamiento médico, tratamiento de salud mental o adaptaciones (como ropa, propiedad, vivienda diferente, duchas separadas o procedimientos de búsqueda).

⇒ Puede pedirle a cualquier miembro del personal que use los pronombres correctos para usted; se requiere que el personal use los pronombres que usted dice que son correctos para usted.

Ejemplos:

- Él, de él, su
- Ella, de ella, suya
- Ellos, de ellos, suyos

⇒ Identificarse como transgénero no significa que tenga una afección de salud mental; sin embargo, podría ser útil hablar con un profesional de la salud mental sobre cómo se siente.

¿QUÉ OCURRE SI QUIERO SOLICITAR ADAPTACIONES PARA EL ALOJAMIENTO (COMO ROPA, PROPIEDAD, VIVIENDA DIFERENTE, DUCHAS SEPARADAS, O PROCEDIMIENTOS DE BÚSQUEDA)?

⇒ Para recibir alojamiento de acuerdo con su identidad de género, hable con su consejero correccional o Gerente de Cumplimiento de la Ley de Eliminación de la Violación en las Prisiones (Prison Rape Elimination Act, PREA) acerca de solicitar un alojamiento diferente.

⇒ Para solicitar adaptaciones para el alojamiento, consulte a su consejero correccional, quien puede ayudarlo a obtener adaptaciones apropiadas para su género según el Manual de Operaciones del Departamento de Correcciones y Rehabilitación de California (California Department of Corrections and Rehabilitation, CDCR).

¿QUÉ SUCEDE SI NO ESTOY SEGURO DE MI IDENTIDAD DE GÉNERO?

⇒ Si tiene pensamientos o sentimientos relacionados con la incomodidad con el sexo que le asignaron al nacer, o no está seguro de su identidad de género, puede hablar con un profesional de la salud mental al respecto. No necesita estar en el Programa de Salud Mental para consultar un profesional de salud mental.

EDUCACIÓN DEL PACIENTE

PREGUNTAS FRECUENTES (FAQS) SOBRE LA SALUD DE LAS PERSONAS TRANSGÉNERO DURANTE LA ENCARCELACIÓN

¿QUÉ SUCEDE UNA VEZ QUE LE DIGO A MI PROVEEDOR MÉDICO QUE SOY TRANSGÉNERO, NO-BINARIO O INTERSEXUAL?

⇒ Su consejero correccional y el comité de clasificación se reunirán para decidir el alojamiento más adecuado para usted en función de factores individuales.
⇒ Puede solicitar que se le emita una tarjeta de acceso para personas transgénero al enviar un formulario 22 a su consejero correccional I o al Gerente de Cumplimiento de PREA. Su tarjeta de acceso para personas transgénero se proporciona para facilitar la recepción de ropa, bienes y otras adaptaciones de alojamiento aprobados para personas transgénero.
⇒ No se requiere tener ningún diagnóstico médico o de salud mental específico para ser transferido a un centro designado para personas transgénero.
⇒ No se le incluirá automáticamente en el Programa de Salud Mental si es transgénero. No obstante, si desea consultar a un proveedor de atención de salud mental, puede enviar un formulario de solicitud de servicios de atención médica CDCR 7362.

¿ME PUEDEN RECETAR HORMONAS PARA CAMBIAR MI CUERPO PARA PARECER MÁS MASCULINO O FEMENINO?

⇒ Puede decirle a su proveedor médico que desea que le receten hormonas por primera vez, o continuar tomando las hormonas que se le hayan indicado anteriormente.
⇒ Su proveedor médico realizará una evaluación y analizará su solicitud con usted. Su proveedor médico también lo referirá a un proveedor de salud mental para una evaluación.
⇒ Si su proveedor médico y su proveedor de salud mental están de acuerdo en que las hormonas son un tratamiento seguro para usted, se le pueden indicar hormonas incluso si nunca las ha tomado antes.
⇒ Su proveedor médico puede recetarle hormonas, o puede remitirlo a un especialista en atención médica transgénero para que le recete hormonas.
⇒ Su proveedor médico tiene disponible un folleto educativo para el paciente sobre el tratamiento hormonal. Puede pedirle a su proveedor médico que le proporcione este folleto.
⇒ Solo debe tomar las hormonas que le hayan indicado. Algunas personas no están satisfechas con su dosis de hormonas o nivel sanguíneo porque no ven los cambios que desean en su cuerpo. Una mayor cantidad de hormonas puede ocasionarle daños en lugar de hacer los cambios físicos que desea. Su genética heredada de sus padres biológicos afecta la manera en que se usan las hormonas en su cuerpo y cuánto cambiará su cuerpo.
⇒ Consulte cualquier inquietud con sus proveedores médicos.

¿PUEDO OBTENER OTRO TRATAMIENTO MIENTRAS ME RECETEN HORMONAS, COMO UNA DIETA MODIFICADA O VITAMINAS O SUPLEMENTOS ESPECÍFICOS?

⇒ No existen recomendaciones dietéticas estandarizadas para las personas que toman hormonas. Las decisiones sobre las necesidades dietéticas y nutricionales deben individualizarse en función de la evaluación médica de cada persona.

EDUCACIÓN DEL PACIENTE

PREGUNTAS FRECUENTES (FAQS) SOBRE LA SALUD DE LAS PERSONAS TRANSGÉNERO DURANTE LA ENCARCELACIÓN

¿PUEDO REALIZARME CIRUGÍA O PROCEDIMIENTOS PARA CAMBIAR MI CUERPO PARA QUE SE AJUSTE MEJOR A MI IDENTIDAD DE GÉNERO (TAMBIÉN LLAMADA CIRUGÍA DE AFIRMACIÓN DE GÉNERO)?

¿CUÁLES SON LAS CIRUGÍAS Y PROCEDIMIENTOS DISPONIBLES CON MÁS FRECUENCIA?

⇒ Las cirugías y procedimientos pueden incluir cirugía de feminización de la zona pélvica (cirugí inferior), aumento de senos (implantes), cirugía facial y depilación facial, por mencionar algunos ejemplos.
⇒ Puede decirle a su proveedor médico que desea someterse a una cirugía de afirmación de género o una revisión de una cirugía anterior. Su proveedor médico hablará con usted sobre sus opciones quirúrgicas.
⇒ Su proveedor médico completará una referencia electrónica para los servicios, lo que iniciará el proceso para considerar su solicitud de cirugía. Puede preguntarle a su proveedor médico si ha completado esta referencia, llamada “eRFS”.
⇒ Se asignará un proveedor de salud mental para completar una evaluación. Este proceso debe completarse dentro de los 90 días posteriores a la remisión. No tiene que formar parte del Programa de Salud Mental para ser evaluado para la cirugía de afirmación de género.
⇒ La evaluación médica y de salud mental se enviará a un comité de la sede que incluye proveedores calificados capacitados para considerar las solicitudes de cirugía de afirmación de género.
⇒ Una vez que se tome una decisión, un proveedor de salud mental le informará y se reunirá con un proveedor médico para hablar sobre los próximos pasos. Debe recibir una copia de este memorándum de decisión y puede solicitar una copia a un proveedor de salud mental o a su proveedor médico.
⇒ Si se aprueba la cirugía, se le programará una cita con un cirujano. Algunas cirugías requieren evaluación y preparación adicional.
⇒ En algunos casos, el alojamiento puede reevaluarse después de la cirugía de afirmación de género. Los cambios de alojamiento se basan en factores individuales y es posible que se le solicite su opinión. También se pueden considerar sus propias solicitudes.

¿QUÉ PASA SI SOLICITO CIRUGÍA Y NO SOY APROBADO? ¿SE ME INFORMARÁ LA RAZÓN?

El comité de la sede sigue las pautas establecidas por la Asociación Profesional Mundial de Salud Transgénero (World Professional Association for Transgender Health, WPATH) y CDCR/CCHCS para decidir si la cirugía es médicamente necesaria y segura. Algunos de los aspectos que se consideran para la decisión incluyen, entre otros:

♦ ¿Tiene una condición que podría empeorar si se somete a una cirugía?
♦ ¿Tiene una afección o un comportamiento que podría impedirle sanar adecuadamente después de la cirugía?
♦ ¿La cirugía mejoría su salud?
♦ ¿Es capaz de comprender los riesgos de la cirugía y puede tomar decisiones independientes?
♦ ¿Alguien más está influyendo en su decisión de someterse a la cirugía o está tomando la decisión libremente?
♦ Si le indican hormonas, ¿las ha estado tomando durante el tiempo suficiente para beneficiarse de ellas (alrededor de un año)? **Nota:** Si no puede tomar hormonas por una razón médica o no quiere tomarlas, este criterio no se aplica.

⇒ Dado que la decisión de la sede tiene en cuenta muchos factores médicos y de salud mental diferentes, el comité no puede describir para cada persona las razones exactas que llevaron a que no se aprobara su cirugía.
⇒ Si el comité de la sede decide que debe recibir información adicional sobre la decisión, el comité puede asignar a un miembro para que se comunique con su equipo de tratamiento y le comunique la información.
⇒ Si no obtiene aprobación para la cirugía, puede solicitar la cirugía nuevamente un año después de la fecha del memorándum de decisión de la sede que comunica que su cirugía no fue aprobada. Su proveedor médico o de salud mental podrá darle este memorándum de decisión.

DEPARTMENT OF CORRECTIONS

Policy Number:	**202.045**
Title:	**Management and Placement of Incarcerated People Who Are Transgender, Gender Diverse, Intersex, or Nonbinary**
Effective Date:	**1/31/23**

PURPOSE: To provide guidelines for the wellbeing, safety, respect, evaluation, placement, and treatment of incarcerated people who are transgender, gender diverse, intersex, or nonbinary, or have gender dysphoria or other similar medical/clinical diagnoses.

APPLICABILITY: Department-wide

DEFINITIONS:

Agency Gender Identity Committee – a department-wide committee responsible for making recommendations regarding placement for incarcerated people who are transgender, gender diverse, intersex, or nonbinary. The committee is chaired by the department's assistant commissioner of the health, recovery, and programming division, and includes the director of diversity, equity, and inclusion or designee, a representative from victim services, the department's medical director, the director of behavioral health, and the director of nursing.

Facility Gender Identity Committee – a committee within a correctional facility responsible for making decisions regarding facility-specific requests, such as single-cell assignments, showering arrangements, and special property for incarcerated people who are transgender, gender diverse, intersex, or nonbinary. The committee is chaired by the associate warden where the person currently resides and includes the director of clinical operations, mental health director, as well as the primary mental health provider and case manager of that facility.

Gender – a set of socially-constructed roles, behaviors, activities, and attributes that society uses to classify an individual as, for example, feminine, masculine, both, or neither.

Gender identity – a person's internal, deeply felt sense of self in relation to gender, such as being a man, a woman, both, or neither. Gender identity does not always correspond to biological sex and can be distinct from sex assigned at birth. Gender identity is a separate concept from sexuality and sexual orientation.

Intersex – means a person is born with a reproductive or sexual anatomy that does not fit the typical definitions of male or female. Not everyone who has one of these conditions identifies as intersex.

Nonbinary – means a person who does not subscribe to the gender binary and may experience a gender identity that is neither exclusively male or female or is in between, beyond, or totally independent of those two binary genders. People with nonbinary gender identities may or may not use more specific terms to describe their genders (for example, agender, genderqueer, gender fluid, two spirit, bigender, pangender, gender nonconforming, gender variant).

Pat search – see policy 301.010, "Searches."

Sex – either of the two major forms of people that also occur in many species and that are distinguished as female or male, especially on the basis of their reproductive organs and structures.

Special property – property requested as connected to a person's gender identity and not already allowable or authorized by DOC Policy 302.250, "Property."

Transgender, gender diverse, and non-binary – means a person whose gender identity is different from their assigned sex at birth. Some people do not identify with these specific terms.

Unclothed body search – see policy 301.010, "Searches."

PROCEDURE:

A. Respectful Communication and Treatment

1. Staff members are expected to treat all incarcerated people with respect. Staff must communicate respectfully with incarcerated people who identify as transgender, gender diverse, intersex, or nonbinary.

2. An incarcerated person who makes a request under this policy may, at any time, choose to identify in an alternate gender identity. The department must then proceed with responding to the request.

B. Pronouns and Honorifics

1. At intake, incarcerated people must be given the opportunity to select one of the following pronouns and honorifics by which they would like to be addressed:
   a) She/Ms;
   b) He/Mr; or
   c) They/Mx (pronounced 'mix').

2. The pronoun and honorific selected must be displayed on the incarcerated person's badge and all staff members must refer to the person using that pronoun and honorific.

3. An incarcerated person may request to change the pronoun and honorific by which they are addressed at any time during their incarceration. To do so, the incarcerated person must follow the process set forth in Policy 302.255, "Offender/Resident Identification Cards."

C. Governance and Training

1. The agency gender identity committee reviews facility placement requests and makes recommendations to the deputy commissioner of the facility safety and security division regarding placement for incarcerated people who are transgender, gender diverse, intersex, or nonbinary at a facility consistent with their gender identity versus their sex assigned at birth.

2. The facility gender identity committees review requests and make decisions regarding matters of facility management, such as single-cell assignments, showering arrangements, special property, and search procedures.

3. The committees must consult with the incarcerated person and may seek consultation from outside health care providers to assist in making recommendations and decisions.

4. To determine whether an incarcerated person's request will be reviewed by the facility gender identity committees or the agency gender identity committee, DOC medical/mental health staff may review the incarcerated person's health records if the individual signs a

release of information form. If a person does not want to sign a release for their medical/mental health records or refuses to participate in requested gender identity psychological screening, their request will not be reviewed by the facility gender identity committees nor the agency gender identity committee.

5. The deputy commissioner and the facility gender identity committees must provide the incarcerated person with a prompt response to their requests, in writing, including a statement of reasons for any denials.

6. The written response from the facility gender identity committee regarding an incarcerated person's requests is retained in ODocS and must be promptly sent to the chair of the agency gender identity committee or designee for awareness and tracking purposes using the Facility Gender Identity Committee Decisions form (attached). The written response from the agency gender identity committee, using the Agency Gender Identity Committee Recommendations form (attached), and as approved, modified, or denied by the deputy commissioner, regarding an incarcerated person's request for facility placement is retained in ODocS and must be promptly returned to the chair of the agency gender identity committee or designee for awareness and tracking purposes.

7. The decisions made by the facility gender identity committees are monitored by the agency gender identity committee and reviewed at least quarterly to ensure consistency in the treatment of transgender, gender diverse, intersex, and nonbinary people across the department.

8. All members of the agency gender identity committee and facility gender identity committees must receive initial and annual training on understanding the experiences and treatment of incarcerated people who are transgender, gender diverse, intersex, or nonbinary.

D. Screening

1. When an incarcerated person identifies through intake, kite, or other communication as transgender, gender diverse, intersex, or nonbinary, facility mental health staff must complete a gender identity psychological screening, including the person's wellbeing, expressed needs with respect to their own safety, and their preference for their placement at a particular facility, or other concerns they may have related to their care and confinement.

2. Mental health or health services staff may not search or physically examine any incarcerated person for the sole purpose of determining the incarcerated person's genital status. This prohibition equally applies to people who are transgender, gender diverse, intersex, or nonbinary. If the incarcerated person's mental health or medical provider needs to know the person's genital status for the purposes of treatment or the incarcerated person's safety, it may be determined through conversations with the individual, by reviewing medical records or, if necessary, by learning that information as part of a broader medical examination conducted in private by a medical practitioner.

3. Upon completion of the gender identity psychological screening, the facility mental health director must directly provide the screening to the incarcerated individual, and to the following based on the nature of the person's requests:

a) Hormones and/or surgical intervention requests related to their gender identity should be forwarded to the mental health provider to schedule a care conference between the mental health provider and the treating medical professional to review and discuss this request.

b) Single-cell placement, showering, special property, or search requests should be forwarded to the facility gender identity committee chair who will schedule a meeting with the committee to review the request.

c) Transfer requests between facilities designated for adult men must follow the procedures outlined in DOC Policy 301.095 Central Transportation – Offenders.

d) Transfer requests between facilities designated for adult men and adult women should be forwarded to the agency gender identity committee chair who will schedule a meeting to review the request.

E. Placement and Transfers

1. Facility staff determine the preliminary placement of an individual who is transgender, gender diverse, intersex, or nonbinary upon intake screening in accordance with DOC Policy 202.040, "Intake Screening and Processing," until the agency gender identity committee makes a placement recommendation and the deputy commissioner of the facility safety and security division determines placement.

2. In deciding whether to assign a person who is transgender, gender diverse, intersex, or nonbinary to a facility for men or women, the department must consider on a case-by-case basis whether a placement would ensure the person's health and safety, including taking into account the person's own views with respect to their own safety, the best interests of the person, their ability to receive necessary and successful programming or treatment, and whether the placement would present facility security problems.

   The department must not place people who are lesbian, gay, bisexual, transgender, gender diverse, intersex, or nonbinary in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such people from harm.

3. The agency gender identity committee makes recommendations to the deputy commissioner of the facility safety and security division regarding facility placement using the Agency Gender Identity Committee Recommendations form. A transfer request to a facility matching an incarcerated person's gender identity should be approved unless the agency gender identity committee or the deputy commission of the facility safety and security division determine, based on the factors listed below, that such placement would pose a heightened risk of physical or sexual harm to the person or to others housed in the facility, or that the person is likely to engage in sexually inappropriate behavior there. The committee must consider the individual's:
   a) Views with respect to their own safety, which must be given serious consideration;

   b) Assigned security level;

   c) Criminal/adjudication and disciplinary history;

d) Gender expression;

e) Medical and mental health needs;

f) Programming and treatment needs and whether a particular facility placement can meet those needs;

g) Vulnerability to sexual victimization;

h) History of perpetrating physical or sexual abuse or engaging in sexually inappropriate behavior targeted at particular people; and

i) Any other individualized factors deemed relevant by the committee.

4. Prior to making a placement recommendation, the agency gender identity committee must consult the wardens of the considered facilities or their designees. Additionally, the following staff may be consulted: facility directors of clinical operations, facility mental health directors, primary mental health providers, facility security representatives, caseworkers, and treating physicians where the person currently resides and of the facility to which the person may be transferring.

5. The agency gender identity committee must promptly forward its recommendations regarding facility placement and transfers between designated facilities for adult men and adult women to the deputy commissioner of the facility safety and security division for a final decision. The deputy commissioner should, whenever possible, review the committee's recommendations within five days, consult with the commissioner of corrections, and inform the committee chair whether the recommendations have been approved, rejected, or modified. The deputy commissioner's determination, including a statement of reasons for any placement or transfer rejection, is sent to the members of the agency gender identity committee and to the incarcerated person, shared with the facility gender identity committee, noted in the Correctional Operations Management System (COMS), and retained in ODocS.

6. Placement and programming assignments for each incarcerated person who is transgender, gender diverse, intersex, or nonbinary must be reassessed at least twice each year by the agency gender identity committee, with recommendations sent to the deputy commissioner of the facility safety and security division or designee, to review programming needs and any threats to safety experienced by the incarcerated individual.

F. Single Cell, Showers, Undergarments, and Special Property Requests

1. Incarcerated people who are transgender, gender diverse, intersex, or nonbinary may request a single-cell assignment. The facility gender identity committee must review such requests and grant a single-cell assignment where necessary and appropriate to address a significant vulnerability or risk of physical or sexual harm to the person. The facility gender identity committee may also assign the individual to housing with other individuals of their gender identity if available.

2. Incarcerated people who are transgender, gender diverse, intersex, or nonbinary must be given the opportunity to shower separately in a manner so as to prevent viewing by other

incarcerated people, unless the facility gender identity committee has articulable safety or security concerns.

3. Facility staff must provide incarcerated people who are transgender, gender diverse, intersex, or nonbinary state-issued undergarments consistent with their gender identity, and the opportunity to purchase additional undergarments, as specified in attachment 302.250C, "DOC Allowable Property List" (attached), regardless of facility placement, unless the facility gender identity committee has articulable safety or security concerns. This is required even if the incarcerated person is housed in a facility with incarcerated people who have different gender identities.

4. Incarcerated people who are transgender, gender diverse, intersex, or nonbinary who reside at a facility designated for men must be permitted to purchase clothing and property allowed for other people housed in that institution, as well as those items allowed at MCF-Shakopee, commensurate with their particular security level unless the facility gender identity committee has articulable safety or security concerns. Incarcerated people who are transgender, gender diverse, intersex, or nonbinary who reside at MCF-Shakopee must be permitted to purchase clothing and property allowed for other people housed in MCF-Shakopee, as well as those items allowed at a facility designated for men, commensurate with their particular security level unless the facility gender identity committee has articulable safety or security concerns. Whether a person has been using such products prior to incarceration is irrelevant and unnecessary for the products to be allowed while incarcerated.

5. The facility gender identity committees considers special property requests not otherwise addressed in this section. These requests must be approved if consistent with someone's expressed gender identity and the facility gender identity committee does not have articulable safety or security concerns. If the item is not medicaly indicated nor prescribed by a treating medical provider, the incarcerated person is responsible for securing funds for the special property. Property staff must make reasonable attempts to assist an incarcerated person in finding an appropriate vendor once an item is approved.

G. Searches of Incarcerated People Who Are Transgender, Gender Diverse, Intersex, or Nonbinary

1. Unless otherwise requested by the incarcerated individual and approved by the facility gender identity committee, pat and unclothed body searches of incarcerated people who are transgender, gender diverse, intersex, or nonbinary must be done in accordance with the gender of the facility in which they are assigned (that is, searches must be conducted by male staff in facilities that house men and by female staff in facilities that house women). Unclothed body searches must be made in a manner designed to ensure as much privacy to the person as practicable and consistent with Policy 301.010, "Searches."

2. Incarcerated people who are transgender, gender diverse, intersex, or nonbinary may request that they receive pat or unclothed body searches from security staff of a specific gender. Such a request must be reviewed and pre-authorized by the facility gender identity committee and should only be denied if there are articulable safety or security concerns. Any exceptions to the general rule on searches must be specifically described (for example, "pat search only by female staff"), clearly communicated to relevant staff through written means, and reflected in COMS. Incarcerated people must be provided with a personal identifier that indicates their individual exception to be carried at all times and presented to staff prior to searches. When such search requests have been granted, staff of a different

gender may only conduct a pat or unclothed body search when exigent circumstances exist, and must complete an incident report documenting the exigent circumstances.

H. Medical and Mental Health Services

1. The department provides incarcerated people who are transgender, gender diverse, intersex, or nonbinary with appropriate gender-related mental health and medical services throughout their incarceration. It is not necessary for a person to have been receiving such services prior to incarceration for the services to be provided while incarcerated.

2. Gender-related hormone or medical treatment may be provided to an incarcerated person after an individualized assessment by facility medical staff. The individualized assessment should, at a minimum, consider the following factors to determine whether the requested treatment is clinically appropriate and medically necessary to address gender dysphoria:
   a) Whether the incarcerated person has been diagnosed with gender dysphoria, either at an earlier time or during the individualized assessment itself;

   b) The nature and severity of any symptoms associated with gender dysphoria and any alternative methods of treatment that may be equally effective at addressing or treating the gender dysphoria;

   c) The treatment and life experiences of the incarcerated person prior to and during incarceration; the absence of relevant treatment and life experiences, by itself, is not a basis for denying otherwise appropriate health services;

   d) Whether the incarcerated person is willing to participate in mental health therapy, if needed, in conjunction with medical treatments;

   e) Available continuity of care upon the individual's release, including considerations of residency upon release, availability of care, and the nature and length of the proposed care to be provided; and

   f) Whether there are any medical and/or mental health conditions that may create an undue risk of adverse health consequences caused by hormones or other treatment.

3. The role of mental health staff in responding to requests from incarcerated people who are transgender, gender diverse, intersex, or nonbinary to the facility gender identity committees and/or agency gender identity committee is to provide information related to the incarcerated individual's mental health stability.

4. Medical staff must consult with facility mental health staff regarding the mental health benefits of gender-related hormone or medical treatment. The medical provider treating the incarcerated person makes the final determination on whether gender-related hormone or medical treatments for the incarcerated person who is transgender, gender diverse, intersex, or nonbinary should be initiated or continued, consistent with generally-accepted medical practices in the treatment of gender dysphoria in correctional settings. This decision is made in consultation with the incarcerated individual, including education about potential risks and benefits as well as consideration of any alternative methods of treatment that may be equally effective at addressing or treating the gender dysphoria. Requests for gender-affirming surgical treatment, if considered medically necessary for treatment of the

incarcerated individual's gender dysphoria, would be managed by the medical provider in the standard manner for requesting outside consultation.

5. If it is unclear to the treating medical provider whether gender-related hormone or medical treatments are medically necessary to treat gender dysphoria, a consultation with a provider who specializes in transgender health care must be initiated.

6. Mental and medical decisions must be documented in the incarcerated person's electronic health record.

I. Grievances

1. Decisions of the facility gender identity committee must be grieved following the procedures outlined in DOC Policy 303.100, Grievance Procedure, for adult facilities and DOC Policy 303,095, Juvenile Grievance Procedure, for juveniles.

2. Recommendations of the agency gender identity committee for placement are reviewed and either approved or rejected by the deputy commissioner of the facility safety and security division. The deputy commissioner's decision is final and cannot be grieved because the deputy commissioner is the highest level on the chain of command for grievance/appeal review and determination.

INTERNAL CONTROLS:

A. The written response from the facility gender identity committee regarding an incarcerated person's requests is retained in ODocS and must be promptly sent to the chair of the agency gender identity committee or designee for awareness and tracking purposes using the Facility Gender Identity Committee Decisions form.

B. The decisions made by the facility gender identity committees are monitored by the agency gender identity committee and reviewed at least quarterly to ensure consistency in the treatment of transgender, gender diverse, intersex, and nonbinary people across the department.

C. The determination and response of the deputy commissioner of the facility safety and security division in response to the agency gender identity committee's placement recommendation is noted in COMS and retained in ODocS.

D. Mental health and medical decisions are documented in the incarcerated person's electronic health record.

E. Authorized requests for general pat/body searches to be conducted by staff of a specific gender are maintained in COMS.

ACA STANDARDS: None

REFERENCES:

Minn. Stat. § 241.01
Policy 301.010, "Searches"
Policy 302.255, "Offender/Resident Identification Cards"
Policy 302.250, "Offender Property"
Prison Rape Elimination Act (PREA), 28 C".F.R. §115.15, 115.41, and 115.42 (2012)

REPLACES: Policy 202.045, "Evaluation and Placement of Transgender/Gender Non-Conforming/Intersex Offenders," 10/06/20.
All facility policies, memos, or other communications whether verbal, written or transmitted by electronic means regarding this topic.

ATTACHMENTS: Agency Gender Identity Committee Recommendations form (202.045A)
Facility Gender Identity Committee Decision form (202.045B)
DOC Allowable Property List (302.250C)

APPROVALS:
Deputy Commissioner, Reintegration and Restorative Services
Deputy Commissioner, Facility Safety and Security
Assistant Commissioner, Organizational and Regulatory Services
Assistant Commissioner, Chief of Staff
Assistant Commissioner, Health, Recovery, and Programming

KENTUCKY CORRECTIONS Policies and Procedures	Policy Number: 14.8	Total Pages: 10
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Authority/References	Subject
KRS 196.035, 197.020, 510.120, 531.090 28 C.F.R. § 115.5, 28 C.F.R. § 115.6, 28 C.F.R. § 115.15, 28 C.F.R. § 115.42, 28 C.F.R. § 115.43 ACA 5-ACI-3D-14, 5-ACI-1C-09; P & P ACA 3C-02, 3E-05 CPP 9.8, 14.7, 18.1, 18.5	**Lesbian, Gay, Bisexual, Transgender, and Intersex Offenders**

I. DEFINITIONS

"Administrative review team" is a team consisting of the Department of Corrections Commissioner, Deputy Commissioners, a member of General Council, and other staff assigned by the Commissioner.

"Gender dysphoria" means a mental health disorder characterized by clinically significant distress and impairment in social, occupational, or other important areas of functioning secondary to a marked incongruence between an individual's experienced/expressed gender and assigned gender.

"Gender identity" is distinct from sexual orientation and refers to a person's internal sense of being male, female, or something else.

"Institutional treatment team" is a multi-disciplinary committee that consists of medical providers, nurses, psychiatric providers, psychologists, security and other staff as needed working together on complex mental health and medical cases at the institutional level.

"Intersex" means a person whose sexual or reproductive anatomy or chromosomal pattern does not seem to fit typical definitions of male or female.

"LGBTI" means lesbian, gay, bisexual, transgender, or intersex.

"Staff member", for purposes of this policy, means full-time, part-time and interim employees, interns, students, volunteers, and contractors doing business on a recurring basis with the Department of Corrections.

"Therapeutic Level of Care (TLOC)" is a multi-disciplinary committee that consists of medical providers, nurses, psychiatric providers, psychologists, security and other staff as needed working together on complex mental health and medical cases.

"Transgender" means a person whose gender identity (i.e. internal sense of feeling male or female) is different from the person's assigned sex at birth. For example, a transgender woman is an individual who was born male but identifies as female. A transgender man is an individual who was born female but identifies as male. Transgender people may or may not be prescribed hormones or have had gender affirming surgery.

II. POLICY and PROCEDURES

It is the policy of the Kentucky Department of Corrections to be sensitive to the unique issues of individuals who are LGBTI and to evaluate and place those individuals in a manner that is safe and consistent with the Prison Rape Elimination Act (PREA) standards and the department's mission, values and security procedures. The Kentucky Department of Corrections has a zero tolerance for sexual abuse or sexual harassment towards any offender, to include LGBTI offenders. There is also zero tolerance for the use of any derogatory terms or discriminatory acts directed towards any LGBTI offender.

Additionally, it is the policy of the Kentucky Department of Corrections to provide staff members a procedure for evaluation, placement, and treatment of offenders who present as intersex or identify as transgender and to ensure appropriate medical/mental health care and offender safety.

A. Facility Determination

1. An assessment to determine the facility a transgender or intersex inmate shall be assigned to shall be made on a case-by-case basis via an individualized assessment of the inmate by the Therapeutic Level of Care (TLOC) committee, which includes input from medical and mental health staff, in consultation with the Director of Classification. A determination shall not be made based on genital status alone.

2. Staff shall consider if placement would ensure the inmate's health and safety and if the placement would present management or security problems.

3. Staff shall give serious consideration to the inmate's own views concerning his or her safety.

4. The individualized assessment shall consider the following:

    a. Classification's housing decision;
    b. The offender's documented choice of whether a male or female facility is safest for him or her;
    c. The inmate's physical characteristics;
    d. Whether the inmate identified as male or female;

e. The offender's prior institutional history, to include incidents and grievances;
f. The offender's prior violent or sexual crime history;
g. The offender's physical appearance, age, and physical build;
h. Any relevant information obtained about the offender from security, medical or mental health staff since arrival;
i. The ability of security staff to house and supervise the offender to ensure his or her safety in each environment;
j. Any management problems that can be identified in each facility; and
k. Any other relevant information about the offender's ability to positively or negatively manage his or herself in each type of environment.

B. Facility Intake

1. Notifications

a. If an inmate is received by the Department of Corrections (DOC) through intake and DOC staff are made aware through the receiving process or if at any time during incarceration an offender identifies as a transgender male or transgender female or is an offender who is intersex, DOC staff shall immediately notify the Shift Supervisor and institutional PREA Compliance Manager.

b. As soon as possible after being notified the institutional PREA Compliance Manager shall notify medical staff, mental health staff, the Warden and the agency PREA Coordinator.

2. Initial Housing Assignment

a. Upon intake at their assigned facility an initial housing assignment shall be made with the safety of the LGBTI inmate as priority.

b. LGBTI inmates shall not be placed into restrictive housing involuntary unless an assessment of all available alternatives has been made and there are no alternative means available. If the inmate is placed in restrictive housing involuntarily , an assessment shall be completed within 24 hours. The inmate shall be kept in restrictive housing involuntarily only until an alternative means of separation from likely abusers can be arranged. This shall not ordinarily exceed 30 days.

c. LGBTI inmates shall be housed in the least restrictive setting possible while considering their safety and well-being.

3. Risk Screening

   a. A risk screening shall be completed on all offenders, including LGBTI offenders, as required in CPP 14.7

   b. If the result of the risk screening or any other assessments completed after the initial housing assignment is given indicate a need for a change in housing assignment, this shall be done as soon as possible after the screening or assessment is completed.

C. Bed, Housing, Work, and Program Assignments

1. All LGBTI inmates shall be classified in accordance with CPP 18.1. Classification staff shall use the results of the risk screening required in CPP 14.7 to help determine bed, housing, work and program assignments as well as safety and custody decisions.

2. Classification staff shall give serious consideration to the inmate's own view concerning his or her safety.

3. LGBTI offenders shall be given the same treatment in determining access to programming and services as other offenders within the correctional facility. However, work, education, and programming assignments can vary for offenders is there is a documented reason to keep separate those offenders at high risk of being sexually victimized from those at high risk of being sexually abusive. Classification staff shall make individualized determinations about these offender's assignments without discrimination.

4. Classification staff shall not make any determinations based primarily on the complaints of staff or other inmates when the complaints are based on gender identity.

5. Any questioning done by staff to make a determination for appropriate housing shall be conducted in a private and respectful manner.

6.. Any question relating to an inmate's anatomy or surgical status shall only be asked by authorized medical staff as necessary for proper medical treatment.

7. Classification staff shall not place LGBTI offenders in dedicated housing areas for LGBTI offenders solely on the basis of the offender's sexual orientation, identification or status.

8. Classification staff shall assess the placement and programming assignments for each transgender or intersex inmate twice a year to review any threats to safety experienced by the offender. This shall be completed at least once every six (6) months during the inmate's reclassification required by CPP 18.1.

9. Transgender or intersex offenders shall have the right to request their housing assignment be re-evaluated. Any offender request shall be made in writing to the Warden or designee of their assigned facility with an explanation of the reason for the request. The Warden or designee shall review and grant or deny the request based on the explanation at their discretion. The decision of the Warden or designee shall be documented.

10. A transgender or intersex inmate may request Protective Custody at any time according to the procedures in CPP 18.15.

D. Staff Training and Awareness – Respectful Communication

1. LGBTI offenders shall be treated with the same rules and respect as other offenders.

2. All DOC employees shall be required to attend training in pre-service and annually in in-service on PREA, which includes how to communicate effectively and professionally with offenders, including lesbian, gay, bisexual, transgender, intersex, or gender non-conforming offenders.

   a. In-service training shall include gender-specific reference and training to staff as it relates to the specific population supervised.

   b. If a staff member transfers to a different facility, they shall receive gender-specific training.

   c. Staff shall also receive LGBTI-specific training in pre-service and in-service training.

3. Respectful communication with transgender offenders is vital to facility safety and security. All staff are responsible for behaving professionally and responsibly around all offenders, to include LGBTI offenders, to maintain order and composure on their shift.

4. To address LGBTI offenders respectfully, staff may not engage in unwelcome verbal comments, gestures, or actions of a derogatory or offensive nature, nor shall staff make demeaning references to the offender's gender or gender identity, or sexually suggestive or derogatory comments about the body or clothing of an offender or use obscene

language or gestures. Terms such as "it," "he-she" and "that" are disrespectful to transgender offenders and shall not be tolerated.

5. Staff shall refer to transgender offenders by their legal last name and shall use the pronoun the offender prefers to address him or her.

6. Staff shall not attempt to change any offender's understanding of his or her gender identity or sexual orientation.

7. Staff shall not permit, condone, or otherwise allow any offender to sexually harass other offenders, including transgender offenders.

8. The DOC shall provide training to security staff about how to conduct cross-gender frisk searches and searches of transgender and intersex inmates in a professional and respectful manner.

9. All volunteers and contractors who have contact with inmates shall also be familiar with their responsibilities regarding LGBTI populations in accordance with Department policies.

E. Showers

1. Transgender and intersex inmates shall be given the opportunity to shower separately from other offenders. They shall not be required to shower separately but shall have the opportunity if they wish to do so. This shall be accomplished by:

   a. Allowing the inmate to shower alone in a community shower at a time separate from other offenders; or

   b. Allowing the inmate to shower alone in a shower that has separate and private walls or curtains.

2. Transgender and intersex inmates shall be given as much privacy as possible without jeopardizing the safety of the inmate and the safety and security of the institution during the shower periods.

F. Searches

1. Offender searches shall be conducted in a professional and respectful manner, in the least intrusive manner possible, and consistent with security needs. Staff who frisk and strip search transgender and intersex offenders must have the requisite search training.

2. DOC staff shall not search or physically examine transgender or intersex inmates for the sole purpose of determining their genital status. If an inmate's genital status is unknown, DOC may determine it through conversations with the inmate, by reviewing medical records, or, if necessary, by learning that information as part of a broader medical examination conducted in private by a medical practitioner.

3. Operationally, four options may be used for searches of transgender or intersex inmates:

   a. Frisk search conducted by female staff only, especially given there is no prohibition on the frisk searches female staff can perform;

   b. Ask inmate to identify the gender of staff with whom he or she would feel most comfortable conducting the search;

   c. Search conducted in accordance with the inmate's gender identity; or

   d. Search conducted only by medical staff.

4. At no time shall one gender staff search a top half of an offender's body and another gender search a bottom half.

5. A determination of the staff gender to search a transgender or intersex inmate shall be made on a case-by-case basis and shall be documented in writing and documented within the offender management system with an explanation for the determination.

6. If the inmate requests to change this determination at any time, it shall be documented and a review completed. The results of the review shall also be documented.

G. Transportation

1. Whenever possible, both a male and female staff should be on a transport that includes a transgender or intersex offender so search options are available to the offender depending on the circumstance, gender identity, and PREA requirements that prohibit cross-gender pat searches.

2. If it is not possible for both a male and female staff to be assigned on a transport that includes a transgender or intersex inmate, a staff member the same gender as designated for searches shall be assigned to the transport.

H. Confidentiality

1. Because LGBTI offenders may be at particularly high risk for physical or sexual abuse or harassment, information learned about an offender, whether received from the offender, from the PREA Risk Screening, from other documents or records, or from a suspicion the offender may be LGBTI, shall be used only for the safety and security of the offender and facility. No person shall share this information with others unless there is a legitimate and documented reason to do so.

2. Sexual safety risk screening information is required to be locked and secured with limited access. Staff shall keep an offender's sensitive personal information confidential.

I. Physical and Mental Health Treatment

1. All offenders, to include those who self-identify or screen on the PREA Risk Screening as transgender or intersex, shall be referred to medical for a review of needs within fourteen (14) days of arrival at their assigned facility or of their identification if made at another time during their incarceration.

2. Medical and mental health practitioners shall document whether an offender has identified as transgender or intersex after a medical assessment and mental health evaluation.

3. DOC shall provide transgender and intersex offenders with individualized assessments and care, to include necessary and appropriate mental health services and, when warranted, hormone treatment throughout their incarceration.

4. If an inmate requests hormone treatment the process shall be as follows:

   a. The inmate shall be reviewed by a Psychologist and a Psychiatrist to determine if the inmate meets the appropriate criteria for hormone treatment. If the Psychologist and Psychiatrist disagree, an independent practitioner shall be brought in to review the inmate.

   b. If it is determined that the inmate meets the criteria for hormone treatment, the inmate shall be reviewed by the institutional treatment team.

c. If the institutional treatment team agrees that the inmate meets the criteria for hormone treatment the inmate shall be referred for review by the TLOC committee.

d. If TLOC agrees that the inmate meets the criteria for hormone treatment, the inmate shall be referred for an appointment with an outside endocrinologist.

e. The endocrinologist shall make the final determination on whether gender-related hormone treatment for a transgender offender should be initiated or continued based on documented medical need.

5. Only medical practitioners shall make decisions regarding gender-related hormone treatment needs.

6. If an inmate requests a transgender specific surgery the process shall be as follows:

a. The inmate shall be reviewed by a Psychologist and a Psychiatrist to determine if the inmate meets the appropriate criteria for transgender specific surgery. If the Psychologist and Psychiatrist disagree, an independent practitioner shall be brought in to review the inmate.

b. If it is determined that the inmate meets the criteria, the inmate shall be reviewed by the institutional treatment team.

c. If the institutional treatment team agrees that the inmate meets the criteria the inmate shall be referred for review by the TLOC committee.

d. TLOC shall review the requests and the healthcare information of the inmate to include consultation with an endocrinologist. If TLOC agrees that the inmate meets the criteria, the inmate shall be referred for review by a separate Administrative Review Team.

e. The Administrative Review Team shall make the final determination on whether transgender specific surgery for an offender should be initiated.

J. Staff and Offender Discipline

Staff or offenders who are found to have participated in the abuse or harassment of an LGBTI offender shall be reviewed for appropriate action, which may include

disciplinary action up to and including dismissal for staff and disciplinary action for offenders. DOC shall not tolerate physical, emotional, or sexual abuse or harassment of any offender.

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Determination and Management of Inmates with Gender Dysphoria	**ACA Standards: None**		
Steven Harpe, Director **Oklahoma Department of Corrections**		**Signature on File**	

Determination and Management of Inmates with Gender Dysphoria

The purpose of this procedure is to establish processes for the appropriate assessment, diagnosis, and management of inmates with gender dysphoria (GD) in the Oklahoma Department of Corrections (ODOC).

I. Definitions

Definitions related to gender nonconforming inmates are outlined in OP-030601 entitled "Oklahoma Prison Rape Elimination Act."

A. Gender Dysphoria (GD)

A condition where there is clinically significant discontent or distress with one's sex assigned at birth and/or the gender roles associated with that sex.

B. Male-to-Female (MtF)

Feminized male (genotypic male) who has physical/medical risk factors of a male with added medical and mental health risks associated with feminization. Transgender female refers to the gender identity of a MtF person.

C. Female-to-Male (FtM)

Masculinized female (genotypic female) who has physical/medical risk factors of a female with medical and mental health risks associated with masculinization. Transgender male refers to the gender identity of a FtM person.

II. Process for the Assessment and Determination of Gender Dysphoria

The "Request for Gender Dysphoria (GD) Evaluation/Treatment" Algorithm (Attachment C, attached) provides an outline of this process.

Inmates may self-identify as transgender, but not have gender dysphoria.

A. Step One

Initial request for gender dysphoria (GD) evaluation and/or treatment.

1. The inmate must submit a "Request for Health Services" form (DOC 140117A) to medical requesting gender dysphoria (GD) treatment, specifying the type(s) of GD related considerations (GD evaluation, property, housing, hormone treatment, etc.) that they are requesting.

2. The facility health care provider, registered nurse (RN), or licensed practical nurses (LPN), will confirm and document the inmate understands the risk associated with Hormone Replacement Therapy (HRT) and wishes to proceed with the GD evaluation process.

3. If the inmate wishes to proceed with the GD evaluation process, refer the inmate to Mental Health.

B. Step Two

Mental health evaluation by a qualified mental health professional (QMHP).

1. The QMHP appointed by the chief Mental Health Officer (CMHO) will:

   a. Review mental health history;

   b. Assess for co-occurring mental health disorders/conditions that may complicate treatment or confound diagnosis of GD;

   c. Determine substance use, past and present; and

   d. Based on the current version of the Diagnostic and Statistical Manual of Mental Disorders, the qualified mental health professional will determine if the inmate meets criteria for a gender dysphoria diagnosis. If the inmate is diagnosed with gender dysphoria, the diagnosis is entered into EHR under the "Problem List."

C. Step Three

Treatment and reasonable accommodations for inmates with a confirmed diagnosis of gender dysphoria.

Following diagnosis of gender dysphoria, if the inmate requests specific treatment and/or reasonable accommodations, the inmate must submit a "Request for Health Services" (DOC 140117A) form for each housing or treatment request. Housing requests will be submitted to mental health services. Medical treatment requests will be submitted to medical services for review and consideration.

D. Housing

Housing will be in accordance with OP-030601 entitled "Oklahoma Prison Rape Elimination Act." The agency shall not place transgender or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status. Health services staff may make housing recommendations to the facility head, after any necessary medical and/or mental health assessments have been completed. Complex cases that require a more extensive review will be submitted to the Personal Identity Administrative Review Authority (PIARA) by health services staff, a facility's PREA compliance manager, or a facility/unit head.

E. Inmate Property

Inmates will be provided standard ODOC attire in accordance with OP-030120 entitled "Inmate Property."

F. Hormone Therapy

1. Assessment and Reception Inmates Only

Inmates arriving at an assessment and reception center, who are received with hormone therapy prescriptions, should have that therapy continued without interruption while the diagnosis is verified. The facility health care provider may temporarily continue the hormone medications after all of the following occur:

a. Ensure there are no medical contraindications to hormone therapy;

b. The inmate has signed the "Female to Male (FtM) Hormone Therapy Risk and Information Form" (Attachment B, attached) or "Male to Female (MtF) Hormone Therapy Risk and Information Form" (Attachment A, attached) acknowledging he or she understands and accepts all risks associated with GD treatment;

c. Inmate is informed that a mental health evaluation will be performed and based upon the mental health evaluation report the medications may be discontinued;

d. If the mental health evaluation confirms the inmate has a GD diagnosis, and the inmate requests specific GD HRT, the facility health care provider will complete a consult for OUMC Endocrine Specialist for HRT medication management. If clinically appropriate, the facility health care provider may order the HRT medications and labs recommended by the OUMC Endocrine Specialist. Approval of GD HRT medication will go through the non-formulary approval review process.

2. Inmates requesting hormone therapy following a GD diagnosis will submit a "Request for Health Services" (DOC 140117A) form requesting hormone therapy.

a. The health care provider confirms that a diagnosis of gender dysphoria has been confirmed by a qualified mental health professional appointed by the CMHO based on the diagnostic criteria of the most current version of the Diagnostic and Statistical Manual of Mental Disorders.

b. If an inmate has a confirmed GD diagnosis, the facility health care provider will complete a consult for OUMC Endocrine Specialist for HRT medication management. If clinically appropriate, the facility health care provider may order the HRT medications and labs recommended by the OUMC Endocrine Specialist. Initial prescriptions for GD HRT medications must have the approval of the Chief Medical Officer (CMO), or their designee, through the non-formulary approval process. Facility provider should engage their regional supervising physician or the chief medical officer for any needed guidance on HRT management. Follow-up appointments at the OUMC Endocrine clinic for GD management is a clinical judgement decision by the facility provider with input from the regional supervising physician or CMO. GD Endocrine Specialty follow-up is recommended for cases involving clinical complications or complexity.

c. Before HRT medications will be prescribed, the inmate must acknowledge he or she understands and consents to all the risks associated with GD treatment and sign the "Female to Male (FtM) Hormone Therapy Risk and Information Form" (Attachment B, attached) or "Male to Female (MtF) Hormone Therapy Risk and Information Form" (Attachment A, attached).

III. Surgical Sex Reassignment

Surgical procedures for the initiation, advancement, or maintenance of sex reassignment will not be performed, except in extraordinary circumstances.

In accordance with OP-140121 entitled "Outside Providers for Health Care Management," the facility's health care provider will refer an inmate's request for surgical treatment of gender dysphoria to the Utilization Review Committee (URC) for consideration of approval. If the referral is approved, URC will forward the referral to the agency director for final review and authorization.

Self-inflicted genital mutilation will not constitute surgical reassignment therapy and will not qualify an inmate for placement in a facility for inmates of the opposite sex from the inmate's birth sex.

IV. Initiating Review by Personal Identity Administrative Review Authority (PIARA)

Inmates with a confirmed gender dysphoria diagnosis may have their housing, clothing, and health care needs specific to their gender associated request assessed by PIARA. This committee will consider each inmate on a case-by-case basis to ensure fair, safe, and appropriate management of their gender associated requests. (PREA 115.42/115.242)

A. The committee may include, but is not limited to any or all of the following:

1. Chief Mental Health Officer;

2. Chief Medical Officer;

3. Agency PREA coordinator;

4. Inmate's facility head or designee; and/or

5. Medical and mental health provider at facility level.

B. In accordance with OP-090124 entitled, "Inmate/Offender Grievance Process," the inmate may initiate a PIARA review through the grievance process.

C. PIARA consideration may be requested by health services staff, a facility's PREA compliance manager, or a facility/unit head, if an exception to policy is needed or to determine consistency of agency practice. The referring staff member will complete a "Referral for Gender Associated Requests" (DOC 140147A, attached). The completed form will be scanned and emailed to PIARA@doc.ok.gov.

D. Upon receipt of a PIARA review request, the PIARA will convene to review the request within 30 days

V. References

OP-030120 entitled “Inmate Property”

OP-030601 entitled “Oklahoma Prison Rape Elimination Act (PREA)”

OP-090124 entitled “Inmate/Offender Grievance Process”

OP-140121 entitled “Outside Providers for Health Care Management”

Rape Elimination Act of 2003, 42 U.S.C.A. §15601

“Diagnostic and Statistical Manual of Mental Disorders”

PREA 115.15/115.215

PREA 115.41/115.241

PREA 115.42/115.242

VI. Action

The chief Medical Officer is responsible for compliance with this procedure and the annual review and revisions.

Any exceptions to this procedure will require prior written approval from the agency director.

This procedure is effective as indicated.

Replaced: OP-140147 entitled “Determination and Management of Inmates with Gender Dysphoria” dated June 24, 2021

Distribution: Policy and Operations Manual
Agency Website

Referenced Forms	Title	Location
DOC 140147A	“Referral for Gender Associated Requests”	Attached
DOC 030120A	“Inmate Property Inventory Form”	OP-030120
DOC 140117A	“Request for Health Services”	OP-140117

Attachments	Title	Location
Attachment A	“Male to Female (MtF) Hormone Therapy Risk and Information Form”	Attached
Attachment B	“Female to Male (FtM) Hormone Therapy Risk and Information Form”	Attached
Attachment C	“Request for Gender Dysphoria (GD) Evaluation/Treatment” Algorithm	Attached

SUBJECT: MENTAL HEALTH TREATMENT OF INMATES WITH GENDER DYSPHORIA

EFFECTIVE DATE: 09/30/2024

I. PURPOSE:

To establish professional guidelines for the mental health evaluation and treatment of inmates meeting the diagnostic criteria [1] for Gender Dysphoria.[2]

II. POLICY:

To ensure inmates diagnosed with Gender Dysphoria receive timely, appropriate mental health services and individualized treatment programming as clinically indicated. Treatment interventions shall target psychological distress/dysphoria, as well as any co- occurring mental health disorders, and be tailored to the unique needs of the inmate.

III. DEFINITIONS:

A. Clinical Group Psychotherapy: a cognitive behavioral or psychodynamic process by which a group of persons is led by a psychologist or behavioral health specialist to guide interpersonal and intrapersonal growth through an examination of the persons' thoughts, feelings, experiences, and skiJls.

B. Gender Dysphoria: a psychological disorder caused by clinically significant distress or impairment due to the perceived discrepancy between a person's expressed/experienced gender identity and his or her biological sex.

C. Gender Identity: a person's internal sense of being *male* or female.

D. Individual Psychotherapy: a collaborative treatment based on the therapeutic relationship between the patient and Mental Health Clinician, including, but not limited to, cognitive behavioral, dialectical behavioral, psychodynamic, and interpersonal modalities.

E. Multidisciplinary Services Team (MDST): a group of staff representing different professions or disciplines, which has the responsibility for ensuring access to necessary assessment, treatment, continuity of care, and services to inmates in accordance with their identified mental health needs, and which collaboratively

[1] As defined by the *Diagnostic and Statistical Manual of Mental Disorders* - 5'h Edition, Text Revision (DSM-5-TR; American Psychiatric Association, 2022), https://doi.orl!/10.11 76/appi.books.9780890425787.

[2] *Id.* at 511-520.

develops, implements, reviews, and revises the DC4-643A, *Individualized Service Plan* (ISP) as needed.

F. **Psychoeducational Group Intervention:** a didactic form of group therapeutic services designed to teach patients about their disorder and help them learn how to manage the related symptoms, behaviors, and consequences. These services may include workbook or homework activities, medication management, stress/anger management, prosocial skills training, coping skills exercises, and managing activities of daily living in a carceral setting.

IV. TARGET POPULATION AND GOALS FOR GENDER DYSPHORIA CARE:

A. **Mental health** staff will offer assessment, consultation, and treatment services to inmates with Gender Dysphoria to facilitate their ability to function adequately in a prison environment. The inmate will be made aware of the limitations and potential risks associated with treatment for Gender Dysphoria in a carceral setting. Therapy will focus on alleviating the distress associated with Gender Dysphoria. Mental health professionals will inform inmates suffering from Gender Dysphoria that no psychotherapeutic, medical, or surgical therapy can permanently eradicate all psychological and physical vestiges of one's biological sex.[3] Mental health care will be provided in the context of a collaborative therapeutic relationship with the inmate.

B. **Crisis intervention** services are offered to inmates who may be experiencing acute distress or acute symptoms of mental illness to prevent suicide and self-injury (in accordance with Procedure 404.001, *Suicide and Self-Injury Prevention)* or to provide relief from symptoms of mental illness and prevent further decompensation.

C. **Assessment and consultation** services are provided in response to referrals by staff, inmate requests, or situational factors (such as the placement of the inmate in special housing). In providing these services, mental health staff should assess an inmate's mental health needs and provide guidance or recommendations regarding treatment or precautions.

D. **Ongoing mental health care** will be provided on an outpatient basis to alleviate symptoms of mental illness that result in the impairment of an inmate's ability to adapt and function in the prison environment. A DC4-643A, *Individualized Service Plan* (ISP) must be developed in accordance with HSB 15.05.11, *Planning and*

[3] *Standards of Care for Gender Identity Disorders* 12 (6th ed. 2001).

Implementation of Individualized Mental Health Services, for those inmates participating in ongoing mental health care.

V. SCREENING:

A. The mental health clinician will complete a clinical interview within 14 days of an inmate's arrival to the reception center or transfer institution and will document the interview on the DC4-642B, *Mental Health Screening Evaluation.*

B. If an inmate presents with a reported or documented history of Gender Dysphoria prior to incarceration, the inmate will complete a DC4-711B, *Consent and Authorization for Use and Disclosure, Inspection, and Release of Corifi.dential Information* to authorize the Department to obtain the inmate's prior mental health records from community providers who diagnosed or treated the inmate.

C. As appropriate, a diagnosis of Gender Dysphoria will be made by a psychologist with the consensus of the MDST. The diagnosis and Problem #124, Gender Dysphoria, wi11 be added to the ISP. At a minimum, the inmate wiU be classified and maintained as an S-3.

D. Ifreferral to medical or psychiatric staff is needed, mental health staff will complete the DC4-529, *Staff Request/Referral,* and route it to the appropriate medical staff member within the electronic medical record (EMR).

VI. EVALUATION:

A. A diagnosis of Gender Dysphoria can encompass a diverse array of conditions, with widely differing pathways and characteristics depending on the patient's age of onset, mental health, intelligence, environment, and motivation for identifyi11g as the opposite sex. Like many DSM-V psychiatric conditions, Gender Dysphoria is complex and often accompanied by other psychiatric comorbidities.[4]

B. All inmates diagnosed with gender dysphoria will be individually evaluated. A complete psychodiagnostic and psychiatric assessment should be performed. Al]

[4] In the scientific research literature, there has been a gradual shift from definitive "gender-affinnative care," which prioritizes access to medical interventions, to a more conservative approach that addresses psychiatric comorbidities and psychotherapeutically explores the developmental etiology oftbe gender dysphoria. *See* Levine, S.B., Abbruzzese, E. Current Concerns About Gender-Affirming Therapy in Adolescents. *Curr Se:x Health Rep* 15, 1 I 3-123 (2023). *See also Standards of Care: The Honnona/ and Surgical Sex Reassignment of Gender Dysphoric Persons* (4th ed. 1990).

medical and psychiatric comorbidities must be identified as these comorbidities can complicate the treatment of Gender Dysphoria.[5]

C. The following complement of assessment instruments (with any additional instruments if they become available in the future) should be used as applicable to evaluate the inmate:

1. Clinical interview
2. *Sex Offender Screening and Selection* as per HSB 15.05.03
3. Adaptive Behavioral Checklist (ABC)
4. Wechsler Adult Intelligence Scale Revised (WAIS-R)
5. Montreal Cognitive Assessment (MoCA)
6. Millon Clinical Multiaxial Inventory-ill (MCMI-III)
7. Columbia Suicide Severity-Rating Scale Lifetime Recent (C-SSRS)
8. Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5)
9. Miller Forensic Assessment of Symptoms Test (M-FAST)
   - If the inmate's score is high enough, then further evaluation for malingering or response style may be warranted *(e.g.,* Structured Interview of Reported Symptoms-2nd edition [SIRS-2]; Minnesota Multiphasic Personality Inventory-2 [MMPI-2])
10. If diagnosed with an Autism Spectrum Disorder (ASD), the inmate may be additionally assessed with the Adaptive Behavior Assessment System 3rd edition (ABAS-3)
    - If the inmate's ASD diagnosis qualifies for an SY-D designator, then refer to 15.05.17, *Intake Mental Health Screening at Reception Centers*
11. If the inmate is diagnosed with Self Injury Behavior (SIB), he or she will be tracked using the Self-Injury Prevention System (SIPS)
12. The evaluation and testing results will be documented on the DC4-643E, *Psychological Evaluation for Gender Dysphoria*

VII. TREATMENT:

A. If treatment for Gender Dysphoria is likely to be necessary based on the results of the foregoing evaluation, the following treatment protocol should be followed:

1. All identified medical and psychiatric comorbidities must first be addressed. As appropriate, psychiatric comorbidities should be addressed through psychotherapy, psychotropic medication, or other appropriate medically

[5] Experts have opined that unaddressed psychiatric issues and unaddressed childhood trauma could lead to misdiagnosis of gender dysphoria. *See* Littman, L., Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned; A Survey of 100 Detransitioners, Arch Sex Behav, 50, 3353- 3369, 3364 (2021).

accepted interventions.[6] Once these medical and psychiatric comorbidities are resolved and ruled out as the potential cause of the Gender Dysphoria, further treatment for Gender Dysphoria may proceed.

2. Psychotherapy should be prioritized. Treatment should include, at a minimum, individual or group clinical psychotherapy weekly and case management at least every 60 days or more frequently as clinically indicated. Additionally, other treatments, such as psychoeducational group interventions, may be added as clinically indicated. Treatment interventions will focus on managing the psychological distress/dysphoria, assisting with adjustment to incarceration, community re-entry, and strengthening resilience. Follow-up mental health care should target any associated emotional or behavioral problems and should emphasize supportive treatment modalities.

3. Psychotropic medication should be considered to determine if its use may alleviate the symptoms of Gender Dysphoria.

4. Diagnosis and treatment of Gender Dysphoria will be discontinued if the MDST decides that the inmate no longer meets the criteria for the diagnosis based on clinical outcomes. The ISP will be updated to reflect discontinuation of diagnosis, and Problem #124 will be removed from the ISP and EMR.

5. The inmate must actively participate in psychotherapy for at least one year to ameliorate the symptoms of Gender Dysphoria, to acclimate the inmate to the prison environment, and to develop an understanding of the limitations of the prison environment. An established pattern of attendance and participation in mental health treatment for at least one year is required prior to the consideration of any variances.

VIII. DOCUMENTATION:

A. All progress notes concerning outpatient mental health care shall be made on the pertinent DC4-642 series form in the EMR in accordance with 15.05.18, *Outpatient Mental Health Services.* All documentation must be completed in its entirety, signed, and dated by the clinician.

B. Each individual clinical encounter must be documented in SOAP (Subjective, Objective, Assessment, and Plan) format in the EMR on a DC4-642 series form on the date of the encounter.

[6] *See Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria,* Agency for Healthcare Administration (June 2022).

C. Group psychotherapy contacts shall be documented with an incidental note on DC4-642U, *Clinical Group Therapy Note,* at least monthly and upon group enrollment and termination. The monthly group psychotherapy note shall include the proportion of scheduled sessions attended, the inmate's relative level of participation, and the inmate's observed progress toward treatment goals as referenced by ISP problem number.

D. Relevant statutes, rules, and procedures:

1. Section 456.52, Florida Statutes (2023)
2. Emergency Rules 64B8ER23-1 land 64B15ER23-12, Florida Administrative Code
3. DC4-529 Staff Request/Referral
4. DC4-642B, Mental Health Screening Evaluation
5. DC4-642U, Clinical Group Therapy Note
6. DC4-643A, Individualized Service Plan
7. DC4-643E Psychological Evaluation for Gender Dysphoria
8. DC4-647 Sex Offender Screening and Selection
9. DC4-711B Consent and Authorization for Use and Disclosure, Inspection, and Release of Confidential Information
10. HSB 15.05.11. Planning and Implementation of Individualized Mental Health Services
11. HSB 15.05.17, Intake Mental Health Screening at Reception Centers
12. HSB 15.05.18, Outpatient Mental Health Services
13. Procedure 404.001, Suicide and Self-Injury Prevention
14. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
15. Department of Health Forms DH5082, Feminizing Medications for Patients with Gender Dysphoria and DH5083, Masculinizing Medications for Patients with Gender Dysphoria

IX. VARIANCES:

A. The use of cross-sex hormones as a treatment for gender dysphoria is extensive in its effects, is invasive to the integrity of the human body, has effects and consequences which are not readily known or reversible, and may be requested by persons experiencing short-termed delusions or beliefs which may later be changed and reversed. Published and unpublished case histories indicate that, in some situations, the decision to undergo hormone therapy was, after the fact, regretted and the final result of such therapy proved to be psychologically and physically debilitating to the patients.[7] The use of cross-sex hormones may result in infertility,

[7] *See Standards of Care: The Hormonal and Surgical Sex Reassignment of Gender Dysphoric Persons§§* 4.1.1, 4.1.2, 4.1.3, 4.1.4 (4th ed. 1990).

neurological issues, cardiovascular disease, disfigurement, and other permanent effects.[8] Studies presenting the benefits to mental health, including those claiming that the services prevent suicide, are either low or very low quality and rely on unreliable methods.[9]

B. State law prohibits the Department from expending any state funds to purchase cross-sex hormones for the treatment of Gender Dysphoria. Section 286.311, Florida Statutes. The Department shall comply with this statutory requirement unless compliance with the U.S. Constitution or a court decision requires otherwise.

C. In rare instances deemed medically necessary, a variance may be approved to permit the use of cross-sex hormones to treat an inmate's Gender Dysphoria. Variances must be unanimously approved after review by a team consisting of the Chief of Medical Services, the Chief of Mental Health Services, and the Chief Clinical Advisor, and shall only be sought (1) after satisfying all preceding provisions of this policy and (2) if necessary to comply with the U.S. Constitution or a court decision.

1. Variances should only be considered after completion of the treatment protocol in Section VII. An inmate may be assessed for cross-sex hormone therapy if the treating physician can demonstrate with documented evidence that such treatment may improve clinical outcomes by treating the etiological basis of the pathology. Such evidence must be based on sound scientific methods and research that were subject to the formal peer review process. Any recommendation for cross-sex hormone therapy must be supported by a consensus of the MDST. The need for continued cross-sex hormone therapy will be re-evaluated every 90 days during the first year of use and every 180 days thereafter, or as determined by the MDST. This will be documented in the ISP.

2. Prior to initiating cross-sex hormone therapy treatment, the physician providing the prescription must fully inform the inmate of the nature of the proposed prescription, the benefits and risks of the prescription, including the potential irreversible effects of such treatment (infertility, hair growth, voice deepening, clitoral enlargement in the female-to-male inmate, and infertility and breast growth in the male-to-female inmate),[10] the possible and likely consequences

[8] *See Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria,* Agency for Healthcare Administration (June 2022).

[9] *See id.*

[10] *Standards of Care: The Hormonal and Surgical Sex Reassignment of Gender Dysphoric Persons§* 4.4.2 (4th ed. 1990).

of cross-sex hormone therapy in the prison environment, and the potential alternative treatments.

3. Before cross-sex hormone therapy commences, the inmate must sign the informed consent form adopted by the Board of Medicine and the Board of Osteopathic Medicine (Forms DH5082 and DH 5083). Consent must be voluntary, and the inmate must be able to understand and appreciate the risks and potential side effects of the pr□scription, the long-term consequences and complications of cross-sex hormone intervention, and the alternative treatment options available. If the required documented evidence is insufficient, or if the inmate fails to sign the consent form, the clinician shall not prescribe hormones for the inmate's Gender Dysphoria.

D. Every inmate who receives cross-sex hormones specifically for Gender Dysphoria will be evaluated by the MOST to determine if the diagnosis is still warranted. For those inmates whose diagnosis is no longer warranted, titration and discontinuation of cross-sex hormone therapy should be initiated over a period of nine weeks. During and following the titration process, the inmate should continue to receive ongoing mental health services and work collaboratively with his or her treatment team in customizing a mental health service plan that best meets the inmate's needs *(e.g.,* individual psychotherapy, group counseling, psychiatric services, psychotropic medications, *etc.).*



Health Services Director

U.S. Department of Justice
Federal Bureau of Prisons

CHANGE NOTICE
OPI RSD/PSB
NUMBER 5324.12, CN-1
DATE February 18, 2025

Sexually Abusive Behavior Prevention and Intervention Program

/s/
Approved: William W. Lothrop
Acting Director, Federal Bureau of Prisons

This Change Notice (CN) implements the following changes to Program Statement 5324.12, **Sexually Abusive Behavior Prevention and Intervention Program**, dated June 4, 2015, to remove references to any concept that may conflict with the January 20, 2025, Executive Order *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*. The additions are marked with a highlight and inserted into the policy. The deletions are marked with a ~~strikethrough~~.

1. PURPOSE AND SCOPE

a. **Summary of Changes**

- Provides reference to policy concerning ~~cross-gender~~ opposite sex pat searches of female inmates.

§ 115.6 Definitions related to sexual abuse.

The Bureau also has zero tolerance for sexual harassment of staff by inmates. Sexual harassment includes actions such as:

(2) Verbal comments or gestures of a sexual nature by an inmate, detainee, or resident to a staff member, contractor, or volunteer, including demeaning references to ~~gender~~ one's sex, sexually suggestive or derogatory comments about body or clothing, or obscene language or gestures.

PREVENTION PLANNING

§ 115.15 Limits to cross-gender viewing and searches.

(b) As of August 20, 2015, or August 21, 2017 for a facility whose rated capacity does not exceed 50 inmates, the facility shall not permit cross-gender pat-down searches of female inmates, absent exigent circumstances. Facilities shall not restrict female inmates' access to regularly available programming or other out-of-cell opportunities in order to comply with this provision.

See the Program Statement **Searches of Housing Units, Inmates, and Inmate Work Areas**, or current version of this policy.

Post assignments may not be restricted on the basis of ~~gender~~ employee's sex. Institutions will evaluate operational concerns consistent with collective bargaining obligations, the Master Agreement, and other laws, rules, and regulations. The agency will continue to comply with Title VII and other Equal Employment Opportunity Commission authorities in implementing this policy.

(c) The facility shall document all cross-gender strip searches and cross-gender visual body cavity searches, and shall document all cross-gender pat-down searches of female inmates.

(**Note.** This provision's requirement to document ~~cross-gender~~ opposite sex pat-down searches of female inmates is **not** implemented by this policy.)

(d) The facility shall implement policies and procedures that enable inmates to shower, perform bodily functions, and change clothing without nonmedical staff of the opposite gender viewing their breasts, buttocks, or genitalia, except in exigent circumstances or when such viewing is incidental to routine cell checks. Such policies and procedures shall require staff of the opposite gender to announce their presence when entering an inmate housing unit.

Changed "gender" to "sex" throughout this section.

(f) The agency shall train security staff in how to conduct cross-gender pat-down searches, and searches of transgender and intersex inmates, in a professional and respectful manner, and in the least intrusive manner possible, consistent with security needs.

The Correctional Services Branch updates and maintains training materials on conducting pat-down searches of ~~transgender and intersex~~ all inmates.

TRAINING AND EDUCATION

§ 115.31 Employee training.

(b) Such training shall be tailored to the gender of the inmates at the employee's facility. The employee shall receive additional training if the employee is reassigned from a facility that houses only male inmates to a facility that houses only female inmates, or vice versa.

Annual refresher training takes the ~~gender~~ sex of the inmate population at each facility into account. Transferring staff members receive training on inmate sexual safety based on the mission(s) of the institution they work.

SCREENING FOR RISK OF SEXUAL VICTIMIZATION AND ABUSIVENESS

§ 115.41 Screening for risk of victimization and abusiveness.

(g) An inmate's risk level shall be reassessed when warranted due to a referral, request, incident of sexual abuse, or receipt of additional information that bears on the inmate's risk of sexual victimization or abusiveness.

Psychology Services staff reassess the inmate's risk level whenever warranted based upon receipt of additional relevant information (e.g., incident of sexual abuse, protective custody request, ~~recent diagnosis of gender dysphoria,~~ new presentation of any risk factors listed in section (d) above, recent intervention for allegation of sexual abuse or harassment, etc.).

(h) Inmates may not be disciplined for refusing to answer, or for not disclosing complete information in response to, questions asked pursuant to paragraphs (d)(1), (d)(7), (d)(8), or (d)(9) of this section.

~~If an inmate refuses to respond or elects not to disclose information that applies only to questions about disabilities; Gay, Lesbian, Bisexual, Transgender, Intersex (GLBTI) status; gender nonconformance; previous sexual victimization; and the inmate's self-perception of vulnerability, he/she may not be disciplined.~~

Attachment A. PREA Intake Objective Screening Instrument

RISK OF VICTIMIZATION
Objective Criteria

Inmate is or may be perceived to be gay, lesbian, bisexual, transgender, intersex, or ~~gender nonconforming~~ any other status listed in 28 CFR § 115.41 based on documentation received (e.g., PSR), or correctional judgment would indicate the inmate would have issues being placed in general population.

U.S. Department of Justice
Federal Bureau of Prisons

P R O G R A M S T A T E M E N T
OPI: RSD/PSY
NUMBER: 5324.12
DATE: June 4, 2015

Sexually Abusive Behavior Prevention and Intervention Program

/s/
Approved: Charles E. Samuels, Jr.
Director, Federal Bureau of Prisons

1. PURPOSE AND SCOPE

To provide a written policy that implements zero tolerance toward all forms of sexual activity, including sexual abuse and sexual harassment, and to provide guidelines to address the following prohibited and/or illegal sexually abusive behavior involving:

- Inmate perpetrator against staff victim.
- Inmate perpetrator against inmate victim.
- Staff perpetrator against inmate victim.

This policy also covers incidents involving contractors and volunteers.

These guidelines are provided to

- Help **detect** incidents, perpetrators, and inmate victims of sexually abusive behavior.
- Help **prevent** sexually abusive behavior.
- Educate staff to **intervene** properly and in a timely manner.
- **Document, report,** and **investigate** reported incidents.
- **Discipline** and/or prosecute perpetrators.

Note. The protection and safety of staff who are sexually victimized is a top priority. It is addressed in sections 115.6 and 115.22 of this Program Statement.

Federal Regulations from 28 CFR are shown in this type.
Implementing instructions are shown in this type.

In the Prison Rape Elimination Act (PREA) of 2003, Congress required the Attorney General to promulgate regulations concerning sexual abuse prevention. The statute further required that the regulations would be binding upon the Federal Bureau of Prisons. See 42 U.S.C. §15607. The **bold, blue** type in this Program Statement is the regulations issued to the Bureau of Prisons, which were not subject to bargaining.

National and Regional PREA Coordinators, and Institution PREA Compliance Managers, will comply with collective bargaining agreements in implementing changes or programs.

a. **Summary of Changes**

Policy Rescinded
P5324.11 Sexually Abusive Behavior Prevention and Intervention Program (01/06/14)

- Updates ACA provisions.
- Provides further information on PREA statute and regulations.
- Provides further information on resources available to staff victims.
- Provides reference to policy concerning ~~cross gender~~ opposite sex pat searches of female inmates.
- Clarifies authorities concerning post assignments in implementing this policy.
- Updates the language of the public address announcement to be used at shift change.
- Provides additional guidance concerning the separation of an inmate alleging to be victims and alleged perpetrator.
- Provides references to Posted Picture File policy.
- Clarifies responsibilies of Psychology and Health Services staff policies.
- Provides additional guidance concerning the reassignment of staff if necessary to protect victim.
- Provides information for safeguarding staff victims of inmate abuse/harassment.
- Provides guidance to Institution PREA Compliance Managers on tracking and distributing Reports of Incident.
- Corrects a typographical error in section 115.67
- Clarifies data collection resposnsibilities of the Office of Internal Affairs.
- Clarifies procedures for filing appeals of audit findings to the Department of Justice.

b. **Program Objectives.** The intent of this Program Statement is to ensure that:

- Staff and inmates are informed of the Bureau's zero-tolerance philosophy in regards to sexually abusive behavior.
- Standard procedures are in place to detect and prevent sexually abusive behavior at all Bureau and contract facilities.
- Victims of sexually abusive behavior receive prompt and effective response to their physical, psychological, and security needs.
- Allegations of sexually abusive behavior receive prompt intervention upon report.
- The perpetrators of sexually abusive behavior will be disciplined and, when appropriate, prosecuted in accordance with Bureau policy and Federal law.

2. INSTITUTION SUPPLEMENT

Each institution is required to have a current Institution Supplement, using negotiated procedures at the local level, which reflects that institution's unique characteristics and specifies how each institution will comply with this Program Statement, including the following:

Specification of Staff Member(s) responsible for:

- Staff training activities to ensure a coordinated response to a report of sexually abusive behavior.
- Inmate education regarding issues pertaining to sexually abusive behavior.

Notification Procedures to be followed when sexually abusive behavior occurs (including notification of appropriate law enforcement agencies).

Responding to the Inmate Victim:

- Providing security to any inmate who alleges that he/she is the victim of sexually abusive behavior and, where appropriate, to inmates who are reported by others to be the victims of sexually abusive behavior.
- Identifying entities (e.g., institution Health Services or community health services) responsible for providing medical assessment (e.g., forensic examination) and treatment of the victim of a sexual assault.

Monitoring the Inmate Perpetrator:

- Monitoring or managing the perpetrator in a way that minimizes the risk of future predation.
- Describing the system in place to ensure that the Chief of Correctional Services is notified of inmates with a serious sexual predation history or who are "at risk" of engaging in sexually abusive behavior while in BOP custody.

3. AGENCY ACA ACCREDITATION PROVISIONS

(See Program Statement **Directives Management Manual**, Sections 2.5 and 10.3.)

- American Correctional Association Standards for Adult Correctional Institutions, 4th Edition: 4-4056, 4-4133, 4-4277, 4-4365, 4-4371, 4-4406M.
- American Correctional Association Performance Based Standards for Adult Local Detention Facilities, 4th Edition: 4-ALDF-2A-29, 4-ALDF-4D-22-5, 4-ALDF-4D-22-6M, 4-ALDF-4D-22-7, 4-ALDF-4D-22-8, 4-ALDF-7B-10.
- American Correctional Association Standards for Administration of Correctional Agencies, 2nd Edition: 2-CO-1C-18.

REFERENCES

Program Statements

P1210.24	Office of Internal Affairs (5/20/03)
P1330.18	Administrative Remedy Program (12/31/13)
P1350.01	Criminal Matter Referrals (1/11/96)
P1351.05	Release of Information (9/19/02)
P3000.03	Human Resource Management Manual (12/19/07)
P3420.11	Standards of Employee Conduct (12/6/13)
P3906.22	Employee Development Manual (4/30/15)
P5141.02	Sex Offender Notification and Registration (12/14/98)
P5180.05	Central Inmate Monitoring System (12/31/07)
P5270.09	Inmate Discipline Program (7/08/11)
P5270.10	Special Housing Units (7/29/11)
P5290.15	Intake Screening (3/30/09)
P5310.12	Psychology Services Manual (3/7/95)
P5500.11	Correctional Services Manual (3/31/15)
P5500.14	Correctional Services Procedures Manual (10/19/12)
P5510.13	Posted Picture File (8/22/11)
P5510.14	Crime Scene Management and Evidence Control (8/22/11)
P5521.06	Searches of Housing Units, Inmates, and Inmate Work Areas (6/4/15)
P5538.05	Escorted Trips (10/6/08)
P6031.03	Patient Care (8/23/12)

28 CFR Part 115, National Standards To Prevent, Detect, and Respond to Prison Rape; Final Rule, dated June 20, 2012, located at http://www.gpo.gov/fdsys/pkg/FR-2012-06-20/pdf/2012-12427.pdf.

Prison Rape Elimination Act of 2003 (Public Law 108-79; September 4, 2003)

U.S. Department of Justice, Office of Violence Against Women, A National Protocol for Sexual Assault Medical Forensic Examinations, Adults/Adolescents, September 2004, located at http://www.ncjrs.gov/pdffiles1/ovw/206554.pdf.

BOP Forms

BP-A0583	Report of Incident
BP-A1002	Safeguarding of Inmates Alleging Sexual Abuse/Assault Allegation

Records Retention Requirements

Requirements and retention guidance for records and information applicable to this program are available in the Records and Information Disposition Schedule (RIDS) on Sallyport.

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§ 115.5 General definitions.

For purposes of this part, the term—

***Agency* means the unit of a State, local, corporate, or nonprofit authority, or of the Department of Justice, with direct responsibility for the operation of any facility that confines inmates, detainees, or residents, including the implementation of policy as set by the governing, corporate, or nonprofit authority.**

As a component of the Department of Justice, all requirements of "agencies" under these regulations apply to the Federal Bureau of Prisons (Bureau).

***Agency head* means the principal official of an agency.**

The Director of the Bureau is the "agency head" under these regulations.

***Community confinement facility* means a community treatment center, halfway house, restitution center, mental health facility, alcohol or drug rehabilitation center, or other community correctional facility (including residential re-entry centers), other than a juvenile facility, in which individuals reside as part of a term of imprisonment or as a condition of pretrial release or post-release supervision, while participating in gainful employment, employment search efforts, community service, vocational training, treatment, educational programs, or similar facility-approved programs during nonresidential hours.**

***Contractor* means a person who provides services on a recurring basis pursuant to a contractual agreement with the agency.**

***Detainee* means any person detained in a lockup, regardless of adjudication status.**

***Direct staff supervision* means that security staff are in the same room with, and within reasonable hearing distance of, the resident or inmate.**

***Employee* means a person who works directly for the agency or facility.**

***Exigent circumstances* mean any set of temporary and unforeseen circumstances that require immediate action in order to combat a threat to the security or institutional order of a facility.**

***Facility* means a place, institution, building (or part thereof), set of buildings, structure, or area (whether or not enclosing a building or set of buildings) that is used by an agency for the confinement of individuals.**

As a component of the Department of Justice, all requirements of a "facility" under these regulations apply to Bureau institutions.

Facility head **means the principal official of a facility.**

A Warden or CEO is a "facility head" under these regulations.

Full compliance **means compliance with all material requirements of each standard except for *de minimis* violations, or discrete and temporary violations during otherwise sustained periods of compliance.**

Gender nonconforming **means a person whose appearance or manner does not conform to traditional societal gender expectations.**

Inmate **means any person incarcerated or detained in a prison or jail.**

Intersex **means a person whose sexual or reproductive anatomy or chromosomal pattern does not seem to fit typical definitions of male or female. Intersex medical conditions are sometimes referred to as disorders of sex development.**

Jail **means a confinement facility of a Federal, State, or local law enforcement agency whose primary use is to hold persons pending adjudication of criminal charges, persons committed to confinement after adjudication of criminal charges for sentences of one year or less, or persons adjudicated guilty who are awaiting transfer to a correctional facility.**

Juvenile **means any person under the age of 18, unless under adult court supervision and confined or detained in a prison or jail.**

Juvenile facility **means a facility primarily used for the confinement of juveniles pursuant to the juvenile justice system or criminal justice system.**

Law enforcement staff **means employees responsible for the supervision and control of detainees in lockups.**

Lockup **means a facility that contains holding cells, cell blocks, or other secure enclosures that are: (1) Under the control of a law enforcement, court, or custodial officer; and (2) Primarily used for the temporary confinement of individuals who have recently been arrested, detained, or are being transferred to or from a court, jail, prison, or other agency.**

Medical practitioner **means a health professional who, by virtue of education, credentials, and experience, is permitted by law to evaluate and care for patients within the scope of his or her professional practice. A "qualified medical practitioner" refers to such a professional who has also successfully completed specialized training for treating sexual abuse victims.**

Mental health practitioner **means a mental health professional who, by virtue of education, credentials, and experience, is permitted by law to evaluate and care for patients within the scope of his or her professional practice. A "qualified mental health practitioner" refers to such a professional who has also successfully completed specialized training for treating sexual abuse victims.**

Mental health professionals with graduate degrees in clinical or counseling psychology or clinical social work are considered to be qualified mental health practitioners based on specific course work required for the completion of their degree.

Pat-down search **means a running of the hands over the clothed body of an inmate, detainee, or resident by an employee to determine whether the individual possesses contraband.**

Prison **means an institution under Federal or State jurisdiction whose primary use is for the confinement of individuals convicted of a serious crime, usually in excess of one year in length, or a felony.**

Resident **means any person confined or detained in a juvenile facility or in a community confinement facility.**

Secure juvenile facility **means a juvenile facility in which the movements and activities of individual residents may be restricted or subject to control through the use of physical barriers or intensive staff supervision. A facility that allows residents access to the community to achieve treatment or correctional objectives, such as through educational or employment programs, typically will not be considered to be a secure juvenile facility.**

Security staff **means employees primarily responsible for the supervision and control of inmates, detainees, or residents in housing units, recreational areas, dining areas, and other program areas of the facility.**

In the Bureau, all institution staff are considered to be "security staff."

Staff **means employees.**

Strip search **means a search that requires a person to remove or arrange some or all clothing so as to permit a visual inspection of the person's breasts, buttocks, or genitalia.**

Substantiated allegation **means an allegation that was investigated and determined to have occurred.**

In the Bureau, this may also be referred to as a "sustained" allegation.

Transgender **means a person whose gender identity (*i.e.,* internal sense of feeling male or female) is different from the person's assigned sex at birth.**

Unfounded allegation **means an allegation that was investigated and determined not to have occurred.**

Unsubstantiated allegation **means an allegation that was investigated and the investigation produced insufficient evidence to make a final determination as to whether or not the event occurred.**

In the Bureau, this may also be referred to as a "not sustained" allegation.

Volunteer **means an individual who donates time and effort on a recurring basis to enhance the activities and programs of the agency.**

Youthful inmate **means any person under the age of 18 who is under adult court supervision and incarcerated or detained in a prison or jail.**

Youthful detainee **means any person under the age of 18 who is under adult court supervision and detained in a lockup.**

§ 115.6 Definitions related to sexual abuse.

For purposes of this part, the term—

Sexual abuse **includes—**

(1) Sexual abuse of an inmate, detainee, or resident by another inmate, detainee, or resident; and

(2) Sexual abuse of an inmate, detainee, or resident by a staff member, contractor, or volunteer.

Sexual abuse of an inmate, detainee, or resident by another inmate, detainee, or resident **includes any of the following acts, if the victim does not consent, is coerced into such act by overt or implied threats of violence, or is unable to consent or refuse:**

(1) Contact between the penis and the vulva or the penis and the anus, including penetration, however slight;

(2) Contact between the mouth and the penis, vulva, or anus;

(3) Penetration of the anal or genital opening of another person, however slight, by a hand, finger, object, or other instrument; and

(4) Any other intentional touching, either directly or through the clothing, of the genitalia, anus, groin, breast, inner thigh, or the buttocks of another person, excluding contact incidental to a physical altercation.

Sexual abuse of an inmate, detainee, or resident by a staff member, contractor, or volunteer **includes any of the following acts, with or without consent of the inmate, detainee, or resident:**

(1) Contact between the penis and the vulva or the penis and the anus, including penetration, however slight;

(2) Contact between the mouth and the penis, vulva, or anus;

(3) Contact between the mouth and any body part where the staff member, contractor, or volunteer has the intent to abuse, arouse, or gratify sexual desire;

(4) Penetration of the anal or genital opening, however slight, by a hand, finger, object, or other instrument, that is unrelated to official duties or where the staff member, contractor, or volunteer has the intent to abuse, arouse, or gratify sexual desire;

(5) Any other intentional contact, either directly or through the clothing, of or with the genitalia, anus, groin, breast, inner thigh, or the buttocks, that is unrelated to official duties or where the staff member, contractor, or volunteer has the intent to abuse, arouse, or gratify sexual desire;

(6) Any attempt, threat, or request by a staff member, contractor, or volunteer to engage in the activities described in paragraphs (1) through (5) of this definition;

(7) Any display by a staff member, contractor, or volunteer of his or her uncovered genitalia, buttocks, or breast in the presence of an inmate, detainee, or resident, and

(8) Voyeurism by a staff member, contractor, or volunteer.

Sexual harassment **includes—**

(1) Repeated and unwelcome sexual advances, requests for sexual favors, or verbal comments, gestures, or actions of a derogatory or offensive sexual nature by one inmate, detainee, or resident directed toward another; and

(2) Repeated verbal comments or gestures of a sexual nature to an inmate, detainee, or resident by a staff member, contractor, or volunteer, including

demeaning references to gender, sexually suggestive or derogatory comments about body or clothing, or obscene language or gestures.

Voyeurism by a staff member, contractor, or volunteer **means an invasion of privacy of an inmate, detainee, or resident by staff for reasons unrelated to official duties, such as peering at an inmate who is using a toilet in his or her cell to perform bodily functions; requiring an inmate to expose his or her buttocks, genitals, or breasts; or taking images of all or part of an inmate's naked body or of an inmate performing bodily functions.**

"Official duties," as referenced above, include, but are not limited to, position descriptions, Institution Supplements, post orders, and other duties as assigned, to ensure the safe and orderly running of the institution. An example includes monitoring inmates to prevent and deter the movement of contraband.

The Bureau recognizes that addressing inappropriate sexual behavior by inmates towards staff furthers the objectives of PREA by increasing the overall security and safety of institutions. The Bureau also has zero tolerance for sexual abuse of a staff member by an inmate, detainee, or resident. Sexual abuse of staff by an inmate, detainee, or resident includes actions such as:

(1) Contact between the penis and vulva or penis and the anus, including penetration, however slight.

(2) Contact between the mouth and penis, vulva, or anus.

(3) Penetration of the anal or genital opening of another person, however slight, by a hand, finger, object, or other instrument.

(4) Any other intentional touching, either directly or through the clothing, of the genitalia, anus, groin, breast, inner thigh, or buttocks, excluding contact incidental to a physical altercation.

(5) Any attempt, threat, or request by an inmate to engage in activities described in paragraphs (1) through (4), above.

(6) Any display by an inmate of his/her uncovered genitalia, buttocks, or breast to a staff member, outside of the staff member's official duties (e.g., searches), with the inmate's intent to harass staff or for sexual gratification.

The Bureau also has zero tolerance for sexual harassment of staff by inmates. Sexual harassment includes actions such as:

(1) Unwelcome sexual advances, requests for sexual favors, or verbal comments, gestures, or actions of a derogatory or offensive sexual nature by an inmate, detainee, or resident directed toward a staff member.

(2) Verbal comments or gestures of a sexual nature by an inmate, detainee, or resident to a staff member, contractor, or volunteer, including demeaning references to ~~gender~~ one's sex, sexually suggestive or derogatory comments about body or clothing, or obscene language or gestures.

Sexual abuse and sexual harassment of staff members should be addressed through other existing statutes, policies, and procedures, such as using the inmate discipline system and referral for criminal prosecutions as appropriate. In addition, staff members will be informed of available resources for assistance as appropriate, to include the Employee Assistance Program, and for bargaining unit employees to the local Union.

PREVENTION PLANNING

§ 115.11 Zero tolerance of sexual abuse and sexual harassment; PREA coordinator.

(a) An agency shall have a written policy mandating zero tolerance toward all forms of sexual abuse and sexual harassment and outlining the agency's approach to preventing, detecting, and responding to such conduct.

The intent of this policy is to ensure that:

- Staff and inmates are informed that this policy implements the Bureau's "zero tolerance" of sexually abusive behavior, and sexual harassment, as defined in this policy;
- Standard procedures are in place to detect and prevent sexually abusive behavior and sexual harassment at all Bureau facilities;
- Victims of sexually abusive behavior and sexual harassment receive timely and effective responses to their physical, psychological, and security needs;
- Allegations of sexually abusive behavior and sexual harassment receive timely intervention upon report; and
- The perpetrators of sexually abusive behavior and sexual harassment will be disciplined and, when appropriate, prosecuted in accordance with Bureau policy and Federal law.

(b) An agency shall employ or designate an upper-level, agency-wide PREA coordinator with sufficient time and authority to develop, implement, and oversee agency efforts to comply with the PREA standards in all of its facilities.

National PREA Coordinator. The National PREA Coordinator's responsibilities include developing, implementing, and overseeing the Bureau's compliance with PREA. The National PREA Coordinator provides oversight to all Regional PREA Coordinators. The National PREA Coordinator assists the Information, Policy, and Public Affairs (IPPA) Division in providing the required information to the U.S. Department of Justice, Bureau of Justice Statistics, through their collection agent (U.S. Census Bureau), of all incidents of sexually abusive behavior. The National PREA Coordinator also coordinates with the Privatization Management and Residential Reentry Branches to ensure contract facilities are in compliance with PREA Standard § 115.11.

Regional PREA Coordinator. The Regional PREA Coordinator ensures policy guidelines are addressed in institutions within each region. Given the sensitivity required when defining and

reporting cases as substantiated, a background in investigations is preferred when selecting a Regional PREA Coordinator.

(c) Where an agency operates more than one facility, each facility shall designate a PREA compliance manager with sufficient time and authority to coordinate the facility's efforts to comply with the PREA standards.

The Warden at each institution must ensure that all aspects of this Program Statement are implemented, including maintaining a current Institution Supplement. He/she must assign an Institution PREA Compliance Manager, who except in rare circumstances will be an Associate Warden, for the overall responsibility of the program.

The Institution PREA Compliance Manager maintains responsibility for the Sexually Abusive Behavior Prevention and Intervention Program. He/she must provide supervisory oversight to ensure the coordination of institution departments in prevention, detection, intervention, and response, as specified in this Program Statement. The Warden may appoint supervisory staff as PREA points of contact in each key department (Correctional Services, Psychology Services, Health Services, etc.), in order to assist the Institution PREA Compliance Manager with the implementation of this policy.

§ 115.12 Contracting with other entities for the confinement of inmates.

(a) A public agency that contracts for the confinement of its inmates with private agencies or other entities, including other government agencies, shall include in any new contract or contract renewal the entity's obligation to adopt and comply with the PREA standards.

(b) Any new contract or contract renewal shall provide for agency contract monitoring to ensure that the contractor is complying with the PREA standards.

The Bureau must ensure its contracts with secure privatized facilities, jails, juvenile facilities, and Residential Reentry Centers include their obligation to adopt and comply with the PREA standards. Privatization Management Branch and Residential Reentry Management Branch field staff must include PREA compliance monitoring within their scheduled contract monitoring activity.

§ 115.13 Supervision and monitoring.

(a) The agency shall ensure that each facility it operates shall develop, document, and make its best efforts to comply on a regular basis with a staffing plan that provides for adequate levels of staffing, and, where applicable, video monitoring, to protect inmates against sexual abuse. In calculating adequate staffing levels and determining the need for video monitoring, facilities shall take into consideration:

(1) Generally accepted detention and correctional practices;

(2) Any judicial findings of inadequacy;

(3) Any findings of inadequacy from Federal investigative agencies;

(4) Any findings of inadequacy from internal or external oversight bodies;

(5) All components of the facility's physical plant (including ''blind-spots'' or areas where staff or inmates may be isolated);

(6) The composition of the inmate population;

(7) The number and placement of supervisory staff;

(8) Institution programs occurring on a particular shift;

(9) Any applicable State or local laws, regulations, or standards;

(10) The prevalence of substantiated and unsubstantiated incidents of sexual abuse; and

(11) Any other relevant factors.

The Human Resource Management Division and Administration Division, Central Office, must consider PREA factors and safety, in general, when allocating overall staffing resources. At the institution, the Salary/Workforce Utilization Committee Meeting Minutes serves as the staffing plan.

(b) In circumstances where the staffing plan is not complied with, the facility shall document and justify all deviations from the plan.

Deviations are documented in the remarks section of the Salary/Workforce Utilization Committee Meeting Minutes. For example, if an allocated position is not filled for budgetary or other reasons, the reasons should be noted in remarks section.

(c) Whenever necessary, but no less frequently than once each year, for each facility the agency operates, in consultation with the PREA coordinator required by § 115.11, the agency shall assess, determine, and document whether adjustments are needed to:

(1) The staffing plan established pursuant to paragraph (a) of this section;

(2) The facility's deployment of video monitoring systems and other monitoring technologies; and

(3) The resources the facility has available to commit to ensure adherence to the staffing plan.

At a minimum, the most recent Salary/Workforce Utilization Committee Meeting Minutes (which include a review of the staffing plan) are annually compiled by the Regional PREA Coordinator by May 1, and submitted to the National PREA Coordinator by June 1.

(d) Each agency operating a facility shall implement a policy and practice of having intermediate-level or higher level supervisors conduct and document unannounced rounds to identify and deter staff sexual abuse and sexual harassment. Such policy and practice shall be implemented for night shifts as well as day shifts. Each agency shall have a policy to prohibit staff from alerting other staff members that these supervisory rounds are occurring, unless such announcement is related to the legitimate operational functions of the facility.

Unannounced rounds by supervisory staff conducted with the intent of identifying and deterring sexual abuse and sexual harassment are conducted every week, including all shifts and all areas. The Institution Duty Officer (IDO) conducts and documents the unannounced rounds. At the end of the IDO's tour week, the documentation is forwarded to the Institution PREA Compliance Manager for retention.

§ 115.14 Youthful inmates.

(a) A youthful inmate shall not be placed in a housing unit in which the youthful inmate will have sight, sound, or physical contact with any adult inmate through use of a shared dayroom or other common space, shower area, or sleeping quarters.

(b) In areas outside of housing units, agencies shall either:

(1) Maintain sight and sound separation between youthful inmates and adult inmates, or

(2) Provide direct staff supervision when youthful inmates and adult inmates have sight, sound, or physical contact.

(c) Agencies shall make best efforts to avoid placing youthful inmates in isolation to comply with this provision. Absent exigent circumstances, agencies shall not deny youthful inmates daily large-muscle exercise and any legally required special education services to comply with this provision. Youthful inmates shall also have access to other programs and work opportunities to the extent possible.

§ 115.15 Limits to cross-gender viewing and searches.

(a) The facility shall not conduct cross-gender strip searches or cross-gender visual body cavity searches (meaning a search of the anal or genital opening) except in exigent circumstances or when performed by medical practitioners.

See the Program Statement **Searches of Housing Units, Inmates, and Inmate Work Areas**, or current version of this policy.

(b) As of August 20, 2015, or August 21, 2017 for a facility whose rated capacity does not exceed 50 inmates, the facility shall not permit cross-gender pat-down searches of female inmates, absent exigent circumstances. Facilities shall not restrict female inmates' access to regularly available programming or other out-of-cell opportunities in order to comply with this provision.

See the Program Statement **Searches of Housing Units, Inmates, and Inmate Work Areas**, or current version of this policy.

Post assignments may not be restricted on the basis of ~~gender~~ employee's sex. Institutions will evaluate operational concerns consistent with collective bargaining obligations, the Master Agreement, and other laws, rules, and regulations. The agency will continue to comply with Title VII and other Equal Employment Opportunity Commission authorities in implementing this policy.

(c) The facility shall document all cross-gender strip searches and cross-gender visual body cavity searches, and shall document all cross-gender pat-down searches of female inmates.

(**Note.** This provision's requirement to document ~~cross-gender~~ opposite sex pat-down searches of female inmates is **not** implemented by this policy.)

(d) The facility shall implement policies and procedures that enable inmates to shower, perform bodily functions, and change clothing without nonmedical staff of the opposite gender viewing their breasts, buttocks, or genitalia, except in exigent circumstances or when such viewing is incidental to routine cell checks. Such policies and procedures shall require staff of the opposite gender to announce their presence when entering an inmate housing unit.

This section applies only to inmate housing units. Further, this section is to provide notice in a housing unit; specific notice to individual inmates is not required.

The Bureau operates Medical Centers, which include medical housing units. This provision does not apply to medical staff working on these units.

Inmates will be appropriately clothed in all common areas of the institution.

Inmates should only shower, perform bodily functions, and change clothing in designated areas (e.g. cells, shower rooms, bathrooms). Housing unit officers of the ~~opposite gender~~, ~~or any other cross-gender staff,~~ opposite sex may view breasts, buttocks, or genitalia only in exigent circumstances, or when incidental to security checks of these designated areas of the housing unit**.**

Staff are not required to make announcements when responding to temporary and unforeseen circumstances that require immediate action in order to combat a threat to the security or institutional order of a facility, or when incidental to routine cell checks, to include circumstances such as responding to alarms, contraband detection, or detecting behavior that would constitute an inmate prohibited act, for example.

Inmates will be notified of the presence of oppostie ~~gender~~ sex staff members in several ways:

- Inmates are advised of the requirement to remain clothed, and the presence of ~~cross-gender~~ opposite sex staff generally, during the Intake Screening process and the Admission and Orientation process.

- The following notice must be posted on inmate bulletin boards and signs within housing units, including segregated housing areas: "NOTICE TO INMATES: Male and female staff routinely work and visit inmate housing areas."

- For housing unit officers, an announcement is made at the beginning of primary shifts, or other appropriate time to be determined locally (e.g., 10:00 count instead of morning watch). The verbal announcement to each housing unit, including segregated housing areas, will be "Notice: Opposite ~~gender~~ sex staff will be in housing units during this shift." This announcement is made using the general public address system (e.g., from Control or Lieutenants' Office). If the public address system does not cover these areas, an individual announcement in each housing area, including segregated housing areas, is made.

- For staff members with offices in the housing units; e.g., the Unit Team, the most recent schedule is posted in the unit so inmates are aware when opposite ~~gender~~ sex staff are present. (**Note**: this provision does not affect local scheduling procedures – quarterly, annually, 18 months, etc.)

As the agency has provided at least four ways to notify inmates that opposite ~~gender~~ sex staff are present in the housing units, the only time an announcement is made is if a public address system is not working, or an opposite ~~gender~~ sex staff member comes into a unit area who is not the assigned housing unit officer, or unit team member working there, and must go into individual cells, showers, or bathroom areas.

Any other announcement mechanism at the local level will be determined through collective bargaining in the local Institution Supplement.

Nothing in this section should preclude opposite ~~gender~~ sex staff from viewing live or recorded video, or participating in an inmate suicide watch.

(e) The facility shall not search or physically examine a transgender or intersex inmate for the sole purpose of determining the inmate's genital status. If the inmate's genital status is unknown, it may be determined during conversations with the inmate, by reviewing medical records, or, if necessary, by learning that

information as part of a broader medical examination conducted in private by a medical practitioner.

This provision does not limit searches of inmates to ensure the safe and orderly running of the institution.

(f) The agency shall train security staff in how to conduct cross-gender pat-down searches, and searches of transgender and intersex inmates, in a professional and respectful manner, and in the least intrusive manner possible, consistent with security needs.

The Correctional Services Branch updates and maintains training materials on conducting pat-down searches of ~~transgender and intersex~~ all inmates.

§ 115.16 Inmates with disabilities and inmates who are limited English proficient.

(a) The agency shall take appropriate steps to ensure that inmates with disabilities (including, for example, inmates who are deaf or hard of hearing, those who are blind or have low vision, or those who have intellectual, psychiatric, or speech disabilities), have an equal opportunity to participate in or benefit from all aspects of the agency's efforts to prevent, detect, and respond to sexual abuse and sexual harassment. Such steps shall include, when necessary to ensure effective communication with inmates who are deaf or hard of hearing, providing access to interpreters who can interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary. In addition, the agency shall ensure that written materials are provided in formats or through methods that ensure effective communication with inmates with disabilities, including inmates who have intellectual disabilities, limited reading skills, or who are blind or have low vision. An agency is not required to take actions that it can demonstrate would result in a fundamental alteration in the nature of a service, program, or activity, or in undue financial and administrative burdens, as those terms are used in regulations promulgated under title II of the Americans With Disabilities Act, 28 CFR 35.164.

The Institution PREA Compliance Manager should reach out to local disabilities assistance offices, as a resource, to ensure the facility is providing effective communication accommodations when a need for such an accommodation is known. Staff take reasonable action to ensure that available methods of communication are provided to all inmates with disabilities for complete access to its efforts of preventing, detecting, and responding to sexual abuse and sexual harassment.

(b) The agency shall take reasonable steps to ensure meaningful access to all aspects of the agency's efforts to prevent, detect, and respond to sexual abuse and sexual harassment to inmates who are limited English proficient, including steps to provide interpreters who can interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary.

The Institution PREA Compliance Manager should reach out to available interpretation services to ensure the facility is providing effective communication accommodations when a need for such an accommodation is known. Staff take reasonable action to ensure that available methods of communication are provided to all inmates who are limited English proficient for complete access to its efforts of preventing, detecting, and responding to sexual abuse and sexual harassment.

(c) The agency shall not rely on inmate interpreters, inmate readers, or other types of inmate assistants except in limited circumstances where an extended delay in obtaining an effective interpreter could compromise the inmate's safety, the performance of first response duties under § 115.64, or the investigation of the inmate's allegations.

§ 115.17 Hiring and promotion decisions.

(a) The agency shall not hire or promote anyone who may have contact with inmates, and shall not enlist the services of any contractor, who may have contact with inmates, who:

(1) Has engaged in sexual abuse in a prison, jail, lockup, community confinement facility, juvenile facility, or other institution (as defined in 42 U.S.C. 1997);

(2) Has been convicted of engaging or attempting to engage in sexual activity in the community facilitated by force, overt or implied threats of force, or coercion, or if the victim did not consent or was unable to consent or refuse; or

(3) Has been civilly or administratively adjudicated to have engaged in the activity described in paragraph (a)(2) of this section.

(b) The agency shall consider any incidents of sexual harassment in determining whether to hire or promote anyone, or to enlist the services of any contractor, who may have contact with inmates.

For the purposes of this section, consideration of incidents of sexual harassment of inmates will not automatically preclude any current staff member from being transferred into another position or promoted within the Bureau, in accordance with its disciplinary/adverse action process and collective bargaining agreement, and applicable laws, rules, and regulations.

(c) Before hiring new employees who may have contact with inmates, the agency shall:

(1) Perform a criminal background records check; and

(2) Consistent with Federal, State, and local law, make its best efforts to contact all prior institutional employers for information on substantiated allegations of sexual abuse or any resignation during a pending investigation of an allegation of sexual abuse.

(d) The agency shall also perform a criminal background records check before enlisting the services of any contractor who may have contact with inmates.

(e) The agency shall either conduct criminal background records checks at least every five years of current employees and contractors who may have contact with inmates or have in place a system for otherwise capturing such information for current employees.

(f) The agency shall ask all applicants and employees who may have contact with inmates directly about previous misconduct described in paragraph (a) of this section in written applications or interviews for hiring or promotions and in any interviews or written self-evaluations conducted as part of reviews of current employees. The agency shall also impose upon employees a continuing affirmative duty to disclose any such misconduct.

For current employees, the "reviews" referenced in this section mean the five-year background checks in section (e).

(g) Material omissions regarding such misconduct, or the provision of materially false information, shall be grounds for termination.

(h) Unless prohibited by law, the agency shall provide information on substantiated allegations of sexual abuse or sexual harassment involving a former employee upon receiving a request from an institutional employer for whom such employee has applied to work.

The Bureau complies with the Federal Privacy Act and Freedom of Information Act, and all other applicable laws, rules, and regulations.

§ 115.18 Upgrades to facilities and technologies.

(a) When designing or acquiring any new facility and in planning any substantial expansion or modification of existing facilities, the agency shall consider the effect of the design, acquisition, expansion, or modification upon the agency's ability to protect inmates from sexual abuse.

(b) When installing or updating a video monitoring system, electronic surveillance system, or other monitoring technology, the agency shall consider how such technology may enhance the agency's ability to protect inmates from sexual abuse.

All new facility designs and upgrades of technology will include consideration of how it could enhance the Bureau's ability to protect against sexual abuse.

RESPONSIVE PLANNING

§ 115.21 Evidence protocol and forensic medical examinations.

(a) To the extent the agency is responsible for investigating allegations of sexual abuse, the agency shall follow a uniform evidence protocol that maximizes the potential for obtaining usable physical evidence for administrative proceedings and criminal prosecutions.

(b) The protocol shall be developmentally appropriate for youth where applicable, and, as appropriate, shall be adapted from or otherwise based on the most recent edition of the U.S. Department of Justice's Office on Violence Against Women publication, "A National Protocol for Sexual Assault Medical Forensic Examinations, Adults/ Adolescents," or similarly comprehensive and authoritative protocols developed after 2011.

The Bureau's response to sexual assault follows the U.S. Department of Justice's Office on Violence Against Women publication, "A National Protocol for Sexual Assault Medical Forensic Examinations, Adults/Adolescents," dated April 2013, or the most current version.

(c) The agency shall offer all victims of sexual abuse access to forensic medical examinations, whether on-site or at an outside facility, without financial cost, where evidentiary or medically appropriate. Such examinations shall be performed by Sexual Assault Forensic Examiners (SAFEs) or Sexual Assault Nurse Examiners (SANEs) where possible. If SAFEs or SANEs cannot be made available, the examination can be performed by other qualified medical practitioners. The agency shall document its efforts to provide SAFEs or SANEs.

When there is a report of a recent incident of sexual abuse, or there is a strong suspicion that a recent serious assault may have been sexual in nature, a physical examination of the alleged victim is conducted. The victim is provided the opportunity for a forensic examination as soon as possible. Physical evidence collection may also include an examination of and collection of physical evidence from the suspected perpetrator(s).

For further information see sections 115.64, 115.65, and 115.81-83.

In the case of inmate-on-staff sexual abuse, community medical/mental health resources and services will be made available to the staff member immediately.

(d) The agency shall attempt to make available to the victim a victim advocate from a rape crisis center. If a rape crisis center is not available to provide victim advocate services, the agency shall make available to provide these services a qualified staff member from a community-based organization, or a qualified agency staff member. Agencies shall document efforts to secure services from rape crisis centers. For the purpose of this standard, a rape crisis center refers to an entity that provides intervention and related assistance, such as the services specified in 42 U.S.C. 14043g(b)(2)(C), to victims of sexual assault of all ages. The agency may utilize a rape crisis center that is part of a governmental unit as long as the center is not part of the criminal justice system (such as a law enforcement agency) and offers a comparable level of confidentiality as a nongovernmental entity that provides similar victim services.

The Institution PREA Compliance Manager, with the assistance of Psychology Services, attempts to enter into agreement with a rape crisis center to make available a victim advocate to inmates being evaluated for the collection of forensic evidence. If an agreement is not reached, efforts must be documented. Properly trained Psychology or Chaplaincy Services staff members may provide victim services locally, if a rape crisis center is not available.

(e) As requested by the victim, the victim advocate, qualified agency staff member, or qualified community-based organization staff member shall accompany and support the victim through the forensic medical examination process and investigatory interviews and shall provide emotional support, crisis intervention, information, and referrals.

Victim advocates from the community used by the Bureau are preauthorized by the agreement established in section (d). The victim advocate serves as emotional and general support, navigating the inmate through the treatment and evidence collection process. The victim advocate has access to the inmate similar to that of medical staff at the facility. He/she is not authorized to make decisions regarding inmate care, or interfere with escort procedures as outlined in the Program Statement **Escorted Trips**.

(f) To the extent the agency itself is not responsible for investigating allegations of sexual abuse, the agency shall request that the investigating agency follow the requirements of paragraphs (a) through (e) of this section.

(g) The requirements of paragraphs (a) through (f) of this section shall also apply to:

(1) Any State entity outside of the agency that is responsible for investigating allegations of sexual abuse in prisons or jails; and

(2) Any Department of Justice component that is responsible for investigating allegations of sexual abuse in prisons or jails.

(h) For the purposes of this section, a qualified agency staff member or a qualified community-based staff member shall be an individual who has been screened for appropriateness to serve in this role and has received education concerning sexual assault and forensic examination issues in general.

A qualified agency staff member meets the education requirement of this section by virtue of his/her degree or vocational training, or through specialized training offered by the Bureau.

§ 115.22 Policies to ensure referrals of allegations for investigations.

(a) The agency shall ensure that an administrative or criminal investigation is completed for all allegations of sexual abuse and sexual harassment.

(b) The agency shall have in place a policy to ensure that allegations of sexual abuse or sexual harassment are referred for investigation to an agency with the legal authority to conduct criminal investigations, unless the allegation does not involve potentially criminal behavior. The agency shall publish such policy on its Web site or, if it does not have one, make the policy available through other means. The agency shall document all such referrals.

Under this section, criminal investigations are referred consistent with the Program Statement **Criminal Matter Referrals**.

(c) If a separate entity is responsible for conducting criminal investigations, such publication shall describe the responsibilities of both the agency and the investigating entity.

(d) Any State entity responsible for conducting administrative or criminal investigations of sexual abuse or sexual harassment in prisons or jails shall have in place a policy governing the conduct of such investigations.

(e) Any Department of Justice component responsible for conducting administrative or criminal investigations of sexual abuse or sexual harassment in prisons or jails shall have in place a policy governing the conduct of such investigations.

TRAINING AND EDUCATION

§ 115.31 Employee training.

(a) The agency shall train all employees who may have contact with inmates on:

(1) Its zero-tolerance policy for sexual abuse and sexual harassment;

(2) How to fulfill their responsibilities under agency sexual abuse and sexual harassment prevention, detection, reporting, and response policies and procedures;

(3) Inmates' right to be free from sexual abuse and sexual harassment;

(4) The right of inmates and employees to be free from retaliation for reporting sexual abuse and sexual harassment;

(5) The dynamics of sexual abuse and sexual harassment in confinement;

(6) The common reactions of sexual abuse and sexual harassment victims;

(7) How to detect and respond to signs of threatened and actual sexual abuse;

(8) How to avoid inappropriate relationships with inmates;

(9) How to communicate effectively and professionally with inmates, including lesbian, gay, bisexual, transgender, intersex, or gender nonconforming inmates; and

(10) How to comply with relevant laws related to mandatory reporting of sexual abuse to outside authorities.

Staff training includes a component on crime scene preservation for first responders, taking into consideration the physical design of the institution, as indicated in section 115.64.

(b) Such training shall be tailored to the gender of the inmates at the employee's facility. The employee shall receive additional training if the employee is reassigned from a facility that houses only male inmates to a facility that houses only female inmates, or vice versa.

Annual refresher training takes the ~~gender~~ sex of the inmate population at each facility into account. Transferring staff members receive training on inmate sexual safety based on the mission(s) of the institution they work.

(c) All current employees who have not received such training shall be trained within one year of the effective date of the PREA standards, and the agency shall provide each employee with refresher training every two years to ensure that all employees know the agency's current sexual abuse and sexual harassment policies and procedures. In years in which an employee does not receive refresher training, the agency shall provide refresher information on current sexual abuse and sexual harassment policies.

- **New Employees.** For new employees, a discussion of the Sexually Abusive Behavior Prevention and Intervention Program must be a part of Introduction to Correctional

Techniques Phase I and Phase II. Specific staff responsibilities included in policy are outlined.

- **Current Employees.** For current staff, information about the program is included yearly as a part of Annual Training. Each Warden designates a staff member to conduct this training from the areas responsible for policy implementation (e.g., the Institution PREA Compliance Manager, or supervisory staff from Correctional Services, Psychology Services, Health Services, etc.).

- **Specialized Training.** Discipline-specific training is available at the institution level to staff who are likely to be most involved in the management and treatment of sexually abused victims and the perpetrators (Health Services staff, Psychologists, Lieutenants, etc.). Specialized training is provided to these disciplines as part of their comprehensive training. Further information on required specialized training is provided below.

(d) The agency shall document, through employee signature or electronic verification, that employees understand the training they have received.

Participation must be documented through employee signature or electronic verification. Participation documentation will note that employees understood the training they have received. At the conclusion of the training, employees are asked to seek additional supervisory direction, if necessary, to ensure understanding of the training.

§ 115.32 Volunteer and contractor training.

(a) The agency shall ensure that all volunteers and contractors who have contact with inmates have been trained on their responsibilities under the agency's sexual abuse and sexual harassment prevention, detection, and response policies and procedures.

(b) The level and type of training provided to volunteers and contractors shall be based on the services they provide and level of contact they have with inmates, but all volunteers and contractors who have contact with inmates shall be notified of the agency's zero-tolerance policy regarding sexual abuse and sexual harassment and informed how to report such incidents.

(c) The agency shall maintain documentation confirming that volunteers and contractors understand the training they have received.

Participation must be documented through volunteer and contractor signature or electronic verification, and will indicate that the volunteer and contractor understood the training they have received. At the conclusion of the training, volunteers and contractors are asked to seek additional direction from Bureau staff, if necessary, to ensure understanding of the training.

§ 115.33 Inmate education.

(a) During the intake process, inmates shall receive information explaining the agency's zero-tolerance policy regarding sexual abuse and sexual harassment and how to report incidents or suspicions of sexual abuse or sexual harassment.

The Bureau's Admission and Orientation (A&O) Pamphlet on Sexually Abusive Behavior Prevention and Intervention is provided to each inmate at intake screening. It describes the key elements of the program and informs inmates of the Bureau's zero-tolerance policy regarding sexual abuse and sexual harassment and how to report incidents of sexual abuse. It also provides inmates notice that male and female staff routinely work and visit inmate housing areas. This pamphlet is available to staff on the PREA Sallyport site.

(b) Within 30 days of intake, the agency shall provide comprehensive education to inmates either in person or through video regarding their rights to be free from sexual abuse and sexual harassment and to be free from retaliation for reporting such incidents, and regarding agency policies and incidents.

During the A&O Program, a staff member, designated by the Warden, presents the Sexually Abusive Behavior Prevention and Intervention Program. This presentation must include:

- Definitions of sexually abusive behavior and sexual harrassment.
- Prevention strategies the inmate can take to minimize his/her risk of sexual victimization while in BOP custody.
- Methods of reporting an incident of sexually abusive behavior against oneself, and for reporting allegations of sexually abusive behavior involving other inmates, including reporting procedures directly to Regional Staff, if desired.
- Methods of reporting an incident of sexual harassment against oneself, and for reporting allegations of sexual harassment involving other inmates.
- Treatment options and programs available to inmate victims of sexually abusive behavior and sexual harassment.
- Monitoring, discipline, and prosecution of sexual perpetrators.
- Notice that male and female staff routinely work and visit inmate housing areas.

In addition, where inmates do not participate in a formal A&O program (e.g., WITSEC, pretrial, or SHU inmates), the Warden designates a staff member to ensure these inmates receive information on the Bureau's Sexually Abusive Behavior Prevention and Intervention Program within 30 days of intake. This is documented in the same manner as for inmates who participated during the regularly scheduled A&O session.

(c) Current inmates who have not received such education shall be educated within one year of the effective date of the PREA standards, and shall receive education upon transfer to a different facility to the extent that the policies and procedures of the inmate's new facility differ from those of the previous facility.

(d) The agency shall provide inmate education in formats accessible to all inmates, including those who are limited English proficient, deaf, visually

impaired, or otherwise disabled, as well as to inmates who have limited reading skills.

Refer to section 115.16 above.

(e) The agency shall maintain documentation of inmate participation in these education sessions.

The A&O forms are filed in the Inmate Central File or pretrial/holdover files.

(f) In addition to providing such education, the agency shall ensure that key information is continuously and readily available or visible to inmates through posters, inmate handbooks, or other written formats.

In each housing unit, the following will be posted:

- A notice to inmates stating, "Male and female staff routinely work and visit inmate housing areas."
- A poster reflecting the BOP's zero tolerance for sexual abuse and harassment and contact information for inmate reporting of sexual abuse allegations.

§ 115.34 Specialized training: Investigations.

(a) In addition to the general training provided to all employees pursuant to § 115.31, the agency shall ensure that, to the extent the agency itself conducts sexual abuse investigations, its investigators have received training in conducting such investigations in confinement settings.

The Chief of Correctional Services ensures his/her Special Investigative Supervisor/Special Investigative Agents are appropriately trained under this section. The Chief of the Office of Internal Affairs ensures his/her staff are appropriately trained under this section.

(b) Specialized training shall include techniques for interviewing sexual abuse victims, proper use of *Miranda* and *Garrity* warnings, sexual abuse evidence collection in confinement settings, and the criteria and evidence required to substantiate a case for administrative action or prosecution referral.

The Bureau trains on the rights and warnings applicable in the Federal sector, and as referenced in the Master Agreement.

(c) The agency shall maintain documentation that agency investigators have completed the required specialized training in conducting sexual abuse investigations.

(d) Any State entity or Department of Justice component that investigates sexual abuse in confinement settings shall provide such training to its agents and investigators who conduct such investigations.

§ 115.35 Specialized training: Medical and mental health care.

(a) The agency shall ensure that all full- and part-time medical and mental health care practitioners who work regularly in its facilities have been trained in:

(1) How to detect and assess signs of sexual abuse and sexual harassment;

(2) How to preserve physical evidence of sexual abuse;

(3) How to respond effectively and professionally to victims of sexual abuse and sexual harassment; and

(4) How and to whom to report allegations or suspicions of sexual abuse and sexual harassment.

The Health Services Division ensures medical staff are appropriately trained under this section. The Reentry Services Division ensures mental health staff are appropriately trained under this section.

Please note, training under this section does **not** refer to certifications needed to conduct forensic examinations.

(b) If medical staff employed by the agency conduct forensic examinations, such medical staff shall receive the appropriate training to conduct such examinations.

(c) The agency shall maintain documentation that medical and mental health practitioners have received the training referenced in this standard either from the agency or elsewhere.

(d) Medical and mental health care practitioners shall also receive the training mandated for employees under § 115.31 or for contractors and volunteers under §115.32, depending upon the practitioner's status at the agency.

SCREENING FOR RISK OF SEXUAL VICTIMIZATION AND ABUSIVENESS

§ 115.41 Screening for risk of victimization and abusiveness.

(a) All inmates shall be assessed during an intake screening and upon transfer to another facility for their risk of being sexually abused by other inmates or sexually abusive toward other inmates.

All inmates entering an institution are screened as directed by Health Services, Psychology Services, and Unit Management policies. Further information on intake mental health screenings is in section 115.81, below. The following steps should be taken:

- **Inmates with a history of sexual victimization while in BOP custody.** When, during the intake screening process, staff identify inmates with a history of sexual victimization within BOP custody (e.g., from self-report or from review of available documents, such as judgment and commitment orders, criminal records, pre-sentence investigation reports, Inmate Central File data, etc.), they must refer the inmate to Psychology Services. If not previously documented on BOP records, staff must notify the Chief of Correctional Services of the inmate's report of victimization to ensure that appropriate steps (investigation, documentation, CIMS concerns, etc.) have been taken. The Chief of Correctional Services also updates any current SENTRY STG assignment pertaining to the alleged victim.

- **Inmates with a history of sexual victimization while in a non-BOP setting.** If victimization occurred in a non-BOP setting, staff should document information, and appropriate psychological treatment and monitoring will be provided if needed.

- **Inmates with a history of sexual predation.** When, during the intake screening process, staff identify inmates with a history of sexual predation (e.g., from self-report or from review of available documents such as judgment and commitment orders, criminal records, pre-sentence investigation reports, Inmate Central File data, etc.), staff must refer the inmate to Psychology Services.

  If incidents of sexual predation have not previously been documented on BOP records, staff must notify the Chief of Correctional Services of the inmate's history of predation to ensure that appropriate steps (investigation, documentation, CIMS concerns, etc.) have been taken. The Chief of Correctional Services also updates a current SENTRY STG assignment pertaining to the alleged perpetrator. In addition, inmates identified as perpetrators will be included in the Posted Picture file, pursuant to policy.

(b) Intake screening shall ordinarily take place within 72 hours of arrival at the facility.

(c) Such assessments shall be conducted using an objective screening instrument.

Staff are required to use the Bureau's Program Statement **Intake Screening**, which outlines issues and steps to take during the intake screening process generally, including issues concerning sexual abuse and sexual assault. The Unit Team uses the Intake Screening Form during the intake process.

To complete the Intake Screening Form, the staff must use the PREA Intake Objective Screening Instrument, Attachment A, for guidance. The PREA Intake Objective Screening Instrument encompasses all factors listed in section (d) of this subsection. Ample copies of the PREA Intake Objective Screening Instrument will be maintained in the area of the institution where intake is conducted by Unit Management.

The PREA Intake Objective Screening Instrument should be completed using only information available to staff at the time of intake, and with the purpose of referring the inmate for further assessment if needed.

After applying the criteria on the PREA Intake Objective Screening Instrument, staff complete the "Intake Screening Form" and must note any specific information in the comment section applicable to victimization or abusiveness. If none of the PREA Intake Screening Objective Instrument criteria apply, staff make an entry stating, "No apparent PREA criteria met," in the comment section applicable to victimization or abusiveness.

If further assessment is needed after documenting and applying the criteria, an inmate is considered "at-risk" until a final determination is made by Psychology Services or Correctional Services. Referrals to Psychology Services or Correctional Services are documented at the local level.

Inmates are encouraged to disclose as much information as possible for the agency to provide the most protection possible under this policy. If an inmate chooses not to respond to questions relating to his/her level of risk, he/she may not be disciplined, as described in section (h) of this subsection.

Sensitive information is limited to staff who have a need to know.

(d) The intake screening shall consider, at a minimum, the following criteria to assess inmates for risk of sexual victimization:

(1) Whether the inmate has a mental, physical, or developmental disability;

(2) The age of the inmate;

(3) The physical build of the inmate;

(4) Whether the inmate has previously been incarcerated;

(5) Whether the inmate's criminal history is exclusively nonviolent;

(6) Whether the inmate has prior convictions for sex offenses against an adult or child;

(7) Whether the inmate is or is perceived to be gay, lesbian, bisexual, transgender, intersex, or gender nonconforming;

(8) Whether the inmate has previously experienced sexual victimization;

(9) The inmate's own perception of vulnerability; and

(10) Whether the inmate is detained solely for civil immigration purposes.

Some inmates are "at risk" for victimization due to one or a combination of factors such as physical appearance (small in stature, effeminate, etc.); demeanor (weak/nonassertive, anxious,

depressed); special situations (e.g., high-profile, sexual activity with a child, first-time offender); or special needs (cognitive limitations, social inadequacy, developmental disability, etc.).

(e) The initial screening shall consider prior acts of sexual abuse, prior convictions for violent offenses, and history of prior institutional violence or sexual abuse, as known to the agency, in assessing inmates for risk of being sexually abusive.

Some inmates pose a serious risk of engaging in sexually abusive behavior while in BOP custody because of their history of sexually abusive behaviors while in prison (stalking, excessive sexual preoccupation, etc.), or from the criminal history. In the case of inmates "at risk" for perpetration, Correctional Services should be notified by Psychology Services.

(f) Within a set time period, not to exceed 30 days from the inmate's arrival at the facility, the facility will reassess the inmate's risk of victimization or abusiveness based upon any additional, relevant information received by the facility since the intake screening.

Psychology Services staff reassess the inmate's risk level whenever warranted and within 30 days of arrival at the institution, based upon any additional information. Reassessment is not required if no additional information is received after intake screening.

(g) An inmate's risk level shall be reassessed when warranted due to a referral, request, incident of sexual abuse, or receipt of additional information that bears on the inmate's risk of sexual victimization or abusiveness.

Psychology Services staff reassess the inmate's risk level whenever warranted based upon receipt of additional relevant information (e.g., incident of sexual abuse, protective custody request, ~~recent diagnosis of gender dysphoria,~~ new presentation of any risk factors listed in section (d) above, recent intervention for allegation of sexual abuse or harassment, etc.).

(h) Inmates may not be disciplined for refusing to answer, or for not disclosing complete information in response to, questions asked pursuant to paragraphs (d)(1), (d)(7), (d)(8), or (d)(9) of this section.

~~If an inmate refuses to respond or elects not to disclose information that applies only to questions about disabilities; Gay, Lesbian, Bisexual, Transgender, Intersex (GLBTI) status; gender nonconformance; previous sexual victimization; and the inmate's self-perception of vulnerability, he/she may not be disciplined.~~

(i) The agency shall implement appropriate controls on the dissemination within the facility of responses to questions asked pursuant to this standard in order to ensure that sensitive information is not exploited to the inmate's detriment by staff or other inmates.

Any information related to sexual victimization or abusiveness, including the information entered into the comment section of the Intake Screening Form, is limited to a need-to-know

basis for staff, only for the purpose of treatment and security and management decisions, such as housing and cell assignments, as well as work, education, and programming assignments.

§ 115.42 Use of screening information.

(a) The agency shall use information from the risk screening required by § 115.41 to inform housing, bed, work, education, and program assignments with the goal of keeping separate those inmates at high risk of being sexually victimized from those at high risk of being sexually abusive.

Once an inmate has been identified as a victim or perpetrator, or as "at risk" for victimization or perpetration, Unit Management should review classification options. These options may include transfer to a special treatment program (e.g., Sex Offender Management Program), transfer to a greater or lesser security facility (e.g., management variable), application of a PSF (e.g., sex offender), or changes in housing units, cell assignments, work assignments, and/or education assignments.

(b) The agency shall make individualized determinations about how to ensure the safety of each inmate.

(c) In deciding whether to assign a transgender or intersex inmate to a facility for male or female inmates, and in making other housing and programming assignments, the agency shall consider on a case-by-case basis whether a placement would ensure the inmate's health and safety, and whether the placement would present management or security problems.

(d) Placement and programming assignments for each transgender or intersex inmate shall be reassessed at least twice each year to review any threats to safety experienced by the inmate.

(e) A transgender or intersex inmate's own views with respect to his or her own safety shall be given serious consideration.

(f) Transgender and intersex inmates shall be given the opportunity to shower separately from other inmates.

(g) The agency shall not place lesbian, gay, bisexual, transgender, or intersex inmates in dedicated facilities, units, or wings solely on the basis of such identification or status, unless such placement is in a dedicated facility, unit, or wing established in connection with a consent decree, legal settlement, or legal judgment for the purpose of protecting such inmates.

§ 115.43 Protective custody.

(a) Inmates at high risk for sexual victimization shall not be placed in involuntary segregated housing unless an assessment of all available alternatives has been

made, and a determination has been made that there is no available alternative means of separation from likely abusers. If a facility cannot conduct such an

assessment immediately, the facility may hold the inmate in involuntary segregated housing for less than 24 hours while completing the assessment.

Inmates are placed in administrative detention in accordance with the Program Statement **Special Housing Units**.

(b) Inmates placed in segregated housing for this purpose shall have access to programs, privileges, education, and work opportunities to the extent possible. If the facility restricts access to programs, privileges, education, or work opportunities, the facility shall document:

(1) The opportunities that have been limited;

(2) The duration of the limitation; and

(3) The reasons for such limitations.

When an inmate is placed in special housing involuntarily, access to programs, privileges, education, or work should not be interrupted, to the extent possible. If they are limited, the Chief of Correctional Services ensures that documentation exists reflecting the limitation, duration, and rationale for limitation.

(c) The facility shall assign such inmates to involuntary segregated housing only until an alternative means of separation from likely abusers can be arranged, and such an assignment shall not ordinarily exceed a period of 30 days.

(d) If an involuntary segregated housing assignment is made pursuant to paragraph (a) of this section, the facility shall clearly document:

(1) The basis for the facility's concern for the inmate's safety; and

(2) The reason why no alternative means of separation can be arranged.

When determining an appropriate method of safeguarding the inmate assigned "at risk" for victimization, the Warden ensures all options are considered by completing, signing, and dating form BP-A1002, Safeguarding of Inmates Alleging Sexual Abuse/Assault Allegation. The Warden should evaluate the least restrictive methods for separation of the alleged victim and alleged perpetrator.

The completed BP-A1002 is stamped "FOI EXEMPT" and placed in the Privacy Section of the Inmate Central File to ensure that sensitive information is not exploited to the inmate's detriment by staff or other inmates. If information gathered leads to an investigation, the BP-A1002 becomes part of the investigative file. The completed form is e-mailed to BOP-CPD/PREA COORDINATOR and filed with the investigative case.

Psychologists are responsible for crisis intervention, assessment of treatment needs, documentation of the evaluation results, treatment, psychiatric referral, and other treatment options related to the alleged at-risk inmate.

(e) Every 30 days, the facility shall afford each such inmate a review to determine whether there is a continuing need for separation from the general population.

The inmate's status is reviewed during weekly Special Housing Unit meetings.

REPORTING

§ 115.51 Inmate reporting.

(a) The agency shall provide multiple internal ways for inmates to privately report sexual abuse and sexual harassment, retaliation by other inmates or staff for reporting sexual abuse and sexual harassment, and staff neglect or violation of responsibilities that may have contributed to such incidents.

Bureau inmates are encouraged to report allegations to staff at all levels, including local, regional and Central Office. They are also currently provided with avenues of internal reporting, such as telephonically to a specific department (such as the Special Investigative lieutenant), or by mail to an outside entity. Inmates are provided information on reporting mechanisms as noted in section 115.33.

(b) The agency shall also provide at least one way for inmates to report abuse or harassment to a public or private entity or office that is not part of the agency, and that is able to receive and immediately forward inmate reports of sexual abuse and sexual harassment to agency officials, allowing the inmate to remain anonymous upon request. Inmates detained solely for civil immigration purposes shall be provided information on how to contact relevant consular officials and relevant officials at the Department of Homeland Security.

Inmates are provided contact information and access to the Office of Inspector General to make such reports.

(c) Staff shall accept reports made verbally, in writing, anonymously, and from third parties and shall promptly document any verbal reports.

For the purpose of this section, information received anonymously refers to "drop-notes" or other written communication. Non-investigatory staff do not offer anonymity to inmates.

(d) The agency shall provide a method for staff to privately report sexual abuse and sexual harassment of inmates.

Staff reporting requirements are addressed in the Program Statement **Standards of Employee Conduct**. For the purposes of this section, staff may contact any supervisory staff at the local institution, Regional staff, or Central Office staff, including the Regional PREA Coordinators and the National PREA Coordinator. Allegations involving staff members may also be reported to the Office of Internal Affairs or the Office of Inspector General, as appropriate.

§ 115.52 Exhaustion of administrative remedies.

See the Program Statement **Administrative Remedy Program**, or current version of the policy.

§ 115.53 Inmate access to outside confidential support services.

(a) The facility shall provide inmates with access to outside victim advocates for emotional support services related to sexual abuse by giving inmates mailing addresses and telephone numbers, including toll-free hotline numbers where available, of local, State, or national victim advocacy or rape crisis organizations, and, for persons detained solely for civil immigration purposes, immigrant services agencies. The facility shall enable reasonable communication between inmates and these organizations and agencies, in as confidential a manner as possible.

The Institution PREA Compliance Manager, with the assistance of Psychology Services staff, seeks to establish an agreement with community service providers who are able to provide confidential emotional support services as it relates to sexual abuse. If an agreement is not feasible, the attempts are documented. Staff take reasonable action to ensure that information on available resources is provided to all inmates so that they have access to the Bureau's efforts in preventing, detecting, and responding to sexual abuse and sexual harassment. Staff also provide contact information and confidential communication services, as reasonably as possible.

"Confidential" communications under this section are distinguished from privileged communications, such as in attorney-client relationship. Communications are monitored in a manner consistent with agency security practices, and should be addressed in any memorandum of understanding with the outside victim advocacy organization.

(b) The facility shall inform inmates, prior to giving them access, of the extent to which such communications will be monitored and the extent to which reports of abuse will be forwarded to authorities in accordance with mandatory reporting laws.

(c) The agency shall maintain or attempt to enter into memoranda of understanding or other agreements with community service providers that are able to provide inmates with confidential emotional support services related to sexual abuse. The agency shall maintain copies of agreements or documentation showing attempts to enter into such agreements.

§ 115.54 Third-party reporting.

The agency shall establish a method to receive third-party reports of sexual abuse and sexual harassment and shall distribute publicly information on how to report sexual abuse and sexual harassment on behalf of an inmate.

The Bureau posts publicly, and maintains, the third-party reporting avenue on its public website.

OFFICIAL RESPONSE FOLLOWING AN INMATE REPORT

§ 115.61 Staff and agency reporting duties.

(a) The agency shall require all staff to report immediately and according to agency policy any knowledge, suspicion, or information regarding an incident of sexual abuse or sexual harassment that occurred in a facility, whether or not it is part of the agency; retaliation against inmates or staff who reported such an incident; and any staff neglect or violation of responsibilities that may have contributed to an incident or retaliation.

All staff must report information concerning incidents or possible incidents of sexual abuse or sexual harassment to the Operations Lieutenant, or, where appropriate, in accordance with the Program Statement **Standards of Employee Conduct**.

Staff provide a written follow-up memorandum to the Operations Lieutenant to document such a report, in accordance with Article 6 of the Master Agreement.

The Operations Lieutenant notifies the PREA Compliance Manager.

Allegations of inmate-on-inmate and inmate-on-staff sexual abuse must be entered in TRUINTEL via the Report of Incident form (BP-A0583). Reports must indicate whether the allegation involved Abusive Sexual Contact or a Non-Consensual Sexual Act. The Institution PREA Compliance Manager will forward a copy of the BP-A0583 to the appropriate Regional PREA Coordinator; the number of BP-A0583's that pertain to inmate-on-inmate and inmate-on-staff sexual abuse will be sent to the National PREA Coordinator.

Once reported, an evaluation by the Institution PREA Compliance Manager of whether a full response protocol is needed will be made (see section 115.65).

In addition to reporting information, staff intervene as appropriate (e.g., writing an incident report), in behaviors that may subsequently lead to an incident of sexual abuse.

Staff should be aware of the following in determining what information to report:

Detection requires an awareness by staff of institution or unit climate and the reputations and behaviors of inmates – through actively paying attention to the following, for example:

- Inmate communications.
- Comments to staff.
- Posted picture files, and Correctional Services "confidentials."
- Inmate interactions.
- Changes in inmate behavior (eating, sleeping, hygiene, work habits, etc.).
- Isolated or "hot" areas of the institution.

By observing factors such as these, staff are able to better detect sexually abusive behavior, and possibly deter problems **before they occur, or before they escalate.**

(b) Apart from reporting to designated supervisors or officials, staff shall not reveal any information related to a sexual abuse report to anyone other than to the extent necessary, as specified in agency policy, to make treatment, investigation, and other security and management decisions.

The information concerning the identity of the alleged inmate victim and the specific facts of the case are limited to staff who need to know because of their involvement with the victim's welfare and the investigation of the incident. This is important not only to preserve the victim's privacy but to preserve maximum flexibility to investigate the allegations. It is appropriate under this section to forward reports to the Operations Lieutenant through the staff member's supervisor.

(c) Unless otherwise precluded by Federal, State, or local law, medical and mental health practitioners shall be required to report sexual abuse pursuant to paragraph (a) of this section and to inform inmates of the practitioner's duty to report, and the limitations of confidentiality, at the initiation of services.

(d) If the alleged victim is under the age of 18 or considered a vulnerable adult under a State or local vulnerable persons statute, the agency shall report the allegation to the designated State or local services agency under applicable mandatory reporting laws.

(e) The facility shall report all allegations of sexual abuse and sexual harassment, including third-party and anonymous reports, to the facility's designated investigators.

Staff must report and respond to allegations of sexually abusive behavior, regardless of the source of the report (e.g., "third party").

The Institution PREA Compliance Manager refers the incident for investigation to the appropriate office, and reviews the incident for any further response. As the severity of the sexually abusive behavior increases, so should the level of response.

§ 115.62 Agency protection duties.

When an agency learns that an inmate is subject to a substantial risk of imminent sexual abuse, it shall take immediate action to protect the inmate.

In cases where the alleged perpetrator is another inmate, the Operations Lieutenant is notified immediately and immediately safeguards the inmate (which will vary depending on the severity of the alleged sexually abusive behavior and could include monitoring the situation, changing housing assignments, changing work assignment, placing alleged victim and perpetrator in Special Housing, etc.). The Operations Lieutenant promptly refers all inmates reported or suspected of being the victim of sexually abusive behavior to Psychology Services for assessment of vulnerability and treatment needs. The Operations Lieutenant also notifies the Institution PREA Compliance Manager.

If the alleged perpetrator is a staff member, all options for safeguarding the inmate should be considered as described in the above paragraph. The decisions made to safeguard the inmate should take impact on staff member into account, in accordance with the Master Agreement. Removal from the facility is an extreme measure, and other options include reassignment to another unit or post, or other measures that will effectively separate the staff member from the inmate.

If the alleged perpetrator is an inmate, and a staff member is the subject of abuse or harassment, all options for safegurading the staff member should be considered. Options should include reassignment of the inmate to another housing unit, writing incident reports, assignment to the Special Housing Unit, criminal prosecution if appropriate, etc., in accordance with the Program Statements **Inmate Discipline Program** and **Special Housing Units**, among other options that will effectively separate the inmate from the staff member.

§ 115.63 Reporting to other confinement facilities.

(a) Upon receiving an allegation that an inmate was sexually abused while confined at another facility, the head of the facility that received the allegation shall notify the head of the facility or appropriate office of the agency where the alleged abuse occurred.

In cases where there is an allegation that sexually abusive behavior occurred at another Bureau facility, the Warden (or his/her designee) of the victim's current facility reports the allegation to the Warden of the identified institution. In cases alleging sexual abuse by staff at another institution, the Warden of the inmate's current facility refers the matter directly to the Office of Internal Affairs.

For non-Bureau secure privatized facilities, jails, juvenile facilities, and Residential Reentry Centers, the Warden will contact the appropriate office of the facility, and notify the Privatization Management or the Residential Reentry Management Branches, as appropriate.

For non-Bureau facilities, the Warden (or his/her designee) contacts the appropriate office of that correctional agency.

(b) Such notification shall be provided as soon as possible, but no later than 72 hours after receiving the allegation.

(c) The agency shall document that it has provided such notification.

(d) The facility head or agency office that receives such notification shall ensure that the allegation is investigated in accordance with these standards.

§ 115.64 Staff first responder duties.

(a) Upon learning of an allegation that an inmate was sexually abused, the first security staff member to respond to the report shall be required to:

(1) Separate the alleged victim and abuser;

(2) Preserve and protect any crime scene until appropriate steps can be taken to collect any evidence;

(3) If the abuse occurred within a time period that still allows for the collection of physical evidence, request that the alleged victim not take any actions that could destroy physical evidence, including, as appropriate, washing, brushing teeth, changing clothes, urinating, defecating, smoking, drinking, or eating; and

(4) If the abuse occurred within a time period that still allows for the collection of physical evidence, ensure that the alleged abuser does not take any actions that could destroy physical evidence, including, as appropriate, washing, brushing teeth, changing clothes, urinating, defecating, smoking, drinking, or eating.

(b) If the first staff responder is not a security staff member, the responder shall be required to request that the alleged victim not take any actions that could destroy physical evidence, and then notify security staff.

The staff first responder must preserve the crime scene. SIS staff are responsible for collecting information/evidence. The investigation, in coordination with the agency to which the case may be referred, must follow the guidance given in agency policies and practices concerning evidence gathering and processing procedures.

§ 115.65 Coordinated response.

The facility shall develop a written institutional plan to coordinate actions taken in response to an incident of sexual abuse, among staff first responders, medical and mental health practitioners, investigators, and facility leadership.

All staff report incidents of sexual abuse to the Operations Lieutenant (see section 115.61).

The Operations Lieutenant immediately safeguards the inmate (see sections 115.43, 115.62).

The Operations Lieutenant promptly refers all inmates reported or suspected of being the victim of sexually abusive behavior to the Health Services Unit (or the on-call clinician during non-business hours) for physical assessment and documentation of injuries (see sections 115.21, 115.82).

The Operations Lieutenant promptly refers all inmates reported or suspected of being the victim of sexually abusive behavior to Psychology Services for assessment of vulnerability and treatment needs (see section 115.82).

In addition, during business hours, the Operations Lieutenant ensures that the SIS, Chief of Correctional Services, Institution PREA Compliance Manager, and Warden are notified. During non-business hours, the Operations Lieutenant ensures that the SIS, Chief of Correctional Services, Institution PREA Compliance Manager, Duty Officer, Health Services staff, and on-call Psychologist are notified.

The Institution PREA Compliance Manager reviews relevant factors and makes a determination whether or not to proceed with full activation of the Response Protocol. Not all allegations of sexually abusive behavior require full activation of the protocol. In some cases, the Institution PREA Compliance Manager will determine that there is not sufficient reason to proceed (the alleged victim credibly recanted; the alleged perpetrator was not in the institution on the date of the allegation, etc.) and the Response Protocol may be terminated.

In cases where more information is needed, or where there is a credible and serious allegation or instance of sexually abusive behavior, the full Response Protocol must be implemented.

Once the Institution PREA Compliance Manager determines that the intervention should continue, a sensitive and coordinated response is necessary. Services will be provided in an environment that meets both security and therapeutic needs**.**

The full Response Protocol, monitored by the Institution PREA Compliance Manager, involves the following components:

- Correctional Services safeguard the inmate (see section 115.62); engage in evidence collection and preservation at the institution, including inmate clothing and footware (see section 115.64); investigate cases involving inmate perpetrators (see section 115.71); arrange for outside medical trips if necessary in accordance with the Program Statement **Escorted Trips**; and ensure that STG categories for victims and predators are entered into SENTRY (see section 115.87).

- Psychologists are responsible for crisis intervention, assessment of treatment needs, documentation of the evaluation results, treatment, psychiatric referral, and other treatment options related to the alleged victim (see section 115.82). Psychologists also notify the

qualified agency staff member or the outside victim advocate, if necessary, to assist the inmate (see section 115.21).

- Properly trained Health Services clinicians are responsible for assessment, examination, documentation, and treatment of inmate injuries arising from incidents of sexual abuse, including testing when appropriate for pregnancy, HIV, and other sexually transmissible infections (STIs) (see sections 115.82 and 115.83). Where indicated, medical staff, trained in the collection of sexual assault evidence (e.g., "rape kit") should conduct an examination for physical evidence that may be used later in formal investigations, or refer the inmate to trained health care professionals from the local community or at the local community facility equipped (in accordance with local laws) to evaluate and treat sexual assault victims (see sections 115.21 and 115.81).

After responding to the initial incident, staff noted above have additional responsibilities for follow-up with the inmate victim, which are covered in sections 115.66-68, 115.76-78, and 115.81-83.

§ 115.66 Preservation of ability to protect inmates from contact with abusers.

The collective bargaining process in the Bureau will be completed pursuant to Title 5 of the United States Code, and all other applicable laws, rules, and regulations, including third-party appeals.

(a) Neither the agency nor any other governmental entity responsible for collective bargaining on the agency's behalf shall enter into or renew any collective bargaining agreement or other agreement that limits the agency's ability to remove alleged staff sexual abusers from contact with any inmates pending the outcome of an investigation or of a determination of whether and to what extent discipline is warranted.

(b) Nothing in this standard shall restrict the entering into or renewal of agreements that govern:

(1) The conduct of the disciplinary process, as long as such agreements are not inconsistent with the provisions of §§ 115.72 and 115.76; or

(2) Whether a no-contact assignment that is imposed pending the outcome of an investigation shall be expunged from or retained in the staff member's personnel file following a determination that the allegation of sexual abuse is not substantiated.

§ 115.67 Agency protection against retaliation.

(a) The agency shall establish a policy to protect all inmates and staff who report sexual abuse or sexual harassment or cooperate with sexual abuse or sexual harassment investigations from retaliation by other inmates or staff, and shall designate which staff members or departments are charged with monitoring retaliation.

(b) The agency shall employ multiple protection measures, such as housing changes or transfers for inmate victims or abusers, removal of alleged staff or inmate abusers from contact with victims, and emotional support services for inmates or staff who fear retaliation for reporting sexual abuse or sexual harassment or for cooperating with investigations.

(c) For at least 90 days following a report of sexual abuse, the agency shall monitor the conduct and treatment of inmates or staff who reported the sexual abuse and of inmates who were reported to have suffered sexual abuse to see if there are changes that may suggest possible retaliation by inmates or staff, and shall act promptly to remedy any such retaliation. Items the agency should monitor include any inmate disciplinary reports, housing, or program changes, or negative performance reviews or reassignments of staff. The agency shall continue such monitoring beyond 90 days if the initial monitoring indicates a continuing need.

The Institution PREA Compliance Manager monitors staff and inmates who have reported sexual abuse allegations to protect them from retaliation for 90 days. However, if the initial monitoring indicates a continuing need, periodic status checks occur.

(d) In the case of inmates, such monitoring shall also include periodic status checks.

(e) If any other individual who cooperates with an investigation expresses a fear of retaliation, the agency shall take appropriate measures to protect that individual against retaliation.

(f) An agency's obligation to monitor shall terminate if the agency determines that the allegation is unfounded.

§ 115.68 Post-allegation protective custody.

Any use of segregated housing to protect an inmate who is alleged to have suffered sexual abuse shall be subject to the requirements of § 115.43.

See section 115.43. Form BP-A1002, Safeguarding of Inmates Alleging Sexual Abuse/Assault Allegation, is also used in cases of post-allegation protective custody.

INVESTIGATIONS

§ 115.71 Criminal and administrative agency investigations.

(a) When the agency conducts its own investigations into allegations of sexual abuse and sexual harassment, it shall do so promptly, thoroughly, and objectively for all allegations, including third-party and anonymous reports.

At the conclusion of the investigation, the allegations must be indicated as:

- Substantiated.
- Unsubstantiated (may have occurred, but insufficient evidence to prove).
- Unfounded (evidence proves that this could not have happened).

Upon activating the full Response Protocol, the investigation phase is initiated and the following notification(s) must be made:

(1) **Inmate Perpetrator on Inmate Victim**. In the event that an inmate is alleged to have perpetrated sexually abusive behavior against another inmate, the Special Investigative Agent (or SIS) is notified immediately.

(2) **Staff Perpetrator on Inmate Victim**. In the event that a staff member is alleged to have perpetrated sexually abusive behavior against an inmate, the Warden is notified immediately. The Warden notifies the Regional Director and the Office of Internal Affairs (OIA), who in turn notify the Office of the Inspector General (OIG), and, when appropriate, the Federal Bureau of Investigation (FBI).

(3) **Inmate Perpetrator on Staff Victim**. In the event that an inmate is alleged to have perpetrated sexually abusive behavior against a staff member, the SIA/SIS must be contacted immediately, with follow-up notification to the Warden. The Warden refers these matters for criminal investigation and possible prosecution in accordance with the Program Statement **Criminal Matter Referrals**.

(b) Where sexual abuse is alleged, the agency shall use investigators who have received special training in sexual abuse investigations pursuant to § 115.34.

(c) Investigators shall gather and preserve direct and circumstantial evidence, including any available physical and DNA evidence and any available electronic monitoring data; shall interview alleged victims, suspected perpetrators, and witnesses; and shall review prior complaints and reports of sexual abuse involving the suspected perpetrator.

Note. this is a separate responsibility from staff first responders addressed in section 115.64. These duties are carried out by the appropriate investigative agency (e.g., SIS, OIA, OIG, FBI).

Previous unsubstantiated or unfounded complaints and reports may not be used as evidence.

(d) When the quality of evidence appears to support criminal prosecution, the agency shall conduct compelled interviews only after consulting with prosecutors as to whether compelled interviews may be an obstacle for subsequent criminal prosecution.

(e) The credibility of an alleged victim, suspect, or witness shall be assessed on an individual basis and shall not be determined by the person's status as inmate

or staff. No agency shall require an inmate who alleges sexual abuse to submit to a polygraph examination or other truth-telling device as a condition for proceeding with the investigation of such an allegation.

(f) Administrative investigations:

(1) Shall include an effort to determine whether staff actions or failures to act contributed to the abuse; and

(2) Shall be documented in written reports that include a description of the physical and testimonial evidence, the reasoning behind credibility assessments, and investigative facts and findings.

Administrative investigations should also consider information on whether other factors such as physical layouts, staffing patterns, institution operations, etc., contributed to the abuse.

(g) Criminal investigations shall be documented in a written report that contains a thorough description of physical, testimonial, and documentary evidence and attaches copies of all documentary evidence where feasible.

(h) Substantiated allegations of conduct that appears to be criminal shall be referred for prosecution.

(i) The agency shall retain all written reports referenced in paragraphs (f) and (g) of this section for as long as the alleged abuser is incarcerated or employed by the agency, plus five years.

(j) The departure of the alleged abuser or victim from the employment or control of the facility or agency shall not provide a basis for terminating an investigation.

(k) Any State entity or Department of Justice component that conducts such investigations shall do so pursuant to the above requirements.

(l) When outside agencies investigate sexual abuse, the facility shall cooperate with outside investigators and shall endeavor to remain informed about the progress of the investigation.

§ 115.72 Evidentiary standard for administrative investigations.

The agency shall impose no standard higher than a preponderance of the evidence in determining whether allegations of sexual abuse or sexual harassment are substantiated.

The Bureau applies this section in accordance with its disciplinary/adverse action process and collective bargaining agreement, and applicable laws, rules, and regulations.

§ 115.73 Reporting to inmates.

(a) Following an investigation into an inmate's allegation that he or she suffered sexual abuse in an agency facility, the agency shall inform the inmate as to whether the allegation has been determined to be substantiated, unsubstantiated, or unfounded.

The Special Investigative Lieutenant provides all notifications to inmates required under this section.

(b) If the agency did not conduct the investigation, it shall request the relevant information from the investigative agency in order to inform the inmate.

(c) Following an inmate's allegation that a staff member has committed sexual abuse against the inmate, the agency shall subsequently inform the inmate (unless the agency has determined that the allegation is unfounded) whenever:

(1) The staff member is no longer posted within the inmate's unit;

(2) The staff member is no longer employed at the facility;

(3) The agency learns that the staff member has been indicted on a charge related to sexual abuse within the facility; or

(4) The agency learns that the staff member has been convicted on a charge related to sexual abuse within the facility.

An assessment of whether actions described in (c)(1)-(4) above are warranted is made in accordance with section 115.65, and may not be appropriate in all cases. Inmates are notified only if there is a nexus between the listed actions in this section and an incident of sexual abuse. The timing of such notifications should not interfere with any pending criminal or administrative investigations. All notifications are made in accordance with the Freedom of Information Act/Privacy Act.

(d) Following an inmate's allegation that he or she has been sexually abused by another inmate, the agency shall subsequently inform the alleged victim whenever:

(1) The agency learns that the alleged abuser has been indicted on a charge related to sexual abuse within the facility; or

(2) The agency learns that the alleged abuser has been convicted on a charge related to sexual abuse within the facility.

(e) All such notifications or attempted notifications shall be documented.

Documentation is maintained in the investigation file.

(f) An agency's obligation to report under this standard shall terminate if the inmate is released from the agency's custody.

The Bureau's obligation to report terminates if the inmate-victim is released from the agency's custody.

DISCIPLINE

§ 115.76 Disciplinary sanctions for staff.

Bureau employees are subject to the Program Statement **Standards of Employee Conduct**, the Master Agreement, and employment-based laws, rules, and regulations.

(a) Staff shall be subject to disciplinary sanctions up to and including termination for violating agency sexual abuse or sexual harassment policies.

(b) Termination shall be the presumptive disciplinary sanction for staff who have engaged in sexual abuse.

If evidence supports that a staff member engaged in sexual abuse, as defined in section 115.6, the matter will first be referred for criminal prosecution. Administrative discipline (including proposed removals for sexual abuse) will be conducted using the Program Statement **Standards of Employee Conduct**, the Program Statement **Human Resource Management Manual**, and the collective bargaining agreement. Any decision made on the proposal will be in accordance with all applicable laws, rules, and regulations.

(c) Disciplinary sanctions for violations of agency policies relating to sexual abuse or sexual harassment (other than actually engaging in sexual abuse) shall be commensurate with the nature and circumstances of the acts committed, the staff member's disciplinary history, and the sanctions imposed for comparable offenses by other staff with similar histories.

(d) All terminations for violations of agency sexual abuse or sexual harassment policies, or resignations by staff who would have been terminated if not for their resignation, shall be reported to law enforcement agencies, unless the activity was clearly not criminal, and to any relevant licensing bodies.

§ 115.77 Corrective action for contractors and volunteers.

(a) Any contractor or volunteer who engages in sexual abuse shall be prohibited from contact with inmates and shall be reported to law enforcement agencies, unless the activity was clearly not criminal, and to relevant licensing bodies.

Generally, this section is applied in cases where there is possible criminal prosecution.

(b) The facility shall take appropriate remedial measures, and shall consider whether to prohibit further contact with inmates, in the case of any other violation of agency sexual abuse or sexual harassment policies by a contractor or volunteer.

Generally, this section is applied in cases where administrative investigation/actions would be appropriate.

§ 115.78 Disciplinary sanctions for inmates.

(a) Inmates shall be subject to disciplinary sanctions pursuant to a formal disciplinary process following an administrative finding that the inmate engaged in inmate-on-inmate sexual abuse or following a criminal finding of guilt for inmate-on-inmate sexual abuse.

(b) Sanctions shall be commensurate with the nature and circumstances of the abuse committed, the inmate's disciplinary history, and the sanctions imposed for comparable offenses by other inmates with similar histories.

(c) The disciplinary process shall consider whether an inmate's mental disabilities or mental illness contributed to his or her behavior when determining what type of sanction, if any, should be imposed.

(d) If the facility offers therapy, counseling, or other interventions designed to address and correct underlying reasons or motivations for the abuse, the facility shall consider whether to require the offending inmate to participate in such interventions as a condition of access to programming or other benefits.

(e) The agency may discipline an inmate for sexual contact with staff only upon a finding that the staff member did not consent to such contact.

Sexual abuse and sexual harassment of staff members should be addressed through other existing statutes, policies, and procedures, such as using the inmate discipline system and referral to criminal prosecutions as appropriate. Please refer to sections 115.6 and 115.62 concerning staff victims.

(f) For the purpose of disciplinary action, a report of sexual abuse made in good faith based upon a reasonable belief that the alleged conduct occurred shall not constitute falsely reporting an incident or lying, even if an investigation does not establish evidence sufficient to substantiate the allegation.

The maintenance of an effective sexual abuse prevention policy, and general secure and orderly running of an institution, requires that inmates be held responsible for manipulative behavior and intentionally making false allegations. Allegations of false reports are considered by staff in accordance with the procedures and standards of the Program Statement **Inmate Discipline Program**. Inmates who have been found to have made false allegations are recommended for

placement in the Posted Picture File in accordance with the Program Statement **Posted Picture File**.

(g) An agency may, in its discretion, prohibit all sexual activity between inmates and may discipline inmates for such activity. An agency may not, however, deem such activity to constitute sexual abuse if it determines that the activity is not coerced.

All sexual activity between inmates is prohibited, and is subject to discipline. See the Program Statement **Inmate Discipline Program**.

MEDICAL AND MENTAL CARE

§ 115.81 Medical and mental health screenings; history of sexual abuse.

Follow-up meetings under this section are conducted by Psychology Services. Psychology Services consults with Health Services if necessary.

(a) If the screening pursuant to § 115.41 indicates that a prison inmate has experienced prior sexual victimization, whether it occurred in an institutional setting or in the community, staff shall ensure that the inmate is offered a follow-up meeting with a medical or mental health practitioner within 14 days of the intake screening.

(b) If the screening pursuant to § 115.41 indicates that a prison inmate has previously perpetrated sexual abuse, whether it occurred in an institutional setting or in the community, staff shall ensure that the inmate is offered a follow-up meeting with a mental health practitioner within 14 days of the intake screening.

Inmates considered high risk for sexual re-offending may be referred to specialty treatment or management programs, referred to individual or group counseling, or managed through standard correctional techniques.

If an inmate perpetrator is determined in need of treatment services and refuses treatment, Psychology Services staff document the refusal, place it in the medical section of the Inmate Central File, and notify referring staff of the refusal. Documentation of treatment compliance or refusal ensures continuity of care within and outside the Bureau.

(c) If the screening pursuant to § 115.41 indicates that a jail inmate has experienced prior sexual victimization, whether it occurred in an institutional setting or in the community, staff shall ensure that the inmate is offered a follow-up meeting with a medical or mental health practitioner within 14 days of the intake screening.

(d) Any information related to sexual victimization or abusiveness that occurred in an institutional setting shall be strictly limited to medical and mental health practitioners and other staff, as necessary, to inform treatment plans and security and management decisions, including housing, bed, work, education, and program assignments, or as otherwise required by Federal, State, or local law.

It is appropriate under this section to provide staff information on an inmate's history of being a sexual abuser; for example, placing the inmate in the Posted Picture File, to maintain the safe, secure, and orderly running of the institution.

(e) Medical and mental health practitioners shall obtain informed consent from inmates before reporting information about prior sexual victimization that did not occur in an institutional setting, unless the inmate is under the age of 18.

§ 115.82 Access to emergency medical and mental health services.

(a) Inmate victims of sexual abuse shall receive timely, unimpeded access to emergency medical treatment and crisis intervention services, the nature and scope of which are determined by medical and mental health practitioners according to their professional judgment.

See section 115.65 for details concerning emergency mental health services.

Procedures for Inmate Victims. Medical staff are responsible for examination, documentation, and treatment of inmate injuries arising from sexually abusive behaviors, including testing when appropriate for pregnancy and sexually transmissible infections (STIs), including HIV.

When an inmate self-reports, or is referred to Health Services, medical staff notify Psychology Services and Correctional Services prior to conducting an injury assessment. The injury assessment, and the inmate's subjective/objective findings, are documented fully in the electronic health record. Health Services staff perform the injury assessment without compromising forensic evidence.

The forensic examination is performed by qualified sexual assault examiners (e.g., Sexual Assault Nurse Examiner, Forensic Nurse Examiner, or Sexual Assault Forensic Examiner). Where indicated, Health Services staff with appropriate qualifications may conduct a forensic examination at the institution. At institutions where Health Services staff are neither trained nor certified in forensic examinations, the inmate is examined at the institution by a qualified health care professional from the community, or at a local community facility (e.g., local hospital or rape crisis center) equipped to conduct such examinations. The forensic examination should occur as soon as practicable, but within 72 hours of BOP staff becoming aware that an inmate reported involvement in a sexually abusive assault. An inmate's refusal of a forensic examination is documented in the electronic health record.

If a trip to a local community facility is needed, Health Services staff coordinate with Correctional Services to transport the inmate to the facility.

When community care is completed, institution providers render follow-up care, including screening for infectious disease (HIV, viral hepatitis, or other sexually transmissible infections), pregnancy testing for female victims, and administration of prophylactic medication (if exposure to bloodborne pathogens is suspected) if these services were not already rendered during the community visit.

Procedures for Alleged Inmate Perpetrators. Health Services clinicians also perform a physical injury assessment on any alleged inmate perpetrators without compromising forensic evidence. Providers document the assessment in the electronic health record and provide a copy to Correctional Services for insertion in the investigation packet.

Forensic examinations of inmate perpetrators will be in consultation with relevant outside law enforcement agencies, and consistent with applicable laws and policies.

(b) If no qualified medical or mental health practitioners are on duty at the time a report of recent abuse is made, security staff first responders shall take preliminary steps to protect the victim pursuant to § 115.62 and shall immediately notify the appropriate medical and mental health practitioners.

The Operations Lieutenant takes preliminary steps, as stated in section 115.65.

(c) Inmate victims of sexual abuse while incarcerated shall be offered timely information about and timely access to emergency contraception and sexually transmitted infections prophylaxis, in accordance with professionally accepted standards of care, where medically appropriate.

Information and access to care as indicated in this section is offered to all inmate victims, as clinically indicated.

(d) Treatment services shall be provided to the victim without financial cost and regardless of whether the victim names the abuser or cooperates with any investigation arising out of the incident.

Bureau policies concerning inmate co-pays for medical treatment shall not be applied to victims of sexual abuse.

§ 115.83 Ongoing medical and mental health care for sexual abuse victims and abusers.

(a) The facility shall offer medical and mental health evaluation and, as appropriate, treatment to all inmates who have been victimized by sexual abuse in any prison, jail, lockup, or juvenile facility.

(b) The evaluation and treatment of such victims shall include, as appropriate, follow-up services, treatment plans, and, when necessary, referrals for continued care following their transfer to, or placement in, other facilities, or their release from custody.

(c) The facility shall provide such victims with medical and mental health services consistent with the community level of care.

(d) Inmate victims of sexually abusive vaginal penetration while incarcerated shall be offered pregnancy tests.

(e) If pregnancy results from the conduct described in paragraph (d) of this section, such victims shall receive timely and comprehensive information about and timely access to all lawful pregnancy-related medical services.

Bureau providers deliver comprehensive prenatal counseling and care for pregnant female offenders.

(f) Inmate victims of sexual abuse while incarcerated shall be offered tests for sexually transmitted infections as medically appropriate.

(g) Treatment services shall be provided to the victim without financial cost and regardless of whether the victim names the abuser or cooperates with any investigation arising out of the incident.

(h) All prisons shall attempt to conduct a mental health evaluation of all known inmate-on-inmate abusers within 60 days of learning of such abuse history and offer treatment when deemed appropriate by mental health practitioners.

DATA COLLECTION AND REVIEW

§ 115.86 Sexual abuse incident reviews.

(a) The facility shall conduct a sexual abuse incident review at the conclusion of every sexual abuse investigation, including where the allegation has not been substantiated, unless the allegation has been determined to be unfounded.

In cases of unsubstantiated allegations, Institution Executive Staff review the incident to assess the facility's response to the allegations. All factors noted within PREA Standard 115.86 (d) noted below are considered. The Institution PREA Compliance Manager documents the review in a report, including recommendations for improvements, if any. If the unsubstantiated allegation involved a staff member, the report under this section must not include the staff member's personally identifiable information. The report is submitted to the Warden, who ensures implementation of the recommendations or documents the reason for not following them.

In cases of substantiated sexual abuse, Institution Executive Staff review the incident to assess the facility's response. All factors noted within PREA Standard 115.86 (d) noted below are considered. The Institution PREA Compliance Manager documents the review in a report, including recommendations for improvements, if any. The report is submitted to the Warden,

who ensures implementation of the recommendations or documents the reason for not following them. A copy of this report is forwarded to the Regional Director through the Regional PREA Coordinator.

Consideration for staff affected by the incident is necessary. Efforts to mitigate potential stress associated with these events should be offered to affected staff, such as offering Employee Assistance Program information.

(b) Such review shall ordinarily occur within 30 days of the conclusion of the investigation.

(c) The review team shall include upper-level management officials, with input from line supervisors, investigators, and medical or mental health practitioners.

The review team also includes input from the local Union President, or his/her designee from the local Union. The local Union representative is provided an opportunity to review the draft and submit the Union's recommendations, taking the time frames of this section into account.

The Union's recommendations are included in the review team's final report and recommendations as an addendum. Adoption of the Union's recommendations in the final report is at the discretion of the review team.

Any subsequent implementation of any final recommendations will comply with collective bargaining agreements as indicated in 115.86(e) below.

(d) The review team shall:

(1) Consider whether the allegation or investigation indicates a need to change policy or practice to better prevent, detect, or respond to sexual abuse;

(2) Consider whether the incident or allegation was motivated by race; ethnicity; gender identity; lesbian, gay, bisexual, transgender, or intersex identification, status, or perceived status; or gang affiliation; or was motivated or otherwise caused by other group dynamics at the facility;

(3) Examine the area in the facility where the incident allegedly occurred to assess whether physical barriers in the area may enable abuse;

(4) Assess the adequacy of staffing levels in that area during different shifts;

(5) Assess whether monitoring technology should be deployed or augmented to supplement supervision by staff; and

(6) Prepare a report of its findings, including but not necessarily limited to determinations made pursuant to paragraphs (d)(1) through (d)(5) of this section, and any recommendations for improvement and submit such report to the facility head and PREA compliance manager.

(e) The facility shall implement the recommendations for improvement, or shall document its reasons for not doing so.

The institution will comply with collective bargaining agreements in implementing changes or programs.

§ 115.87 Data collection.

(a) The agency shall collect accurate, uniform data for every allegation of sexual abuse at facilities under its direct control using a standardized instrument and set of definitions.

The Bureau tracks information concerning sexual abuse using the methods listed below. In disseminating this information within the Bureau, or releasing information to a third party, the Bureau complies with the Federal Privacy Act and Freedom of Information Act, and all other applicable laws, rules, and regulations.

(1) **SIS Data.** The SIS must maintain secure investigative files and data, which include:

- The victim(s) and perpetrator(s) of sexually abusive behavior.
- A factual description of the events.
- Formal and informal action(s) taken.
- All collateral reports, supporting memoranda, and videotapes.
- Medical forms (e.g., injury assessments).
- Any other evidentiary materials pertaining to the allegation.

(2) **Office of Internal Affairs Data.** The Office of Internal Affairs reports the cumulated data on the inmate victims of staff sexually abusive behavior to all Chief Executive Officers and the Psychology Services Administrator at the end of each quarter and at the end of each fiscal year.

(3) **Inmate Data.** The Information, Policy, and Public Affairs Division collects and reports on the data used in the Bureau of Justice Statistics Survey of Sexual Violence.

(4) **SENTRY Data.** The Chief of Correctional Services in each institution is responsible for accurate STG SENTRY assignments related to sexually abusive behavior. Access to this SENTRY assignment must be limited to those staff who are involved in managing and treating the inmate victim or inmate perpetrator, or investigating the incident.

- **Unverified Codes.** These two SENTRY assignments ensure that alleged inmate victims of inmates or staff, and alleged inmate perpetrators, are identified, evaluated, and monitored **as soon as the allegation is made**.

  V SA UNV (Victim of Sexually Abusive Behavior - Unverified). This assignment is entered into the SENTRY record of the alleged victim at the time an allegation of sexually abusive behavior is reported. It remains current until it is found to be unsubstantiated or

unfounded (in which case it is discontinued), or until it is verified and changed to **V INMT SA** or **V STAFF SA**.

SA UNV (Perpetrator of Sexually Abusive Behavior - Unverified). This assignment is entered into the SENTRY record of the alleged inmate perpetrator at the time the allegation is made. It remains current until it is found to be unsubstantiated or unfounded (and discontinued), or until it is verified and changed to **SA INMT** or **SA STAFF**.

- **Verified Codes.** These four SENTRY Assignments are used when there is a substantial evidence of sexually abusive behavior against an inmate, or by an inmate:

  V INMT SA (Victim of Inmate Sexually Abusive Behavior). This assignment should be entered into SENTRY when a sexually abusive behavior has been committed against an inmate victim. It remains current for the length of the inmate victim's incarceration.

  V STAFF SA (Victim of Staff Sexually Abusive Behavior). This assignment should be entered into SENTRY when a sexually abusive behavior has been committed against an inmate victim by a staff member after the allegation has been sustained.

  SA INMT (Perpetrator of Sexually Abusive Behavior Against an Inmate). This assignment should be entered into SENTRY when there has been a sustained finding (incident report or legal finding) against an inmate perpetrator who has engaged in sexually abusive behavior towards another inmate.

  SA STAFF (Perpetrator of Sexually Abusive Behavior Against a Staff Member/ Contractor/Volunteer). This assignment should be entered into SENTRY when there has been a sustained finding (incident report or legal finding) against an inmate perpetrator who has committed a sexually abusive behavior against a staff member.

(b) The agency shall aggregate the incident-based sexual abuse data at least annually.

The National PREA Coordinator, with the assistance of the Regional PREA Coordinators, aggregates and reviews data from all sources annually.

(c) The incident-based data collected shall include, at a minimum, the data necessary to answer all questions from the most recent version of the Survey of Sexual Violence conducted by the Department of Justice.

The Information, Policy, and Public Affairs Division collects and reports on the data used in the Bureau of Justice Statistics Survey of Sexual Violence.

(d) The agency shall maintain, review, and collect data as needed from all available incident-based documents, including reports, investigation files, and sexual abuse incident reviews.

(e) The agency also shall obtain incident-based and aggregated data from every private facility with which it contracts for the confinement of its inmates.

(f) Upon request, the agency shall provide all such data from the previous calendar year to the Department of Justice no later than June 30.

§ 115.88 Data review for corrective action.

(a) The agency shall review data collected and aggregated pursuant to § 115.87 in order to assess and improve the effectiveness of its sexual abuse prevention, detection, and response policies, practices, and training, including by:

(1) Identifying problem areas;

(2) Taking corrective action on an ongoing basis; and

(3) Preparing an annual report of its findings and corrective actions for each facility, as well as the agency as a whole.

The National PREA Coordinator reviews data compiled by the Regional PREA Coordinators, the Information, Policy, and Public Affairs Division, and the Office of Internal Affairs, and issues a report to the Director on an annual basis, meeting the requirements of this section.

(b) Such report shall include a comparison of the current year's data and corrective actions with those from prior years and shall provide an assessment of the agency's progress in addressing sexual abuse.

(c) The agency's report shall be approved by the agency head and made readily available to the public through its Web site or, if it does not have one, through other means.

(d) The agency may redact specific material from the reports when publication would present a clear and specific threat to the safety and security of a facility, but must indicate the nature of the material redacted.

The Bureau complies with the Federal Privacy Act and Freedom of Information Act, and all other applicable laws, rules, and regulations.

§ 115.89 Data storage, publication, and destruction.

(a) The agency shall ensure that data collected pursuant to § 115.87 are securely retained.

(b) The agency shall make all aggregated sexual abuse data, from facilities under its direct control and private facilities with which it contracts, readily available to the public at least annually through its Web site or, if it does not have one, through other means.

(c) Before making aggregated sexual abuse data publicly available, the agency shall remove all personal identifiers.

The Bureau complies with the Federal Privacy Act and Freedom of Information Act, and all other applicable laws, rules, and regulations.

(d) The agency shall maintain sexual abuse data collected pursuant to § 115.87 for at least 10 years after the date of the initial collection unless Federal, State, or local law requires otherwise.

AUDITS

§ 115.93 Audits of standards.

The agency shall conduct audits pursuant to §§ 115.401 through 115.405.

AUDITING AND CORRECTIVE ACTION

§ 115.401 Frequency and scope of audits.

Information provided to auditors under this section is released consistent with the Freedom of Information Act/Privacy Act and all other applicable laws, rules, and regulations.

(a) During the three-year period starting on August 20, 2013, and during each three-year period thereafter, the agency shall ensure that each facility operated by the agency, or by a private organization on behalf of the agency, is audited at least once.

(b) During each one-year period starting on August 20, 2013, the agency shall ensure that at least one-third of each facility type operated by the agency, or by a private organization on behalf of the agency, is audited.

(c) The Department of Justice may send a recommendation to an agency for an expedited audit if the Department has reason to believe that a particular facility may be experiencing problems relating to sexual abuse. The recommendation may also include referrals to resources that may assist the agency with PREA-related issues.

(d) The Department of Justice shall develop and issue an audit instrument that will provide guidance on the conduct of and contents of the audit.

(e) The agency shall bear the burden of demonstrating compliance with the standards.

(f) The auditor shall review all relevant agency-wide policies, procedures, reports, internal and external audits, and accreditations for each facility type.

(g) The audits shall review, at a minimum, a sampling of relevant documents and other records and information for the most recent one-year period.

(h) The auditor shall have access to, and shall observe, all areas of the audited facilities.

(i) The auditor shall be permitted to request and receive copies of any relevant documents (including electronically stored information).

(j) The auditor shall retain and preserve all documentation (including, *e.g.,* video tapes and interview notes) relied upon in making audit determinations. Such documentation shall be provided to the Department of Justice upon request.

(k) The auditor shall interview a representative sample of inmates, residents, and detainees, and of staff, supervisors, and administrators.

The local Union will be given the opportunity to have the designated representative interviewed.

(l) The auditor shall review a sampling of any available videotapes and other electronically available data (*e.g.,* Watchtour) that may be relevant to the provisions being audited.

(m) The auditor shall be permitted to conduct private interviews with inmates, residents, and detainees.

This section refers to in-person interviews. Institutions may use attorney-client rooms or other appropriate areas, taking institution security concerns into account.

(n) Inmates, residents, and detainees shall be permitted to send confidential information or correspondence to the auditor in the same manner as if they were communicating with legal counsel.

Inmates are able to use Special Mail procedures relevant to attorneys and legal counsel when sending confidential information or correspondence to PREA auditors, consistent with the Program Statement **Correspondence.** The Institution PREA Compliance Manager will notify the institution mailroom when the PREA audit is beginning and ending, which will determine the time frame for PREA auditor mail to be treated as Special Mail.

(o) Auditors shall attempt to communicate with community-based or victim advocates who may have insight into relevant conditions in the facility.

§ 115.402 Auditor qualifications.

(a) An audit shall be conducted by:

(1) A member of a correctional monitoring body that is not part of, or under the authority of, the agency (but may be part of, or authorized by, the relevant State or local government);

(2) A member of an auditing entity such as an inspector general's or ombudsperson's office that is external to the agency; or

(3) Other outside individuals with relevant experience.

(b) All auditors shall be certified by the Department of Justice. The Department of Justice shall develop and issue procedures regarding the certification process, which shall include training requirements.

(c) No audit may be conducted by an auditor who has received financial compensation from the agency being audited (except for compensation received for conducting prior PREA audits) within the three years prior to the agency's retention of the auditor.

(d) The agency shall not employ, contract with, or otherwise financially compensate the auditor for three years subsequent to the agency's retention of the auditor, with the exception of contracting for subsequent PREA audits.

§ 115.403 Audit contents and findings.

(a) Each audit shall include a certification by the auditor that no conflict of interest exists with respect to his or her ability to conduct an audit of the agency under review.

(b) Audit reports shall state whether agency-wide policies and procedures comply with relevant PREA standards.

(c) For each PREA standard, the auditor shall determine whether the audited facility reaches one of the following findings: Exceeds Standard (substantially exceeds requirement of standard); Meets Standard (substantial compliance; complies in all material ways with the standard for the relevant review period); Does Not Meet Standard (requires corrective action). The audit summary shall indicate, among other things, the number of provisions the facility has achieved at each grade level.

(d) Audit reports shall describe the methodology, sampling sizes, and basis for the auditor's conclusions with regard to each standard provision for each audited facility, and shall include recommendations for any required corrective action.

(e) Auditors shall redact any personally identifiable inmate or staff information from their reports, but shall provide such information to the agency upon request, and may provide such information to the Department of Justice.

(f) The agency shall ensure that the auditor's final report is published on the agency's Web site if it has one, or is otherwise made readily available to the public.

The final report will be posted on the Bureau's public website within 15 working days of receipt. The most recent final report for each facility must be posted.

§ 115.404 Audit corrective action plan.

(a) A finding of ''Does Not Meet Standard'' with one or more standards shall trigger a 180-day corrective action period.

To allow the auditor 60 days to write and submit a final report, institutions have 120 days to develop, implement, and submit to the Program Review Divison the corrective action(s) from the date the preliminary report is received.

(b) The auditor and the agency shall jointly develop a corrective action plan to achieve compliance.

Implementation of a corrective action plan will be in accordance with the collective bargaining agreement.

(c) The auditor shall take necessary and appropriate steps to verify implementation of the corrective action plan, such as reviewing updated policies and procedures or re-inspecting portions of a facility.

(d) After the 180-day corrective action period ends, the auditor shall issue a final determination as to whether the facility has achieved compliance with those standards requiring corrective action.

(e) If the agency does not achieve compliance with each standard, it may (at its discretion and cost) request a subsequent audit once it believes that is has achieved compliance.

§ 115.405 Audit appeals.

(a) An agency may lodge an appeal with the Department of Justice regarding any specific audit finding that it believes to be incorrect. Such appeal must be lodged within 90 days of the auditor's final determination.

The Program Review Division files an appeal on behalf of the facility. Appeals are filed in accordance to procedures issued by the Office of Justice Programs, U.S. Department of Justice.

(b) If the Department determines that the agency has stated good cause for a re-evaluation, the agency may commission a re-audit by an auditor mutually agreed

upon by the Department and the agency. The agency shall bear the costs of this re-audit.

Re-audits are funded by the institution.

(c) The findings of the re-audit shall be considered final.

Attachment A. PREA Intake Objective Screening Instrument

Instructions: Intake screening in the Bureau of Prisons is completed according to the Program Statement Intake Screening. In accordance with 28 CFR §115.41 of the Prison Rape Elimination Act regulations, staff use this instrument when conducting intake screening per the Program Statement. Any specific information must be noted in the comment sections of the Intake Screening Form. If none of the criteria below apply, staff must make an entry stating "No PREA criteria met," in the comment section applicable to victimization or abusiveness.

RISK OF VICTIMIZATION		
Factor	**Objective Criteria**	**Referral Guidance**
Answers to Intake Screening Form	Questions 1, 6a, 6b, concerning history of sexual assault and inmate perception of whether he can be housed in general population.	If inmate responds yes to any of the questions, refer to Psychology Services in all cases.
General Physical Appearance and Presentation	Inmate is under 21 or over 65; Inmate has small physical stature (5'6, 120 lbs or under for males; 5'0 and 118 lbs or under for females). Developmental/mental/medical disability, if apparent or identified as SCRN4-MH, SCRN3-MH, CARE4-MH, CARE3-MH, SCRN4, SCRN3, CARE4, CARE 3. Inmate is or may be perceived to be gay, lesbian, bisexual, transgender, intersex, or ~~gender nonconforming~~ any other status listed in 28 CFR § 115.41 based on documentation received (e.g., PSR), or correctional judgment would indicate the inmate would have issues being placed in general population.	If inmate meets two or more criteria, leading staff to determine that the inmate is at risk, then consider a referral to Psychology Services. Please take institution security and mission into account in deciding to make the referral (e.g., older inmates with disabilities may not need to be referred at a medical facility).
Criminal history from available documentation	Inmate has not previously been incarcerated. Inmate's criminal history is exclusively nonviolent. Inmate has prior convictions for sex offenses against an adult or child. Inmate is in custody solely under civil immigration detention.	Criminal history should be evaluated; however, the existence of only one of these factors alone may not warrant a referral to Psychology Services based on the security level of the institution and mission of the facility (e.g., SOMP sites).
RISK OF ABUSIVENESS		
Documented history of abusiveness, from available documentation (PSR, incident reports, etc.)	Inmate has prior acts of sexual abuse. Inmate has prior convictions for violent offenses. Inmate has history of prior institutional violence or sexual abuse.	Referral to Psychology Services should be made if inmate previously perpetrated sexual abuse in community or in an institutional setting. Staff must notify Correctional Services of the inmate's history of predation to ensure that appropriate steps (investigation, documentation, CIMS concerns, etc.) have been taken. The Chief of Correctional Services also updates a current SENTRY STG assignment.

REFERRAL FOR CONSIDERATION OF GENDER AFFIRMING SURGERY

I. CLINICAL PROCESS

California Correctional Health Care Services (CCHCS) patients may request Gender Affirming Surgery (GAS) or revision of prior GAS. In accordance with California Code of Regulations Title 15, Section 3999.200, those who request GAS shall be referred by the institution to the Gender Affirming Surgery Review Committee (GASRC).

II. REFERRAL

When a patient submits a written or verbal request to any health care staff (or a staff member submits a request on behalf of a patient) for GAS, an appointment shall be scheduled with the primary care provider (PCP) within 30 calendar days. The PCP shall submit an electronic Request For Services (eRFS) for GAS as treatment for Gender Dysphoria (GD). If the patient has never been diagnosed with GD, the PCP shall refer the patient to a mental health provider in order to assess for a diagnosis of GD. The eRFS shall indicate the GAS to be considered (examples in Section 2). The Chief Medical Executive or Chief Physician and Surgeon shall forward the request to headquarters. Once an eRFS is submitted, appointments shall be scheduled based on local operating procedure to ensure evaluation from the treating medical provider and a written report from the mental health clinician are completed.

A. The institution shall compile and submit the information as listed below in Section I – Request for GAS within 90 calendar days following an appointment generated by receipt of a documented request for GAS to CDCRCCHCSGASRC@cdcr.ca.gov, absent a showing of good cause for an extension, in which case an extension may be granted by GASRC.

B. The patient shall receive one random comprehensive urine toxicology screening between the time the eRFS is submitted and the time the referral is sent to GASRC. The results of the toxicology screening shall remain confidential and not be disclosed as part of a disciplinary process.

C. The institution shall neither recommend approval nor non-approval of the request for GAS at the first and second institutional levels of review.

INSTITUTION EVALUATION FOR CONSIDERATION OF GENDER AFFIRMING SURGERY

Section 1 – Request for GAS

CASE MATERIALS TO BE SUBMITTED TO INSTITUTIONAL LEVELS OF REVIEW AND TO GASRC FOR GAS CONSIDERATION

Institution staff shall prepare the following items for submission to the institutional second level of review of a request for consideration of GAS:

I. AN ELECTRONIC REQUEST FOR SERVICES

II. CDCR 7466 GENDER AFFIRMING SURGERY REQUEST CHECKLIST

III. MEDICAL EVALUATION

A. Primary care evaluation to include:
   1. A complete medical history and physical exam pertinent to the requested surgery/surgeries within the past year including a notation regarding patient adherence to recommended medical therapies and compliance with scheduled appointments;
   2. Body Mass Index;
   3. Comprehensive urine toxicology screening results;
   4. Identification of all medical conditions; and
   5. A complete history of medical therapy for gender dysphoria including pertinent laboratory monitoring and any current hormone therapy.

   Note: A physical exam or laboratory refusal should not preclude processing a GAS eRFS but can be noted in the medical documentation.

B. For requests for revision to GAS, a description of prior GAS and details of current surgery requested; any prior specialist recommendations for additional surgery.

IV. MENTAL HEALTH EVALUATION

A. The mental health evaluator shall attend the Regional GAS Mental Health Evaluation Training. Send training inquiries to CDCRCCHCSGASRC@cdcr.ca.gov.

B. For initial requests and re-referrals, complete an **Institution Evaluation for Consideration of Gender Affirming Surgery**.

C. For requests for revision to GAS, complete an **Institution Evaluation for Consideration of Gender Affirming Surgery Revision**.

NOTE: Patients who are not approved for GAS may submit a new request for GAS no sooner than one year after the date of the GASRC decision memorandum not approving the request unless new information is provided that was not previously considered at the time the GASRC reviewed the case.

INSTITUTION EVALUATION FOR CONSIDERATION OF GENDER AFFIRMING SURGERY

Section 2 – Surgical Procedures

Examples of gender affirming procedures that are commonly requested are provided below. For procedures including those that are not listed below, follow the referral guidelines in Section 1 - Request for GAS

Transwoman/Feminizing:
Vaginoplasty
Orchiectomy
Penectomy
Clitoroplasty
Labioplasty
Vulvoplasty
Breast Augmentation
Facial Feminization
Tracheal Shave

Transman/Masculinizing:
Vaginectomy
Hysterectomy
Salpingo-oophorectomy
Metoidioplasty
Phalloplasty
Urethroplasty
Scrotoplasty
Placement of testicular prostheses
Mastectomy and reduction mammoplasty
Reduction Mammoplasty
Facial Masculinization

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALISHEA KINGDOM, et al., Plaintiff, v. DONALD J. TRUMP, et al., Defendants.	Case No. 1:25-cv-00691

DECLARATION OF DR. DAN H. KARASIC IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

I, Dan H. Karasic, M.D., hereby declare and state as follows:

1. I am over the age of 18, of sound mind, and in all respects competent to testify.

2. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

3. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

I. BACKGROUND AND QUALIFICATIONS

A. Qualifications

4. I am a Professor Emeritus of Psychiatry at University of California – San Francisco (UCSF). I have been on faculty at UCSF since 1991. I have also had a telepsychiatry private practice since 2020.

5. I received my Doctor of Medicine (M.D.) degree from the Yale Medical School in 1987. In 1991, I completed my residency in psychiatry at the University of California – Los Angeles (UCLA) Neuropsychiatric Institute, and from 1990 to 1991, I was a postdoctoral fellow in a training program in mental health services for persons living with AIDS at UCLA.

6. For over 30 years, I have worked with patients with gender dysphoria. I am a Distinguished Life Fellow of the American Psychiatric Association and have been the chair of the American Psychiatric Association Workgroup on Gender Dysphoria, as well as the sole author of the chapter on transgender care in the American Psychiatric Press's Clinical Manual of Cultural Psychiatry, Second Edition.

7. Over the past 30 years, I have provided care for thousands of transgender patients.

8. I previously sat on the Board of Directors of the World Professional Association for Transgender Health (WPATH) and am a co-author of WPATH's Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, Version 7, and the lead author on the Mental Health chapter of Version 8. The WPATH Standards of Care are the internationally accepted guidelines designed to promote the health and welfare of transgender, transsexual, and gender variant persons. I remain active in the work of WPATH.

9. As a member of the WPATH Global Education Initiative, I helped develop a specialty certification program in transgender health and helped train over 2,000 health providers.

10. At UCSF, I developed protocols and outcome measures for the Transgender Surgery Program at the UCSF Medical Center. I also served on the Medical Advisory Board for the UCSF Center of Excellence for Transgender Care and co-wrote the mental health section of the original Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People and the revision in 2016.

11. I have worked with the San Francisco Department of Public Health, helping to develop and implement their program for the care of transgender patients and conducting mental health assessments for gender-affirming surgery. I served on the City and County of San

Francisco Human Rights Commission's LGBT Advisory Committee, and I have been an expert consultant for California state agencies and on multiple occasions for the United Nations Development Programme on international issues in transgender care.

12. I have held numerous clinical positions concurrent to my clinical professorship at UCSF. Among these, I served as an attending psychiatrist for San Francisco General Hospital's consultation-liaison service for AIDS care, as an outpatient psychiatrist for HIV-AIDS patients at UCSF, as a psychiatrist for the Transgender Life Care Program and the Dimensions Clinic at Castro Mission Health Center, and the founder and co-lead of the UCSF Alliance Health Project's Transgender Team. In these clinical roles, I specialized in the evaluation and treatment of transgender, gender dysphoric, and HIV-positive patients.

13. I also regularly provide consultation on challenging cases to psychologists and other psychotherapists working with transgender and gender dysphoric patients. I have been a consultant in transgender care to the California Department of State Hospitals, which treats patients held by forensic commitment and psychiatric patients from the state prisons, and have been a consultant for the California Department of Corrections and Rehabilitation on the care of incarcerated transgender people. I am currently a consultant in transgender mental health to the Alameda County Jails. In my 29 years working with transgender patients in San Francisco public health clinics, I worked with many formerly incarcerated people, including those who spoke of their experiences being denied care while incarcerated.

14. As part of my psychiatric practice treating individuals diagnosed with gender dysphoria and who receive other medical and surgical treatment for that condition, as well as a co-author of the WPATH Standards of Care and UCSF's Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People, I am and must be familiar with

additional aspects of medical care for the diagnosis of gender dysphoria, beyond mental health treatment, assessment, and diagnosis.

15. In addition to this work, I have done research on the treatment of depression.

16. I have authored many articles and book chapters on the diagnosis and treatment of gender dysphoria and edited the book Sexual and Gender Diagnoses of the Diagnostic and Statistical Manual (DSM): A Reevaluation.

17. Since 2018, I have performed over 130 independent medical reviews for the State of California to determine the medical necessity of transgender care in appeals of denial of insurance coverage.

18. My professional background, experiences, publications inclusive of those authored in the past ten years, and presentations are detailed in my curriculum vitae ("CV"). A true and correct copy of my most up-to-date CV is attached as Exhibit A.

B. Compensation

19. I am being compensated for my work on this matter at a rate of $400.00 per hour for preparation of declarations and expert reports. I will be compensated $3,200.00 per day for any deposition testimony or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

C. Previous Testimony

20. Over the past four years, I have given expert testimony by deposition or trial in the following cases: *L.B. v. Premera Blue Cross*, No. 3:20-cv-06145-RJB (W.D. Wash.); *Misanin v. Wilson*, No. 2:24-cv-04734-BHH (D.S.C.); *Voe v. Mansfield*, No. 1:23-CV-864-LCB-LPA (M.D.N.C.); *Boe v. Marshall*, No. 2:22-cv-184-LCB (N.D. Ala.); *Doe v. Ladapo*, No. 4:23-cv-00114 (N.D. Fla.); *Dekker v. Weida*, No. 4:22-cv-00325 (N.D. Fla.); *K.C. v. The Individual Members of the Medical Licensing Board of Indiana*, No. 1:23-cv-00595 (S.D. Ind.); *Brandt v.*

Rutledge, No. 4:21-cv-00450 (E.D. Ark.); *C.P. v. Blue Cross Blue Shield of Illinois*, No. 3:20-cv-06145 (W.D. Wash.); *Kadel v. Folwell*, No. 1:19-cv-00272 (M.D.N.C.); and *Fain v. Crouch*, No. 3:20-cv-00740 (S.D. W. Va.). To the best of my recollection, I have not given expert testimony at a trial or at a deposition in any other case during this period.

II. BASIS FOR OPINIONS

21. In preparing this report, I have relied on my training and my decades clinical experience as a psychiatrist treating patients with gender dysphoria, as well as my experience conducting research, as set out in my curriculum vitae (attached hereto as Exhibit A).

22. I have also relied on my knowledge of the peer-reviewed research regarding the treatment of gender dysphoria, which reflects advancements in the field of transgender health. I have reviewed the materials listed in the bibliography attached hereto as Exhibit B. The sources cited therein include authoritative, scientific peer-reviewed publications. They include the documents specifically cited as supportive examples in particular sections of this report.

23. I have also relied on my knowledge of the clinical practice guidelines for the treatment of gender dysphoria, including my work as a contributing author of the WPATH Standards of Care, Versions 7 and 8, and the UCSF Guidelines.

24. The materials I have relied upon in preparing this declaration are the same types of materials that experts in my field of study regularly rely upon when forming opinions on the subject. I reserve the right to revise and supplement the opinions expressed in this report or the bases for them if any new information becomes available in the future, including as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

25. Additionally, I have reviewed Executive Order 14168, titled "Defending Women from Gender Ideology Extremism and Restoring Biological Truth to The Federal Government,"

issued on January 20, 2025 ("EO 14168").

III. SUMMARY OF EXPERT OPINIONS

26. Gender dysphoria is a serious condition which, if left untreated, can impair a person's ability to function and cause significant depression, anxiety, self-harm and suicidality.

27. EO 14168, by prohibiting "any medical procedure, treatment, or drug for the purpose of conforming an inmate's appearance to that of the "opposite sex," with "sex" being defined as immutable from the time of conception, prohibits treatments that are part of widely accepted protocols for the treatment of gender dysphoria that are supported by every major medical association in the country—social transition and gender-affirming medical care.

28. Decades of scientific research and clinical experience have demonstrated that social transition and gender-affirming medical care can significantly relieve the distress of gender dysphoria and are medically necessary for many people with this condition. I have seen first-hand, countless times over decades of practice, the many benefits of social transition and gender-affirming medical care.

29. For individuals for whom gender-affirming medical care is indicated, there are no alternative evidence-based treatments for gender dysphoria.

30. Prohibiting people with gender dysphoria from socially transitioning and withdrawing or denying gender-affirming medical care to those for whom it is indicated would put them at risk of significant harm to their health and well-being, including heightened risk of self-harm and suicidality.

31. When incarcerated people are unable to receive gender-affirming medical care to treat their gender dysphoria, some have resorted to self-castration or other self-harm to get relief, or have attempted to end their lives.

IV. EXPERT OPINIONS

A. Sex and Gender Identity

32. At birth, infants are assigned a sex, either male or female, based on the appearance of their external genitalia.

33. While the terms "male sex" and "female sex" are sometimes used in reference to a person's genitals, chromosomes, and hormones, the reality is that sex is complicated and multifactorial. Aside from external genital characteristics, chromosomes, and endogenous hormones, other factors related to sex include gonads, gender identity, and variations in brain structure and function.

34. EO 14168 defines "sex" as "an individual's immutable biological classification as either male or female," that "does not include the concept of 'gender identity.'" EO 14168 § 2(a). It further defines "Female" as "a person belonging, at conception, to the sex that produces the large reproductive cell," and "[m]ale" as "a person belonging, at conception, to the sex that produces the small reproductive cell." EO 14168 §§ 2(d), (e).

35. EO 14168's definition of "sex" is not consistent with how it is commonly understood in medicine. According to the American Medical Association, sex is made up of many diverse components. (AMA, 2023). Similarly, the Endocrine Society notes that because a person's sex characteristics "may not [always] be in line with each other …, the terms biological sex and biological male or female are imprecise and should be avoided." (Hembree, et al., 2017).

36. Gender identity is "a person's deeply felt, inherent sense of being a girl, woman, or female; a man, or male; a blend of male or female; or an alternative gender" (American Psychological Association, 2015, at 834).

37. Gender identity does not always align with sex assigned at birth.

38. Gender identity, which has biological bases (Fischer and Cocchetti, 2020), is not merely a product of external influence, nor is it subject to voluntary change.

39. As documented by multiple leading medical authorities, efforts to change a person's gender identity are ineffective, can cause harm, and are unethical. (American Psychological Association, 2021, Byne, et al., 2018, Coleman, et al., 2012).

40. EO 14168 defines "gender identity" as "a fully internal and subjective sense of self, disconnected from biological reality and sex and existing on an infinite continuum, that does not provide a meaningful basis for identification and cannot be recognized as a replacement for sex." EO 14168 § 2(g).

41. EO 14168's definition of "gender identity" differs from how this term is commonly understood and used in medicine and science. Gender identity does provide a meaningful basis for identification and has been a basis for identification federally as well as in most states, and in many other countries, for years.

42. For most people, their sex assigned at birth, or assigned sex, matches their gender identity. For transgender people, their assigned sex does not align with their gender identity.

43. Based on data from the Williams Institute, approximately 0.6% of the United States population age 13 or older, or about 1.6 million people, identify as transgender. (Herman, et al., 2022).

44. Being transgender is widely accepted as a normal variation in human development. Simply being transgender or gender nonconforming is not a medical condition to be treated and is not considered a mental illness. People who are transgender have no impairment in their ability to be productive, contributing members of society simply because of their transgender status.

45. In the replacement of Gender Identity Disorder in DSM-IV with Gender Dysphoria in DSM-5, the American Psychiatric Association recognized that the clinically significant distress and social/occupational impairment of gender dysphoria is the disorder, not transgender identity. DSM-5 notes that diagnosis and treatment are "focus[ed] on dysphoria as the clinical problem, not identity per se." (DSM-5, at 451). The World Health Organization, in placing Gender Incongruence outside the chapter of mental health conditions, states, "trans-related and gender diverse identities are not conditions of mental ill-health." (World Health Organization, Gender Incongruence).

46. Similarly, WPATH's Standards of Care, Version 8 states: "The expression of gender characteristics, including identities, that are not stereotypically associated with one's sex assigned at birth is a common and a culturally diverse human phenomenon that should not be seen as inherently negative or pathological. … It should be recognized gender diversity is common to all human beings and is not pathological. However, gender incongruence that causes clinically significant distress and impairment often requires medically necessary clinical interventions." (Coleman, et al. 2022).

B. Gender Dysphoria

47. The term "gender dysphoria" is distress related to the incongruence between one's gender identity and attributes related to one's sex assigned at birth.

48. The diagnosis of Gender Dysphoria (capitalized) is a serious medical condition, and it is codified in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM). The current version, known as the *Fifth Edition, Text Revision* (DSM-5-TR), was released in 2022.

49. The DSM's diagnosis of Gender Dysphoria in Adolescents and Adults involves two major diagnostic criteria:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by at least two of the following (one of which must be Criterion A1):

1. A marked incongruence between one's experienced/expressed gender and primary or secondary sex characteristics.
2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender.
3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

50. Gender dysphoria is a condition that is highly amenable to treatment, and the prevailing treatment for it is highly effective.

51. When untreated, gender dysphoria can cause significant distress including increased risk of depression, anxiety, self-harm and suicidality. It can also impair individuals' ability to function in all aspects of life, including school or work, and in family and other personal relationships. These risks decline when transgender individuals are supported and live according to their gender identity.

52. With access to medically-indicated care, transgender people can experience significant and potentially complete relief from their symptoms of gender dysphoria. Not only is this documented in scientific literature and published data, but I have witnessed this in thousands of patients over three decades.

C. Evidence-Based Guidelines for Treatment of Gender Dysphoria

53. The World Professional Association of Transgender Health (WPATH) has issued *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* ("WPATH SOC") since 1979. The current version, published in 2022, is WPATH SOC 8. The SOC 8 provides guidelines for multidisciplinary care of transgender individuals and describes criteria for medical interventions to treat gender dysphoria, including hormone treatment and surgery when medically indicated.

54. The SOC 8 utilized a rigorous evidence-based approach to developing the guidelines. (Coleman, et al., 2022). The process of developing the SOC 8 was a multistep, several years long effort that started in 2017. This process is outlined in great detail in Appendix A to SOC 8.

55. This "process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and the World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process." (Coleman, et al., 2022, at S247 (citing Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice, 2011; World Health Organization, 2019)). And "[t]he SOC-8 revision committee was multidisciplinary and consisted of subject matter experts, health care professionals, researchers and stakeholders with diverse perspectives and geographic representation." (Coleman, et al., 2022, at S247).

56. WPATH SOC 8's evidence-based recommendations were drafted "based on the results of the systematic, and background literature reviews plus consensus-based expert opinions." (Coleman, et al., 2022, at S250). The recommendations were developed and are based on available evidence supporting interventions, a discussion of risks and harms, as well as feasibility and acceptability within different contexts and country settings. A consensus of the

final recommendations was attained using the Delphi process that included all members of the Standards of Care Revision committee, and supportive and explanatory text of the evidence for the statements was written.

57. The Delphi process is a procedure by which a panel of experts are asked for their opinion on a relevant issue, summarizing and presenting their collective responses and repeating this process for a certain number of rounds. (Shang, 2023; Hsu and Sanford, 2019). It is "a well-established approach to answering a research question through the identification of a consensus view across subject experts." (Barrett and Healey, 2020).

58. The recommendations submitted to a vote under the Delphi process required approval of 75% of the authors of SOC 8 as a whole. More specifically, for a recommendation to be approved, a minimum of 75% of the voters had to approve the statement. (Coleman, et al., 2022, at S250). With regards to SOC 8, every member of the SOC revision committee voted for each statement. Following the aforementioned process, recommendations contained in SOC 8, as published in 2022, were approved by 75% or more of the revision committee.

59. A clinical practice guideline from the Endocrine Society (the Endocrine Society Guideline) provides similar guidelines for clinicians to provide safe and effective treatment for gender dysphoria. (Hembree, et al., 2017).

60. Each of these guidelines are evidence-based and supported by scientific research and literature, as well as extensive clinical experience.

61. The evidence base supporting the recommendations in these guidelines is comparable to the evidence base supporting treatment for other conditions.

62. The protocols and policies set forth by the WPATH Standards of Care and the Endocrine Society Guideline are endorsed and cited as authoritative by the major professional

medical and mental health associations in the United States, including the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, the American Psychological Association, the American College of Obstetrics and Gynecology, the American College of Physicians, and the World Medical Association, among others. They are also relied upon by clinicians treating patients with gender dysphoria.

D. Treatment of Gender Dysphoria

63. Under the WPATH SOC and the Endocrine Society Guideline, the overarching goal of treatment is to eliminate the distress of gender dysphoria by helping the patient live consistently with their gender identity by aligning their presentation and body with their gender identity.

64. Social transition is an integral part of addressing gender dysphoria for transgender people. Social transition involves changing appearance (e.g. garments, hair, make-up) and social role, with change of signifiers of gender, including name and pronouns, and public presentation in the identified gender.

65. In earlier versions of the Standards of Care, social transition was required before medical interventions were considered. While the current WPATH SOC 8 recognizes the necessity for individualized paths for transition, social transition remains central to addressing gender dysphoria for many transgender people.

66. While social transition alone can adequately address gender dysphoria for some people, many individuals with gender dysphoria cannot obtain relief without also receiving medical interventions to align the body with their gender identity. In accordance with the WPATH SOC and the Endocrine Society Guidelines, medical interventions to treat adults with gender dysphoria may include hormone therapy and surgeries, based on a patient's individual needs.

67. For assessing an adult for gender-affirming medical care, WPATH SOC 8 states that the health professional should be licensed and trained in identifying gender dysphoria as well as co-existing mental health and psychosocial concerns, and that medical or surgical treatment should only be recommended when "gender incongruence is marked and sustained," when there is capacity for consent, when other conditions that might affect outcomes have been assessed, and when diagnostic criteria for Gender Dysphoria of DSM 5-TR (in the US) or Gender Incongruence of ICD-11(outside the US) are met.

68. If a patient is assessed to have a medical need for hormone therapy, gender-affirming hormone therapy involves administering testosterone for transgender men and estrogen and testosterone suppression for transgender women. The purpose of this treatment is to attain the appropriate masculinization or feminization of the transgender person that matches as closely as possible to their gender identity. Gender-affirming hormone therapy is a partially reversible treatment.

69. Some transgender individuals need surgical interventions to help bring their phenotype into alignment with their gender. Surgical interventions may include, inter alia, vaginoplasty and orchiectomy for transgender female individuals, and chest reconstruction and hysterectomy for transgender male individuals.

70. For patients for whom gender-affirming medical care is indicated, no alternative treatments have been demonstrated to be effective.

71. The treatment protocols for gender dysphoria are comparable to those for other mental health and medical conditions. Indeed, these or similar procedures are provided for cisgender people with other diagnoses. For example, breast reduction surgery is much more commonly performed on cisgender males who have unwanted excess breast tissue

(gynecomastia), than on transgender males. Dai, et al. (2024) recently found that of the adolescents who had these surgeries, 97% were cisgender males and only 3% were transgender males. Testosterone treatment for transgender males, like for cisgender males with testosterone insufficiency (hypogonadism), involves administering testosterone to bring blood levels up to the normal male range.

E. Social Transition Has Been Shown to Help Alleviate Gender Dysphoria.

72. Social transition has been shown to positively affect mental health (Hughto, et al 2020). Bringing one's presentation into alignment with gender identity can help one see oneself and be recognized and treated by others consistent with one's gender identity. Recognition of chosen name with social transition has been associated with decreases in depression and suicidality. (Russell, et al 2018). In my work with thousands of transgender patients, social transition has been a critical step towards improved mental health. In patients who have been forced to socially detransition, while incarcerated or due to family or career, mental health impacts have been severe to my patients, with increased gender dysphoria, depression, anxiety and in some patients, suicidality and self-harm.

F. Gender-Affirming Medical Care Has Been Shown To Be Safe and Effective Treatment for Gender Dysphoria.

73. There is a substantial body of research and clinical evidence that gender-affirming medical care is effective in treating gender dysphoria. This evidence includes scientific studies assessing mental health outcomes for transgender people who are treated with these interventions, and decades of clinical experience, including my own.

74. The research and studies supporting the necessity, safety, and effectiveness of medical care for gender dysphoria are the same type of evidence that the medical community routinely relies upon when treating other medical conditions.

75. Medical treatment for gender dysphoria has been studied for over half a century, and there is substantial evidence that it improves quality of life and measures of mental health.[1] There is also substantial evidence that the risks of these treatments are low and manageable, and comparable to the type of risks that exist in the same treatments when given to cisgender patients and in many other medical treatments. For example, the cardiovascular risks associated with estrogen apply whether the person is receiving treatment for gender dysphoria, menopause, or other conditions. Regret rates for gender-affirming surgeries are very low, often much lower than for similar surgeries in cisgender patients. (Thornton, et al 2024).

76. The studies on gender-affirming medical care for treatment of dysphoria are consistent with decades of clinical experience of mental health providers across the U.S. and around the world. At professional conferences and other settings in which I interact with colleagues, clinicians report that gender-affirming medical care, for those for whom it is indicated, provides great clinical benefit. In my over 30 years of clinical experience treating gender dysphoric patients, I have seen the benefits of gender-affirming medical care on my patients' health and well-being. I have seen many patients show improvements in mental health, as well as in performance in school and work, in social functioning with peers, and in family relationships when they experience relief from gender dysphoria with gender-affirming medical care.

77. As part of the treatment process for gender dysphoria, patients provide informed consent to their care. In addition, a treating doctor will not offer gender-affirming medical

[1] *See, e.g.*, Dopp, et al., 2024; Shelemy, et al., 2024; Ascha, et al., 2022; Aldridge, et al., 2021; Almazan, et al., 2021; Baker, et al., 2021; Murad, et al., 2010; Nobili, et al., 2018; Pfafflin & Junge, 1998; T'Sjoen et al. 2019; Turan, et al., 2018; van de Grift et al., 2018; Olson-Kennedy, et al., 2018; Cornell, What We Know, 2018; Nguyen, et al., 2018; Oda, et al.,2017; White, Hughto and Reisner, 2016; Fisher, et al., 2016; Keo-Meier, et al., 2015; Wierckx et al., 2014; Colizzi, et al., 2014; Colizzi, et al., 2013.

treatments unless they have concluded after weighing the risks and benefits of care that treatment is appropriate. The risks and benefits of care are discussed with the transgender patient, who must consent.

78. Gender-affirming medical interventions provided in accordance with the WPATH SOC 8 and Endocrine Society Guidelines are widely recognized in the medical community as safe, effective, and medically necessary for many people with gender dysphoria. (*See, e.g.*, the American Psychological Association, 2024 and 2021; American Academy of Pediatrics, 2018 (reaffirmed in 2023); the American Medical Association, 2021; the Pediatric Endocrine Society, 2021; the American College of Obstetricians and Gynecologists, 2021; the Endocrine Society, 2020; the American Academy of Family Physicians, 2020; the American Psychiatric Association, 2018; and WPATH, 2022).

79. For all the reasons above, I am aware of no basis in medicine or science for categorically prohibiting gender-affirming medical care.

G. Harms of a Blanket Prohibition Against Social Transition and Hormone Therapy[2]

80. The overarching goal of treatment is to eliminate the distress of gender dysphoria by aligning an individual patient's body and presentation with their internal sense of self. The denial of medically-indicated care to transgender people not only results in the prolonging of their gender dysphoria, but causes additional distress and poses other health risks, such as depression, post-traumatic stress disorder, and suicidality. In other words, lack of access to gender-affirming care directly contributes to poorer mental health outcomes for transgender people. (Owen-Smith, et al., 2018).

[2] Because the preliminary injunction motion does not seek relief related to gender-affirming surgeries, this portion of the declaration does not address surgery.

81. For patients for whom gender-affirming medical care is indicated, no alternative treatments have been demonstrated to be effective. To the extent one proposed alternative is psychotherapeutic treatment to encourage identification with a person's assigned sex at birth, the American Psychological Association has stated that such efforts provide no benefit and instead do harm. (APA, 2021). Or if an alternative approach is to treat the worsening dysphoria only with therapy, that has not shown to be effective in any research. (Dopp, et al., 2024). Psychotherapy is a critical treatment modality for many patients, but it does not address the underlying gender dysphoria, which when persistent can only be addressed by bringing a patient's body and sex characteristics into alignment with the patient's gender identity.

82. Denying patients with gender dysphoria the ability to socially transition or obtain gender-affirming medical care where indicated predictably will lead to significant deterioration in mental health.

83. I have had patients over the years who were unable to access gender-affirming medical care when it was clinically indicated, including in the years before this care was more widely available. In many of these patients, delayed or denied care resulted in increased depression, anxiety, suicidal ideation and self-harm, increased substance use, and a deterioration in school or work performance. Some patients attempted to self-castrate or remove breasts. For patients with severe distress due to their gender dysphoria, psychotherapeutic approaches did not alleviate this distress absent medical intervention. Some of my patients had years of intensive mental health interventions, including long-term psychotherapy, without relief of gender dysphoria until receiving medical intervention.

84. Research documents the harms to incarcerated individuals with gender dysphoria who have not been able to receive necessary treatment, including attempts at self-castration.

(Brown, 2010, Aldrich et al, 2023). I have provided care for transgender patients after incarceration who had suffered severe mental health consequences, including intolerable gender dysphoria, depression, anxiety, self-harm and suicidality, from denial of the ability to socially and medically transition.

85. A blanket policy withdrawing hormone therapy and the ability to socially transition from individuals with gender dysphoria currently receiving that care would be expected to cause severe negative impact on patients' mental health. I have cared for or consulted on patients who were forced to socially and medically detransition and I've seen the suffering that it caused. For example, I consulted on a patient who, while in the long-term custody of a forensic psychiatry unit, was forced to detransition—both medically and socially. He severely decompensated and attempted suicide. After obtaining legal representation to request that the institution bring in an expert in the treatment of gender dysphoria, he was able to resume gender-affirming hormone therapy and live consistently with his male identity, and his mental health greatly improved. Eventually he was able to have gender affirming surgery, and then be released, and he has flourished in his life and work after release.

V. CONCLUSION

86. Executive Order 14168, which categorically prohibits gender-affirming medical care and social transition for individuals with gender dysphoria who are in the custody of the Bureau of Prisons, regardless of their medical needs, is contrary to widely accepted evidence-based medical protocols for the treatment of gender dysphoria and puts these individuals at risk of significant harm, including heightened risk of depression, self-harm, and suicidality.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 14th day of March, 2025

Dan H. Karasic

EXHIBIT A

University of California, San Francisco

CURRICULUM VITAE

Name: Dan H. Karasic, MD

Position: Professor Emeritus
Psychiatry
School of Medicine

[redacted]

EDUCATION

1978 - 1982	Occidental College, Los Angeles	A.B.; Summa Cum Laude	Biology
1982 - 1987	Yale University School of Medicine	M.D.	Medicine
1987 - 1988	University of California, Los Angeles	Intern	Medicine, Psychiatry, and Neurology
1988 - 1991	University of California, Los Angeles; Neuropsychiatric Institute	Resident	Psychiatry
1990 - 1991	University of California, Los Angeles; Department of Sociology	Postdoctoral Fellow	Research Training Program in Mental Health Services for Persons with AIDS

LICENSES, CERTIFICATION

1990	Medical Licensure, California, License Number G65105
1990	Drug Enforcement Administration Registration Number BK1765354
1993	American Board of Psychiatry and Neurology, Board Certified in Psychiatry

PRINCIPAL POSITIONS HELD

1991 - 1993	University of California, San Francisco	Health Sciences Psychiatry Clincial Instructor
1993 - 1999	University of California, San Francisco	Health Sciences Psychiatry Assistant Clinical Professor

1999 - 2005	University of California, San Francisco	Health Sciences Psychiatry	Associate Clinical Professor
2005 - 2020	University of California, San Francisco	Health Sciences Psychiatry	Clinical Professor
2020-present	University of California, San Francisco	Professor Emeritus of Psychiatry	

OTHER POSITIONS HELD CONCURRENTLY

1980 - 1980	Associated Western Universities / U.S. Department of Energy	Honors Undergraduate Research Fellow	UCLA Medicine
1981 - 1981	University of California, Los Angeles; UCLA Medicine American Heart Association, California Affiliate	Summer Student Research Fellow	
1986 - 1987	Yale University School of Medicine; American Heart Association, Connecticut Affiliate	Medical Student Research Fellow	Psychiatry
1990 - 1991	University of California, Los Angeles	Postdoctoral	Sociology Fellow
1991 - 2001	SFGH Consultation-Liaison Service; AIDS Care	Attending Psychiatrist	Psychiatry
1991 - 2001	AIDS Consultation-Liaison Medical Student Elective	Course Director	Psychiatry
1991 - present	UCSF Positive Health Program at San General Hospital (Ward 86)	HIV/AIDS Outpatient Psychiatrist	Psychiatry Francisco
1991 - present	UCSF AHP (AIDS Health Project/Alliance Health Project)	HIV/AIDS Outpatient Psychiatrist	Psychiatry
1994 - 2002	St. Mary's Medical Center CARE Unit. The CARE Unit specializes in the care of patients with AIDS dementia.	Consultant	Psychiatry
2001 - 2010	Depression and Antiretroviral Adherence Study (The H.O.M.E. study: Health Outcomes of Mood Enhancement)	Clinical Director	Psychiatry and Medicine
2003 - 2020	Transgender Life Care Program and Clinic, Castro Mission Health	Psychiatrist Clinic	Dimensions Dimensions Center
2013 - 2020	UCSF Alliance Health Project, Co-lead, Transgender Team	Co-Lead and Psychiatrist	Psychiatry

HONORS AND AWARDS

1981	Phi Beta Kappa Honor Society	Phi Beta Kappa
1990	NIMH Postdoctoral Fellowship in Health Services for People with AIDS (1990-1991)	National Institute of Mental Health Mental
2001	Lesbian Gay Bisexual Transgender Leadership Award, LGBT Task Force of the Cultural Competence and Diversity Program	SFGH Department of Psychiatry
2006	Distinguished Fellow	American Psychiatric Association
2012	Chancellor's Award for Leadership in LGBT Health	UCSF
2023	Alumni Seal Award for Achievement	Occidental College Professional

MEMBERSHIPS

1992 - present Northern California Psychiatric Society

1992 - present American Psychiatric Association

2000 - 2019 Bay Area Gender Associates (an organization of psychotherapists working with transgendered clients)

2001 - present World Professional Association for Transgender Health

SERVICE TO PROFESSIONAL ORGANIZATIONS

1981 - 1982	The Occidental	News Editor
1984 - 1985	Yale University School of Medicine	Class President
1989 - 1991	Kaposi's Sarcoma Group, AIDS Project Los Angeles	Volunteer Facilitator
1992 - 1996	Early Career Psychiatrist Committee, Association of Gay Lesbian Psychiatrists	Chair and
1992 - 1996	Board of Directors, Association of Gay and Lesbian	Member Psychiatrists
1993 - 1993	Local Arrangements Committee, Association of Gay and Psychiatrists	Chair Lesbian
1994 - 1995	Educational Program, Association of Gay and Lesbian 1995 Annual Meeting	Director Psychiatrists,
1994 - 1998	Board of Directors, BAY Positives	Member
1994 - 2020	Committee on Lesbian, Gay, Bisexual and Transgender	Member

Issues, Northern California Psychiatric Society

1995 - 1997 Board of Directors, Bay Area Young Positives. BAY Positives is the nation's first community-based organization providing psychosocial and recreational services to HIV-positive youth — President

1995 - 1997 Executive Committee, Bay Area Young Positives. — Chair

1996 - 2004 Committee on Lesbian, Gay, Bisexual and Transgender Issues, Northern California Psychiatric Society — Chair

1998 - 2002 City of San Francisco Human Rights Commission, Gay Bisexual Transgender Advisory Committee — Member

2000 - 2004 Association of Gay and Lesbian Psychiatrists. the organization's educational programs — Vice President Responsible for

2004 - 2005 Association of Gay and Lesbian Psychiatrists — President-elect

2005 - 2007 Caucus of Lesbian, Gay, and Bisexual Psychiatrists of the American Psychiatric Association — Chair

2005 - 2007 Association of Gay and Lesbian Psychiatrists — President

2007 - 2009 Association of Gay and Lesbian Psychiatrists — Immediate Past President

2009 - 2010 Consensus Committee for Revision of the Sexual and Gender Identity Disorders for DSM-V, GID of Adults subcommittee. (Wrote WPATH recommendations as advisory body to the APA DSM V Committee for the Sexual and Gender Identity Disorders chapter revision.) — Member

2010 - 2011 Scientific Committee, 2011 WPATH Biennial Symposium, Atlanta — Member

2010 -2022 World Professional Association for Transgender Care Standards of Care Workgroup and Committee (writing seventh and eighth revisions of the WPATH Standards of Care, which is used internationally for transgender care.) — Member

2010 - 2018 ICD 11 Advisory Committee, World Professional Association for Transgender Health — Member

2012 - 2014 Psychiatry and Diagnosis Track Co-chair, Scientific Committee, 2014 WPATH Biennial Symposium, Bangkok — Member

2014 - 2016 Scientific Committee, 2016 WPATH Biennial Symposium, Amsterdam — Member

2014 - 2018 Board of Directors (elected to 4 year term), World Professional Association for Transgender Health — Member

2014 - 2018 Public Policy Committee, World Professional Association for Transgender Health — Chair

2014 - 2018 WPATH Global Education Initiative: Training providers and specialty certification in transgender health — Trainer and Steering

		Committee Member
2014 - 2016	American Psychiatric Association Workgroup on Gender Dysphoria	Member
2016 - present	American Psychiatric Association Workgroup on Gender Dysphoria	Chair
2016	USPATH: Inaugural WPATH U.S. Conference, Los Angeles, 2017	Conference Chair

SERVICE TO PROFESSIONAL PUBLICATIONS

2011 - present Journal of Sexual Medicine, reviewer

2014 - present International Journal of Transgenderism, reviewer

2016 - present LGBT Health, reviewer

INVITED PRESENTATIONS - INTERNATIONAL

2009	World Professional Association for Transgender Health, Oslo, Norway	Plenary Session Speaker
2009	World Professional Association for Transgender Health, Oslo, Norway	Symposium Speaker
2009	Karolinska Institutet, Stockholm Sweden	Invited Lecturer
2012	Cuban National Center for Sex Education (CENESEX), Havana, Cuba	Invited Speaker
2013	Swedish Gender Clinics Annual Meeting, Stockholm, Sweden	Keynote Speaker
2013	Conference on International Issues in Transgender care, United Nations Development Programme - The Lancet, Beijing, China	Expert Consultant
2014	World Professional Association for Transgender Health, Thailand	Track Chair Bangkok,
2014	World Professional Association for Transgender Health, Bangkok, Thailand	Invited Speaker
2014	World Professional Association for Transgender Health, Bangkok, Thailand	Invited Speaker
2015	European Professional Association for Transgender Health, Ghent, Belgium	Invited Speaker
2015	European Professional Association for Transgender Health, Ghent, Belgium	Symposium Chair
2015	Israeli Center for Human Sexuality and Gender Identity, Tel Aviv	Invited Speaker
2016	World Professional Association for Transgender Health, Amsterdam	Symposium Chair
2016	World Professional Association for Transgender Health, Amsterdam	Invited Speaker

2016 World Professional Association for Transgender Health, Amsterdam 2017 Brazil Professional Association for Transgender Health, Sao Paulo — Invited Speaker

2017 Vietnam- United Nations Development Programme Asia Transgender Health Conference, Hanoi

2018 United Nations Development Programme Asia Conference on Transgender Health and Human Rights, Bangkok

2018 World Professional Association for Transgender Health, Invited Speaker Buenos Aires

2021 Manitoba Psychiatric Association, Keynote Speaker

2022 World Professional Association for Public Health, invited speaker, Montreal

INVITED PRESENTATIONS - NATIONAL

1990 Being Alive Medical Update, Century Cable Television — Televised Lecturer

1992 Institute on Hospital and Community Psychiatry, Toronto — Symposium Speaker

1992 Academy of Psychosomatic Medicine Annual Meeting, San Diego — Symposium Speaker

1994 American Psychiatric Association 150th Annual Meeting, Philadelphia — Workshop Chair

1994 American Psychiatric Association 150th Annual Meeting, Philadelphia — Workshop Speaker

1994 American Psychiatric Association 150th Annual Meeting, Philadelphia — Paper Session Co-chair

1995 Spring Meeting of the Association of Gay and Lesbian Psychiatrists, Miami Beach — Symposium Chair

1996 American Psychiatric Association 152nd Annual Meeting, New York — Workshop Speaker

1997 American Psychiatric Association Annual Meeting, San Diego — Workshop Speaker

1997 Gay and Lesbian Medical Association Annual — Invited Speaker Symposium

1998 American Psychiatric Association Annual Meeting, Toronto — Workshop Chair

1998 American Psychiatric Association Annual Meeting, Toronto — Workshop Chair

1998	American Psychiatric Association Annual Meeting, Toronto	Media Session Chair
1998	American Psychiatric Association Annual Meeting, Toronto	Media Session Chair
1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Symposium Chair
1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Symposium Presenter
1999	American Psychiatric Association Annual Meeting, Washington, D.C.	Workshop Chair
2000	American Psychiatric Association Annual Meeting, Chicago	Workshop Chair
2000	National Youth Leadership Forum On Medicine, University of California, Berkeley	Invited Speaker
2001	American Psychiatric Association Annual Meeting, New Orleans	Workshop Chair
2001	American Psychiatric Association Annual Meeting, New Orleans	Media Program Chair
2001	Association of Gay and Lesbian Psychiatrists Chair Symposium, New Orleans	
2001	Harry Benjamin International Gender Dysphoria Association Biennial Meeting, Galveston, Texas	Invited Speaker
2002	American Psychiatric Association Annual Meeting, Philadelphia	Media Program Chair
2002	American Psychiatric Association Annual Meeting, Philadelphia	Workshop Chair
2002	American Psychiatric Association Annual Meeting, Philadelphia	Workshop Chair
2003	Association of Gay and Lesbian Psychiatrists CME	Chair Conference
2003	American Psychiatric Association Annual Meeting, San Francisco	Symposium Chair
2003	American Psychiatric Association Annual Meeting, San Francisco	Symposium Co-Chair
2003	American Psychiatric Association Annual Meeting, San Francisco	Workshop Chair
2003	American Public Health Association Annual Meeting, San Francisco	Invited Speaker
2004	Mission Mental Health Clinic Clinical Conference	Invited Speaker

2004	Association of Gay and Lesbian Psychiatrists Conference, New York	Co-Chair
2004	Mental Health Care Provider Education Program: Los Angeles. Sponsored by the American Psychiatric Association Office of HIV Psychiatry	Invited Speaker
2005	American Psychiatric Association Annual Meeting, Atlanta	Workshop Speaker
2005	Association of Gay and Lesbian Psychiatrists Saturday Symposium	Invited Speaker
2008	Society for the Study of Psychiatry and Culture, San Francisco	Invited Speaker
2009	American Psychiatric Association Annual Meeting, San Francisco	Symposium Speaker
2011	National Transgender Health Summit, San Francisco	Invited Speaker
2011	National Transgender Health Summit, San Francisco	Invited Speaker
2011	American Psychiatric Association Annual Meeting, Honolulu, HI	Symposium Chair
2011	American Psychiatric Association Annual Meeting, Honolulu, HI	Symposium Speaker
2011	World Professional Association for Transgender Health Conference, Atlanta, GA	Invited Speaker Biennial
2011	World Professional Association for Transgender Health Conference, Atlanta, GA	Invited Speaker Biennial

		Invited Speaker
2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA	
2011	Institute on Psychiatric Services, San Francisco	Invited Speaker
2012	Gay and Lesbian Medical Association Annual Meeting	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	National Transgender Health Summit, Oakland, CA	Invited Speaker
2013	American Psychiatric Association Annual Meeting, San Francisco	Invited Speaker
2013	Gay and Lesbian Medical Association, Denver, CO	Invited Speaker
2014	American Psychiatric Association Annual Meeting, New York	Invited Speaker
2014	Institute on Psychiatric Services, San Francisco	Moderator
2014	Institute on Psychiatric Services, San Francisco	Invited Speaker
2014	Institute on Psychiatric Services, San Francisco	Invited Speaker
2015	National Transgender Health Summit, Oakland, CA	Invited Speaker
2015	National Transgender Health Summit, Oakland, CA	Invited Speaker
2015	American Psychiatric Association Annual Meeting, Toronto	Workshop Speaker
2015	American Psychiatric Association Annual Meeting, Toronto	Course Faculty
2016	American Psychiatric Association Annual Meeting	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Atlanta	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Springfield, MO	Course Faculty
2016	World Professional Association for Transgender Health Global Education Initiative, Fort Lauderdale, FL	Course Faculty
2017	World Professional Association for Transgender Health, GEI, Los Angeles Course Faculty	
	World Professional Association for Transgender Health	

Surgeon's Training, Irvine, CA Course Faculty

2017 American Urological Association Annual Meeting, San Francisco CA Invited Speaker

2018 World Professional Association for Transgender Health GEI, Portland OR, Course Faculty

2018 World Professional Association for Transgender Health GEI, Palm Springs, Course Faculty

2019 American Society for Adolescent Psychiatry Annual Meeting, San Francisco, Speaker

2019 American Psychiatric Association Annual Meeting, San Francisco, Session Chair

2020 Psychiatric Congress, Invited Speaker

2022 World Professional Association for Transgender Health, Montreal, invited speaker

2023 National Transgender Health Summit, San Francisco, invited speaker

2023 American Psychiatric Association Annual Meeting, San Francisco, invited speaker

2023` US Professional Association for Transgender Health, speaker

2024 World Professional Association for Transgender Health, Lisbon

INVITED PRESENTATIONS - REGIONAL AND OTHER INVITED PRESENTATIONS

1990	Advanced Group Therapy Seminar, UCLA Neuropsychiatric Institute	Invited Lecturer
1991	Joint Project of the Southern California AIDS Interfaith Council and UCLA School of Medicine	Symposium Speaker
1991	Joint Project of the Southern California AIDS Interfaith Council and UCLA School of Medicine	Workshop Panelist
1992	Advanced Group Therapy Seminar, UCLA Neuropsychiatric Institute	Invited Lecturer
1993	UCSF School of Nursing	Invited Lecturer
1995	UCSF/SFGH Department of Medicine Clinical Care Conference	Invited Speaker
1996	UCSF School of Nursing	Invited Speaker

		Invited Speaker
1996	Psychopharmacology for the Primary Care AIDS/Clinician, series of four lectures, UCSF Department of Medicine	Invited Lecturer
1996	UCSF AIDS Health Project Psychotherapy Internship Training Program	
1996	UCSF/SFGH Department of Medicine AIDS Quarterly Update	Invited Speaker
1996	San Francisco General Hospital, Division of Addiction Medicine	Invited Speaker
1996	UCSF Langley Porter Psychiatric Hospital and Clinics	Invited Speaker Grand Rounds
1997	UCSF School of Nursing	Invited Speaker
1997	UCSF Department of Medicine AIDS Program	Invited Speaker
1997	Northern California Psychiatric Society Annual Meeting, Monterey	Workshop Speaker
1997	San Francisco General Hospital Department of Psychiatry Grand Rounds	Invited Speaker
1997	San Francisco General Hospital Department of Psychiatry Grand Rounds	Invited Speaker
1997	Northern California Psychiatric Society LGBT Committee	Chair Fall Symposium
1997	Progress Foundation, San Francisco	Invited Speaker
1998	San Francisco General Hospital Department of Psychiatry Grand Rounds	Invited Speaker
1999	Northern California Psychiatric Society Annual Meeting, Rosa	Invited Speaker Santa
1999	Northern California Psychiatric Society Annual Meeting, Rosa	Invited Speaker Santa
1999	University of California, Davis, Department of Psychiatry	Invited Speaker Grand Rounds
1999	California Pacific Medical Center Department of Grand Rounds	Invited Speaker Psychiatry
1999	San Francisco General Hospital Department of Psychiatry Departmental Case Conference	Discussant
2000	Langley Porter Psychiatric Hospital and Clinics Consultation Liaison Seminar	Invited Speaker
2000	San Francisco General Hospital, Psychopharmacology Seminar	Invited Speaker

2000	UCSF Transgender Health Conference, Laurel Heights Conference Center	Invited Speaker
2000	Psychiatry Course for UCSF Second Year Medical Students	Invited Lecturer
2000	Community Consortium Treatment Update Symposium, California Pacific Medical Center, Davies Campus	Invited Speaker
2000	San Francisco General Hospital Department of Psychiatry Grand Rounds	Invited Speaker
2001	Psychiatry Course for UCSF Second Year Medical Students	Invited Lecturer
2003	Tom Waddell Health Center Inservice	Invited Speaker
2003	San Francisco Veterans Affairs Outpatient Clinic	Invited Speaker
2004	San Francisco General Hospital Psychiatric Emergency Service Clinical Conference	Invited Speaker
2004	South of Market Mental Health Clinic, San Francisco	Invited Speaker
2005	Northern Psychiatric Psychiatric Society Annual Meeting	Invited Speaker
2005	Equality and Parity: A Statewide Action for Transgender HIV Prevention and Care, San Francisco	Invited Speaker
2005	San Francisco General Hospital Department of Psychiatry Grand Rounds.	Invited Speaker
2006	SFGH/UCSF Department of Psychiatry Grand Rounds	Invited Speaker
2007	UCSF Department of Medicine, HIV/AIDS Grand Rounds, Positive Health Program	Invited Speaker
2007	California Pacific Medical Center LGBT Health Symposium, San Francisco LGBT Community Center	Invited Speaker
2007	UCSF CME Conference, Medical Management of HIV/AIDS, Fairmont Hotel, San Francisco	Invited Speaker
2008	UCSF Department of Medicine, Positive Health Program, HIV/AIDS Grand Rounds	Invited Speaker
2008	San Francisco General Hospital Psychiatry Grand Rounds	Invited Speaker
2008	UCSF CME Conference, Medical Management of HIV/AIDS, Fairmont Hotel, San Francisco	Invited Speaker
2010	Northern California Psychiatric Society Annual Meeting, Monterey, CA	Invited Speaker
2011	Transgender Mental Health Care Across the Life Span, Stanford University	Invited Speaker
2011	San Francisco General Hospital Department of Psychiatry Grand Rounds	Invited Speaker

Invited Speaker

2012 UCSF AIDS Health Project Invited Speaker 2012 San Francisco Veterans Affairs Medical Center.

2013 Association of Family and Conciliation Courts Conference, Invited Speaker Los Angeles, CA

2014 UCSF Transgender Health elective Invited Speaker

2014 UCSF Department of Psychiatry Grand Rounds Invited Speaker

2014 California Pacific Medical Center Department of Invited Speaker Psychaitry Grand Rounds

2014 UCLA Semel Institute Department of Psychiatry Grand Invited Speaker Rounds

2015 UCSF Transgender Health elective Invited Speaker

2015 Fenway Health Center Boston, MA (webinar) Invited Speaker

2015 Transgender Health Symposium, Palm Springs Invited Speaker

2015 Transgender Health Symposium, Palm Springs Co-Chair

2015 Santa Clara Valley Medical Center Grand Rounds Invited Speaker

2016 UCSF School of Medicine Transgender Health elective Invited Speaker

2016 Langley Porter Psychiatric Institute APC Case Conference Invited Speaker (2 session series)

2016 Zuckerberg San Francisco General Department of Psychiatry Grand Rounds Invited Speaker

2016 UCSF Mini-Medical School Lectures to the Public Invited Speaker

2021 Los Angeles County Department of Mental Health, Invited Speaker

2023 Alameda County Department of Behavioral Health, Invited Speaker

CONTINUING EDUCATION AND PROFESSIONAL DEVELOPMENT ACTIVITIES

2005 Northern California Psychiatric Society

2005 Northern California Psychiatric Society Annual Meeting, Napa

2005 Association of Gay and Lesbian Psychiatrist Annual Conference

2006 Annual Meeting, American Psychiatric Association, Atlanta

2006 Annual Meeting, American Psychiatric Association, Toronto

2006 Institute on Psychiatric Services, New York

2007 Association of Gay and Lesbian Psychiatrists Annual Conference

2007	American Psychiatric Association Annual Meeting, San Diego
2007	The Medical Management of HIV/AIDS, a UCSF CME Conference
2008	Society for the Study of Psychiatry and Culture, San Francisco
2009	American Psychiatric Association, San Francisco
2009	World Professional Association for Transgender Health, Oslo, Norway
2010	Annual Meeting of the Northern California Psychiatric Society, Monterey, CA
2011	Transgender Mental Health Care Across the Life Span, Stanford University
2011	National Transgender Health Summit, San Francisco
2011	American Psychiatric Association Annual Meeting, Honolulu, HI
2011	World Professional Association for Transgender Health Biennial Conference, Atlanta, GA
2011	Institute on Psychiatric Services, San Francisco
2012	Gay and Lesbian Medical Association Annual Meeting, San Francisco
2013	National Transgender Health Summit, Oakland, CA
2013	American Psychiatric Association Annual Meeting, San Francisco
2013	Gay and Lesbian Medical Association, Denver, CO
2014	American Psychiatric Association Annual Meeting, New York
2014	Institute on Psychiatric Services, San Francisco
2015	European Professional Association for Transgender Health, Ghent, Belgium
2015	National Transgender Health Summit, Oakland
2015	American Psychiatric Association Annual Meeting, Toronto
2016	American Psychiatric Association Annual Meeting, Atlanta
2016	World Professional Association for Transgender Health, Amsterdam

GOVERNMENT AND OTHER PROFESSIONAL SERVICE

1998 - 2002	City and County of San Francisco Human Rights Member Commission LGBT Advisory Committee

I am the chair of the American Psychiatric Association Workgroup on Gender Dysphoria, which developed a CME course fort the 2015 and 2016 APA Annual Meetings, and has an larger educational mission to train American psychiatrists to better care for transgender patients. I have been leading education efforts in transgender health at APA meetings since 1998. On the APA Workgroup on Gender Dysphoria, I am a co-author of a paper of transgender issues that has been approved by the American Psychiatric Association as a resource document and is in press for the American Journal of Psychiatry. I am also the sole author of the chapter on transgender care in the American Psychiatric Press's Clinical Manual of Cultural Psychiatry, Second Edition.

I have been active internationally in transgender health through my work as a member of the Board of Directors of the World Professional Association for Transgender Health. I am an author of the WPATH Standards of Care, Version 7, and am Chapter Lead for the Mental Health Chapter of SOC 8.
I chaired of the WPATH Public Policy Committee and was a member of the Global Education Initiative, which developed a specialty certification program in transgender health. I helped plan the 2016 WPATH Amsterdam conference, and was on the scientific committee for the last four biennial international conferences. I was on the founding committee of USPATH, the national affiliate of WPATH, and I chaired the inaugural USPATH conference, in Los Angeles in 2017. As a member of the steering committee of the WPATH Global Educational Initiative, I helped train over 2000 health providers in transgender health, and helped develop a board certification program and examination in transgender health.

UNIVERSITY SERVICE UC SYSTEM AND MULTI-CAMPUS SERVICE

1991 – 2003 HIV/AIDS Task Force Member

1992 - 1993 HIV Research Group Member

1992 - 1997	Space Committee	Member
1992 - 2003	Gay, Lesbian and Bisexual Issues Task Force	Member
1994 - 1997	SFGH Residency Training Committee	Member
1996 - 1997	Domestic Partners Benefits Subcommittee.	Chair
1996 - 2000	Chancellor's Advisory Committee on Gay, Lesbian, and Transgender Issues.	Member Bisexual
1996 - 2003	HIV/AIDS Task Force	Co-Chair
1996 - 2003	Cultural Competence and Diversity Program	Member
2009 - present	Medical Advisory Board, UCSF Center of Excellence for Health	Member Transgender
2010 - 2013	Steering Committee, Child Adolescent Gender Center	Member
2011 – 2017	Mental Health Track, National Transgender Health Summit	Chair

DEPARTMENTAL SERVICE

1991 - 2003 San Francisco General Hospital, Department of Psychiatry, Member HIV/AIDS Task Force

1992 - 1993 San Francisco General Hospital, Department of Psychiatry, Member HIV Research Group

1992 - 1997 San Francisco General Hospital, Department of Psychiatry, Member Space Committee

1992 - 2003 San Francisco General Hospital, Department of Psychiatry, Member GLBT Issues Task Force

1994 - 1997 San Francisco General Hospital, Department of Psychiatry, Member Residency Training Committee

1996 - 2003 San Francisco General Hospital, Department of Psychiatry, Member Cultural Competence and Diversity Program

1996 - 2003 San Francisco General Hospital, Department of Psychiatry, Co-Chair HIV/AIDS Task Force

2012 - 2020 San Francisco Department of Public Health Gender Member Competence Trainings Committee

2013 - 2020 San Francisco Department of Public Health Transgender Member Health Implementation Task Force

2014 - 2020San Francisco General Hospital, Department of Psychiatry, Member Transgender Surgery Planning Workgroup

PEER REVIEWED PUBLICATIONS

1. Berliner JA, Frank HJL, **Karasic D**, Capdeville M. Lipoprotein-induced insulin resistance in aortic endothelium. Diabetes. 1984; 33:1039-44.
2. Bradberry CW, **Karasic DH**, Deutch AY, Roth RH. Regionally-specific alterations in mesotelencephalic dopamine synthesis in diabetic rats: association with precursor tyrosine. Journal of Neural Transmission. General Section, 1989; 78:221-9.
3. Targ EF, **Karasic DH**, Bystritsky A, Diefenbach PN, Anderson DA, Fawzy FI. Structured group therapy and fluoxetine to treat depression in HIV-positive persons. Psychosomatics. 1994; 35:132-7.
4. Karasic DH. Homophobia and self-destructive behaviors. The Northern California Psychiatric Physician. 1996; 37 Nov.-Dec. Reprinted by the Washington State Psychiatric Society and the Southern California Psychiatric Society newsletters.
5. Karasic D. Anxiety and anxiety disorders. Focus. 1996 Nov; 11(12):5-6. PMID: 12206111
6. Polansky JS, **Karasic DH**, Speier PL, Hastik KL, Haller E. Homophobia: Therapeutic and training considerations for psychiatry. Journal of the Gay and Lesbian Medical Association. 1997 1(1) 41-47.

7. Karasic DH. Progress in health care for transgendered people. Editorial. Journal of the Gay and Lesbian Medical Association, 4(4) 2000 157-8.

8. Perry S, **Karasic D**. Depression, adherence to HAART, and survival. Focus: A Guide to AIDS Research and Counseling. 2002 17(9) 5-6.

9. Fraser L, **Karasic DH**, Meyer WJ, Wylie, K. Recommendations for Revision of the DSM Diagnosis of Gender Identity Disorder in Adults. International Journal of Transgenderism. Volume 12, Issue 2. 2010, Pages 80-85.

10. Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., Fraser, L., Green, J., Knudson, G., Meyer, W., Monstrey, S., **Karasic D** and 22 others. (2011). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version. International Journal of Transgenderism, 13:165-232, 2011

11. Tsai AC, **Karasic DH**, et al. Directly Observed Antidepressant Medication Treatment and HIV Outcomes Among Homeless and Marginally Housed HIV-Positive Adults: A Randomized Controlled Trial. American Journal of Public Health. February 2013, Vol. 103, No. 2, pp. 308-315.

12. Tsai AC, Mimmiaga MJ, Dilley JW, Hammer GP, **Karasic DH**, Charlebois ED, Sorenson JL, Safren SA, Bangsberg DR. Does Effective Depression Treatment Alone Reduce Secondary HIV Transmission Risk? Equivocal Findings from a Randomized Controlled Trial. AIDS and Behavior, October 2013, Volume 17, Issue 8, pp 2765-2772.

13. **Karasic DH**. Protecting Transgender Rights Promotes Transgender Health. LGBT Health. 2016 Aug; 3(4):245-7. PMID: 27458863

14. Winter S, Diamond M, Green J, **Karasic D**, Reed T, Whittle S, Wylie K. Transgender people: health at the margins of society. Lancet. 2016 Jul 23;388(10042):390-400. doi: 10.1016/S0140-6736(16)00683-8. Review./> PMID: 27323925

15. Grelotti DJ, Hammer GP, Dilley JW, **Karasic DH**, Sorensen JL, Bangsberg DR, Tsai AC. Does substance use compromise depression treatment in persons with HIV? Findings from a randomized controlled trial. AIDS Care. 2016 Sep 2:1-7. [Epub ahead of print]/> PMID: 27590273

16. Strang JF, Meagher H, Kenworthy L, de Vries AL, Menvielle E, Leibowitz S, Janssen A, Cohen-Kettenis P, Shumer DE, Edwards-Leeper L, Pleak RR, Spack N, **Karasic DH**, Schreier H, Balleur A, Tishelman A, Ehrensaft D, Rodnan L, Kuschner ES, Mandel F, Caretto A, Lewis HC, Anthony LG.
Initial Clinical Guidelines for Co-Occurring Autism Spectrum Disorder and Gender Dysphoria or Incongruence in Adolescents. J Clin Child Adolesc Psychol. 2016 Oct 24:1-11. [Epub ahead of print]/> PMID: 27775428

17. Milrod C, **Karasic DH**. Age Is Just a Number: WPATH-Affiliated Surgeons' Experiences and Attitudes Toward Vaginoplasty in Transgender Females Under 18 Years of Age in the United States. J Sex Med 2017;14:624–634.

18. William Byne, Dan H. Karasic, Eli Coleman, A. Evan Eyler, Jeremy D. Kidd, Heino F.L. Meyer-Bahlburg, Richard R. Pleak, and Jack Pula.Gender Dysphoria in Adults:

An Overview and Primer for Psychiatrists.Transgender Health.Dec 2018.57-A3.http://doi.org/10.1089/trgh.2017.0053

19. Identity recognition statement of the world professional association for transgender health (WPATH). International Journal of Transgenderism. 2018 Jul 3; 19(3):1-2. Knudson KG, Green GJ, Tangpricha TV, Ettner ER, Bouman BW, Adrian AT, Allen AL, De Cuypere DG, Fraser FL, Hansen HT, **Karasic KD**, Kreukels KB, Rachlin RK, Schechter SL, Winter WS, Committee and Board of Direct

20. **Karasic, DH** & Fraser, L Multidisciplinary Care and the Standards of Care for Transgender and Gender Non-conforming Individuals. Schechter, L & Safa, B. (Eds.) Gender Confirmation Surgery, Clinics in Plastic Surgery Special Issue, Vol 45, Issue 3, pp 295-299. 2018 Elsevier,Philadelphia**.** https://doi.org/10.1016/j.cps.2018.03.016

21. Milrod C, Monto M, **Karasic DH.** Recommending or Rejecting "the Dimple": WPATHAffiliated Medical Professionals' Experiences and Attitudes Toward GenderConfirming Vulvoplasty in Transgender Women. J Sex Med. 2019 Apr;16(4):586-595. doi: 10.1016/j.jsxm.2019.01.316. Epub 2019 Mar 2.

22. ICD-11 and gender incongruence of childhood: a rethink is needed. Lancet Child Adolesc Health. 2019 10; 3(10):671-673. Winter S, Ehrensaft D, Telfer M, T'Sjoen G, Koh J, Pickstone-Taylor S, Kruger A, Griffin L, Foigel M, De Cuypere G, **Karasic D**. PMID: 31439494.

23. Gender Dysphoria in Adults: An Overview and Primer for Psychiatrists. Focus (Am Psychiatr Publ). 2020 Jul; 18(3):336-350. Byne W, **Karasic DH**, Coleman E, Eyler AE, Kidd JD, Meyer-Bahlburg HFL, Pleak RR, Pula J. PMID: 33343244; PMCID: PMC7587914.

24. WPATH Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. E. Coleman, A. E. Radix, W. P. Bouman, G. R. Brown, A. L. C. de Vries, M. B. Deutsch, R. Ettner, L. Fraser, M. Goodman, J. Green, A. B. Hancock, T. W. Johnson, **D. H. Karasic**… J. Arcelus (2022) Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, International Journal of Transgender Health, 23:sup1, S1-S259, DOI: 10.1080/26895269.2022.2100644

BOOKS AND CHAPTERS

1. **Karasic DH**, Dilley JW. Anxiety and depression: Mood and HIV disease. In: The UCSF AIDS Health Project Guide to Counseling: Perspectives on Psychotherapy, Prevention, and Therapeutic Practice. Dilley JW and Marks R, eds. Jossey-Bass. San Francisco, 1998, pp.227-248.

2. **Karasic DH**, Dilley JW. Human immunodeficiency-associated psychiatric disorders. In: The AIDS Knowledge Base, Third Edition. Cohen PT, Sande MA, Volberding PA, eds. Lippincott-Williams &Wilkens, Philadelphia, 1999, pp. 577-584.

3. **Karasic DH** and Drescher J. eds. Sexual and Gender Diagnoses of the Diagnostic and Statistical Manual (DSM): A Reevaluation. 2005. Haworth Press, Binghamton, NY. (Book Co-Editor)
4. **Karasic DH**. Transgender and Gender Nonconforming Patients. In: Clinical Manual of Cultural Psychiatry, Second Edition. Lim RF ed. pp 397-410. American Psychiatric Publishing, Arlington VA. 2015.
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3. **Karasic DH**. A primer on transgender care. In: Gender and sexuality. The Carlat Report Psychiatry. April 2012. Vol 10, Issue 4.
4. **Karasic D and Ehrensaft D.** We must put an end to gender conversion therapy for kids. Wired. 7/6/15.

EXPERT WITNESS AND CONSULTATION ON TRANSGENDER CARE AND RIGHTS

2008 Consultant, California Department of State Hospitals

2012 Dugan v. Lake, Logan UT

2012 XY v. Ontario http://www.canlii.org/en/on/onhrt/doc/2012/2012hrto726/2012hrto726.html

2014 Cabading v California Baptist University

2014 CF v. Alberta
http://www.canlii.org/en/ab/abqb/doc/2014/2014abqb237/2014abqb237.html

2017 United Nations Development Programme consultant, transgender health care and legal rights in the Republic of Vietnam; Hanoi.

2017- 2018 Forsberg v Saskatchewan; Saskatchewan Human Rights v Saskatchewan
https://canliiconnects.org/en/summaries/54130
https://canliiconnects.org/en/cases/2018skqb159

2018 United Nations Development Programme consultant, transgender legal rights in Southeast Asia; Bangkok.

2018 Consultant, California Department of State Hospitals

2019, 2021 Consultant/Expert, Disability Rights Washington

2019, 2021 Consultant/Expert, ACLU Washington

2021 Consultant, California Department of Corrections and Rehabilitation

2021 Expert, Kadel v. Folwell, 1:19-cv-00272 (M.D.N.C.).

2021 Expert, Drew Glass v. City of Forest Park - Case No. 1:20-cv-914 (Southern District Ohio)

2021-2022 Expert, Brandt et al v. Rutledge et al. 4:21-cv-00450 (E.D. Ark.)

2021-2022 Expert, Fain v. Crouch, 3:20-cv-00740 (S.D.W. Va.)

2022 Expert, C.P. v. Blue Cross Blue Shield of Illinois, No. 3:20-cv-06145-RJB (W.D. Wash.)

2022-3 Expert, Dekker, et al. v. Weida, et al., No. 4:22-cv-00325-RH-MAF

2019-2023 Expert, Disability Rights Washington v Washington State Department of Corrections

2023 Expert, K.C. et al. v Individual Members of the Indiana Licensing Board, et al- No. 1:23-CV-595

2023 Expert, Doe, et al v Ladapo -No. 4:23-cv-00114-RH-MAF

2023 Expert, Doe et al v Thornbury -No. 3:23-cv-00230-DJH

2024 Expert Voe v Mansfield, *No. 1:23-CV-864-LCB-LPA*

2024 Expert *Boe v. Marshall, No. 2:22-cv-184-LCB (N.D. Ala.)*

2024 Expert *.B. v. Premera Blue Cross, No. 3:20-cv-06145-RJB (W.D. Wash.)*

2024 Expert *Misanin v. Wilson, No. 2:24-cv-04734-BHH (D.S.C.)*

EXHIBIT B

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALISHEA KINGDOM, et al., Plaintiff, v. DONALD J. TRUMP, et al., Defendants.	Case No. 1:25-cv-00691

SECOND DECLARATION OF DR. DAN H. KARASIC IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

I, Dan H. Karasic, M.D., hereby declare and state as follows:

1. I am over the age of 18, of sound mind, and in all respects competent to testify.

2. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

3. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

4. I submitted an expert declaration in this case on March 14, 2025. My background and qualifications are discussed in that declaration.

5. I submit this declaration to respond to a few points made in defendants' opposition to Plaintiff's motion and to provide observations regarding the subsequently filed amici brief.

6. First, defendants' brief asserts that there is "ongoing scientific and medical debate over the necessity and efficacy of hormone medication as a treatment for gender dysphoria." *See, e.g.*, Defendants' brief, at 2; *see also id.* at 15 (suggesting treating for gender dysphoria is a "highly controversial area of medical practice"). This is simply untrue. While there is some

discussion within the field about how to best care for minors with gender dysphoria,[1] there is no serious debate or controversy within the medical and mental health fields about the necessity and efficacy of hormone therapy to treat adults with gender dysphoria. As I explained in my first declaration, decades of research and clinical experience have shown the benefits of hormone therapy to individuals with gender dysphoria.

7. Defendants' brief suggests that if BOP were to discontinue hormone therapy, there will be no harm because, it says, there are alternative treatments that could be provided. *See* Defendants' brief, at 10. That is untrue. As I discussed in my first declaration, while not everyone with gender dysphoria needs hormone therapy, for those for whom it is clinically indicated, there is no alternative treatment. There is no evidence-based psychotherapeutic treatment to treat gender dysphoria. Withdrawing hormone therapy from those who have a medical need for it would be expected to result in an exacerbation of their gender dysphoria, putting them at significant risk of depression, anxiety, self-harm and suicidality.

8. The declaration of the Bureau of Prisons' Assistant Director of the Health Services Division, Chris Bina, suggests that if incarcerated people are taken off of hormone therapy, there will be no harm because he says they would "receive treatment for any symptoms they may experience as clinically indicated." *See* Bina declaration, par. 15. But the symptom that people would experience if hormones are withdrawn is a rise in gender dysphoria, and, as discussed above, there are no alternative treatments for gender dysphoria for those who need gender-affirming medical interventions. Thus, withdrawing or withholding such care when

[1] *See, e.g.*, The Cass Review, Independent Review of Gender Identity Services for Children and Young People: Final Report at 195 (April 2024) (the "Cass review") (recommending that puberty blockers be provided within the context of clinical research trials and that hormone therapy be provided "with caution" for youth ages 16 and 17). I do not reference the Cass Review to suggest that I agree with it; indeed, it has been widely criticized. *See, e.g.*, British Medical Association, "BMA to undertake an evaluation of the Cass Review on gender identity services for children and youth people," July 31, 2024, available at https://www.bma.org.uk/bma-media-centre/bma-to-undertake-an-evaluation-of-the-cass-review-on-gender-identity-services-for-children-and-young-people.

indicated puts people at risk of significant harm to their mental health.

9. Defendants cite the Cass Review's finding that "while deaths by suicide in trans-identifying individuals are tragically above the national average, there is 'no evidence that gender-affirmative treatments reduce this.'" Defendants' brief, at 16. As an initial matter, suicide prevention is not the only reason for providing hormone therapy to individuals with gender dysphoria. This condition can cause other severe harms to mental health as I discussed in my first declaration. Moreover, the Cass Review and the cited passage are focused on minors. The cited passage that was excerpted in Defendants' brief specifically refers to "risk of death by suicide among gender diverse youth." Cass Review, at 94. It is difficult to get data on completed suicides for any population,[2] but there is substantial evidence that gender-affirming medical care reduces suicidal ideation and suicide attempts,[3] which are significant risk factors for suicide (*see* n. 2, *supra*), and it is a serious mental health concern in its own right when people think about ending their lives.

10. I'd like to address some confusion reflected in the Defendants' brief about the purpose of hormone therapy in the treatment of gender dysphoria. Defendants' brief states that "[t]he Court apparently assumed that all hormone medication provided to treat gender dysphoria is 'for the purpose of conforming an inmate's appearance to that of the opposite sex,' Exec.

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[2] Because completed suicides are so rare, it's difficult to get data. For example, in clinical trials of over 4400 youth receiving antidepressants, there were no suicides. Nevertheless, there's a black box warning about increased risk of suicidality when antidepressants are used for people under the age of 25, which is based on increased suicidal ideation and attempts. *See* https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/suicidality-children-and-adolescents-being-treated-antidepressant-medications

[3] *See, e.g* Kaltiala, R., Heino, E., Työläjärvi, M., & Suomalainen, L. (2019). Adolescent development and psychosocial functioning after starting cross-sex hormones for gender dysphoria. Nordic Journal of Psychiatry, 74(3), 213–219. https://doi.org/10.1080/08039488.2019.1691260; Allen, et al 2019
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doi:10.1001/jamanetworkopen.2022.0978

Order No. 14168, § 4(c), regardless of the inmate's individual medical condition.'" Defendants' brief, at 13. Hormone therapy alleviates gender dysphoria by conforming an individual's body to be consistent with their gender identity. Defendants appear to assert that medically necessary hormone treatment and hormone treatment "for the purpose of conforming an inmate's appearance to that of the opposite sex" are separate things. They are not. The use of hormones to change the patient's appearance is medically necessary for the treatment of gender dysphoria.

11. Defendants point to some statements suggesting that WPATH's guidelines are based on ideology, not science or "extensive clinical experience." *See* Defendants' brief at 17. This is not true. As I discussed in my first declaration, WPATH's guidelines were developed by experts in the field using a rigorous evidence-based approach. *See* Karasic initial declaration, pars. 53-62. The authors of the WPATH guidelines include university professors and individuals with extensive clinical experience in providing care for people with gender dysphoria. I myself have been involved in the development of the WPATH guidelines and have over 30 years of clinical experience treating individuals with gender dysphoria. Since the first WPATH guidelines in 1979, WPATH has drawn on the expertise of the most experienced clinicians. And these guidelines were developed using widely accepted methods recommended by the National Academy of Medicine that have been used to develop other medical guidelines such as all American Psychiatric Association's practice guidelines for various psychiatric illnesses, such as schizophrenia, eating disorders, and alcohol use disorder, since 2011.[4] The WPATH guidelines are recognized as authoritative by every major medical association in the United States, including the National Commission on Correctional Health Care.[5]

[4] *See* https://www.psychiatry.org/psychiatrists/practice/clinical-practice-guidelines/guideline-development-process.
[5] *See* National Commission on Correctional Health Care, Position Statement- Transgender and Gender Diverse Health Care in Correctional Settings, November, 2020, available at https://www.ncchc.org/position-statements/transgender-and-gender-diverse-health-care-in-correctional-settings-2020/.

12. Defendants' brief also attempts to discredit the WPATH guidelines by citing references in Judge Lagoa's concurring opinion in *Eknes-Tucker v. Governor of Alabama* in which she cites a publication entitled "The WPATH Files." The WPATH Files is a collection of select out-of-context excerpts of communications among WPATH members on a message board over a four-year period that was obtained and published by a journalist and activist opposed to gender-affirming medical care, along with a narrative she created based on those cherry-picked excerpts in an attempt to discredit WPATH. These select, out-of-context statements do not permit the conclusions about WPATH asserted by the author. Moreover, the author is not someone within the field of medicine or mental health nor experienced in the treatment of gender dysphoria, and this document is not published in a scientific journal. It is an activist's opinion piece based on a highly misleading presentation of excerpts of communications.

13. I have reviewed the amicus brief filed by several states in this case and have a few observations.

a. First, while the amicus brief claims that hormone therapy is a "controversial practice" and attempts to support that claim by citing three studies, none of those studies permit such a conclusion. The first study[6] did not evaluate the evidence because the authors set criteria for inclusion in their review that excluded all of the studies. *See id.* ("We could not appraise the quality of the evidence because no studies met our review's inclusion criteria."). The second study[7] found that hormone therapy was associated with increased quality of life, decreased depression, and decreased anxiety. That the authors were unable to

[6] Haupt et al, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 11 Cochrane Database of Systematic Reviews, Art. No. CD013138, at 2, 11 (2020).
[7] Kellan E. Baker, et al., Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review, 5 J. Endocrine Soc. 1, 12–13 (2021).

draw conclusions about the impact on death by suicide is an ongoing challenge in research. *See supra*, par. 9. Finally, the state amici suggest that a third study[8] indicated that hormone therapy increased suicidality, but that study showed a "reduction in suicidality following gender-affirming treatment." Within the medical and mental health fields, hormone therapy has long been widely recognized as an effective treatment for gender dysphoria.

b. The states' amicus brief also suggests that that psychotherapy is "widely recognized" as an alternative treatment for gender dysphoria in lieu of gender-affirming medical care, citing Anderson et al., Gender Dysphoria and Its Non-Surgical and Surgical Treatments, 10 Health Psych. Rsch., at 4 (2022). But that study, which notes the benefits of psychotherapy for patients with gender dysphoria (e.g. providing support, help with coming out), does not suggest that psychotherapy is a substitute for gender-affirming medical interventions when indicated. Indeed, the study cites to the WPATH Standards of Care and a paper that discusses psychotherapy in the context of preparation for gender-affirming surgery. As discussed above, there is no evidence-based psychotherapeutic treatment to treat gender dysphoria in lieu of hormones.

c. In sum, the amici states make baseless assertions about treatment for gender dysphoria based on a highly misleading characterization of the sources they cite.[9]

[8] Daniel Jackson, Suicide-Related Outcomes Following Gender-Affirming Treatment: A Review, 15(3) Cureus 11–13 (2023).

[9] The states' amicus brief also offers a misleading presentation of the evidence on gender-affirming surgery, but since the motion before the court does not address surgery, I have not provided an analysis of that discussion.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct,

Executed this 3rd day of March, 2025

Dan H. Karasic