Immunization

Federal Bureau of Prisons
Clinical Guidance

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ABOUT THIS DOCUMENT

The goal for this Clinical Guidance is to provide a comprehensive, user-friendly document that provides all the tools and information needed to successfully guide an immunization program in the BOP.

The document is divided into the following five CHAPTERS:

CHAPTER 1. OVERVIEW AND KEY PRINCIPLES: Includes general information about immunizations and the immunization program in the BOP based upon recommendations from the Advisory Committee on Immunization Practices (ACIP).

CHAPTER 2. BOP IMMUNIZATION INDICATIONS: Provides an at-a-glance reference of recommended vaccine indications for BOP inmates.

CHAPTER 3. VACCINE PROCEDURE MODULES: Provides detailed guidance regarding vaccine indications and vaccine administration, including contraindications, precautions, dose, route, site, and documentation instructions.

It is recommended that the Infection Prevention & Control Committee and Governing Body first review how the immunization program is implemented. Then, Clinical Directors can authorize specific categories of health care personnel, within their scope of practice, to administer vaccines using the Vaccine Procedure Modules—instead of writing individual patient orders. Personnel authorized to administer vaccine should have demonstrated vaccine administration skills.

CHAPTER 4. ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE: Provides a two-page reference regarding vaccine administration, including illustrations of vaccine administration sites and methods.

CHAPTER 5. STORAGE AND HANDLING OF IMMUNIZATIONS: Provides guidance on developing storage and handling procedures for vaccines to maintain a "cold chain," including monitoring and maintaining temperature ranges within the storage units and responding to temperature excursions.

The CHAPTERS are followed by four sets of ATTACHMENTS:

ATTACHMENT 1. SKILLS CHECKLIST FOR VACCINE ADMINISTRATION

ATTACHMENT 2. WORKSHEETS FOR VACCINE STORAGE AND HANDLING

ATTACHMENT 3. HANDLING A TEMPERATURE EXCURSION IN YOUR VACCINE STORAGE UNIT

ATTACHMENT 4. VACCINE REFRIGERATOR TEMPERATURE LOG

Finding your way around the document:

Each of the Chapters and, in the case of Chapter 3, each of the Modules, begins on its own "page 1" so that individual topics can be printed separately and stand on their own. The following are links to some introductory pages that you may find helpful:

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Acronyms Used for Vaccines

PRINTING FROM THE PDF VERSION

If you are viewing this document in PDF format you can print an individual topic without printing the entire document, by utilizing the page numbers listed below:

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Click on any of the following **links** to go to that topic. Page numbers are not provided since each chapter and module starts on its own page 1.

ACRONYMS USED FOR VACCINES

HepA	Hepatitis A vaccine
HepA-HepB	Hepatitis A and hepatitis B vaccines
HepB	Hepatitis B vaccine
HepB-CpG	Hepatitis B vaccine, recombinant, adjuvanted (Heplisav-B)
Hib	*Haemophilus influenzae* type b vaccine
HPV	Human papillomavirus vaccine
HZV or ZVL	Herpes zoster vaccine or zoster vaccine, *live*
IIV	Inactivated influenza vaccine
IIV3	Inactivated influenza vaccine, trivalent
IIV3 high dose	Inactivated influenza vaccine, trivalent, high dose
aIIV3	Adjuvanted inactivated influenza vaccine, trivalent
IIV4	Inactivated influenza vaccine, quadrivalent
IIV4-ID	Inactivated influenza vaccine, quadrivalent intradermal
ccIIV4	Cell culture inactivated influenza vaccine, quadrivalent
LAIV4	Live attenuated influenza vaccine quadrivalent
MenACWY	Meningococcal ACWY conjugate vaccine (Menactra® or Menveo®)
MenB	Meningococcal B vaccine (Bexsero® or Trumenba®)
MMR	Measles, mumps, and rubella vaccine, *live*
PCV13	13-valent pneumococcal conjugate vaccine
PPSV23	23-valent pneumococcal polysaccharide vaccine
RIV	Recombinant (inactive) influenza vaccine (egg-free)
RIV3	Recombinant influenza vaccine, trivalent (egg-free)
RIV4	Recombinant influenza vaccine, quadrivalent (egg-free)
RZV	Recombinant zoster vaccine (Shingrix®)
Td	Tetanus-diphtheria vaccine
Tdap	Tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine
TIG	Tetanus immune globulin
VAR	Varicella vaccine, *live* (Varivax®)

CHAPTER 1. OVERVIEW AND KEY PRINCIPLES

CONTENTS:

A. Goals of the BOP Immunization Program

1. Screen inmates for indications for immunizations as defined in this BOP *Immunization* Clinical Guidance.
2. Administer vaccines based upon indications.
3. Decrease vaccine-preventable disease burden.
4. Prevent unintentional vaccination adverse effects based upon health care provider knowledge of contraindications and precautions.
5. Store and handle vaccine in such a way that the "cold chain" is not interrupted.

B. Immunization Program Implementation

1. Overview

It is recommended that each BOP facility (1) have an immunization program that is implemented in conjunction with the Preventive Health Program; (2) make a decision regarding when and by whom inmates will be screened and scheduled for needed vaccinations; and (3) ensure that responsibility be assigned to health care personnel for patient assessment and vaccine administration.

The following are possible interventions for facilitating implementation of the immunization program:

- Schedule preventive vaccines for administration during specific clinic visits when need for vaccine is noted (e.g., history and physical, preventive health, chronic care clinics).
- Utilize a template (e.g., during chronic care clinic) summarizing vaccine administration, for example:
  - Last TST (PPD)
  - Last influenza
  - PCV13 (wait 1 year after PPSV23, if PPSV 23 given first)
  - PPSV23 (at least 8 weeks after PCV13)
  - Tdap (one adult dose; one dose 3rd trimester of each pregnancy)
  - MMR (evidence of immunity; otherwise 1 dose unless precaution or contraindicated)
  - Hep A (series dates)
  - Hep B (series dates, immune status)
  - HPV (Females: administer up to age 26; Males: administer up to age 21 or age 26 if MSM, HIV, or immunocompromised)
  - MenACWY (two dose series and one every 5 years for HIV, asplenia, complement disorder)
  - MenB (Asplenia or complement disorder; Bexsero 2-dose or Trumenba 3-dose)
- Conduct active surveillance of administration of specific vaccines.
- Implement performance improvement projects related to the administration of specific vaccines.

2. BOP Vaccine Indications

A table summarizing indications for vaccination of BOP inmates is located in **Chapter 2. BOP Immunization Indications**. These indications are based on ACIP guidelines, with modifications unique to the highly mobile inmate population. A common challenge for BOP health-care providers is vaccinating adults with unknown vaccination histories. ACIP guidance for adult MMR and Td/Tdap vaccines assumes childhood vaccination history and recommends single booster doses of MMR and Tdap. (Tdap is also recommended for the third trimester of each pregnancy.) For HPV and pneumococcal vaccines, ACIP recommends taking into account *self-reported* history of vaccinations. These considerations are incorporated into **Chapter 2**.

3. Use of Vaccine Procedure Modules

Chapter 3. Vaccination Procedure Modules cover the following elements for each vaccine: indications, contraindications, precautions, dose, route, site, and documentation instructions.

It is recommended that the Infection Prevention & Control Committee and Governing Body first review how the immunization program will be implemented. Then, Clinical Directors can authorize specific categories of health care personnel, within their scope of practice, to administer vaccines using the Vaccine Procedure Modules—instead of writing individual patient orders. Personnel authorized to administer vaccine should have demonstrated vaccine administration skills.

A signature sheet template, located at the beginning of **Chapter 3**, includes check boxes to indicate which vaccine modules are permitted to be used and which categories of providers are authorized to use them. It is recommended that the timing of updates to the signature sheet coincide with the timing of other nursing protocols and when these vaccine procedure modules are updated. The influenza vaccine module will be updated annually by the Health Services Division.

➔ ***Guidance in the modules is based on the ACIP Adult Immunization Schedule for persons age 19 years or older****. For patients age 18 or younger, consult the package insert and local pharmacist.*

4. Health Care Provider Education

- It is recommended that healthcare workers who are responsible for administration of vaccinations be educated at initial orientation and whenever vaccines or vaccine procedures change.
- The following Chapters can be used for health care worker education:
  - **Chapter 3. Vaccine Modules**, covers indications, contraindications, precautions, routes of administration, reporting adverse effects, and documentation of vaccines.
  - **Chapter 4. Administering Vaccines: Dose, Route, Site, and Needle Size** is useful as a reference tool for vaccine administration.
- The **Skills Checklist for Vaccine Administration** is available in *Attachment 1*.

(list for Health Care Provider Education continues on next page)

- Additional training resources can be found below in this chapter, under **D. RESOURCES FOR HEALTH CARE PROVIDER VACCINE EDUCATION**.
- ***Vaccine Information Statements (VISs)***, which provide vaccine-specific information for providers and patients, are available from the CDC

  ➔ *See link under **5. PATIENT EDUCATION** below.*

5. PATIENT EDUCATION

- ***Discussion of the benefits and risks of vaccination is sound medical practice and is required by federal law.*** Patients should be informed about the benefits and risks associated with vaccines in a language the patient understands and at an appropriate educational level. An opportunity to ask questions should be provided before each vaccination.
- ***The National Childhood Vaccine Injury Act of 1986 requires that VISs be provided to patients each time a vaccine dose is administered.***
  - Copies of VISs are available from the CDC at *https://www.cdc.gov/vaccines/hcp/vis/index.html* or by navigating to the CDC website within the vaccine consent in BEMR medical forms.
  - Translations of VISs into languages other than English are available from the Immunization Action Coalition website at *http://www.immunize.org*.

6. SAFE VACCINE ADMINISTRATION

While life-threatening reactions to vaccines are extremely rare, it is recommended when administering vaccines that epinephrine and equipment for managing an airway be available for immediate use in the case of a severe anaphylactic reaction to a vaccine. Persons administering vaccines should be familiar with identifying severe allergic reactions, including anaphylaxis, and be competent in responding to these events.

➔ *See **C.4. PREVENTING AND MANAGING ADVERSE REACTIONS** below.*

7. INFECTION CONTROL

The following are CDC recommended infection control guidelines related to vaccine administration:

- Clean hands either with an alcohol-based hand rub or with soap and water *both* before preparing vaccines for administration *and* between patient contacts.
- Occupational Safety and Health Administration (OSHA) regulations do not require gloves to be worn when administering vaccinations, unless persons administering vaccinations have open lesions on their hands or are likely to come into contact with a patient's body fluids.

  ➔ *If gloves are worn, change gloves in-between patients, with hand hygiene performed each time gloves are removed.*
- Draw up vaccines in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed. Do not keep or access multi-dose vials in the immediate patient treatment area to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment.

(list for Infection Control continues on next page)

- Cleanse the access diaphragms of medication vials with 70% alcohol before inserting a device (needle) into the vial.
- Do not administer vaccines from single-dose vials to more than one patient.
- Do not mix vaccines in the same syringe unless they are specifically licensed for such use.
- Single-dose vials and manufacturer-filled syringes are designed for single-dose administration; discard them if vaccine has been withdrawn or reconstituted.
- Syringes that are prefilled by the manufacturer and activated (i.e., syringe cap removed or needle attached) but not used, are to be *discarded* at the end of the clinic day.
- The routine practice of providers prefilling syringes is discouraged. Prefilling might result in administration errors if syringes are not labeled.
  - In certain circumstances when a single vaccine type is being used (e.g., in preparation for a mass influenza vaccination), filling a small number of syringes may be considered (i.e., the contents of one multi-dose vial).
    - Individually label pre-filled syringes or place them in a labeled tray and store them at the proper temperature.
    - Administer doses as soon as possible after filling—by the same person who filled the syringes.
  - Discard unused prefilled syringes if not used the same day that they are filled.
- Prevent needle stick injuries. Immediately place used needles and syringes into a sharps container following administration. Do not recap needles.
- For more information, see *https://www.cdc.gov/injectionsafety/providers.html*.

8. Vaccine Storage and Handling

Failure to adhere to recommended specifications for storage and handling of vaccines can reduce or destroy their potency, resulting in no or inadequate immune response in the recipient and poor protection against disease. It is critically important that the vaccine "cold chain" be maintained to assure that the vaccine retains its potency. (An unbroken "cold chain" is an uninterrupted series of storage and distribution activities that maintain a given temperature range.)

It is recommended that each facility designate a primary vaccine coordinator who is responsible for oversight of vaccine acquisition and storage to assure the "cold chain" is not interrupted. It is also recommended that local standard operating procedures for vaccine storage and handling be developed based upon the guidance in *Chapter 5. Vaccine Storage and Handling*, including managing after-hours emergencies.

C. Summary of ACIP Immunization Best Practices Guidance

Health care providers must navigate a number of issues when vaccinating patients, including the screening for contraindications and precautions, timing of each dose, the number of vaccines to be administered, and interpreting and responding to adverse events.

Key sections of the 2017 ACIP guidelines are summarized below to provide information for health care providers about concerns that commonly arise when vaccinating patients.

➔ *The full text of the ACIP guidelines is available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf*

1. Contraindications and Precautions

1.A. Introduction

Contraindications and precautions to vaccination generally dictate circumstances when vaccines should not be given. The majority of contraindications and precautions are temporary, and the vaccine can be given at a later time.

➔ *Contraindications and precautions for each vaccine are listed in each BOP vaccine module. They are based upon the ACIP Adult Combined Schedule, available at: https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf.*

Contraindications are conditions that increase the risk for a serious adverse reaction to a vaccine in a person with that condition. In general, a vaccine *should not be given* if a patient has a contraindication condition.

Precautions are conditions that might increase the risk for a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity. In general, vaccinations should be deferred when a precaution is present unless the benefit of protection from the vaccine outweighs the risk of an adverse reaction.

Screening Questions for Vaccines

Prior to vaccine administration, screen patients for contraindications and precautions. The key to preventing serious adverse reactions is screening. Effective screening is not difficult or complicated and can be accomplished with just a few questions depending on the precautions and contraindications for the vaccine being administered.

➔ *Routine physical examinations and procedures (e.g., measuring temperatures) are not prerequisites for vaccinating persons who appear to be healthy.*

Examples of screening questions include:

- Are you sick today?
- Do you have allergies to medications, food, or any vaccine?
- Have you had a serious reaction to a vaccine in the past?
- Can you eat eggs?
- Have you had a seizure, brain, or nerve problem?

(list of examples continues on next page)

- Do you have a health problem such as asthma, lung disease, heart disease, kidney disease, or a metabolic disease such as diabetes or a blood disorder?
- Do you have cancer, leukemia, HIV, or any other immune system problem?
- In the past 3 months, have you taken cortisone, prednisone, other steroids, or anticancer drugs, or have you had x-ray treatments?
- Have you received a transfusion of blood or blood product, or been given a medicine called immune globulin in the past year?
- Are you pregnant or is there a chance you will be pregnant in the next month?
- Have you received vaccinations in the past 4 weeks?

➔ *A sample screening checklist is available at: http://immunize.org/catg.d/p4065.pdf*

INVALID CONTRAINDICATIONS TO VACCINATION

- Mild illness
- Allergies that are not anaphylactic or allergies to products not in the vaccine
- Antimicrobial therapy
- Disease exposure or convalescence
- Having a pregnant or immunosuppressed person in the household
- Family history of adverse events
- Multiple vaccines

1.B. PERMANENT CONTRAINDICATIONS

- Severe (anaphylactic) allergic reaction to a vaccine (including influenza vaccine). Examples of symptoms and signs typical of anaphylactic reactions include: generalized urticaria (hives), swelling of the mouth and throat, difficulty breathing, wheezing, hypotension, or shock.
- Severe allergic reaction to a vaccine component or following a prior dose of vaccine, e.g., anaphylactic reaction to gelatin in MMR vaccine.
- Encephalopathy not due to another identifiable cause, within 7 days of receipt of vaccine.

1.C. TEMPORARY CONTRAINDICATIONS OR PRECAUTIONS

- ***Pregnancy:*** Live vaccine and some non-live vaccines are contraindicated during pregnancy (e.g., MMR, ZVL VAR, RZV, HPV) because of the theoretical risk to the fetus**.**
- ***Immunosuppression:*** Live vaccines (e.g., MMR and VAR) are contraindicated in persons with immunosuppression.

  EXAMPLES: Hematologic and solid tumors, chemotherapy, congenital immunodeficiency or long-term immunosuppressive therapy (20 mg or more of prednisone or equivalent for two or more weeks), and HIV infection in patients who are severely immunocompromised (CD4+ T-cell count <200 cells/mm^3). Live vaccine is deferred for at least 1 month after discontinuation of steroid therapy.
- ***Moderate or severe acute illness:*** Vaccination should be deferred for persons with a moderate or severe acute illness.
- ***Persons receiving immune globulin preparations or blood products*** may need to defer MMR and VAR vaccines for a period of 3–11 months (see **SECTION 2.E**. below).

1.D. Egg Allergies

Severe allergic and anaphylactic reactions can occur in response to a number of vaccine components, including egg protein, although such reactions are rare. The most common animal protein allergen is egg protein, which is found in vaccines such as many influenza vaccines that are prepared using embryonated chicken eggs. Of the influenza vaccines, all but RIV may contain egg protein.

Ordinarily, a person who can eat eggs or egg products can receive vaccines that contain egg. It is recommended that persons with histories of anaphylactic or anaphylactic-like allergy to eggs or egg proteins be further evaluated. *A reasonable way to screen for those who might be at risk from egg-containing influenza vaccine is to ask people if they can eat eggs without adverse effects.*

Recommendations for Flu Vaccination of Persons with Egg Allergy

- ***Hives only:*** Those with an egg allergy history who have only experienced hives can receive the flu vaccine (any form of IIV or RIV) appropriate for their age and health status.
- ***Anaphylactic allergy to eggs:*** Those with an egg allergy history involving angioedema, respiratory distress, lightheadedness, or recurrent emesis or who required epinephrine or another emergency medical intervention, may receive the flu vaccine (any form of IIV or RIV) appropriate for their age and health status, ***using the following special precautions***:
  The vaccine should be administered in a medical setting and be supervised by a health care provider who is able to recognize and manage severe allergic conditions. The patient should be observed for at least 30 minutes for signs of a reaction after each dose of flu vaccine.

1.E. Latex Allergy

- ***Contact allergy to latex:*** The most common type of latex hypersensitivity is a delayed-type, allergic contact dermatitis. Patients with a history of a contact allergy to latex can receive vaccines if they are contained in vials or syringes that contain *dry natural rubber or natural rubber latex*.
- ***Anaphylactic allergy to latex:*** In general, if a person reports a severe anaphylactic allergy to latex, do not administer vaccine supplied in vials or syringes that contain natural rubber latex. ***If vaccine is deemed beneficial despite risk of an allergic reaction, providers should be prepared to treat allergic reactions, including anaphylaxis.***

1.F. History of Allergy to Other Substances

Consult the patient's healthcare provider if there is a prior history of allergic reactions to any added substances in vaccines. Additives used in the production of vaccines may include:

- ***Suspending fluid*** (e.g., sterile water, saline, or fluids containing protein).
- ***Preservatives and stabilizers*** to help the vaccine remain unchanged (e.g., albumin, phenols, and glycine).
- ***Adjuvants or enhancers*** to help the vaccine to be more effective, including gelatin, antimicrobial agents, thimerosal, and aluminum.
  - ***Gelatin:*** Persons who have had an anaphylactic reaction to gelatin or gelatin-containing products should be evaluated by an allergist prior to receiving gelatin-containing vaccines. *Example vaccines:* VAR, MMR, ZVL

- ***Antimicrobial Agents:*** Certain vaccines contain trace amounts of antimicrobial agents, i.e., neomycin. Allergies to these substances are rare. Usually neomycin hypersensitivity manifests as contact dermatitis.
  Example vaccines: Afluria® (IIV3, IIV4), Twinrix® (HepA and HepB), Havrix® (HepA), MMR, Zostavax® (ZVL)
- ***Thimerosal:*** This organic mercurial compound is added to certain vaccines as a preservative. Reactions to thimerosal have been described as local, delayed-type hypersensitivity reactions with only rare reports of immediate reactions. A local or delayed-type hypersensitivity reaction to thimerosal is not a contraindication to receiving a vaccine containing thimerosal.
  Example vaccine: Fluzone® Quadrivalent (multi-dose)
- ***Aluminum:*** Aluminum is sometimes added as adjuvant to help the vaccine stimulate a better or more persistent immune response to a vaccine.
  Example vaccines: Bexsero® (MenB), Td, Tdap

ADDITIONAL INFORMATION ON VACCINE COMPONENTS

- An extensive list of vaccine components and their use, as well as the vaccines that contain each component is available from the CDC: *https://www.cdc.gov/vaccines/vac-gen/additives.htm*
- Additional information and tables of potential allergens in different vaccines are available at http://www.vaccinesafety.edu/components-Allergens.htm. The allergens identified in the patient's history can be cross-checked against the allergens identified in package inserts.

2. TIMING AND SPACING OF VACCINATIONS

2.A. AGE

Recommendations for the age at which vaccines are administered are influenced by age-specific risks for disease, age-specific risks for complications, and age-specific responses to vaccine.

➔ *Age-specific immunization indications are noted in the vaccine package inserts, in* ***CHAPTER 2,*** *and in the individual vaccine modules in* ***CHAPTER 3****.*

2.B. INTERVALS FOR MULTI DOSE VACCINES

It is recommended that health care providers follow the CDC guidelines for the recommended intervals between vaccine doses.

➔ *See the CDC vaccine schedules at: http://www.cdc.gov/vaccines/schedules/hcp/index.html.*
For most BOP inmates, see the adult immunization, full version.

- ***Vaccines should be administered as close as possible to the recommended dosing intervals.*** However, if a vaccine schedule is lapsed, increasing the interval between doses of a multi-dose vaccine generally does not diminish the effectiveness of a vaccine series. Thus, it is usually not necessary to restart the vaccine series if a dose is given late; instead, when the lapsed schedule is identified, simply complete the vaccine series.

  Example: *If two Hepatitis B vaccine doses were given a month apart one year ago, do not restart the series. Complete the third hepatitis B vaccine dose and, if indicated, obtain a titer for surface antibody one to two months later.*

- ***In certain situations, it may be necessary to administer multi-dose vaccines at shorter intervals*** between doses than is typically recommended, i.e., when a person is behind schedule on vaccinations, but needs rapid protection. In these situations, an accelerated schedule can be considered utilizing the vaccine package insert.

2.C. Simultaneous Administration of Different Vaccines

Simultaneous administration of vaccines is defined as administering more than one vaccine on the same clinic day, at different anatomic sites, and not combined in the same syringe. With some exceptions, it is safe and acceptable to simultaneously administer the most widely used live and inactivated vaccines. There are two exceptions to this rule:

- *The pneumococcal vaccines (PCV13 and PPSV23) should not be administered simultaneously. See the Pneumococcal Vaccine module in **Chapter 3** for guidance.*
- *MenACWY (Menactra) and PCV13 should not be administered simultaneously; PCV13 should be administered first and MenACWY (Menactra) administered 4 weeks later. **Note:** This warning does NOT apply to MenACWY (Menveo).*

2.D. Spacing of Multiple Live Vaccines

In general, two or more live vaccines are not administered on the same day and should be separated by at least 28 days to minimize the potential risk for interference.

- When a live injectable vaccine (e.g., MMR or VAR) or a live attenuated influenza virus (LAIV) is to be administered, providers should ensure that no live injectable or intranasal vaccines have been given in the previous 28 days.
- If two different live vaccines are administered, and they have been separated by less than 28 days, the second vaccine dose should not be counted, and another dose of the second vaccine should be given at least 28 days after the first dose.

2.E. Spacing of Live Vaccines and Antibody-Containing Blood Products

Blood (e.g., whole blood, packed red blood cells, plasma) and other antibody-containing blood products (e.g., immune globulin) can inhibit the immune response to MMR (and possibly VAR) vaccine for up to 3 to 11 months, depending on the product and dose. Providers should screen potential recipients of live vaccines for recent history of receipt of blood products.

- *See Tables 3-4 and 3-5, beginning on page 34 of the ACIP guidelines, for recommended intervals: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf*

If a dose of MMR or VAR vaccine is administered following receipt of a blood product, at a shorter than recommended interval, then that vaccine dose should be repeated (unless serologic testing indicates a response to the vaccine). The repeat vaccine dose (or serologic testing) should be performed after the CDC-recommended interval indicated for that specific antibody-containing product.

2.F. Spacing of Tuberculin Skin Testing (TST) or Other Assays and Live Vaccines

A TST may be administered on the same day as live vaccines (e.g., MMR or VAR), or the TST should be deferred for 28 days after vaccination for MMR and 6 weeks after VAR. These TST guidelines also apply to obtaining interferon gamma release assays (IGRAs) such as T-Spot® or QuantiFERON-G®.

3. Special Situations

3.A. Altered Immunocompetence

Altered immunocompetence, a term often used synonymously with *immunosuppression*, *immunodeficiency*, and *immunocompromise*, can be classified as primary or secondary:

- ***Primary immunodeficiency*** generally is inherited and includes conditions defined by an inherent absence or quantitative deficiency of the cellular or humoral components (or both) that normally provide immunity.
- ***Secondary immunodeficiency*** is acquired. It is defined by loss or qualitative deficiency in cellular or humoral immune components that occurs as a result of a disease process or its therapy. Examples include HIV infection, hematopoietic malignancies, treatment with radiation or chemotherapy, and treatment with immunosuppressive drugs. Certain conditions like asplenia and chronic renal disease also can cause altered immunocompetence.

Administration of live vaccines may need to be deferred until immune function has improved. This is primarily a safety concern, because persons with altered immunocompetence who receive live vaccines might be at increased risk for an adverse reaction due to uninhibited growth of the attenuated live virus or bacteria. Vaccines also might be less effective during the period of altered immunocompetence.

- ***Vaccination during chemotherapy or radiation should generally be avoided EXCEPT for influenza vaccination.*** The reason for this is that the antibody response might be suboptimal. Patients vaccinated within a 14-day period before starting immunosuppressive therapy, or vaccinated while receiving immunosuppressive therapy, should be considered unimmunized. They should be revaccinated at least 3 months after therapy is discontinued, if immune competence has been restored.
- ***Vaccinations recommended because of immunosuppression:***
  - ***Pneumococcal vaccine:*** Persons with altered immunocompetence generally are recommended to receive polysaccharide-based vaccines (PCV13, PPSV23), on the basis of increased risk for disease. See the Pneumococcal Vaccine module in **Chapter 3** for guidance.
  - ***Meningococcal vaccines:*** These vaccines are recommended for persons with anatomic or functional asplenia (including sickle cell disease). See the Meningococcal Vaccine module in **Chapter 3** for guidance.

3.B. Antiviral Drugs

- Antiviral drugs used for treatment or prophylaxis of influenza virus infections have no effect on the response to inactivated influenza vaccine. Live, attenuated influenza (intranasal) vaccine should NOT be administered until 48 hours after cessation of therapy with antiviral influenza drugs.
- Antiviral drugs active against herpes viruses (e.g., acyclovir or valacyclovir) might reduce efficacy of vaccines containing live, attenuated varicella zoster virus. Ideally, these drugs should be discontinued at least 24 hours *before* administration of VAR and ZVL, and held for 14 days *after* the receipt of VAR and ZVL.

3.C. Pregnancy

No evidence exists of risk to the fetus from vaccinating pregnant women with inactivated virus or bacterial vaccines, or toxoids.

- ***HPV vaccine, an inactivated vaccine, is NOT recommended during pregnancy,*** despite the lack of evidence of risk.
- ***Live vaccines pose a theoretical risk to the fetus.*** Therefore, live, attenuated virus and live bacterial vaccines (i.e., MMR, VAR, ZLV) generally are contraindicated during pregnancy.
  - *Women should avoid conception for 4 weeks after vaccination with MMR and 12 weeks after vaccination with VAR.*
- ***Tdap vaccine is recommended for all pregnant women during EVERY pregnancy.*** Pregnant women should receive a dose of Tdap for the prevention of infant pertussis, whether or not they have previously received a dose of Tdap. Vaccination of the mother generates antibodies that pass transplacentally to the fetus. Vaccination in the third trimester optimizes the duration of this antibody protection for the baby after birth. Post-partum women for whom follow-up Td vaccination is indicated, but who did not complete the recommended 3-dose series during pregnancy, should receive follow-up after delivery to ensure that the series is completed.
- ***The inactivated influenza vaccine (IIV)*** is recommended for all women who are or will be pregnant (in any trimester) during influenza season. Pregnant women are at increased risk of influenza complications.
- ***The HepB vaccine*** is not contraindicated in pregnancy and should be given to a pregnant woman for whom it is indicated.
- ***The HepA, pneumococcal, and meningococcal vaccines*** should be considered for pregnant women at increased risk for those infections.

3.D. Hematopoietic Cell Transplant (HCT) Recipients

HCT is the infusion of hematopoietic cells from a donor into a patient who has received chemotherapy and often radiation. HCT recipients are at increased risk for certain vaccine-preventable diseases. As a result, HCT recipients should be routinely revaccinated *after* HCT.
The timing of vaccination of HCT recipients is recommended as follows:

- ***Inactivated influenza vaccine (IIV):*** At least 6 months post-transplant, and annually thereafter.
- ***Inactivated vaccines (Tdap/Td, HepA, HepB, Hib, PCV13, PPSV23):*** At least 6 months post-transplant.
- ***MMR and VAR vaccines:*** At least 24 months post-transplant, only if immunocompetent.

4. Managing Adverse Reactions

A vaccine ***adverse event*** is an untoward event, which occurs after immunization, and that might be caused by the vaccine product or the vaccination process itself. These events range from common, minor local reactions to rare, severe allergic reactions (e.g., anaphylaxis). Adverse reactions are also called ***side effects*** and are classified as ***local***, ***systemic***, or ***allergic***.

➔ *More complete information about adverse reactions to a specific vaccine is available in the package insert for each vaccine and from the CDC at: http://www.cdc.gov/vaccines/vac-gen/side-effects.htm.*

➔ *A two-page handout on emergency medical management of anaphylactic reactions after vaccines is available at: http://www.immunize.org/catg.d/p3082.pdf.*

4.A. Local Adverse Reactions

- Most common
- Usually mild and self-limited
- Occur within a few hours of injection
- Common symptoms: Slight bleeding, pain, swelling, itching, and redness at injection site

4.B. Systemic Adverse Reactions

- More generalized than local reactions and may be unrelated to vaccine
- Common symptoms: fever, malaise, headache, and syncope
- Preventing and Managing Syncope:
  - Syncope (vasovagal or vasodepressor reaction) can occur after vaccination and is most common among adolescents and young adults.
  - When vaccinating persons with a history of syncope, have them sit or lie down for vaccination. Consider observing patients (with patients seated or lying down) for 15 minutes after vaccination to decrease the risk for injury should they faint.
  - If syncope develops, patients should be assessed for injury and treated appropriately, or observed until the symptoms resolve.

4.C. Severe Allergic Reactions

Severe allergic reactions are a common concern for the vaccine provider, although they are very rare. Anaphylactic reactions occur at a rate of approximately one per million doses for most vaccines.

- ***The best practice to prevent allergic reactions is to carefully screen individuals at increased risk*** by obtaining a history of allergy to previous vaccinations and vaccine components that might indicate an underlying hypersensitivity
- ***When administering vaccines, epinephrine and equipment for managing an airway should be available for immediate use in the case of a severe anaphylactic reaction to a vaccine.***
  - Epinephrine is available as an aqueous 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen and Auvi-Q).

4.D. Reporting Adverse Events After Vaccination

Mandated reporting: If an adverse event occurs after vaccination, it should be reported to the Vaccine Adverse Event Reporting System (VAERS). Health-care providers are required to report certain events as described on the VAERS website at: *https://vaers.hhs.gov/reportevent.html*.

In addition to the mandated reporting of events listed on the reportable events table, health care personnel should report to VAERS all events listed in product package inserts as contraindications, as well as all clinically significant adverse events, even if they are uncertain that the adverse event is related causally to vaccination.

Information needed for VAERS report:

- Patient information (age, date of birth, sex)
- Vaccine information (brand name, dosage)
- Date, time, and location administered
- Date and time when adverse event(s) started
- Symptoms and outcome of the adverse event(s)
- Medical tests and laboratory results (if applicable)
- Physician's contact information (if applicable)

There are 2 ways to report to VAERS:

- Submit the report online via a secure website at: *https://vaers.hhs.gov/esub/index.jsp.*
- Report by using the writable PDF form that can be downloaded and completed from: *https://vaers.hhs.gov/uploadFile/index.jsp*

D. RESOURCES FOR HEALTH CARE PROVIDER VACCINE EDUCATION

- **The CDC *Vaccine Storage & Handling Toolkit*:** *https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf*

- **The CDC's "You Call the Shots"** is a series of Web-based training modules on vaccine-preventable diseases and the latest recommendations for vaccine use, eligible for continuing education (CE) credits. Available at: *https://www.cdc.gov/vaccines/ed/youcalltheshots.html*

- **The CDC Vaccine Administration Education:** *https://www.cdc.gov/vaccines/ed/courses.html#elearn-vaccadmin*

- **The Immunization Action Coalition (IAC)** website provides information and educational materials for both patients and professionals, available at: *http://www.immunize.org*.
  - To subscribe to their free online publications, go to: *www.immunize.org/subscribe*.
  - To find manufacturers' vaccine package inserts and FDA product approvals, go to: *http://www.immunize.org/fda/*
  - A comprehensive guidebook, ***Vaccinating Adults:* A Step-by-Step Guide,** is available at: *http://www.immunize.org/guide/pdfs/vacc-adults-entire.pdf*

- **The Pinkbook Online Webinars** provide an overview of the principles of vaccination, general recommendations, immunization strategies for providers, and specific information about vaccine-preventable diseases and the vaccines that prevent them: *https://www.cdc.gov/vaccines/ed/webinar-epv/index.html*

- **The Vaccine Adverse Event Reporting System (VAERS) website** provides information about reporting an adverse event following vaccination, including access to online reporting. Available at: *http://vaers.hhs.gov/index*

E. REFERENCES

- Centers for Disease Control and Prevention (CDC). General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2011;60(2):1–64. Available at: *https://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf*.
- Centers for Disease Control and Prevention (CDC). Vaccine Storage & Handling Toolkit. January 2018: *https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html*
- Kroger AT, Duchin J, Vázquez M. General best practice guidelines for immunization. Best practices guidance of the Advisory Committee on Immunization Practices (ACIP). Available at: *https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html*. Accessed on May 8, 2017.
- Hamborsky J, Kroger A, Wolfe S, eds. *Epidemiology and Prevention of Vaccine-Preventable Diseases,* a.k.a. the "Pink Book," 13th ed. Washington D.C.: Public Health Foundation; 2015 and 2017 Supplement Available at: *https://www.cdc.gov/vaccines/pubs/pinkbook/index.html*.
- ***The following Appendices may be of particular interest to providers:***
  - Appendix A, p.24: Recommended intervals between administration of immune globulin preparations and MMR or VAR. Available at: *https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/mmr_ig.pdf*
  - Appendix A, pp. 28–30: Guide to Contraindications and Precautions to Commonly Used Vaccines. Available at: *https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/contraindications.pdf*
  - Appendix B, pp. 15 –32: Foreign Language Terms – Aids to translating foreign immunization records. Available at: *https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/foreign-products-tables.pdf*
  - Appendix F, p.3: Contact Information for Selected Vaccine Manufacturers & Distributors. Available at: *https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-f.pdf*

CHAPTER 2. BOP IMMUNIZATION INDICATIONS

Indications for immunization in the Federal Bureau of Prisons are summarized on the following pages of this chapter:

- ***For more information about the use of these vaccines in the BOP, see the VACCINE PROCEDURE MODULES in CHAPTER 3. (The numbers above and in the chart correspond to the Module numbers.)***
- ***Guidance in this document is based on the ACIP Adult Immunization Schedule for persons age 19 years or older. For patients age 18 or younger, consult the package insert and the local pharmacist.***

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGES 19 OR OLDER* * For persons ages 18 or younger consult pharmacist and package inserts.		
VACCINE/POPULATION	**INDICATION FOR VACCINE**	**KEY POINTS**
1. HEPATITIS A (HEPA) *Sentenced Inmates*	**HepA vaccine is indicated for individuals with the following RISK FACTORS *and* no documented history of HepA vaccine or positive lab titer:** • Men who have sex with men. • Injection or non-injection drug use. • Liver disease or cirrhosis, including chronic hepatitis C (HCV RNA+) and hepatitis B (HBsAg+). • Clotting factor disorders. • HIV-infected individuals with any of the above risk factors. **OUTBREAKS:** Vaccinate Individuals at risk for infection during HAV outbreaks who have no documented immunity or positive lab titer. **EXPOSURE:** See *post-exposure information* in Section C of Vaccine Procedure Module 1 (HepA). **FOR FOREIGN-BORN INMATES:** Consider pre-screening for hepatitis A immunity prior to vaccination.	**AT SCREENING VISIT:** Determine risk, and immunity or vaccine history related to hepatitis A. **NO DOCUMENTED OR KNOWN HISTORY OF VACCINE:** • Administer on a 2-dose schedule of 0 & 6 months. **DOCUMENTED HISTORY OR KNOWN HISTORY OF 1 DOSE:** • Administer 1 dose. **GENERAL:** • The two HepA vaccines (Vaqta® and Havrix®) can be used interchangeably. • For candidates for both HepA and HepB, utilize Twinrix® vaccine.
2. HEPATITIS B (HEPB) *Sentenced Inmates*	**HepB vaccine is indicated for individuals with the following RISK FACTORS. *Vaccine is not indicated if documented history of HepB vaccine series or positive HBsAb or HBsAg lab titer.*** • Men who have sex with men. • Injection drug use. • Chronic liver disease or cirrhosis, including hepatitis C (HCV RNA+). • Adults in predialysis care. • Hemodialysis/peritoneal dialysis recipients. See *dialysis dosing schedule* in Vaccine Procedure Module 2 (HepB). • Diabetic adults younger than age 60 (≥60 at discretion of clinician). • Inmate workers at risk for bloodborne pathogen exposure. • HIV-infected (see below★). • History of syphilis, gonorrhea, or chlamydia in last 6 months. • Post-exposure prophylaxis. ★ **HIV INFECTION (NON-RESPONDER)**: The *dialysis dosing schedule* (in Module 2) can be considered for HIV patients not responding with positive HBsAb after initial HepB series.	**AT SCREENING VISIT:** Determine previous vaccine history and whether individual has risk factors for hepatitis B. **NO DOCUMENTED OR KNOWN HISTORY OF VACCINE:** • Engerix or Recombivax: Administer on a 3-single dose schedule of 0, 1, & 6 months. • Heplisav-B: Administer on a 2-single dose schedule of 0 and 1 month. **FOREIGN-BORN INMATES:** • Consider pre-screening for positive HBsAg prior to vaccination. **GENERAL:** • Candidates for both HepA and HepB, utilize Twinrix® vaccine.

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGES 19 OR OLDER* * For persons ages 18 or younger consult pharmacist and package inserts.		
VACCINE/POPULATION	**INDICATION FOR VACCINE**	**KEY POINTS**
3. HAEMOPHILUS INFLUENZAE B (HIB) *Sentenced Inmates*	**Hib vaccine is indicated for individuals with no documented vaccination history as an adult (19 years and older) *and* any of the following conditions:** • Diagnosis of anatomic or functional asplenia (e.g., sickle cell disease). • Pending elective splenectomy. • Recipient of hematopoietic stem cell transplant (HSCT).	**AT SCREENING VISIT:** Determine previous vaccine history and whether individual has risk conditions. **NO DOCUMENTED HISTORY OF VACCINE:** • For asplenia (e.g., sickle cell disease), administer 1 dose of vaccine. • For elective splenectomy, administer 1 dose of vaccine at least 14 days prior to surgery. **FOR HSCT, REGARDLESS OF VACCINATION HISTORY:** • Initiate 3-dose series when immunocompetent (6–12 months post-transplant).
4. HUMAN PAPILLOMAVIRUS (HPV) *Sentenced Inmates*	**HPV vaccine is indicated for persons with no documented or *self-reported* history of vaccine *and* who meet the following AGE and RISK FACTORS:** • Females ≤ age 26 (*Do not vaccinate during pregnancy. Delay administration until after pregnancy*). • Males ≤ age 21. • Males age 22–26 if immunocompromised (e.g., HIV) or men who have sex with men.	**AT SCREENING VISIT:** Determine previous vaccine history and whether patient meets age and risk factor indications for HPV vaccine. Initiate dose or dose series as appropriate: • **NO PREVIOUS DOSES:** Administer 3-dose schedule of 0, 1-2, & 6 months. • **IF REPORTS PREVIOUS DOSE(S):** See information under *Administer the HPV vaccine* in Vaccine Procedure Module 4 (HPV) in Chapter 3
5. INFLUENZA *All Inmates*	**Influenza vaccine is indicated annually for all adults without known contraindications. Order of priority is based on risk and vaccine availability.** **PRIORITY 1 –** Adults with the following risk factors: • Pregnancy. • Chronic pulmonary disease, including asthma. • Cardiovascular disease (except isolated HTN). • Renal, hepatic, neurological (including epilepsy), or metabolic disorders (e.g., diabetes). • Immunosuppression (including HIV and immunosuppression caused by medications, cancer, anti-alpha inhibitors, steroids, etc.). • Morbid obesity (BMI > 40). • Native Americans. • Inmates housed on Nursing Care Center Units. • Inmates working in Health Services Units (HSUs). **PRIORITY 2 –** Inmates ≥ 65 and older. **PRIORITY 3 –** Inmates ≥ 50–64 years. **PRIORITY 4 –** Inmates < age 50.	**ANNUALLY:** • Administer 1 dose of influenza vaccine per product directions annually unless *self-reported* history of influenza vaccine for the current season. • Document the specific brand and type of influenza vaccine administered in the BEMR immunization comment box (e.g., *Fluzone, trivalent high dose vaccine administered*). **ALLERGIES:** • See information on *contradictions and precautions* in Vaccine Procedure Module 5 (Influenza) in Chapter 3.

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGES 19 OR OLDER* * For persons ages 18 or younger consult pharmacist and package inserts.		
VACCINE/POPULATION	**INDICATION FOR VACCINE**	**KEY POINTS**
6. MEASLES- MUMPS-RUBELLA (MMR) *Sentenced Inmates*	**MMR vaccine is indicated for non-pregnant women of childbearing age and other persons born in 1957 or after who have no evidence of immunity to measles, mumps, or rubella.** **EVIDENCE OF IMMUNITY is one of the following:** • Born before 1957. • Documentation of receipt of MMR. • Laboratory evidence of immunity or disease. **MEASLES OR MUMPS OUTBREAKS:** See *outbreak* information in Section C of Vaccine Procedure Module 6 (Measles/Mumps/Rubella).	**AT SCREENING VISIT:** Determine if patient is a candidate for MMR. Administer 1 dose of MMR to those with no evidence of immunity unless contraindications. **MMR CONTRAINDICATIONS:** • **PREGNANCY:** For women of childbearing age, pregnancy MUST be ruled out with a negative pregnancy test. • **HIV INFECTION WITH CD4+ T-CELL COUNT <200 CELLS/MM³.** **Note:** For HIV Infection and CD4+ T-cell count ≥ 200 cells/mm³ for at least 6 months, administer 2 doses at least 1 month apart. • **SEVERE IMMUNODEFICIENCY:** Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy) **MMR PRECAUTION:** • Recent (within 11 months) receipt of antibody-containing blood product or if history of thrombocytopenia.
7. MENINGOCOCCAL VACCINES **MENINGOCOCCAL B (MENB)** ***and*** **MENINGOCOCCAL ACWY (MENACWY)** *Sentenced Inmates*	**MenB and MenACWY are two different vaccines protecting against different serogroups of meningococcal disease.** **The MenB series is indicated for persons with no documented history of MenB vaccine and any of the following RISK FACTORS:** • Anatomic, functional, or anatomic asplenia (including sickle cell disease). • Persistent complement component deficiency (e.g., inherited chronic deficiencies in C3, C5-C9, properdin, factor D, and factor H). • Eculizumab (Soliris®): Administer 1st dose of meningococcal vaccines at least 2 weeks ***prior*** *to* initiating Soliris. **The MenACWY series and an *every* 5-year MenACWY booster dose are indicated for persons with no documented history of MenACWY vaccine and:** • Have any of the RISK FACTORS listed above for MenB and/*or* • HIV-infected.	**AT SCREENING VISIT:** Determine previous vaccine history and risk factor indications for MenB or MenACWY vaccine. If in a risk group, administer as follows: **NOTE:** MenB and MenACWY vaccines may be given at the same time, but in different sites (e.g., different arms). **MenB Vaccine:** • **IF NO DOCUMENTED DOSES:** Administer 2- or 3-dose series, dependent on vaccine brand.★ • **IF DOCUMENTATION OF ONE OR MORE PREVIOUS DOSES:** Administer completion of series with same brand of MenB vaccine.★ ★ *The two different brands of MenB vaccine (Trumenba® and Bexsero® are NOT interchangeable. Use same brand for all doses.* **MenACWY Vaccine:** • **If NO DOCUMENTED DOSES OR NONE KNOWN:** Administer 2-dose series at least 8 weeks apart; revaccinate with one additional dose every 5 years if risk factor remains. • **IF DOCUMENTATION OF ONE OR MORE PREVIOUS DOSES:** Administer additional dose *every* 5 years as long as risk continues.

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGES 19 OR OLDER* * *For persons ages 18 or younger consult pharmacist and package inserts.*		
VACCINE/POPULATION	**INDICATION FOR VACCINE**	**KEY POINTS**
8. PNEUMOCOCCAL VACCINES **PNEUMOCOCCAL 13-VALENT (PCV13)** ***and*** **PNEUMOCOCCAL 23-VALENT (PPSV23)** *Sentenced Inmates*	**PCV13 is indicated for persons with the following AGE and RISK FACTORS *and* who do not have documentation of history of adult vaccine**: • **Age 65 and older.** • **Risk-factor based, age 19–64:** ◆ Chronic renal failure or nephrotic syndrome (CKD) ★ ◆ Functional or anatomic asplenia (e.g., sickle cell disease or splenectomy) ★ ◆ Immunocompromising conditions (e.g., congenital immunodeficiency, HIV infection, leukemia, lymphoma, multiple myeloma, Hodgkin disease, generalized malignancy, or organ transplantation) ★ ◆ Chemotherapy with alkylating agents, antimetabolites, or long-term systemic corticosteroids★ ◆ Cochlear implants ◆ Cerebrospinal fluid leaks **PPSV23 is indicated when there is no documentation or *self-reported* (★★) adult history *for*:** ◆ Those with RISK FACTORS listed above for PCV13 ◆ Chronic lung disease (including asthma) ◆ Chronic cardiovascular diseases ◆ Chronic liver diseases, cirrhosis ◆ Diabetes mellitus ◆ Chronic alcoholism ◆ Long-term care residents ★ A one-time 5-year PPSV23 booster is indicated after the initial adult dose for persons with the RISK FACTORS starred (★) in the list under PCV13. ★★ Self-reported history of PPSV23 is acceptable because high frequency of vaccination leads to increased risk of local reaction.	**AT SCREENING VISIT:** Determine previous vaccine history and whether individual meets the age and risk factor indications for PCV13 and PPSV23 vaccines. ➔ ***The following are KEY POINTS only. For more complete information, see the algorithm for administering PCV13 and PPSV23 based on vaccination history in Vaccine Procedure Module 8 (Pneumococcal).*** **AGE 65 AND OLDER, with no previous PCV13 or PPSV23:** • Administer 1 dose PCV13. • Administer 1 dose PPSV23 at least 1 year after PCV13. **FOR RISK-FACTOR BASED VACCINATION (AGES 19-64) for whom both PCV13 and PPSV23 are indicated:** • Administer PCV13 first, and then PPSV23 at least 8 weeks later. **TOTAL LIFE-TIME DOSES OF PPSV23** may equal 3, if initial dose was given at age ≤ 55, followed by a booster at 5 years. ➔ ***Do NOT give PCV 13 and PPSV23 during the same visit.***

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGES 19 OR OLDER* * For persons ages 18 or younger consult pharmacist and package inserts.		
VACCINE/POPULATION	**INDICATION FOR VACCINE**	**KEY POINTS**
9. TETANUS-DIPHTHERIA-PERTUSSIS (TDAP) AND TETANUS-DIPHTHERIA (TD) *Sentenced Inmates*	**TDAP VACCINE** is indicated for persons who do not have documentation history of vaccination as an adolescent or as an adult. **TD VACCINE** is indicated every ten years after a documented Tdap adult dose. **PREGNANCY:** Tdap is indicated during *each* pregnancy. **WOUNDS:** See information in *Section C* of Vaccine Procedure Module 9 (Tetanus/ Diphtheria/Pertussis).	**AT SCREENING VISIT:** Determine previous vaccine history and whether individual meets indications or timing for Tdap or Td vaccine. **NO DOCUMENTED HISTORY OF TDAP:** Administer a one-time Tdap dose. Thereafter, a Td booster should be administered every 10 years. **PREGNANCY AND NO DOCUMENTED TDAP:** Administer 1 dose of Tdap during *each* pregnancy, preferably at 27–36 weeks of gestation.
10. VARICELLA LIVE VACCINE(VAR) *Non-Formulary*	**VAR is non-formulary:** In rare circumstances, VAR vaccine may be indicated for persons without evidence of varicella immunity who are exposed to varicella, but **only after determination has been made with the Regional/Central Office** that vaccination is indicated.	Before reconstitution, vaccine must be stored in a freezer (−58°F to +5°F; −50°C to −15°C). → *See Vaccine Procedure Module 10 (Varicella).*
11. RECOMBINANT ZOSTER VACCINE (RZV) *Non-Formulary*	**RZV is non-formulary and must be requested through the non-formulary process.**	→ *See Vaccine Procedure Module 11 (Herpes Zoster).*

CHAPTER 3. VACCINE PROCEDURE MODULES

MODULES: This chapter contains a series of procedure modules, one for each vaccine. Each module begins on its own page 1, so that they are easier to use if printed out. The modules cover indications, contraindications, precautions, dose, route, and documentation instructions for the following vaccines. The modules are listed below as **links**:

SIGNATURE SHEET: Preceding the modules, *on the next page of this chapter*, is a template Signature Sheet that can be used by Clinical Directors to authorize selected institution health care personnel to administer vaccines by using the vaccine modules in this chapter—instead of individual patient orders. The Clinical Director may check (✓) the appropriate boxes to indicate which healthcare provider categories and which vaccine modules are covered. The Signature Sheet is designed to be signed by the Clinical Director and filed in health care provider credential files. It is recommended that updates to the Signature Sheet coincide with other nursing protocols and/or updates to the vaccine procedure modules.

Personnel authorized to administer vaccine should have demonstrated vaccine administration skills. The **SKILLS CHECKLIST FOR VACCINE ADMINISTRATION** is available in *Attachment 1*.

➔ ***Guidance in these modules is primarily based on the ACIP Adult Immunization Schedule for persons age 19 years or older. For patients age 18 or younger, consult the package insert and the local pharmacist.***

VACCINE PROCEDURE MODULES SIGNATURE SHEET*

BOP HEALTH SERVICES UNIT

Institution:	
Authorization is given for the checked (✓) categories of healthcare providers to use the checked (✓) vaccine procedure modules (below) for administration of vaccines without individual patient medication orders. Health care providers who are authorized to administer vaccines using these Vaccine Procedure Modules should have demonstrated vaccine administration skills. File a copy of this Signature Sheet in each authorized health care provider's credential file.	
	Registered Nurses
	Licensed Practical Nurses
	Pharmacists
	Advanced Practice Providers
	Other:
The following vaccine procedure modules are approved for use in this facility if checked (✓) below:	
	1. Hepatitis A vaccine (HepA)
	2. Hepatitis B vaccine (HepB)
	3. *Haemophilis influenzae* type B vaccine (Hib)
	4. Human papillomavirus vaccine (HPV)
	5. Influenza vaccines: inactivated (IIV) and recombinant (RIV) – trivalent, quadrivalent, high-dose *(Module 5 will be updated annually with BOP formulary contract-specific vaccines.* ***REPRINT IT ANNUALLY*** *before each flu season.)*
	6. Measles, mumps, rubella (MMR)
	7. Meningococcal vaccines (MenB and MenACWY)
	8. Pneumococcal vaccines (PCV13 and PPSV23)
	9. Tetanus, diphtheria, pertussis vaccines (Td and Tdap)
	10. Varicella vaccine (VAR)
	11. Recombinant zoster vaccine (RZV) – Shingrix®

Signatures:

Infection Prevention and Control Coordinator	*Date*
Health Services Administrator	*Date*
Clinical Director	*Date*

Health Care Provider (Last, First)--PRINT	*Signature*	*Date*

MODULE 1. HEPATITIS A VACCINE

A. Purpose

The purpose of this guidance is to reduce morbidity and mortality from hepatitis A virus (HAV) infection by vaccinating all adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

➔ *The full text of the ACIP guidelines is available at:*
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf

B. Procedure

Using this vaccine module, eligible nurses and other healthcare professionals, as defined by scope of duty, may vaccinate adults who meet the indications below for hepatitis A vaccine (HepA).

1. ***Identify adults in need of vaccination against HAV, which is indicated for any of the following risk factors who do not have evidence of immunity to HAV or history of HepA vaccination:***
   - Men who have sex with men
   - Injection or non-injection drug use
   - Liver disease or cirrhosis, including chronic hepatitis C (HCV antibody positive, HCV RNA positive) and chronic hepatitis B (HBsAg positive)
   - Clotting factor disorders
   - HIV-infected patients with any of the above risk factors
   - ***During an HAV outbreak:*** Persons at risk for HAV infection. Administer one dose of HepA vaccine. A second dose may be considered, based on risk factors and status of outbreak, at 6–18 months after initial vaccination.
   - ***Post-exposure:*** Persons who have been exposed to HAV within the prior 14 days, and have not previously completed the HepA or TWINRIX vaccine series, should receive a single dose of HepA vaccine as soon as possible.
     - In addition to HepA vaccine, hepatitis A immune globulin (IG) (0.1 mL/kg) may be administered to persons age >40 years depending on the providers' risk assessment, which should include considerations of the exposed person's age, immune status and underlying conditions, exposure type (risk of transmission), and availability of IG.

2. *Screen all patients for contraindications and precautions to HepA vaccine:*

- **CONTRAINDICATIONS:** A history of a serious reaction (e.g., anaphylaxis) after a previous dose of HepA vaccine or to a HepA vaccine component.
  - **LATEX ALLERGY:** Tip caps of some prefilled syringes and some multi-dose vials contain natural rubber latex, which may cause allergic reactions (see package insert).
  - **YEAST/NEOMYCIN ALLERGY:** Severe allergic reaction (e.g., anaphylaxis) to yeast or neomycin, is a contraindication to administration of HepA vaccines.

  → *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.*
- **PRECAUTIONS:** A moderate or severe acute illness with or without fever.
- **PREGNANCY OR NURSING:** Refer to primary provider.

3. *Provide all patients with a copy of the most current Vaccine Information Statement (VIS).*

- Review the vaccination information with the patient and have the patient sign the immunization consent or declination form (BP-A0808).
- Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred by the patient.

→ *The current VIS, in English and other languages, can be found linked to vaccine consent forms in BEMR or at www.immunize.org/vis.*

4. *Administer HepA Vaccine to Individuals ≥19 Years Old:*

→ *For patients ages 18 or younger, consult the package insert and local pharmacist.*

Patient Group	Vaqta® (Merck)			Havrix® (GSK)			Twinrix® HepA &HepB (GSK)			Considerations
	Dose	Volume (Route)	Schedule	Dose	Volume (Route)	Schedule	Dose	Volume (Route)	Schedule	
Adults w/ Risk Factors or Exposure	50 units	1 mL (IM)	0 & 6–18 months **Outbreak:** 1 dose	1,440 EL units	1 mL (IM)	0 & 6–12 months **Outbreak:** 1 dose	**HepA:** 720 EL units **HepB:** 20 mcg	1 mL (IM)	0, 1, & 6 months	**Contraindications:** **Severe allergy** or anaphylaxis to neomycin or yeast **Severe allergy** to latex (see package insert) **Precaution:** Pregnancy

- ***To prevent syncope***, have patient sit or lie down for vaccination and consider observing the patient for 15 minutes after receipt of the vaccine.
- Administer vaccine dose.
  - Give vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle; alternatively, the anterolateral thigh also can be used.

    → *See Chapter 4, Administering Vaccines: Dose, Route, Site, and Needle Size.*
  - ***Note:*** A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taught, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

- The two available single-antigen adult vaccines (Vaqta and Havrix) can be used interchangeably.
- Provide a subsequent dose of HepA vaccine to complete each patient's 2-dose schedule by observing a minimum interval of 6 months between the first and second doses.
  - Schedule the subsequent vaccination in the electronic medical record (BEMR).
  - Do not restart the vaccine series if the second dose is delayed beyond 6 months.
- For candidates for whom both the HepA and HepB vaccines are recommended, administer the 3-dose Twinrix (combination HepA and HepB) vaccine at 0, 1, and 6 months.

5. ***Document patient vaccine administration information in:***
   - ***Patient Medical Record (BEMR):*** Record the vaccine administration location, the manufacturer and lot number, dosage and route, and expiration date.
     - ***If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).***
   - ***BOP Immunization Consent Form (BP-A0808):***
     - Document the publication date of the VIS.
     - Have patient sign and date form.
     - The person administering immunization signs and dates the form.
   - ***Scan the signed consent form (BP-A0808) into the Document Manager in BEMR.***

6. ***MEDICAL EMERGENCY OR ANAPHYLAXIS:*** Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.
   - In the event of a medical emergency related to the administration of a vaccine, ***immediately call a medical emergency.***
   - ***Epinephrine 1:1000 and respiratory support should be immediately available.***

7. ***Report all clinically important vaccine adverse reactions to the Federal Vaccine Adverse Event Reporting System (VAERS) at: https://vaers.hhs.gov/reportevent.html.***
   - Complete reports online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call: (800) 822-7967.

MODULE 2. HEPATITIS B VACCINE

A. Purpose

The purpose of this guidance is to reduce morbidity and mortality from hepatitis B virus (HBV) infection by vaccinating all adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

➔ *The full text of the ACIP guidelines is available at:*
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf

B. Procedure

Using this vaccine module, eligible nurses and other healthcare professionals, as defined by scope of duty, may vaccinate adults who meet the indications below for the hepatitis B vaccine (HepB).

1. ***Identify adults in need of vaccination against HBV, based on any of the following indications with consideration for age and chronic illness appropriate dosing:***
   - Men who have sex with men
   - Injection drug use
   - Chronic liver disease or cirrhosis, including hepatitis C (HCV RNA+)
   - Adults in predialysis care
   - Hemodialysis/peritoneal dialysis recipients (use dialysis dosing schedule in *table* below under #4)
   - Diabetic adults younger than age 60 (≥60 at discretion of clinician)
   - Inmate workers at risk for bloodborne pathogen exposure
   - HIV-infected
   - History of syphilis, gonorrhea, or chlamydia in last 6 months
   - Post-exposure prophylaxis

   Note: In the table below, there is an alternative dose option for patients who do not convert to HBsAb positive post-vaccination.

   Note: For persons born in Asia, the Pacific Islands, Africa, or other countries identified as having high rates of HBV, consider hepatitis B surface antigen (HBsAg) testing—without delaying the first vaccine dose—to find out if they are chronically infected.

2. ***Screen all patients for contraindications and precautions to hepatitis B vaccine:***
   - **CONTRAINDICATIONS:** A history of a serious reaction (e.g., anaphylaxis) after a previous dose of HepB vaccine or to a HepB vaccine component.
     - **LATEX ALLERGY:** Tip caps of some prefilled syringes contain natural rubber latex which may cause allergic reactions (see package insert).
     - **YEAST ALLERGY:** Severe allergic reaction (e.g., anaphylaxis) to yeast, is a contraindication to administration of HepB vaccines.

➔ *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.*

➢ **PRECAUTIONS:** A moderate or severe acute illness with or without fever, or pregnancy.

3. Provide all patients with a copy of the most current Vaccine Information Statement (VIS).

➢ Review the vaccination information with the patient and have the patient sign the immunization consent or declination form (BP-A0808).

➢ Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred by the patient.

➔ *The current VIS, in English and other languages, can be found linked to vaccine consent forms in BEMR or at www.immunize.org/vis.*

4. Administer HepB Vaccine:

Vaccine	Dose/ Volume/ Schedule	Most At-Risk Adults	Adults (≥ age 20) on Dialysis *and* Alternative Dose/Schedule for HIV Infection**	Considerations
Recombivax® HB (Merck)*	**Dose**	10 mcg IM for age ≥20 5 mcg IM for age ≤19	N/A	**Contraindications:** **Severe allergy** or anaphylaxis to yeast or neomycin (Twinrix) **Severe allergy** to latex (see package insert) **Precaution:** Pregnancy
	Volume	1 mL for age ≥20 0.5 mL for age ≤19	N/A	
	Schedule	0, 1, & 6 months	N/A	
Recombivax HB (Merck)* Dialysis Formulation	**Dose**	N/A	40 mcg	
	Volume	N/A	1 mL	
	Schedule	N/A	0, 1, & 6 months	
Engerix-B® (GSK)* Adult Dose	**Dose**	20 mcg IM for age ≥20 10 mcg IM for age ≤19	40 mcg (two separate 20 mcg doses)	
	Volume	1 mL for age ≥20 0.5 ml for age ≤19	Two 1 mL doses at same site, 1" apart	
	Schedule	0, 1, & 6 months	0, 1, 2, & 6 months	
Heplisav-B®* (Dynavax) Approved for age 18 and older**	**Dose**	20 mcg HBsAg AND 3000 mcg CpG adjuvant IM	Safety and effectiveness of Heplisav-B have not been established in adults on hemodialysis.	
	Volume	0.5 mL		
	Schedule	0 and 1 month		
Twinrix® HepA &HepB (GSK) Approved for age 18 and older	**Dose**	**HepA:** 720 EL.Units **HepB:** 20 mcg EL.Units	N/A	
	Volume	1 mL	N/A	
	Schedule	0, 1, & 6 months	N/A	

* Recombinant hepatitis B surface antigen proteins.
** Use as alternate dose schedule for HIV patients not responding with HBsAb after initial HepB series.
*** For Heplisav-B (HepB-CpG): 2-dose HepB vaccine series only applies when both doses consist of HepB-CpG, are administered at least 4 weeks apart. See vaccine insert for dosing schedule if interchanging with Recombivax-HB or Engerix-B.

- ***To prevent syncope***, have patient sit or lie down for vaccination and consider observing the patient for 15 minutes after receipt of the vaccine.
- Administer vaccine dose.
  - Administer adult and medical condition appropriate hepatitis vaccine brand dose. Give vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle; alternatively, the anterolateral thigh also can be used.
    - ➔ *See Chapter 4, Administering Vaccines: Dose, Route, Site, and Needle Size.*
  - ***Note:*** A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taught, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.
- ***Schedule and provide subsequent doses of HepB vaccine*** to complete each patient's dose schedule.
  - ***Observe the following dosing intervals (Engerix-B & Recombivax HB):*** Four weeks between doses 1 and 2; 5 months between doses 2 and 3.
  - ***If an accelerated schedule is needed***, read package insert for dosing.
    - ➔ *The minimum dosing intervals are at least 4 weeks between doses 1 and 2; and at least 8 weeks between doses 2 and 3. Doses given at less than minimum intervals should not be counted and should be repeated.*
  - Do not restart the vaccine series if a dose is given late in the sequence.
  - Schedule the subsequent vaccinations in the electronic medical record (BEMR).
- For candidates for whom both the HepA and HepB vaccines are recommended, administer the 3-dose Twinrix (combination of HepA and HepB) vaccine at 0, 1, and 6 months.
- ***For hemodialysis patients and as an alternative 2nd series dosing schedule for HIV-positive adults:***
  - Recombivax HB Dialysis Formulation: Administer 3-dose series of 1 mL (40 mcg total) at 0, 1, and 6 months.
    or
  - Engerix-B: Administer *4-dose* series as follows. Each dose consists of two 1 mL (20 mcg) vaccinations that are administered at the same time (separated by at least an inch). The "two shot" doses are administered at 0, 1, 2, and 6 months (total of four 40 mcg doses).

5. *Document patient vaccine administration information in the following places:*

- ***Patient Medical Record (BEMR):*** Record the vaccine location, the manufacturer and lot number, the dosage and route, and the expiration date.
  - If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).
- ***BOP Immunization Consent Form (BP-A0808):***
  - Document the publication date of the VIS.
  - Have patient sign and date form.
  - The person administering immunization signs and dates the form.
- ***Scan the signed consent form (BP-A0808) into the Document manager in BEMR.***

6. ***MEDICAL EMERGENCY OR ANAPHYLAXIS:*** Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.
   - In the event of a medical emergency related to the administration of a vaccine, ***immediately call a medical emergency.***
   - ***Epinephrine 1:1000 and respiratory support should be immediately available.***

7. ***Report all clinically important vaccine adverse reactions to the Federal Vaccine Adverse Event Reporting System (VAERS) at: https://vaers.hhs.gov/reportevent.html.***
   - Complete reports online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call (800) 822-7967.

MODULE 3. *HAEMOPHILUS INFLUENZAE* VACCINE

A. Purpose

The purpose of this guidance is to reduce morbidity and mortality from *Haemophilus influenzae* type b infection by vaccinating all adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

➔ *The full text of the ACIP guidelines is available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf*

B. Procedure

Using this vaccine module, eligible nurses and other healthcare professionals, as defined by scope of duty, may vaccinate adults who meet the indications below for the *Haemophilus influenzae* type b vaccine (Hib).

1. ***Identify adults in need of the Hib vaccine, which is indicated for any of the following risk factors:***
   - Diagnosis of anatomic or functional asplenia (e.g., sickle cell disease) and no prior documented history of Hib vaccination.
   - Pending elective splenectomy and no prior documented history of Hib vaccination.
     ➔ *Vaccine is recommended to be administered at least 14 days prior to splenectomy (see table under #4 below).*
   - Recipient of hematopoietic stem cell transplant (HSCT).
     ➔ *Initiate series at 6–12 months after transplant, regardless of Hib vaccination history (see table under #4 below).*
2. ***Screen all patients for contraindications and precautions to Hib vaccine:***
   - **CONTRAINDICATIONS:** A history of a serious reaction (e.g., anaphylaxis) after a previous dose of Hib vaccine or to a Hib vaccine component.
     ➔ *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.*
   - **PRECAUTIONS:** A moderate or severe acute illness with or without fever, or history of Guillain-Barre´ syndrome (GBS) within 6 weeks of prior vaccine.
3. ***Provide all patients with a copy of the most current Vaccine Information Statement (VIS).***
   - Review the vaccination information with the patient and have patient sign the consent or declination form (BP-A0808).
   - Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred by the patient.

   ➔ *The current VIS, in English and other languages, can be found linked to vaccine consent forms in BEMR or at www.immunize.org/vis.*

4. Administer Hib (Haemophilus influenzae type b conjugate) vaccine:

Patient Group	ActHIB (Sanofi Pasteur) or Hiberix (GSK)			
	Volume (Dose)	Schedule	Route	Contraindications/Comments
Anatomic or functional asplenia	0.5 mL (10 mcg)	**One-Time Dose:** *Recommended that dose be administered at least 14 days prior to splenectomy.*	IM	• Do NOT give if history of serious reaction or allergy to a component of vaccine. • Precaution: History of Guillain-Barré Syndrome within 6 weeks after previous vaccine. • Vaccine is reconstituted with accompanying saline diluent. • After reconstitution, administer Hib immediately.
Recipient of HSCT	0.5 mL (10 mcg)	**3-Dose Series:** *Administer 6–12 months post-transplant when immunocompetent, regardless of vaccination history. Separate each dose by at least 4 weeks.*	IM	

- ***To prevent syncope***, have patient sit or lie down for vaccination, and consider observing the patient for 15 minutes after receipt of the vaccine.
- Administer vaccine.
  - Give vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle; alternatively, the anterolateral thigh also can be used.

    ➔ *See Chapter 4, Administering Vaccines: Dose, Route, Site, and Needle Size.*
  - ***Note:*** A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taught, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.
- After reconstitution, store refrigerated between 2° and 8°C (36° and 46°F). Discard the reconstituted vaccine if not used within 24 hours.
- The two available single-antigen adult vaccines (ActHIB or Hiberix) can be used interchangeably. Provide Hib vaccine 3-dose series to HSCT patients with minimum of 4-week intervals, 6–12 months after transplant (when patient is immunocompetent).
- At time of dose, schedule the subsequent vaccinations in the electronic medical record (BEMR).

5. Document patient vaccine administration information in the following places:

- ***Patient Medical Record (BEMR):*** Record the vaccine administration location the manufacturer and lot number, dosage and route, and expiration date.
  - If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).
- ***BOP Immunization Consent Form (BP-A0808):***
  - Document the publication date of the VIS.
  - Have patient sign and date form.
  - The person administering the immunization signs and dates form.
- ***Scan the signed consent form (BP-A0808) into the Document manager in BEMR.***

6. ***MEDICAL EMERGENCY OR ANAPHYLAXIS:*** Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.
   - In the event of a medical emergency related to the administration of a vaccine, ***immediately call a medical emergency***.
   - ***Epinephrine 1:1000 and respiratory support should be immediately available.***

7. ***Report all clinically important vaccine adverse reactions to the Federal Vaccine Adverse Event Reporting System (VAERS) at: https://vaers.hhs.gov/reportevent.html.***
   - Complete reports online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call: (800) 822-7967.

MODULE 4. HUMAN PAPILLOMAVIRUS VACCINE

A. Purpose

The purpose of this guidance is to reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

➔ *The full text of the ACIP guidelines is available at:* https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf

B. Procedure

Using this vaccine module, eligible nurses and other healthcare professionals, as defined by scope of duty, may vaccinate adults who meet the indications below for the HPV vaccine.

1. ***Identify persons in need of vaccination against HPV, based on the following indications and with no documented or self-reported history of receiving the complete vaccine series:***
   - Females, age 26 years or younger (Do not vaccinate during pregnancy. Delay administration until after pregnancy).
   - Males, age 21 years or younger
   - Males, age 22–26 years, meeting any of the following conditions:
     - Immunocompromised as a result of infection (including HIV), disease, or medications
     - Men who have sex with men
2. ***Screen all patients for contraindications and precautions to HPV vaccine:***
   - **CONTRAINDICATIONS:** A history of a serious reaction (e.g., anaphylaxis) after a previous dose of HPV vaccine or to a HPV vaccine component (e.g., yeast, aluminum).
     - ➔ *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.*
   - **PRECAUTIONS:**
     - A moderate or severe acute illness with or without fever.
     - Pregnancy
3. ***Provide all patients with a copy of the most current Vaccine Information Statement (VIS).***
   - Review the vaccination information with the patient and have the patient sign the immunization consent or declination form (BP-A0808).
   - Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred by the patient.
   - ➔ *The current VIS, in English and other languages, can be found linked to vaccine consent forms in BEMR or at www.immunize.org/vis.*

4. Administer the HPV vaccine.

PATIENT GROUPS	9vHPV GARDASIL (MERCK) NOTE: THIS GUIDANCE IS SPECIFIC TO 9-VALENT GARDASIL.			
	VOLUME	DOSE SCHEDULE	ROUTE	CONTRAINDICATIONS/PRECAUTIONS
0 doses, documented or self-reported: • Females ≤ age 26 • Males ≤ age 21 • Males age 22–26*	0.5 mL	Give the complete 3-dose series at 0, 1–2, and 6 months. *Observe the minimum time frames between doses—see below*	IM	• CONTRAINDICATION: History of a serious reaction (e.g., anaphylaxis) after a previous dose of HPV vaccine. • CONTRAINDICATION: Severe allergy (anaphylaxis) to yeast or aluminum. • PRECAUTION: Pregnancy (delay until pregnancy is complete).
1–2 doses documented or self-reported as given at age ≥ 15 or unknown: • Females ≤ age 26 • Males ≤ age 21 • Males age 22–26*	0.5 mL	Complete the 3-dose series as outlined above (with either one dose or two, as needed) with at least 12 weeks between 2nd and 3rd doses.	IM	
1 dose documented or self-reported as given *before* age 15: • Females ≤ age 26 • Males ≤ age 21 • Males age 22–26*	0.5 mL	Give 1 additional dose.	IM	
* Males age 22–26, immunocompromised as a result of infection (including HIV), disease, or medications, OR who have sex with other males.				

- ***To prevent syncope***, have patient sit or lie down for vaccination, and consider observing the patient for 15 minutes after receipt of the vaccine.
- ***Administer vaccine.***
  - Give vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle; alternatively, the anterolateral thigh also can be used.
    → *See Chapter 4, Administering Vaccines: Dose, Route, Site, and Needle Size.*
  - ***Note:*** A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taught, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.
- ***After the first dose, schedule the subsequent vaccinations in the electronic medical record (BEMR).***
- ***Minimum intervals between doses:*** Complete each patient's 3-dose schedule by observing ***(1)*** a minimum interval of 4 weeks month between the first and second doses, ***(2)*** 12 weeks between the second and third dose, and ***(3)*** at least 24 weeks between the first and third doses.
- It is not necessary to restart the HPV vaccine if longer than the suggested interval has elapsed between doses.

5. ***Document patient vaccine administration information in the following places:***
   - ***Patient Medical Record (BEMR):*** Record the vaccine administration location the manufacturer and lot number, dosage and route, and expiration date.
     - If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).
   - ***BOP Immunization Consent Form (BP-A0808):***
     - Document the publication date of the VIS.
     - Have patient sign and date form.
     - The person administering the immunization signs and dates form.
   - ***Scan the signed consent form (BP-A0808) into the Document manager in BEMR.***

6. ***MEDICAL EMERGENCY OR ANAPHYLAXIS:*** Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.
   - In the event of a medical emergency related to the administration of a vaccine, ***immediately call a medical emergency.***
   - ***Epinephrine 1:1000 and respiratory support should be immediately available.***

7. ***Report all clinically important vaccine adverse reactions to the Federal Vaccine Adverse Event Reporting System (VAERS) at:*** *https://vaers.hhs.gov/reportevent.html*.
   - Reports can be completed online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call: (800) 822-7967.

MODULE 5. INFLUENZA VACCINES

A. Purpose

The purpose of this guidance is to reduce morbidity and mortality from the influenza virus by vaccinating all adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

➔ *The full text of the ACIP guidelines is available at:*
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf

Influenza Vaccine Abbreviations:
- Inactivated influenza vaccine – **IIV**
- Inactivated influenza vaccine, trivalent – **IIV3**
- Inactivated influenza vaccine, trivalent high dose – **IIV3 high dose**
- Inactivated influenza vaccine, quadrivalent – **IIV4**
- Recombinant influenza vaccine – **RIV**, **RIV3, RIV4**
- Adjuvanted inactivated influenza vaccine, trivalent – **aIIV3**
- Live attenuated influenza vaccine – **LAIV**

B. Procedure

Using this vaccine module, eligible nurses and other healthcare professionals, as defined by scope of duty, may vaccinate adults who meet the indications below for the influenza vaccine. The ACIP recommends annual influenza vaccination for everyone 6 months of age and older. In the BOP, priority of vaccine administration will be directed by Central Office and Clinical Director, based on influenza risk and vaccine availability.

➔ *This module is updated annually based on the BOP contract formulary flu vaccines available; it will need to be reprinted annually with updates.*

1. ***Influenza vaccination is indicated annually for all adults. Identify adults in need of vaccination against influenza infection, utilizing the priority categories outlined below:***
   - ***PRIORITY 1 –*** Inmates with any of the following medical risk factors:
     - Pregnancy
     - Chronic pulmonary disease (including asthma)
     - Cardiovascular disease (except isolated hypertension)
     - Renal, hepatic, neurological (including epilepsy), or metabolic disorders (including diabetes mellitus)
     - Immunosuppression (including immunosuppression caused by medications, cancer, or HIV)
     - Morbid obesity (BMI > 40)
     - Native Americans
     - Inmates who are housed on nursing care center (long-term care) units
     - Inmates working in Health Services
   - ***PRIORITY 2 –*** All other inmates ages 65 or older
   - ***PRIORITY 3 –*** All other inmates ages 50 to 64
   - ***PRIORITY 4 –*** All other inmates less than age 50

2. ***Screen all patients for contraindications and precautions to influenza vaccine:***
   - **CONTRAINDICATIONS:** Individuals with known severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine, including egg protein, neomycin, or to a previous dose of any influenza vaccine.
     - *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.*
   - **PRECAUTIONS:**
     - If ***Guillain-Barré Syndrome (GBS)*** has occurred within 6 weeks after a previous influenza vaccination, the decision to give influenza vaccine should be based on the potential benefits and risks.
     - If the individual has an ***acute to moderate illness***, defer vaccination until resolution of illness.
     - If the individual has ***allergy to latex***, review the vaccine package insert for presence of latex in vial and syringe components. Afluria, Fluarix, and Fluzone High-Dose are all latex-free and can be administered.
     - ***Egg Allergy:***
       - ***Hives only:*** Those with an egg allergy history who have only experienced hives can receive the flu vaccine (any form of IIV or RIV) appropriate for their age and health status.
       - ***Anaphylactic allergy to eggs:*** Those with an egg allergy history involving angioedema, respiratory distress, lightheadedness, or recurrent emesis or who required epinephrine or another emergency medical intervention, may receive the flu vaccine (any form of IIV or RIV) appropriate for their age and health status, using the following special precautions:

         The vaccine should be administered in a medical setting and be supervised by a health care provider who is able to recognize and manage severe allergic conditions. The patient should be observed for at least 30 minutes for signs of a reaction after each dose of flu vaccine.

3. ***Provide all patients with a copy of the most current Vaccine Information Statement (VIS).***
   - Review the flu vaccination information with the patient and have the patient sign the immunization consent or declination form (BP-A0808).
   - Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred by the patient.

   The current VIS, in English and other languages, can be found linked to vaccine consent forms in BEMR or at www.immunize.org/vis.

4. ***Administer influenza vaccine as outlined above, unless contraindicated. The table below provides information on influenza vaccines for the 2018–19 BOP contract:***

Influenza Vaccine By Type	Form	Strength	Dose	Route	Timing	Age Indications/Comments
Afluria (Sequiris) **IIV4: Inactivated Influenza Vaccine** ***Quadrivalent***	Suspension **Multi-dose** vial (contains ten 0.5 ml doses)	60 mcg HA	0.5 ml	IM	One time annually	**18 years of age and older (*including age 65 and older*):** • Shake the vial thoroughly before use. • Contains thimerosal. • Latex-free. • Use syringe with safety device. • Disinfect top of vial before entering with sterile syringe. • Opened vial must be discarded within 28 days. • Protect from light.
Afluria (Sequiris) **IIV4: Inactivated Influenza Vaccine** ***Quadrivalent***	Suspension **Single-dose**, pre-filled syringes	60 mcg HA	0.5 ml	IM	One time annually	**18 years of age and older (*including age 65 and older*):** • Preservative-free. • Latex-free. • Use appropriate size safety needle.
Fluad High-Dose (Sequiris) **aIIV3 HD: Adjuvanted Inactivated Influenza Vaccine** ***Trivalent High Dose***	Suspension Single-dose, pre-filled syringes	~45 mcg HA total	0.5 ml	IM	One time annually	**An option for use *only* for persons 65 years of age and older:** • Before administering, shake the prefilled syringe. • Thimerosal-free. • Tip caps of pre-filled syringes contain natural rubber latex • Use appropriate size safety needle.

➤ Administer vaccine.

- Give vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle; alternatively, the anterolateral thigh also can be used.

  ➔ *See Chapter 4, Administering Vaccines: Dose, Route, Site, and Needle Size.*

- ***Note:*** A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taught, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

5. ***Document the patient vaccine administration information:***

➤ ***Patient Medical Record (BEMR):*** Under Influenza Immunization (brand required), record the vaccine administration location, the manufacturer and lot number, dosage and route, and expiration date.

- If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).
- In the comment section, note the specific brand of vaccine (e.g., Alfluria Quadrivalent, Fluad high dose trivalent) and any other pertinent information.

  For example: *"Patient 65 or older, Fluad high-dose trivalent vaccine administered. No contraindications, VIS explained and given to patient."*

- ***BOP Immunization Consent Form (BP-A0808):***
  - Document the publication date of the VIS on the immunization consent form (BP-A0808).
  - Document the vaccine being given and have the patient sign consent or declination.
  - The person administering the immunization signs and dates the form.
- ***Scan the signed consent form (BP-A0808) into the Document Manager.***

6. ***MEDICAL EMERGENCY OR ANAPHYLAXIS:*** Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.
   - In the event of a medical emergency related to the administration of a vaccine, ***immediately call a medical emergency.***
   - ***Epinephrine 1:1000 and respiratory support should be immediately available.***
   - ***To prevent syncope***, vaccinate patients while they are seated or lying down, and consider observing the patient for 15 minutes after receipt of the vaccine.

7. ***Report all clinically important vaccine adverse reactions to the Federal Vaccine Adverse Event Reporting System (VAERS) at: https://vaers.hhs.gov/reportevent.html.***
   - Reports can be completed online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call: (800) 822-7967.

MODULE 6. MEASLES, MUMPS, AND RUBELLA VACCINE

A. Purpose

The purpose of this guidance is to reduce morbidity and mortality from measles, mumps, and rubella infection by vaccinating all adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

➔ *The full text of the ACIP guidelines is available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf*

B. Procedure

Utilizing this vaccine module, eligible nurses and other healthcare professionals, as defined by scope of duty, may vaccinate adults who meet the indications below for the measles, mumps, and rubella (MMR) vaccine.

1. ***Identify adults in need of vaccination against measles, mumps, and rubella, based on the following indications:***
   - Females of childbearing age unless evidence of immunity★ to measles, mumps, or rubella.
   - Sentenced inmates born in 1957 or later, without evidence of immunity★ to measles, mumps, or rubella.
   - ***In the context of a mumps outbreak:*** Give 1 dose of MMR vaccine to adults identified to be at increased risk of disease and who have no documentation or known history of ≥ 2 doses of MMR vaccine.
   - ***In the context of a measles outbreak:*** Ideally within 72 hours of exposure, give 1 dose of MMR vaccine to persons identified to be at risk and who have no evidence of immunity★ to measles.

   ★ ***EVIDENCE OF IMMUNITY:*** *Born before 1957, OR documentation of having received 2 doses of MMR vaccine, OR Laboratory evidence of immunity or disease.*

2. ***Screen all patients for contraindications and precautions to MMR vaccine:***
   - **CONTRAINDICATIONS:**
     - ***History of a serious reaction*** (e.g., anaphylaxis) after a previous dose of MMR vaccine or to an MMR vaccine component (e.g., albumin, neomycin, sorbitol, or gelatin).
       ➔ *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.*
     - ***Pregnancy:*** Pregnant now or could become pregnant within 12 weeks.
       ➔ *For women of childbearing age, pregnancy must be ruled out with a negative pregnancy test.*

(list of contraindications continues on next page)

- ***Immunodeficiency:*** Known severe immunodeficiency, hematologic or solid tumor, congenital immunodeficiency, or receiving long-term immunosuppressive therapy or family history of altered immunocompetence.

  In particular:

  - HIV patient with (CD4 + T-cell count <200 cells/mm³)
    - *If HIV Infection and CD4+ T-cell count ≥200 cells/mm³ for least 6 months can administer 1 dose.*
  - Patients receiving chemotherapy
  - Patients treated with certain steroids (see vaccine insert)

- **PRECAUTIONS:**
  - Recent (within the past 11 months) receipt of antibody-containing blood product. For recommended intervals, see Tables 3-4 and 3-5, beginning on page 34 of the ACIP guidelines: *https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf*
  - History of thrombocytopenia or thrombocytopenic purpura. Individuals may develop more severe thrombocytopenia following vaccination (consider serologic status).
  - Moderate or severe acute illness, with or without fever, or taking antibiotics for acute illness.
  - Recent receipt of another live vaccine, e.g., Varicella (defer for 4 weeks) unless administered simultaneously.
  - Caution should be employed in administration of MMR to persons with a history of cerebral injury, individual or family histories of convulsions, or any other condition in which stress due to fever should be avoided.

3. Provide all patients with a copy of the most current Vaccine Information Statement (VIS).

- Review the vaccination information with the patient and have the patient sign the immunization consent or declination form (BP-A0808).
- Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred by the patient.

→ *The current VIS, in English and other languages, can be found linked to vaccine consent forms in BEMR or at www.immunize.org/vis.*

4. *Administer MMR vaccine.*

For males and females who meet vaccine indications, administer 1 dose of MMR vaccine subcutaneously (SQ) in the posterolateral fat of the upper arm.

Patient Groups	MMR II (Merck)			
	Volume	Schedule	Route	Contraindications/Precautions/Instructions
Females of childbearing age, unless there is evidence of immunity	0.5 mL	1 dose	SQ	• Do not give if history of serious reaction to MMR vaccine or severe allergy to neomycin, gelatin, or other components (see package insert). • Do not give if pregnant or if attempting to become pregnant within 4 weeks. • Do not give if severely immunosuppressed. • Precautionary period after recent (11 months) receipt of antibody-containing blood product or if history of thrombocytopenia. • Wait 4 weeks after administration of any other *live* vaccine (e.g., Varicella VAR or Zostavax ZVL). • Check expiration date. • Protect vaccine from light. • **Reconstitute with proper diluent** (this will result in more than 0.5mL, but dose is recorded as 0.5mL of medication). • Give immediately after reconstitution.
Sentenced inmates born in 1957 or after, unless there is evidence of immunity	0.5 mL	1 dose	SQ	
HIV-infected with CD4 + T-cell count ≥200 cells/mm³ for 6 months or more	0.5 ml	1 dose		
Mumps Outbreak: Persons identified to be at risk of disease who have ≤2 doses of MMR	0.5 mL	1 dose	SQ	
Measles Outbreak: Persons identified to be at risk unless there is evidence of immunity to measles	0.5mL	1 dose	SQ	

- ***To prevent syncope***, vaccinate patients while they are seated or lying down, and consider observing the patient for 15 minutes after receipt of the vaccine.
- For patients age 19 years and older, administer 0.5 mL MMR vaccine subcutaneously (SQ) with a 23–25g, 5/8" needle, in the posterolateral fat (tricep) of the upper arm.
- ***The MMR vaccine may be administered at the same time as:*** influenza vaccine, hepatitis vaccines, or Tdap vaccine with separate needles and syringes.
- ***A tuberculin skin test (TST) can be administered at the same time as the MMR.*** HOWEVER, if they are not given concurrently, do NOT give the TST until 28 days AFTER the MMR vaccine, as live attenuated viruses such as MMR can result in suppression of TST or a false negative. Similarly, interferon gamma release assay (IGRA), i.e., QuantiFERON-G® or T-Spot® can be obtained concurrently with MMR vaccination or be obtained 28 days AFTER the MMR vaccine.

5. *Document patient vaccine administration information in the following places:*

- ***Patient Medical Record (BEMR):*** Record the vaccine administration location, the manufacturer and lot number, the dosage and route, and expiration date.
- If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
- ***BOP Immunization Consent Form (BP-A0808):***
  - Document the publication date of the VIS,
  - Have patient sign and date form
  - The person administering the immunization signs and dates form
- ***Scan the signed consent form (BP-A0808) into the Document manager in BEMR.***

6. ***MEDICAL EMERGENCY OR ANAPHYLAXIS:*** Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.
   - In the event of a medical emergency related to the administration of a vaccine, ***immediately call a medical emergency.***
   - ***Epinephrine 1:1000 and respiratory support should be immediately available.***

7. ***Report all clinically important vaccine adverse reactions to the Federal Vaccine Adverse Event Reporting System (VAERS) at: https://vaers.hhs.gov/reportevent.html.***
   - Complete reports online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call: (800) 822-7967.

MODULE 7. MENINGOCOCCAL DISEASE VACCINES

A. Purpose

The purpose of this guidance is to reduce morbidity and mortality from meningococcal disease by vaccinating all adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

➔ *The full text of the ACIP guidelines is available at:*
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf

B. Procedure

Using this vaccine module, eligible nurses and other healthcare professionals, as defined by scope of duty, may vaccinate adults who meet the indications below for meningococcal disease vaccines.

1. ***Assess adults for need of vaccination against meningococcal disease—caused by serogroup B AND/OR serogroups A, C, W, and Y—based on any of the following indications.***

   ➔ *These indications are also summarized in TABLE 1 below.*

INDICATIONS FOR MENINGOCOCCAL SEROGROUP B (MENB) VACCINE:

- ***Anatomic, functional, or anatomic asplenia*** (including sickle cell disease).
- ***Persistent complement component deficiency*** (e.g., inherited chronic deficiencies in C3, C5-C9, properdin, factor D, and factor H).
- ***Eculizumab (Soliris®)***
  - Soliris is used for adult patients with atypical hemolytic uremic syndrome (AHUS) and paroxysmal nocturnal haemoglobinuria (PNH).
  - Immunize patients with meningococcal vaccines *at least 2 weeks prior to* administering the first dose of Soliris.

INDICATIONS FOR MENINGOCOCCAL SEROGROUPS A, C, W, & Y (MENACWY) CONJUGATE VACCINE:

Note: Menactra® and Menveo® are formulary-approved MenACWY vaccines.

- ***Anatomic, functional, or anatomic asplenia*** (including sickle cell disease).
- ***Persistent complement component deficiency*** (e.g., inherited chronic deficiencies in C3, C5-C9, properdin, factor D, and factor H).
- ***HIV-infected persons***
  - Adults with HIV infection who have no documented history of vaccination should receive a 2-dose primary series of MenACWY, with the doses at least 2 months apart, and be revaccinated every 5 years.
  - Adults with HIV who previously received 1 dose of MenACWY should receive a second dose at least 2 months after the first dose, and then be revaccinated every 5 years.

(list of MenACWY indications continues on next page)

➤ ***Persons taking eculizumab (Soliris)***

- Soliris is used for adult patients with atypical hemolytic uremic syndrome (aHUS) or paroxysmal nocturnal hemoglobinuria (PNH).
- Immunize patients with meningococcal vaccines at least 2 weeks prior to administering the first dose of Soliris.

TABLE 1. INDICATIONS FOR RECOMMENDED MENINGOCOCCAL VACCINES

MEDICAL INDICATION	MENB	MENACWY	MENACWY EVERY 5-YEAR BOOSTER
Anatomic or functional asplenia (including sickle cell disease)	X	X	X
Persistent complement component deficiency	X	X	X
HIV-infected persons		X	X
Eculizumab (Soliris)—two weeks prior to initiation	X	X	X

2. *Screen all patients for contraindications and precautions to meningococcal vaccine:*

➤ **CONTRAINDICATIONS:** A history of a serious systemic reaction or anaphylactic after a previous dose of MenB or MenACWY vaccine, or to a meningococcal vaccine component (e.g., diphtheria-toxoid, latex).

➔ *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.*

➤ **PRECAUTIONS:**

- A moderate or severe acute illness with or without fever.
- Previous diagnosis of Guillain-Barré syndrome (GBS) - Menactra.
- Pregnancy.
- Persons with any bleeding disorder, or who are receiving anticoagulant therapy.
- MenACWY (Menactra) and PCV13 should not be administered simultaneously; PCV13 should be administered first and MenACWY (Menactra) administered 4 weeks later. Note: this guidance does NOT apply to MenACWY (Menveo).

3. *Provide all patients with a copy of the most current Vaccine Information Statement (VIS).*

➤ Review the vaccination information with the patient and have the patient sign the immunization consent or declination form (BP-A0808).

➤ Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred by the patient.

➔ *The current VIS, in English and other languages, can be found linked to vaccine consent forms in BEMR or at www.immunize.org/vis.*

4. ***Administer MenB and MenACWY vaccines for individuals meeting the indications described above and the age requirements, as shown in TABLE 2 below.***

   ➔ *For more about contradictions and precautions, see #2 on previous page.*

TABLE 2. ADMINISTRATION OF MENINGOCOCCAL VACCINES*

MENINGOCOCCAL SEROGROUP B VACCINE (MENB)**					
Type of Vaccine	***Age***	***Dose***	***Route***	***Schedule***	***Contraindications, Precautions***
Bexsero® (*GSK*)**:** MenB-4c	≥10 yrs	0.5 mL	IM	Two doses at 0 & at least 4 weeks later (use same brand for entire series).	**Contraindication:** Allergy to vaccine component **Precaution:** Pregnancy **Bexsero and Trumenba are NOT interchangeable. Start and finish series with same brand.** **Bexsero:** Pre-filled syringe tip caps may contain latex.
Trumenba® (*Pifizer*)**:** MenB-FHbp ***(Non-Formulary)***	≥10 yrs	0.5 mL	IM	Three doses at 0, 2, & 6 months (use same brand for entire series).	
MENINGOCOCCAL SEROGROUP A,C,W,Y CONJUGATE VACCINE (MENACWY)					
Type of Vaccine	***Age***	***Dose***	***Route***	***Schedule***	***Contraindications, Precautions***
Menactra (*Sanofi Pasteur*)**:** MenACWY ***(Non-Formulary)***	NA	0.5mL	IM	0 and 2 months. Booster every 5 years if risk remains.	**Contraindication:** Allergy to vaccine component or diphtheria toxoid. **Precautions:** History of GBS, bleeding disorder or anticoagulation therapy; pregnancy. **Do not administer MenACWY (Menactra) and PCV13 simultaneously**—see Precautions above in the text. **Menveo diluent contains antigens CWY; do not use any other diluent.**
Menveo (*GSK*)**:** MenACWY	NA	0.5mL *Reconstitute and give immediately.*	IM	0 and 2 months. Booster every 5 years if risk remains.	

* MenB and MenACWY may be given at the same time, but in different sites (e.g., different arms).

- For both MenB vaccines, ***shake vaccine vigorously*** to form a white suspension prior to administration.
- ***To prevent syncope***, have patient sit or lie down for vaccination, and consider observing the patient for 15 minutes after receipt of the vaccine.
- ***Administer vaccine.***
  - Give vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle; alternatively, the anterolateral thigh also can be used.

    ➔ *See Chapter 4, Administering Vaccines: Dose, Route, Site, and Needle Size.*
  - ***Note:*** A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taught, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

- After the first dose, schedule the subsequent vaccinations in the electronic medical record (BEMR).
- ***The two available MenB vaccines, Bexsero (formulary) and Trumenba, are NOT interchangeable*** and have different schedules of administration. Once initiated, subsequent doses must remain the *same vaccine*, observing the correct intervals between doses.
- MenB vaccine and MenACWY vaccines may be administered at the same time, but at different sites (e.g., different arms).

5. ***Document patient vaccine administration information in the following places:***
   - ***Patient Medical Record (BEMR):*** Record the vaccine location, the manufacturer and lot number, the dosage and route, and the expiration date.
     - If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   - ***BOP Immunization Consent Form (BP-A0808):***
     - Document the publication date of the VIS,
     - Have patient sign and date form
     - The person administering the immunization signs and dates the form
   - ***Scan the signed consent form (BP-A0808) into the Document manager in BEMR.***

6. ***MEDICAL EMERGENCY OR ANAPHYLAXIS:*** Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.
   - In the event of a medical emergency related to the administration of a vaccine, ***immediately call a medical emergency.***
   - ***Epinephrine 1:1000 and respiratory support should be immediately available.***

7. ***Report all clinically important vaccine adverse reactions to the Federal Vaccine Adverse Event Reporting System (VAERS) at: https://vaers.hhs.gov/reportevent.html.***
   - Complete reports online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call: (800) 822-7967.

MODULE 8. PNEUMOCOCCAL VACCINES

A. Purpose

The purpose of this guidance is to reduce morbidity and mortality from pneumococcal disease by vaccinating all adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

➔ *The full text of the ACIP guidelines is available at:*
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf

B. Procedure

Using this vaccine module, eligible nurses and other healthcare professionals, as defined by scope of duty, may vaccinate adults who meet the indications below for pneumococcal vaccines.

1. ***Identify persons in need of vaccination against Streptococcus pneumoniae (pneumococcus) infection*** according to the INDICATIONS in TABLES 1 and 2A and who have no documentation of a history of adult vaccine.

   ➔ **PCV13** = *pneumococcal conjugate vaccine,* **PPSV23** = *pneumococcal polysaccharide vaccine*

   ➔ *See the Algorithm for PCV13 and PPSV23 Vaccinations at the end of this module for a flow chart summarizing TABLES 1, 2A, and 2B below.*

   ➔ ***Do NOT give PCV13 and PPSV23 at the same visit.*** *See TABLE 1 and TABLE 2B for SCHEDULING.*

   ➔ ***Self-reported doses of PPSV23 are acceptable*** *because re-vaccination leads to increased risk of local reaction.*

TABLE 1. ADULTS AGE ≥ 65: ROUTINE ADMINISTRATION OF PCV13 AND PPSV23*

VACCINATION HISTORY	ROUTINE ADMINISTRATION OF PCV13 & PPSV23 ≥ AGE 65	DOSE	ROUTE**	SCHEDULING CONCERNS
None or unknown.	• Administer PCV13, followed in 1 year by PPSV23 (in 8 weeks if immunocompromised)	0.5 mL	**PCV13:** IM only **PPSV23:** IM or SQ	• Do not give PCV13 and PPSV23 during same visit. • Routine vaccination: In most cases, wait 1 year between PCV13 & PPSV23. • If PPSV23 given before age 65, repeat after 65, at least 5 years between doses. • Certain chronic conditions require a PPSV23 booster (see Risk-Based table below) • A person may receive a total of 3 lifetime doses of PPSV23 if originally vaccinated before age 65. • Do not administer PCV13 simultaneously with MenACWY (Menactra)—see Precautions (below).
No/unknown PPSV23 history; Prior history of PCV13.	• Administer PPSV23 at least 1 year after PCV13.	0.5 mL		
PPSV23 given before age 65; No/unknown PCV13 history.	• Administer PCV13 at least 1 year after previous PPSV23. • Administer another PPSV23 at least 5 years after previous PPSV23, and at least 1 year after PCV13.	0.5 mL		
PPSV23 given before age 65; Prior history of PCV13.	• Administer another PPSV23 at least 5 years after previous PPSV23, and at least 1 year after PCV13.	0.5 mL		
PPSV23 given at age 65 or older; No/unknown PCV13 history	• Administer PCV13 at least 1 year after PPSV23.	0.5 mL		

* See *Algorithm* later in this module. ** **IM** = Intramuscular; **SQ** = Subcutaneous

TABLE 2A. AGES 19–64: RISK-BASED INDICATIONS FOR PNEUMOCOCCAL VACCINATIONS OF ADULTS*

MEDICAL CONDITION OR OTHER RISK FACTOR	RECOMMENDED VACCINES***		
	PCV13	PPSV23	PPSV23 5-YEAR BOOSTER**
Chronic heart disease (excluding hypertension)		X	
Chronic lung disease (including asthma)		X	
Diabetes mellitus		X	
Chronic liver disease, cirrhosis		X	
Cigarette smoking		X	
Alcoholism		X	
Cochlear implant, cerebrospinal fluid leak	X	X	
Sickle cell disease, other hemoglobinopathy	X	X	X
Congenital or acquired asplenia	X	X	X
Congenital or acquired immunodeficiency,[1] HIV	X	X	X
Chronic renal failure, nephrotic syndrome (CKD)	X	X	X
Leukemia, lymphoma	X	X	X
Generalized malignancy, Hodgkin disease	X	X	X
Iatrogenic immunosuppression[2]	X	X	X
Solid organ transplant, multiple myeloma	X	X	X

* See *Algorithm* later in this module.

** A PPSV23 booster: Second dose 5 years after the first dose of PPSV23. Note that total lifetime doses of PPSV23 may be three if vaccinated before age 55 due to a specific chronic condition.

*** See *TABLE 2B* below for the Recommended Schedule.

[1] Including B- (humoral) or T-lymphocyte deficiency, complement deficiencies

[2] Diseases requiring treatment with immuno-suppressive drugs, including long-term systemic corticosteroids and radiation therapy

TABLE 2B. AGES 19–64: RECOMMENDED SCHEDULE FOR RISK-BASED PNEUMOCOCCAL VACCINATIONS

PNEUMOCOCCAL VACCINE(S) INDICATED BY MEDICAL CONDITION OR RISK*	VACCINATION HISTORY	VACCINATION ADMINISTRATION**
1 dose PPSV23 (Pneumovax 23-Merck)	None or unknown history	• Administer PPSV23.
1 dose PCV13 (Prevnar 13 - Wyeth) PLUS 1 dose PPSV23	None or unknown history	• Administer PCV13 followed in 8 weeks by PPSV23.
	None or unknown PPSV23 history; 1 dose PCV13	• Administer PPSV23 at least 8 weeks after PCV13.
	1 dose PPSV23; none or unknown PCV13 history	• Administer PCV13 at least 1 year after PPSV23.
Booster Doses PPSV23	If 5-year booster dose is indicated (see TABLE 2A above), then administer PPSV23 at least 8 weeks after PCV13 AND 5 years after the previous PPSV23 dose.	
For adults age 19-64 with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leaks, or cochlear implants, the minimum interval between PCV13 and PPSV23 is 8 weeks. IF PPSV23 is given prior to PCV13, administer PCV13 at least 1 year after PPSV23 regardless of medical condition.		

* **See TABLE 2A above for RISK-BASED RECOMMENDATIONS.**

** Do not give PCV 13 and PPSV23 during same visit; Dose: 0.5 mL; PPSV23: IM or SQ; PCV13: IM only

➔ ***TABLES 1, 2A, AND 2B, IN SUMMARY: Only one dose of PCV13 is recommended for adults. Based on medication condition or risk factors and age of first dose, a total of three PPSV23 doses may be given during a lifetime.***

2. ***Screen all patients for contraindications and precautions to pneumococcal vaccines:***

   - **CONTRAINDICATIONS:** A history of a serious systemic reaction (e.g., anaphylaxis) after a previous dose of pneumococcal vaccine or to any of its components. Prev13 is contraindicated if previous severe allergic reaction to any diphtheria toxoid-containing vaccine.

     → *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.*

   - **PRECAUTIONS:**
     - A moderate or severe acute illness with or without fever.
     - MenACWY (Menactra) and PCV13 should not be administered simultaneously; PCV13 should be administered first and MenACWY (Menactra) administered 4 weeks later. Note: this guidance does NOT apply to MenACWY (Menveo).

3. ***Determine appropriate vaccination, based upon indication and vaccine history.***

4. ***Provide all patients with a copy of the most current Vaccine Information Statement (VIS).***

   - Review the vaccination information with the patient and have the patient sign the immunization consent or declination form (BP-A0808).
   - Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred by the patient.

   → *The current VIS, in English and other languages, can be found linked to vaccine consent forms in BEMR or at www.immunize.org/vis.*

5. ***Administer the vaccine(s):***

   - ***To prevent syncope***, have patient sit or lie down for vaccination and consider observing the patient for 15 minutes after receipt of the vaccine.
   - ***Do not give PCV13 and PPSV23 at the same visit.*** If both the PCV13 and PPSV23 are recommended, the PCV13 is administered first, and the PPSV23 is administered either 8 weeks later (for certain medical or risk conditions) or 1 year later (routine age 65 dosing). If PCV13 is indicated (e.g., asplenia, HIV) and a PPSV23 was given previously, administer PCV13 ***at least*** one year after the PPSV23. See the tables above.

     Note: Schedule the subsequent vaccinations in the electronic medical record (BEMR).

   - Shake Prevnar 13 vaccine vigorously prior to administration.
   - *PCV13 must be administered by the IM route*, preferably in the deltoid muscle of the arm. Use 22–25g, 1–1½" needle.

     → *See Chapter 4, Administering Vaccines: Dose, Route, Site, and Needle Size.*

     Note: A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taught, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

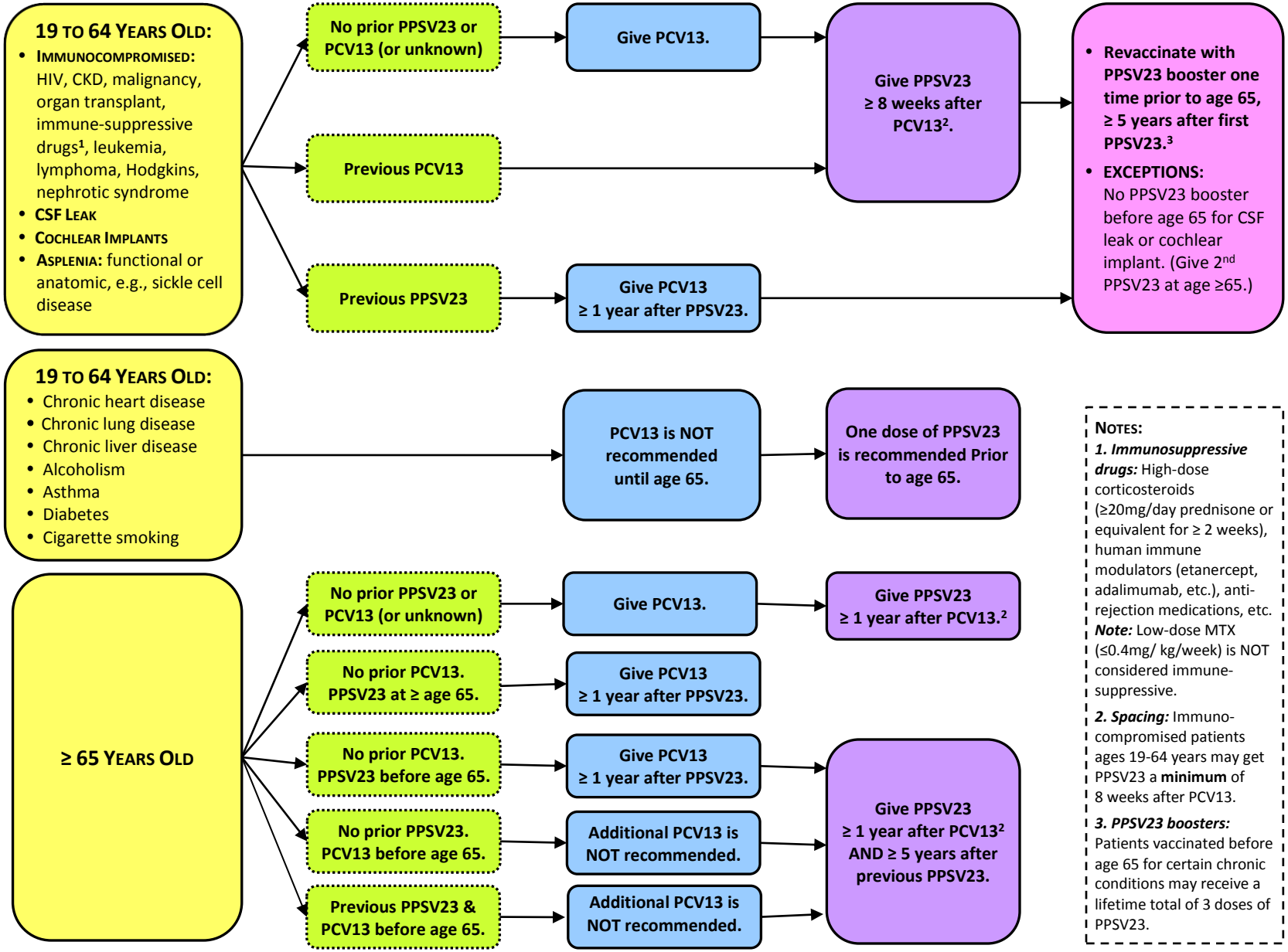
   - ***PPSV23 may be administered either IM*** (in the deltoid muscle of the arm) ***or SQ*** (overlying the triceps muscle). ***For IM:*** Use 22–25g, 1–1½" needle. ***For SQ:*** Use 23–25g, 5/8" needle.

6. ***Document the patient vaccine administration information in the following places:***
   - ***Patient Medical Record (BEMR):*** Record the vaccine location, the manufacturer and lot number, the dosage and route, and the expiration date.
     - Use comment section to clarify which pneumococcal vaccine is given (PCV13 or PPSV23).
     - If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).
   - ***BOP Immunization Consent Form (BP-A0808):***
     - Document the publication date of the VIS.
     - Have the patient sign and date form.
     - The person administering the immunization signs and dates the form.
   - ***Scan the signed consent form (BP-A0808) into the Document manager in BEMR.***

7. **MEDICAL EMERGENCY OR ANAPHYLAXIS:** Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.
   - In the event of a medical emergency related to the administration of a vaccine, ***immediately call a medical emergency.***
   - ***Epinephrine 1:1000 and respiratory support should be immediately available.***

8. ***Report all clinically important vaccine adverse reactions to the Federal Vaccine Adverse Event Reporting System (VAERS) at: https://vaers.hhs.gov/reportevent.html.***
   - Complete reports online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call (800) 822-7967.

D. Algorithm for PCV13 and PPSV23 Vaccinations



MODULE 9. TETANUS, DIPHTHERIA, & PERTUSSIS VACCINES

A. Purpose

The purpose of this guidance is to reduce morbidity and mortality from tetanus, diphtheria, and pertussis infection by vaccinating all adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

➔ *The full text of the ACIP guidelines is available at:*
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf

B. Procedure

Using this vaccine module, eligible nurses and other healthcare professionals, as defined by scope of duty, may vaccinate adults who meet the indications below for the tetanus, diphtheria, and pertussis vaccines.

1. ***The following vaccines are indicated for adults for protection against tetanus, diphtheria, and pertussis:***
   - **TDAP VACCINE:** ***Tetanus and diphtheria toxoid and acellular pertussis vaccine***
   - **TD VACCINE:** ***Tetanus and diphtheria toxoid vaccine***

2. ***Identify adults in need of vaccination against tetanus, diphtheria, and pertussis, or tetanus and diphtheria, based on the following indications:***
   - Lack of documentation or history of receipt of Tdap vaccine as an adult or adolescent: Administer Tdap followed by a Td booster every ten years.
   - Currently pregnant and no *documentation* of Tdap having been given during current pregnancy. Tdap is indicated for *each* pregnancy, preferably during gestational weeks 27-36. Vaccination in the third trimester optimizes the duration of this antibody protection for the baby after birth.
   - ***Clean or minor wound:*** Assess for *documented* history of Tdap or Td *in the last 10 years*.
   - ***All other wounds*** (contaminated with dirt, feces, saliva, soil; puncture wounds; avulsions; wounds from flying or crushing objects, animal bites, burns, or frostbite): Assess for *documented* history of Td or Tdap *in the last 5 years*. Tetanus vaccine and tetanus immune globulin (TIG) may be indicated. For further information about tetanus wound management consult: *http://www.eziz.org/assets/docs/IMM-154.pdf*

3. ***Screen all patients for contraindications and precautions to Td or Tdap vaccine:***

   - **CONTRAINDICATIONS:**
     - ***History of a serious systemic reaction or anaphylaxis*** to a previous dose of Td or Tdap vaccine or to a vaccine component. (Adacel® and Boostrix® may contain latex in pre-filled syringe tip caps.)
       - *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.*
     - ***Do not give Tdap to a person who has experienced encephalopathy within 7 days following pertussis-containing vaccines***, not attributable to another identifiable cause.
   - **PRECAUTIONS:**
     - ***History of Guillain-Barré syndrome (GBS)*** within 6 weeks of a previous dose of tetanus toxoid-containing vaccine.
     - ***History of an arthus-type hypersensitivity reaction*** (acute local inflammation marked by edema, hemorrhage, and necrosis at the site of the injection) after a previous dose of tetanus or diphtheria toxoid-containing vaccine. In such cases, defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine.
     - ***Current moderate or severe acute illness***, with or without fever.
     - ***For Tdap only:*** Progressive or unstable neurologic disorder, uncontrolled seizures, or progressive encephalopathy until the patient's treatment regimen has been established and the condition has stabilized.

4. ***Provide all patients with a copy of the most current Vaccine Information Statement (VIS).***

   - Review the vaccination information with the patient and have the patient sign the immunization consent or declination form (BP-A0808).
   - Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred by the patient.

   The current VIS, in English and other languages, can be found linked to vaccine consent forms in BEMR or at www.immunize.org/vis.

5. *Administer Tdap or Td vaccine.*

Administer Tdap or Td vaccine for adults (age 19 and older) who meet the indications described above and summarized below:

History/Condition	Dose	Route	Schedule	Contraindications or Precautions*
No adult or adolescent history of Tdap, either documented or self-reported.	0.5 mL	IM	• Give 1 dose Tdap, then Td booster every 10 yrs.	**Contraindications:** • Severe allergy. • **Tdap only:** Previous encephalopathy post-vaccine. **Precautions:** • History of GBS within 6 weeks of receipt of previous vaccine. • Hypersensitivity. • Acute illness. • **Tdap only:** Unstable neurologic disorder or seizures or progressive encephalopathy.
Documented history of adult Tdap vaccine, no Td booster within last 10 years.	0.5 mL	IM	• Give one dose Td, then Td booster every 10 yrs.	
Each pregnancy, regardless of history.	0.5 mL	IM	• Give 1 dose Tdap **during each pregnancy**, preferably at 27–36 wks of gestation.	
Clean, minor wound and no documented history of Td or Tdap in last 10 yrs.	0.5 mL	IM	• Give 1 dose, Tdap preferred.	
All other wounds with no documented history of Td or Tdap in last 5 yrs: *Contaminated with dirt, feces, saliva, soil; puncture wounds; avulsions; wounds from flying or crushing objects, animal bites, burns, frostbite.*	0.5 mL	IM	• Give 1 dose, Tdap preferred. • CDC recommends 1 dose of tetanus immune globulin at same time as vaccination.	

* **Tdap vaccines:** Adacel (Sanofi)– Ages 11–64 years; Boostrix (GSK) all adults
Td: Generic (Mass Biologics)-all adults

- ***Shake Td/Tdap vaccine suspension vigorously*** prior to administration.
- ***To prevent syncope***, have patient sit or lie down for vaccination, and consider observing the patient for 15 minutes after receipt of the vaccine.
- ***Administer vaccine.***
  - Give vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle; alternatively, the anterolateral thigh also can be used.
    ➔ *See Chapter 4, Administering Vaccines: Dose, Route, Site, and Needle Size.*
  - ***Note:*** A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taught, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

6. *Document patient vaccine administration information in the following places:*

- ***Patient Medical Record (BEMR):*** Record the vaccine administration location, the manufacturer and lot number, the vaccination dosage route, and the expiration date of vaccine.
- If vaccine was *not* given, record the reason(s) (e.g., medical contraindication, patient refusal).
- ***BOP Immunization Consent Form (BP-A0808):***
  - Document the publication date of the VIS.
  - Have patient sign and date form.
  - The person administering the immunization signs and dates the form.
- Scan the signed consent form (BP-A0808) into the Document manager in BEMR

7. ***MEDICAL EMERGENCY OR ANAPHYLAXIS:*** Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.
   - In the event of a medical emergency related to the administration of a vaccine, ***immediately call a medical emergency.***
   - ***Epinephrine 1:1000 and respiratory support should be immediately available.***

8. ***Report all clinically important vaccine adverse reactions to the Federal Vaccine Adverse Event Reporting System (VAERS) at: https://vaers.hhs.gov/reportevent.html.***
   - Complete reports online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call: (800) 822-7967.

MODULE 10. VARICELLA VACCINE

A. Purpose

The purpose of this guidance is to reduce morbidity and mortality from varicella infection by vaccinating adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

➔ *The full text of the ACIP guidelines is available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf*

B. Procedure

Using this vaccine module, eligible nurses and other healthcare professionals, as defined by scope of duty, may vaccinate adults who meet the indications below for the varicella live vaccine (VAR).

➔ ***Request the vaccine through the non-formulary process.*** *It is only administered rarely, on a case-by-case basis, in varicella exposure situations, after consultation with Regional/Central Office.*

➔ *Vaccine must remain* ***FROZEN*** *(at −58°F to +5°F; −50°C to −15°C until it is administered. Vaccine should not be ordered until a plan is in place for freezing it at these temperatures or administering immediately upon receipt of vaccine.*

1. ***Indication:*** The patient has been exposed to varicella, without evidence of varicella immunity, and a determination has been made in consultation with the Regional/Central Office that varicella vaccination is indicated.
   - The vaccine is 70–100% effective if given within 3 days (possibly 5 days) of exposure.
   - The vaccine will not prevent varicella infection if administered more than 5 days after exposure, but will still produce immunity if recipient does not become infected from this exposure.
   - Obtain non-formulary approval through the non-formulary process.

2. ***Screen patients for CONTRAINDICATIONS and PRECAUTIONS.***

   ➔ *VAR is a live attenuated varicella virus vaccine.*

   CONTRAINDICATIONS:

   - ***Do NOT give varicella vaccine to a person who has experienced a serious systemic or anaphylactic reaction*** to a prior dose of the vaccine or to any of its components (e.g., neomycin or gelatin).

     ➔ *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.*

   - ***Do NOT give varicella vaccine in the following situations:***
     - ***Pregnant females:*** Do not give varicella vaccine to pregnant females. In addition, pregnancy should be avoided for 3 months following vaccination (vaccinate upon completion or termination of pregnancy).

- ***Individuals with any malignant condition***, including blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.
- ***Individuals receiving high-dose systemic immunosuppressive therapy*** (e.g., two weeks or more of daily receipt of ≥20 mg [or ≥2 mg/kg body weight] of prednisone or equivalent).
- ***Individuals with HIV and a CD4+ T-lymphocytes count <200 cells/µL***.
- ***Family history of altered immunocompetence***.

PRECAUTIONS:

➤ ***Defer vaccination in the following situations:***

- For up to 11 months following blood or plasma transfusions, or administration of immune globulins (IG); see package insert for specific recommendations.
- For 24 hours after administration of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir); avoid use of these antiviral drugs for 14 days after vaccination.
- For moderate or severe acute illness, with or without fever.
- For individuals with a family history of congenital or hereditary immunodeficiency until the individual's immune status is shown to be immunocompetent.

➤ ***Simultaneous vaccinations and procedures:***

- Perform tuberculin skin testing (TST) prior to or on the same day as varicella vaccine, ***OR*** wait to perform TST until *at least 6 weeks after varicella vaccination*; live virus vaccines may cause a temporary depression of TST sensitivity, leading to false negative results.
- If needed, administer varicella and MMR vaccines at the same visit; otherwise, separate vaccines by at least 4 weeks.
- Varicella vaccine may be administered simultaneously with other vaccines, but at separate sites at least 1 inch apart, with separate syringes and needles.

3. *Provide all patients with a copy of the most current Vaccine Information Statement (VIS).*

➤ Review the vaccination information with the patient and have the patient sign the immunization consent or declination form (BP-A0808). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred by the patient.

➔ *The current VIS, in English and other languages, can be found linked to vaccine consent forms in BEMR or at www.immunize.org/vis.*

4. *Safe handling and use of the varicella vaccine (VARIVAX®):*

➤ ***Before reconstitution, store the lyophilized (freeze-dried) vaccine in a freezer*** (−58°F to +5°F; −50°C to −15°C).

➤ ***After reconstitution, the lyophilized vaccine may be stored in a refrigerator*** (36°F to 46°F; 2°C to 8°C) ***for up to 72 continuous hours***.

➔ *Discard the lyophilized vaccine if not used within 72 hours after removal from freezer.*

- The vial of diluent (sterile water) should be stored separately from the lyophilized vaccine, at room temperature (68°F to 77°F, 20°C to 25°C), or in the refrigerator.
- Before reconstitution, protect the lyophilized vaccine from light.

- ***To reconstitute the vaccine***, first withdraw the total volume of provided sterile diluent into a syringe (use only the sterile diluent supplied with VARIVAX)
  - Inject all of the withdrawn diluent into the vial of lyophilized vaccine and gently agitate to mix thoroughly.
  - VARIVAX, when reconstituted, is a clear, colorless to pale yellow liquid.
- ***Injection:*** Withdraw the entire contents into the syringe and inject the total volume (approximately 0.5 mL) of reconstituted vaccine subcutaneously.
- ***DISCARD the reconstituted vaccine if it is not used WITHIN 30 MINUTES.***
- ***Do NOT freeze the reconstituted vaccine.***
- For further product information, call 1-800-9-VARIVAX (1-800-982-7482).

5. Administer varicella vaccine.

INDICATION FOR ADULTS	VARICELLA VACCINE (VARIVAX – MERCK)				
	VOLUME	ROUTE	SITE	SCHEDULE	CONTRAINDICATIONS/NOTES
HISTORY: 0 doses documented or none known	0.5 mL	SQ	Give in fatty tissue over triceps.	2-dose series. Separate doses by at least 4 weeks.	• **DO NOT GIVE** if history of serious reaction or allergy to vaccine or components (neomycin, gelatin). • **CONTRAINDICATIONS:** Pregnancy, severe immunodeficiency (chemotherapy, CD4 <200, 2 weeks or more of 20mg prednisone or equivalent) • **PRECAUTIONS:** Defer for 11 months after blood products (see vaccine insert), or receipt of specific antivirals 24 hours before or 14 days after vaccine; hold vaccine for 2 months post discontinuation of anti-rejection drugs. • **CAN ADMINISTER SAME DAY** as MMR, TST, or IGRA, OR wait 6 weeks to give MMR, TST, or IGRA testing • **RECONSTITUTE VACCINE** with accompanying sterile water diluent. After reconstitution, administer within 30 minutes.
HISTORY: 1 previous dose	0.5 mL	SQ	Give in fatty tissue over triceps.	One-time dose. Separate 1st dose from 2nd dose by at least 4 weeks.	

- ***To prevent syncope***, have patient sit or lie down for vaccination, and consider observing the patient for 15 minutes after receipt of the vaccine.
- Administer 0.5 mL of reconstituted vaccine. Give vaccine subcutaneously (SQ), using a 23-25g, 5/8" needle in the fatty tissue over triceps.

  ➔ *See Chapter 4, Administering Vaccines: Dose, Route, Site, and Needle Size.*
- Provide a subsequent dose of varicella vaccine, if needed to complete the patient's 2-dose series, by observing a minimum interval of at least 4 weeks between doses.
  - Schedule subsequent vaccinations in the electronic medical record (BEMR).
  - Do not restart the vaccine series if the second dose is given more than 4 weeks later.

6. ***Document the patient vaccine administration information in the following places:***
   - ***Patient Medical Record (BEMR):*** Record the vaccine administration location, the manufacturer and lot number, the vaccination dosage and route, and the expiration date.
   - If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).
   - ***BOP Immunization Consent Form (BP-A0808):***
     - Document the publication date of the VIS.
     - Have patient sign and date the form.
     - The person administering the immunization signs and dates the form.

7. ***MEDICAL EMERGENCY OR ANAPHYLAXIS:*** Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.
   - In the event of a medical emergency related to the administration of a vaccine, ***immediately call a medical emergency.***
   - ***Epinephrine 1:1000 and respiratory support should be immediately available.***

8. ***Report all clinically important vaccine adverse reactions to the Federal Vaccine Adverse Event Reporting System (VAERS) at:*** *https://vaers.hhs.gov/reportevent.html*.
   - Complete reports online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call: (800) 822-7967.

MODULE 11. HERPES ZOSTER VACCINE

A. Purpose

The purpose of this guidance is to reduce morbidity and mortality from herpes zoster (shingles) by vaccinating adults who meet the criteria established by the Bureau of Prisons (BOP), with guidance from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

➔ *The full text of the ACIP guidelines is available at:*
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf

B. Procedure

Using this vaccine module, eligible nurses and other healthcare professionals, as defined by scope of duty, may vaccinate adults who meet the indications below for **the recombinant zoster vaccine (RZV), Shingrix®.**

➔ ***RZV is non-formulary and must be requested through the non-formulary process.***

1. ***Assess adults for need of vaccination against the herpes zoster virus with RZV—an inactivated, recombinant varicella virus vaccine—based on the following indications:***
   - ACIP recommendations: RZV is indicated for *immunocompetent individuals 50 years and older* with no known history or documentation of prior herpes zoster vaccine.
   - ACIP recommendations: RZV is also indicated for individuals 60 years and older that have been vaccinated previously with Zoster Vaccine Live (ZVL), Zostavax®.

2. ***Screen patients for CONTRAINDICATIONS and PRECAUTIONS.***

   CONTRAINDICATIONS:

   - ***Do NOT give RZV to a person who has experienced a serious systemic or anaphylactic reaction*** to a prior dose of the vaccine or to any of its components.
     ➔ *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.*
   - ***Do NOT administer the RZV in the following situations:***
     - ***Pregnant females***
     - ***Individuals with any malignant condition***, including blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.
     - ***Individuals receiving high-dose systemic immunosuppressive therapy*** (e.g., two weeks or more of daily receipt of ≥20 mg [or ≥2 mg/kg body weight] of prednisone or equivalent).
     - ***Individuals with HIV and a CD4+ T-lymphocytes count <200 cells/µL***.

(list continues on next page)

- ***Individuals with clinical or laboratory evidence of other unspecified cellular immunodeficiency.***
- ***Individuals with history of hematopoietic stem cell transplantation.***

PRECAUTIONS:

- Defer RZV vaccination for moderate or severe acute illness, with or without fever.

3. *Provide all patients with a copy of the most current Vaccine Information Statement (VIS).*

- Review the vaccination information with the patient and have the patient sign the immunization consent or declination form (BP-A0808).
- Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred by the patient.

→ *The current VIS, in English and other languages, can be found linked to vaccine consent forms in BEMR or at www.immunize.org/vis.*

4. *Safe handling and use of RZV:*

- ***Before reconstitution:*** Store both vials together in the refrigerator, at 36–46°F.
  - → *Adjuvant has blue-green cap and red ring; antigen has brown cap and green ring.*
- ***DO NOT FREEZE.*** Discard if vaccine has been frozen.
- ***Protect vials from light.***
- ***Administer immediately after reconstitution or store in refrigerator for up to six hours (label appropriately).***

5. *Administer herpes zoster vaccine.*

HERPES ZOSTER VACCINE	Recombinant Zoster Vaccine (RZV; Shingrix, GSK)
VACCINE TYPE	Inactivated, recombinant subunit with adjuvant
DOSE	2 doses (0.5 mL each), 2–6 months apart (minimum interval is 8 weeks apart)
RECOMMENDED AGE	50 years and older
STORAGE TEMPERATURE	Refrigerated, 36-46°F; do not freeze.
ROUTE	IM
CONTRAINDICATIONS	Severe allergic reaction to previous dose of vaccine or a component of the vaccine, pregnancy, severe immunodeficiency
PRECAUTIONS	Acute moderate or severe illness
SIDE EFFECTS *Educate patient prior to vaccination on compliance with vaccine series and use of OTC medication for discomfort.*	Frequent (1 of 6): • Local: Redness, pain, swelling • Systemic: Achiness, tiredness, headache, shivering, fever • Side effects may affect daily activities for 1–3 days.

- ***To prevent syncope***, have patient sit or lie down for vaccination, and consider observing the patient for 15 minutes after receipt of the vaccine.
- ***Administer vaccine.***
  - Give vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle; alternatively, the anterolateral thigh also can be used.
    → *See Chapter 4, Administering Vaccines: Dose, Route, Site, and Needle Size.*
  - ***Note:*** A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taught, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.
- The vaccine is given in 2 doses (0.5 mL each), scheduled 2–6 months apart.
- Schedule second dose at time of the initial vaccine dose.

6. ***Document the patient vaccine administration information in the following places:***
   - ***Patient Medical Record (BEMR):*** Record the vaccine administration location, the manufacturer and lot number, the vaccination dosage and route.
     - If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).
   - ***BOP Immunization Consent Form (BP-A0808):***
     - Document the publication date of the VIS,
     - Have the patient sign and date the form
     - The person administering the immunization signs and dates the form
   - ***Scan the signed consent form (BP-A0808) into the Document Manager in BEMR.***

7. **MEDICAL EMERGENCY OR ANAPHYLAXIS:** Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.
   - In the event of a medical emergency related to the administration of a vaccine, ***immediately call a medical emergency.***
   - ***Epinephrine 1:1000 and respiratory support should be immediately available.***
8. ***Report all clinically important vaccine adverse reactions to the Federal Vaccine Adverse Event Reporting System (VAERS) at: https://vaers.hhs.gov/reportevent.html.***
   - Complete reports online in one sitting or by using a writable PDF form. For further assistance email *info@VAERS.org* or call: (800) 822-7967.

CHAPTER 4. ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE

ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE (2 PAGES) AGE 19 AND OLDER – SEE PACKAGE INSERT FOR AGES 18 AND YOUNGER				
VACCINE	**DOSE >18 YRS**	**ROUTE**	**INJECTION SITE**	**KEY POINTS – SEE MODULES FOR COMPLETE INFORMATION**
Diphtheria, Tetanus, & Pertussis **(Tdap**, **Td)**	0.5 mL	IM	Deltoid	• Tdap at each pregnancy unless contraindicated. • Wounds: Tdap preferred.
Hepatitis A **(HepA)**	1 mL	IM	Deltoid	*Contraindication*: severe allergy to neomycin.
Hepatitis B **(HepB)**	1 mL	IM	Deltoid	• *Contraindication*: severe allergy to yeast. • Higher dosing for dialysis patients. • Alternative dosing schedule option for immunocompromised 1st series non-responders
HepA – HepB Combination **(Twinrix)**	1 mL	IM	Deltoid	• *Contraindications*: severe allergy to yeast, neomycin. • Stopper cap may contain latex.
Haemophilus influenza type b **(Hib)**	0.5 mL	IM	Deltoid	• Reconstitute prior to administration. • ActHIB® and Hiberix® are interchangeable.
Human Papillomavirus **(HPV)**	0.5 mL	IM	Deltoid	*Contraindications:* Pregnancy, allergies to yeast or aluminum.
Influenza: Inactivated **(IIV)**, trivalent **(IIV3)**, or quadrivalent (**IdIV4**); recombinant **(RIV)**; high dose	0.5 mL	IM	Deltoid	• High dose vaccine is for age 65 and older *only*. Document type/brand of flu vaccine (e.g., "Afluria Quadrivalent IIV4 administered IM in right arm"). • RIV vaccine is the only influenza vaccine that is egg-free.
Measles, Mumps, Rubella vaccine live **(MMR)**	0.5 mL	SQ	Tricep	• ***Live vaccine***; reconstitute just prior to vaccination. • *Contraindications:* Pregnancy, immunocompromised. • Can administer same day as TST, or, wait 4 weeks to administer TST. • Screen for receipt of blood products or thrombocytopenia.
Meningococcal Conjugate **(MenACWY** [Menactra® or Menveo®]**)**	0.5 mL	IM	Deltoid	• *Contraindications:* Pregnancy, allergies to diphtheria toxoids • *Precautions:* bleeding disorder, anticoagulant therapy. • 5-year booster: HIV, Asplenia, complement deficiency, patients on eculizumab • Menveo brand: Reconstitute prior to use with proper diluent—contains CWY antigens. • Menactra brand only: do not administer with PCV13. Administer PCV13 first and Menactra 4 weeks later.
Meningococcal serogroup B **(MenB** [Bexsero® or Trumenba®]**)**	0.5 mL	IM	Deltoid	• Contraindication: Pregnancy. • Bexsero and Trumenba are NOT interchangeable; start and finish the MenB series with same brand.

ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE (2 PAGES)

AGE 19 AND OLDER – SEE PACKAGE INSERT FOR AGES 18 AND YOUNGER

VACCINE	DOSE >18 YRS	ROUTE	INJECTION SITE	KEY POINTS – SEE MODULES FOR COMPLETE INFORMATION
Pneumococcal conjugate **(PCV13)**	0.5 mL	IM	Deltoid	• Do not administer PCV13 and PPSV23 at same visit. • If PCV 13 is given prior to PPSV23, then wait at least 8 weeks to give PPSV23. • Do not administer PCV13 with Menactra (MenACWY). Administer PCV 13 first and Menactra 4 weeks later.
Pneumococcal polysaccharide **(PPSV23**)	0.5 mL	IM or SQ	Deltoid IM *or* Tricep SQ	• Do not administer PPSV23 and PCV13 at same visit. If PPSV23 given prior to PCV13, wait 1 year to give PCV13
Varicella vaccine live **(VAR)**	0.5 mL	SQ	Tricep	• ***Live vaccine. Store vaccine in freezer, diluent in refrigerator.*** Reconstitute prior to use. • *Contraindications:* Immune suppression; pregnancy; history of recent antivirals, antibody products *Contraindicated:* Severe allergy to gelatin or neomycin.
Recombinant Zoster vaccine **(RZV)**	0.5mL	IM	Deltoid	• ***Store both vials in refrigerator***. Reconstitute prior to use. • Not a live vaccine. • *Precaution:* Pregnancy, breastfeeding, immunodeficiency • Educate on expected side effects.

NEEDLE SIZE

FOR INTRAMUSCULAR (IM) INJECTIONS

Administer IM injections in the deltoid muscle, with a 22–25 gauge needle. Choose needle length based on person's age and body mass:

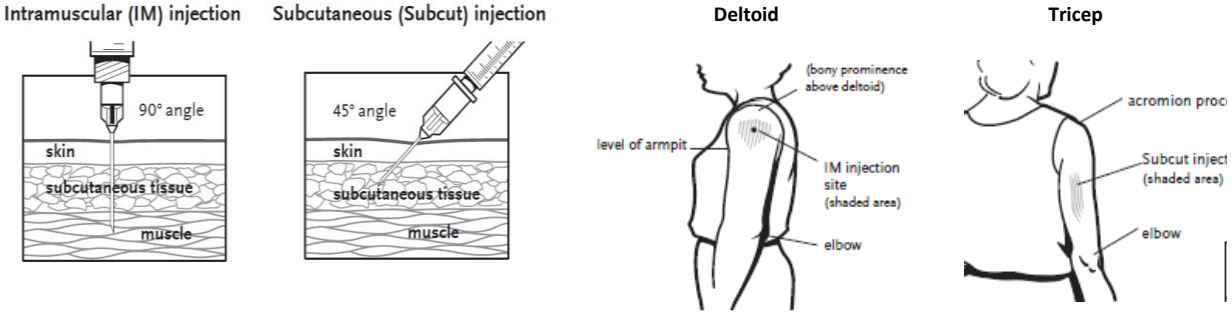
<130 lbs.	5/8*–1" length needle
Female 130–152 lbs.	1" length needle
Female 153–200 lbs.	1-1½" length needle
Female 200 + lbs.	1½" length needle
Male 130–260 lbs.	1-1 ½" length needle
Male 260+ lbs.	1½" length needle

* A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taught, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

FOR SUBCUTANEOUS (SQ) INJECTIONS

Administer SQ (or SubCut) injections in the fatty tissue overlying the tricep muscle, with a 23–25 gauge needle, 5/8" in length.

Note:
Always refer to the package insert included with each immunization for complete vaccine administration information. CDC's Advisory Committee on Immunization Practices (ACIP) recommendations for the particular vaccine should be reviewed, as well. Access the ACIP recommendations at http://www.immunize.org/acip/.



CHAPTER 5. STORAGE AND HANDLING OF VACCINES

Proper vaccine storage and handling is an important factor in preventing and eradicating many common vaccine-preventable diseases. Failure to adhere to recommended specifications for storage and handling of vaccines can reduce or destroy their potency, resulting in no or inadequate immune response in the recipient and poor protection against disease.

➔ *For a comprehensive guide on this subject, see the CDC's online* ***Vaccine Storage and Handling Toolkit***, available at: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html. *A PDF version of the Toolkit is available from the website, or directly at the following link:* https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

➔ *For more information on vaccine storage and handling, see STEP 3 in* ***Vaccinating Adults: A Step-by-Step Guide*** *at:* http://www.immunize.org/guide/pdfs/vacc-adults-step3.pdf.

➔ *The following Attachments are designed to assist BOP institutions with internal communication regarding vaccine storage, handling, and temperature monitoring:*

- Attachment 2. ***Worksheets for Vaccine Storage and Handling***
- Attachment 3. ***Handling a Temperature Excursion in Your Vaccine Storage Unit (poster)***
- Attachment 4. ***Vaccine Refrigerator Temperature Log***

A. Developing Storage and Handling Procedures

1. Designate **PRIMARY VACCINE COORDINATOR(S)** for the facility, including coverage for after-hours emergencies.
2. Develop storage and handling plans and **STANDARD OPERATING PROCEDURES (SOPS)** to serve as a reference and training tool for vaccine management and after hour emergencies. SOPs guide procedures and provide guidance for identifying, reporting, and correcting problems related to vaccine storage and handling.

   ➔ *To assess current vaccine storage and handling, see the* ***Checklist for Safe Vaccine Storage and Handling*** *at:* http://www.immunize.org/catg.d/p3035.pdf.
3. Develop a plan for vaccine delivery. Maintenance of vaccine quality is the shared responsibility of all handlers of vaccines from the time a vaccine is manufactured until administration. Individuals who receive vaccine deliveries need to be educated regarding the importance of immediate vaccine inspection and cold chain maintenance.

   All vaccines should be inspected on delivery:

   - Check the cold chain maintenance for any indication of a **TEMPERATURE EXCURSION** (out-of-range temperature) during transit.
   - Check that vaccines come with proper diluents.
   - Check expiration dates.
   - Add vaccine into inventory.

B. Using Appropriate Vaccine Storage Units

- *Vaccines licensed for **REFRIGERATOR STORAGE** should be stored at 36°F through 46°F (2°C through 8°C).*
- *Vaccines licensed for **FREEZER STORAGE** (e.g., for varicella vaccine) should be stored at -58°F through 5°F (-50°C through -15°C).*

The CDC makes the following recommendations regarding vaccine storage units:

1. ***The preferred type of vaccine storage unit is a PURPOSE-BUILT (pharmaceutical grade) unit*** designed to either refrigerate or freeze. These units can be either compact, under-the-counter-style, or large units.
   - Purpose-built units have microprocessor-based temperature controls, with a digital temperature sensor and fan-forced air circulation to promote uniform temperature.
   - Water bottles can be used, if necessary to stabilize temperatures. Check manufacturer guidance for use of water bottles with specific refrigerator or freezer.
   - Use safeguards to ensure the doors of the unit remain closed (e.g., self-closing door hinges, door alarms, door locks, etc.).

2. ***If a purpose-built unit is not available, use a stand-alone HOUSEHOLD-GRADE unit*** and follow the special instructions and considerations below.
   - *Do NOT under ANY circumstances store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit. These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment, and have been shown to pose a significant risk of freezing vaccines.*
   - ***If the unit is a combination refrigerator/freezer**, **use ONLY the refrigerator compartment for storing refrigerated vaccines.***
     - *Do NOT use the freezer compartment for any reason, but do NOT turn the freezer off.*
     - *Note that household-grade units have cold spots and temperature fluctuations, and air circulating from the freezer could expose refrigerated vaccines to freezing temperatures. However, do NOT turn the freezer off.*
   - ***Use only a separate stand-alone freezer to store frozen vaccines.*** Do not store frozen vaccines in the freezer portion of a combination refrigerator/freezer.
   - ***Remove any deli, fruit, and vegetable drawers from the household refrigerator units.*** This prevents the drawers from being used for storing food, beverages, or vaccines. It also provides more space for placing water bottles to help maintain stable temperatures (see next bullet).
   - If using a household-grade unit—either the refrigerator section of a combination refrigerator-freezer or a stand-alone (freezerless) refrigerator—placing filled water bottles against the walls, in the back, on the floor, and in the door racks is recommended to help stabilize temperatures if the refrigerator door is open for long periods or there is a loss of power.
     - *Label all water bottles: **"DO NOT DRINK!"***
   - Use safeguards to ensure the doors of the unit remain closed (e.g., self-closing door hinges, door alarms, door locks, etc.).

C. Using Vaccine Storage Best Practices

1. Store vaccines in their original packaging, with lids closed to protect them from light.
2. Whenever possible, store diluent with the corresponding refrigerated vaccine. Never store any diluent in a freezer.
3. Attach labels to shelves and containers to clearly identify vaccines. The CDC provides examples of vaccine labels and photos to make identification of vaccines easier (available at https://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf).
4. Place vaccines and diluents in the center of the storage unit, 2 to 3 inches away from the walls, ceiling, floor, and door of the unit. Avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow, *such as directly under cooling vents*, in drawers, or in shelves on the door.
5. Arrange vaccines and diluents in rows, allowing space between rows to promote air circulation. This helps each vaccine and diluent to maintain a consistent temperature.
   - ***Do not pack a storage unit too tightly.*** *Restricted air flow can impact vaccine temperature.*
6. Place vaccines and diluents with the earliest expiration dates in the front of the storage unit.
   - *Check expiration dates of vaccines weekly.*
7. Prevent refrigerator and freezer temperature fluctuations:
   - Plug the storage unit into an emergency outlet with back-up power supply.
   - Post warning signs on all vaccine storage units, for example, "***Do NOT adjust temperature controls!***"
   - Label all vaccine storage plugs: "***Do NOT unplug unit!***"
   - Sample warning signs are available on pages 71–77 of the CDC's ***Vaccine Storage and Handling Toolkit***, available at: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.
8. Maintain and document maintenance and repair of vaccine refrigerators and freezers, as indicated in the SOPs for storage and handling. (A form for documenting vaccine storage unit maintenance is included in *Attachment 2. **Worksheets for Vaccine Storage and Handling***.)
9. Enroll the vaccine storage unit(s) in the institution's HVAC routine maintenance schedule.

D. Monitoring Vaccine Storage Temperature

The CDC recommends—for every vaccine storage unit— the use of a specific type of temperature monitoring device (TMD) known as a digital data logger (**DDL**) for continuous temperature monitoring and recording. The DDL should be set to measure and record temperatures no less frequently than every 30 minutes and should have a current and valid Certificate of Calibration Testing (also known as a Report of Calibration). Calibration testing should be completed every 1–2 years according to manufacturer's suggested timeline.

1. ***The CDC recommends that DDLs have the following characteristics*** (*list continues on next page*):
   - Detachable probe in a thermal buffered material (e.g., glycol, glass beads, sand, Teflon®)
   - Alarm for out-of-range temperatures
   - Low-battery indicator

- Current, minimum, and maximum temperature indicator
- Recommended uncertainty of +/-0.5° C (+/-1° F)
- User ability to program the logging interval (or reading rate)

2. ***The CDC recommends that a DDL's current and valid Certificate of Calibration Testing include:***
   - Model/device name or number
   - Serial number
   - Date of calibration (report or issue date)
   - Confirmation that the instrument passed testing (or instrument is within tolerance)
   - Recommended uncertainty of +/-0.5° C (+/-1° F) or less

3. ***Specifically, CDC recommends against the use of the following types of TMDs:***
   - Alcohol or mercury thermometers, even if placed in a fluid-filled biosafe liquid vial
   - Bi-metal stem TMDs
   - Food TMDs
   - Chart recorders
   - Infrared TMDs
   - TMDs that do not have a current and valid Certificate of Calibration Testing

4. ***Manually record refrigerator and freezer temperatures at least twice each workday even if using a digital monitoring device.***
   - *See the **Vaccine Refrigerator Temperature Log**, available in Attachment 4.*

E. Responding to Temperature Excursions

- *See the poster, **Handling a Temperature Excursion in Your Vaccine Storage Unit**, available in Attachment 3.*
- *It is recommended that the poster be laminated and posted next to your vaccine storage unit.*

An out-of-range temperature is considered a **TEMPERATURE EXCURSION** and should prompt immediate action through a **RESPONSE PLAN**.

The response plan should indicate specific steps to follow in the case of a temperature excursion, for example:

1. Immediately notify the vaccine coordinator(s) or report the problem to the supervisor and the pharmacist.
2. Label affected vaccines ***"DO NOT USE"*** and place them in a separate container apart from other vaccines in the storage unit.
   - *DO NOT discard the affected vaccines.*
3. Document the event so that the following information is available when consulting with the manufacturer:
   - Date and time of the temperature excursion
   - Storage unit temperature AND room temperature, if available (including minimum/maximum temperatures during the time of the event)

- Name of the person completing the report
- Description of the event:
  - General description of what happened
  - If using a DDL, the length of time the vaccines may have been affected
  - Inventory of affected vaccines
  - A list of items in the unit (including water bottles) other than vaccines
  - Any problems with the storage unit and/or affected vaccines before the event
  - Other relevant information

4. Contact immunization vaccine manufacturer(s) for further guidance on whether to use affected vaccines and whether patients will need to be recalled for revaccination.
5. Implement facility SOPs to adjust storage unit temperature to the appropriate range.
6. Check the temperature monitoring device to make sure it is appropriately placed in the center of the vaccines.
7. Document actions taken as a result of the excursion:
   - Chronology of what was done with the vaccines, including the time frame (e.g., *"Vaccine temperature alarm at 0800 and placed in pharmacy fridge at 0815."*).
   - Whom was contacted and what instructions were received (e.g., *"Manufacturers contacted. Recommended that patients be revaccinated."*).
   - The actions that were taken. (e.g., *"Patients recommended for revaccination were contacted."*)
   - Root cause analysis conducted to identify reasons that the problem occurred.
   - Actions taken to prevent a similar event in the future.
   - The final disposition of the affected vaccines.

F. Preparing for Portable and Emergency Vaccine Storage

The SOPs for vaccine storage and handling should include emergency planning for equipment failures and power outages, as well as for portable storage needs in the case of mass vaccination procedures outside of the clinic. Portable medical grade vaccine refrigerator/freezer units with temperature monitoring devices are available for emergency transport of vaccines or for mass vaccine clinics.

➔ *In the event of a vaccine emergency, consult the CDC's printable handout, "**Packing Vaccines for Transport During Emergencies**," available at: https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf.*

Key points from the CDC handout are outlined below:

1. **KEY POINTS FOR MASS VACCINE CLINICS:** If vaccines cannot be stored in an on-site storage unit, they should be kept in the portable vaccine refrigerator during an off-site clinic.
   - Place a TMD (preferably with a probe in a thermal buffer) as close as possible to the vaccines, and check and record temperatures at least hourly.
   - Keep the container closed as much as possible.
   - Remove only 1 multi-dose vial or 10 doses at a time for preparation and administration by each person administering vaccines.
   - Transport diluents with their corresponding vaccines to ensure there is sufficient diluent for reconstituting each vaccine. Follow the manufacturer's guidance for specific temperature requirements.

2. **KEY POINTS DURING EMERGENCIES:** Hard-sided coolers or Styrofoam vaccine shipping containers can be used for transport of refrigerated vaccines. Do NOT use soft-sided coolers**.** Pack vaccine as follows:
   - Utilize conditioned frozen water bottles to prevent vaccine from freezing.
     - To condition frozen water bottles, place them in lukewarm water until the water starts to melt (a layer of water forms near surface of bottle and ice spins inside bottle).
   - Do not use frozen gel packs or coolant packs from vaccine shipments to pack refrigerated vaccines. Even if they appear to be sweating, they can damage and freeze refrigerated vaccines.
   - Phase change materials (PCMs) at 4°C to 5°C, available commercially, can help maintain proper temperatures.
   - Use at least 1 inch of insulating material such as bubble wrap, packing foam, or Styrofoam for a layer above and below vaccine
   - Temperature monitoring device: Digital data logger (DDL) with buffered probe.

ATTACHMENT 1.
SKILLS CHECKLIST FOR VACCINE ADMINISTRATION

The checklist on the following page can be used as an assessment tool for health care staff who administer vaccines.

SKILLS CHECKLIST FOR VACCINE ADMINISTRATION

FACILITY: **EMPLOYEE:**

The following checklist (✓) can be used as an assessment tool for health care staff who administer vaccines.

Self-Assessment		Supervisor/ Preceptor Review		SKILLS
Needs to Improve	Meets or Exceeds	Needs to Improve	Meets or Exceeds	
PATIENT EDUCATION				
				Welcomes patient; validates identification.
				Explains what vaccines will be given.
				Accommodates language/literacy barriers and special needs of patients.
				Provides Vaccine Information Statements (VIS) for all vaccine doses. Answers questions.
				Reviews potential side effects, comfort measures, and after care instructions.
MEDICAL PROTOCOLS				
				Can locate Vaccine Procedure Modules, emergency protocol, VIS, and reference material.
				Screens patient for vaccine eligibility (based on age, job, chronic conditions), history of adverse reactions, allergies, contraindications, and precautions.
				Demonstrates how to refer/schedule for lab serology or pregnancy test, as appropriate.
				Is able to administer epinephrine, and initiate CPR and maintain airway, if necessary.
				Can state procedure for responding to and reporting needlestick injuries.
VACCINE HANDLING				
				Checks vial expiration date. Double-checks vial label and contents prior to drawing up.
				Follows Vaccine Procedure Module for needle selection, vaccine reconstitution with diluent, if indicated, and other specifics.
				Demonstrates knowledge of proper vaccine handling to maintain the "cold chain."
				Documents vaccine temperature monitoring appropriately.
ADMINISTERING VACCINES				
				Rechecks prepared syringe against physician order or Vaccine Procedure Module.
				Washes or disinfects hands before and in-between patient encounters. If gloves are worn, they are changed and hand hygiene performed between patients.
				Demonstrates knowledge of the appropriate route for each vaccine.
				Cleans the vaccine vial top with alcohol prior to withdrawing dose.
				Appropriately positions patient for vaccination.
				Properly preps the injection site with an alcohol wipe.
				Injects vaccine using steady pressure; withdraws needle at the angle of insertion.
				Upon needle withdrawal, applies gauze/bandage with gentle pressure to injection site.
				Disposes of needle and syringe in sharps container. Properly disposes of vaccine vial.
DOCUMENTATION				
				Consent/declination form is signed, and the current VIS date is documented.
				Documents each vaccine dose, including: date, lot number, manufacturer, site, VIS date, name/initials.
				Demonstrates vaccine documentation for specific vaccine information (e.g., age 65, high-dose trivalent flu vaccine, HepB #1 of 3 doses, etc.).
				If vaccine is given as a series, future appointments are added to scheduler.
				Can properly document a vaccine adverse event in VAERS and identifies the appropriate healthcare personnel to notify in the case of an adverse event.

PLAN OF ACTION: _____

Employee Signature _____ Date _____ Supervisor Signature _____ Date _____ Plan of Action Deadline _____ Next Review Date _____

Adapted from: Skills Checklist for Pediatric Immunization. California Department of Health, Immunization Branch.

ATTACHMENT 2.
WORKSHEETS FOR VACCINE STORAGE AND HANDLING

The following forms are attached in this section:

- First page:
  - Staff Contact List for Vaccines
  - Vaccine Refrigerator Key Number and Alarm Reset
  - Emergency Staff Contact List
- Second page:
  - General Resources Contact List
- Third page:
  - Alternative Vaccine Storage Facilities
  - Packing Material /Storage Supplier Contact List
  - Vaccine Storage Unit Information
- Fourth page:
  - Storage Unit Maintenance Log

STAFF CONTACT LIST FOR VACCINES			
NAME	**TITLE**	**TELEPHONE NUMBERS (OFFICE/CELL/PAGER)**	**E-MAIL ADDRESS**
	Primary Vaccine Coordinator		
	Alternate Vaccine Coordinator		
	Receiving Unit – Back Gate		
	Primary Vaccine Pharmacist		
	Off-Shift Supervisor		
	Institution Duty Officer		
	On-Call Pharmacy (Pager)		
OTHER INFORMATION			
Vaccine Refrigerator Key Number:			
Vaccine Refrigerator Alarm Reset:			

EMERGENCY STAFF CONTACT LIST*			
NAME	**TITLE**	**TELEPHONE NUMBERS (OFFICE/CELL/PAGER)**	**E-MAIL ADDRESS**
1.			
2.			
3.			
4.			
5.			
6.			

*** List EMERGENCY CONTACTS in order of preference. Determine whether all or certain persons on the list should be contacted or if the first person reached is sufficient. Include the Primary and Alternate Vaccine Coordinators on the list.**

GENERAL RESOURCES CONTACT LIST			
AGENCY/COMPANY (NAME)	**CONTACT PERSON (NAME/TITLE)**	**TELEPHONE NUMBERS (OFFICE/CELL/OTHER)**	**E-MAIL ADDRESS**
Local Health Dept. Immunization Program:			
State Health Dept. Immunization Program:			
Vaccine Manufacturer:			
Vaccine Manufacturer:			
Vaccine Manufacturer:			
Vaccine Manufacturer:			
Utility/Power Company:			
Temperature Monitoring Device (TMD) Company:			
Vaccine Storage Alarm Company (if applicable):			
Generator Repair Company (if applicable):			
Refrigerator Repair Company:			
Medical Equipment Repair Company:			

ALTERNATIVE VACCINE STORAGE FACILITIES			
ALTERNATIVE VACCINE STORAGE FACILITY (NAME/ADDRESS)	CONTACT PERSON (NAME/TITLE)	TELEPHONE NUMBERS (OFFICE/CELL/OTHER)	E-MAIL ADDRESS

PACKING MATERIAL /STORAGE SUPPLIER CONTACT LIST			
SUPPLIER (NAME/ADDRESS)	CONTACT PERSON (NAME/TITLE)	TELEPHONE NUMBERS (OFFICE/CELL/OTHER)	E-MAIL ADDRESS
Portable vaccine refrigerator/freezer units:			
Qualified containers and pack-out materials:			
Packing materials #1:			
Packing materials #2:			

VACCINE STORAGE UNIT INFORMATION*			
TYPE OF UNIT (REFRIGERATOR OR FREEZER)	BRAND	MODEL NUMBER	SERIAL NUMBER
1.			
2.			
3.			
4.			
5.			

***** Keep this information handy in case repairs are needed.

STORAGE UNIT MAINTENANCE LOG

Vaccine Storage Area	
Vaccine Unit Brand/Date of Purchase	
Manufacturer/Contact for Repair	
Location of Storage Unit Instructions for Use (IFU)	

CHECKLIST FOR STORAGE UNIT IFU RECOMMENDED MAINTENANCE

DIRECTIONS: Fill in the shaded column headings (1–7) below with IFU recommendations, schedule of maintenance, etc. For example, you might include: check door seals, check door hinges, clean inside of unit, unit plugged into generator outlet, unit/cord has "DO NOT UNPLUG" tag visible, clean coils/motor, defrost unit, etc. Also indicate FREQUENCY, if needed. To expand your maintenance checklist, print another copy of this chart, and renumber the column headings 8–14. To save yourself some time, fill in the STORAGE UNIT information above, fill in column headings 1–7 below, and then make copies for future use.

DATE	1.	2.	3.	4.	5.	6.	7.

ATTACHMENT 3.
HANDLING A TEMPERATURE EXCURSION IN YOUR VACCINE STORAGE UNIT

It is recommended that the poster on the following page be laminated and posted next to your vaccine storage unit.

HANDLING A TEMPERATURE EXCURSION IN YOUR VACCINE STORAGE UNIT

Any temperature reading outside the ranges recommended in the manufacturers' package inserts is considered a **TEMPERATURE EXCURSION**. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.

NOTIFY!

Immediately notify the Primary or Alternate Vaccine Coordinator or report the problem to a supervisor.

- To notify other staff, label the affected vaccines, **"DO NOT USE,"** and place them in a separate container, apart from the other vaccines in the storage unit.
- Keep affected vaccines refrigerated or frozen, as appropriate.
- **DO NOT discard these vaccines.** Await instructions from the manufacturer.

DOCUMENT!

Document details on the Vaccine Refrigerator Temperature Log:

- Date and time.
- Storage unit temperature (including min/max temperatures at the time of the event, if available).
- Room temperature, if available.
- Name of the person completing the report.
- General description of what happened.
- If using a digital data logger (DDL), estimate the length of time vaccines were out of range.
- Inventory of affected vaccines.
- List of items in the unit other than vaccines (including water bottles).
- Any problems with the storage unit and/or affected vaccines before the event.
- Other relevant information.

CONTACT!

Contact your facility's immunization program and/or the vaccine manufacturer(s) for guidance per your Standard Operating Procedures (SOPs).

- Be prepared to provide documentation and DDL data so they can offer you the best guidance.
- Contact medical equipment repair or facilities manager for assessment or repair of storage unit.

MANUFACTURER CONTACT NUMBERS:

- **Merck**
  1-800-672-6372
- **Sanofi Pasteur**
  1-800-822-2463
- **GlaxoSmithKline**
  1-888-825-5249
- **Pfizer**
  1-800-438-1985
- **Seqirus**
  1-855- 358-8966

CORRECT!

If the temperature alarm goes off repeatedly, do NOT disconnect the alarm until you have determined and addressed the cause.

Check the basics, including:

- Power supply
- Unit door(s)
- Thermostat settings

If the excursion is the result of a temperature fluctuation, refer to the CDC's online *Vaccine Storage and Handling Toolkit* for detailed guidance on adjusting the storage unit temperature to the appropriate range.

- **If you believe the storage unit has failed**, implement your emergency vaccine SOPs.
- **NEVER allow vaccines to remain in a nonfunctioning unit.**

ATTACHMENT 4.
VACCINE REFRIGERATOR TEMPERATURE LOG

Manually record refrigerator and freezer temperatures at least twice each workday even if you are using a digital monitoring device. Attached is a two-page temperature log that can be used for this purpose.

Page 2 of the log is for reporting corrective actions for out of range temperatures. Note that the "Corrective Action Steps" information at the bottom of page 2 can be filled in and then copied for multiple use.

Federal Bureau of Prisons

VACCINE REFRIGERATOR TEMPERATURE LOG (PAGE 1 OF 2)

FACILITY: _____ **LOCATION OF REFRIGERATOR:** _____ **MONTH/YEAR:** _____

◆ At the beginning of each month, "**X" OUT THE DATES THAT ARE NOT WORK DAYS** (to avoid entering data in the wrong box). ◆ Document the vaccine refrigerator temperature **TWICE DAILY DURING THE WORK WEEK** (in the morning and at the end of the day) ◆ Write the **EXACT TIME** and the monitor's **INITIALS** below. ◆ Each morning, record the pre-recorded **MINIMUM AND MAXIMUM TEMPERATURES** for the previous 24 hours. ◆ Mark with a checkmark (✓) when **EXPIRATION DATES** on vaccines and diluents are checked (recommend at least weekly). ◆ Mark with a "**C**" when refrigerator is **CLEANED** (recommend at least monthly). ◆ Record the twice-daily observed temperatures in accordance with instructions below.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
AM Time/ Initials																															
PM Time/ Initials																															
MIN Temp																															
MAX Temp																															
Exp Date (✓) Cleaned (C)																															

◆ Twice a day, place a dot in a box below to indicate the **CURRENT TEMPERATURE**. For the **AM READING**, put the dot in the upper box, above the dotted line. For the **PM READING**, put the dot in the lower box, below the dotted line. ◆ **ACCEPTABLE RANGE: 36 TO 46°F (2 TO 8°C). OPTIMAL TEMPERATURE IS AROUND 40°F.**

→ **IF TEMPERATURE IS OUT OF RANGE, CORRECTIVE ACTION MUST BE TAKEN.** Write any out-of-range temperatures below (instead of placing a dot), and then see page 2.

F°	C°	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
HIGHER ↑		**OUT OF RANGE (47°F OR 9°C): NOTE CORRECTIVE ACTIONS ON PAGE 2 →**																														
46.0	8																															
44.6	7																															
42.8	6																															
41	5																															
39.2	4																															
37.4	3																															
36.2	2																															
LOWER ↓		**OUT OF RANGE (35°F OR 1°C): NOTE CORRECTIVE ACTIONS ON PAGE 2 →**																														

VACCINE REFRIGERATOR TEMPERATURE LOG (PAGE 2 OF 2)

FACILITY: _____ LOCATION OF REFRIGERATOR: _____ MONTH/YEAR: _____

CORRECTIVE ACTION REPORT FOR OUT OF RANGE TEMPERATURES						
DATE & TIME WHEN OUT OF RANGE TEMP WAS DISCOVERED	REFRIG TEMP (F°/C°)	ROOM TEMP (F°/C°)	TIME WHEN VACCINES MOVED TO PROPER STORAGE	ESTIMATED TIME VACCINES WERE OUT OF RANGE	NAME & TITLE OF PERSON COMPLETING THIS REPORT	DOCUMENT ALL CORRECTIVE ACTIONS TAKEN (STEPS 1–3 BELOW*):

*** CORRECTIVE ACTION STEPS:**

1. **NOTIFY _____ about the problem and the "out of range" temperature.**
2. **CALL _____ to determine safety of medication and take action as directed. If necessary, LABEL vaccines "Do NOT Use." LIST all affected vaccines in chart above and document disposition of these vaccines.**
3. **DETERMINE THE CAUSE AND WHETHER REPAIR OF UNIT IS NECESSARY. CHECK to see if the refrigerator is plugged in and running. CHECK to see if the door was left open/ajar for a prolonged time (i.e., restocking) or does not seal or close properly. CHECK the thermostat, and adjust if necessary. If there is no apparent explanation for the "out of range" temperature, CALL the _____, who will contact HVAC to check the unit.**
4. **AT THE END OF THE MONTH, place both pages of this form in the _____, to be retained for _____ years.**