IMMUNIZATION

Federal Bureau of Prisons

Clinical Guidance

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WHAT'S NEW IN THIS DOCUMENT?

This guidance is an update to the October 2020 version. The following major changes were made in this guidance:

- **Hepatitis A Vaccine Procedure Module:** Clotting factor disorder is no longer an indication for vaccine. Pregnancy may be an indication if at risk for hepatitis A infection or severe outcome from hepatitis A infection during pregnancy.
- **Hepatitis B Vaccine Procedure Module:** Updated to reflect indication for persons with sexual exposure risk (Men who have sex with men [MSM], history of sexually transmitted disease [STD], and multiple sexual partners).
- **Human Papillomavirus (HPV) Vaccine Procedure Module:** HPV vaccine is now recommended for all adults through age 26 years. The vaccine series also may be given to some adults aged 27-45 years based on shared clinical decision making. A 3-dose series of HPV vaccine is recommended for immunosuppressed persons. Pregnancy testing prior to vaccination is not required.
- **Influenza Vaccine Procedure Module:** Updated to reflect the 2022–2023 CDC vaccine recommendations and the BOP contract vaccines.
- **Meningococcal Disease Vaccines Procedure Module:** Updated to include a one-dose MenB booster 1 year after primary series and revaccination every 2–3 years if risk remains.
- **Pneumococcal Vaccines Procedure Module:** Addition of the newer conjugate vaccines (i.e., PCV15 and PCV20) and PCV13 vaccine is no longer recommended.
- **Tetanus, Diphtheria, and Pertussis Vaccines Procedure Module:** After the initial Tdap, either a TD or Tdap booster can be given every 10 years.

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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VACCINE ACRONYMS AND ABBREVIATIONS

HAV	Hepatitis A virus
HBV	Hepatitis B virus
HepA	Hepatitis A vaccine
HepA-HepB	Combined hepatitis A and hepatitis B vaccine (Twinrix®)
HepB	Hepatitis B vaccine
HepB-CpG	Hepatitis B vaccine, recombinant, adjuvanted (Heplisav-B®)
Hib	*Haemophilus influenzae* type b
HPV	Human papillomavirus
9vHPV	9-valent Human papillomavirus vaccine (Gardasil 9®)
IIV	Inactivated influenza vaccine
IIV4	Inactivated influenza vaccine, quadrivalent (Afluria®, Fluarix®, Fluzone®, and FluLaval®)
ccIIV4	Inactivated influenza vaccine, quadrivalent, cell-based
HD-IIV4	Inactivated influenza vaccine, quadrivalent, high dose
aIIV	Adjuvanted inactivated influenza vaccine
aIIV4	Adjuvanted inactivated influenza vaccine, quadrivalent (Fluad®)
LAIV	Live attenuated influenza vaccine
MenACWY	Meningococcal serogroups ACWY conjugate vaccine (Menactra® or Menveo®)
MenB	Meningococcal B vaccine (Bexsero® or Trumenba®)
MMR	Measles, mumps, and rubella vaccine, *live*
PCV13, 15 or 20	Pneumococcal conjugate vaccine, 13-valent, 15-valent, or 20-valent
PPSV23	Pneumococcal polysaccharide vaccine, 23-valent
RIV	Recombinant (inactive) influenza vaccine (egg-free)
RZV	Recombinant herpes zoster vaccine (Shingrix®)
Td	Tetanus-diphtheria toxoids vaccine
Tdap	Tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine
TIG	Tetanus immune globulin
VAR	Varicella vaccine, *live* (Varivax®)
ZVL	Herpes zoster vaccine, *live* (Zostavax®)

CHAPTER 1. OVERVIEW AND KEY PRINCIPLES

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A. GOALS OF THE BOP IMMUNIZATION PROGRAM

- Screen inmates for indications for immunizations as defined in this Clinical Guidance.
- Administer vaccines based upon indications.
- Decrease vaccine-preventable disease burden.
- Prevent unintentional vaccination adverse effects based upon health care provider knowledge of contraindications and precautions.
- 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) decide 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.

It is recommended that the Clinical Director, in consultation with the Health Services Administrator and the Infection Prevention & Control Committee, annually determine priorities for vaccination in each facility.

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 preventive health clinic or chronic care clinic) summarizing vaccine administration, for example:
  - Last TST (PPD)
  - Last influenza
  - PCV15
  - PCV20
  - PPSV23
  - Tdap
  - MMR
  - HepA
  - HepB
  - HPV vaccination)
  - MenACWY
  - MenB
- 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 general indications for vaccination of BOP inmates is in **Chapter 2, BOP Immunization Indications**. These indications are based on Advisory Committee on Immunization Practices (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. For those who received vaccinations elsewhere (i.e., not in the BOP), enter vaccination information into BEMR as "History Of" along any available information to include manufacturer name, dose number, vaccination date(s), and location.

- Scan any supporting documentation into the EHR document manager (using the scan type of "civilian records") or provide information in the comment box regarding source of information.
- If vaccination history is not reliable, and the patient does not wish to receive the vaccination in the BOP, obtain a signed declination of the BOP-offered vaccination and include prior vaccination as the reason for declination. There should also be an explanation as to why the reported vaccination history does not seem reliable (e.g., cannot remember the name of the vaccine, estimated date, or location of administration).

Note that ACIP guidance for adult MMR and Td/Tdap vaccines assumes childhood vaccination history and recommends single booster doses of MMR and Tdap. However, Tdap is also recommended in the third trimester of each pregnancy.

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 aged 19 years or older.*** *For patients aged 18 years or younger, consult the package insert and local pharmacist.*

4. Health Care Provider Education

- It is recommended that health care 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*.
- 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 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 the EHR 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, waterless antiseptic 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 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.
- Cleanse the access diaphragms of medication vials with an alcohol pad (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 different single components of combination 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 and subsequently not used within the time frame specified by the manufacturer.
- 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 and activated (i.e., syringe cap removed or needle attached) 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 several 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 2022 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:* Advisory Committee on Immunization Practices (ACIP) General Best Guidance for Immunization (cdc.gov)

1. Contraindications and Precautions

Contraindications and precautions to vaccination generally dictate circumstances when vaccines should not be given. Most 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.

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.

- *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/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. The allergens identified in the patient's history can be cross-checked against the allergens identified in package inserts.*

1.A. Screening Questions for Vaccines

The key to preventing serious adverse reactions is screening. Prior to vaccine administration, screen patients for contraindications and precautions. 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?
- 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

1.B. 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.C. 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 pertussis-containing vaccine.

1.D. Temporary Contraindications or Precautions

- ***Pregnancy:*** Live vaccine and some non-live vaccines are contraindicated during pregnancy (e.g., MMR, 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 or more months (see **Section 2.E**. below).

1.E. 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 the RIV and cell-based vaccine 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.F. 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.G. History of Allergy to Other Substances

Consult the patient's health care 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
  - ***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® (IIV4), Twinrix® (HepA and HepB), Havrix® (HepA), MMR
  - ***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: Afluria® 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® and Trumenba® (MenB), Td, Tdap

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 (for example, 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.
- ***Vaccine doses administered at less than the recommended minimum interval (if not described as part of an accelerated schedule) should be repeated.***

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 (PCV15 and PPSV23) should not be administered simultaneously. See the Pneumococcal Vaccine module in **CHAPTER 3** for guidance.*

➔ *MenACWY-D (Menactra) and PCV15 or PCV20 should not be administered simultaneously; PCV15 or PCV20 should be administered first and MenACWY-D (Menactra) administered 4 weeks later. This warning does NOT apply to MenACWY-CRM (Menveo).*

2.D. Spacing of Multiple Live Vaccines

Two or more live injectable vaccines and live intranasal vaccines may be administered on the same day. However, if they are not administered on the same day, they 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 administered 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 3 or more 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 3-5 and 3-6 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. 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 vaccines:*** Persons with altered immunocompetence, including anatomic or functional asplenia, are recommended to receive pneumococcal vaccines (PCV15 followed by PPSV23 or PCV20 alone), based on 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) and persistent complement component deficiency (including persons taking eculizumab [Soliris®]). 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 held for 14 days *after* the receipt of VAR.

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. Postpartum women for whom 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. One dose of the tetanus vaccine series should be Tdap, if Tdap has not already been received.
- ***The inactivated influenza vaccine (IIV)*** is recommended for all women who are or will be pregnant (in any trimester) during influenza season. Pregnant and postpartum women are at increased risk for severe illness and complications from influenza.

- ***The HBV vaccine*** is not contraindicated in pregnancy and should be given to a pregnant woman for whom it is indicated.
- ***The HAV, pneumococcal, and meningococcal vaccines*** should be considered for pregnant women at increased risk for those infections.

3.D. Hematopoietic Stem Cell Transplant (HSCT) Recipients

A hematopoietic stem cell transplant involves ablation (by chemotherapy and often radiation) of the bone marrow followed by reimplantation or infusion) of the person's own stem cells or stem cells from a donor. HSCT recipients are at increased risk for certain vaccine-preventable diseases since the ablation gradually removes immune memory from previous vaccination. As a result, HSCT recipients should be routinely revaccinated *after* HSCT. ***The timing of vaccination of HSCT 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, pneumococcal vaccines [PCV15, PCV20, PPSV23], and if indicated, meningococcal and HPV vaccines):*** At least 6 months post-transplant.
- ***MMR, VAR and RZV vaccines:*** At least 24 months post-transplant only if immunocompetent and with no graft-vs-host disease.

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 day or two 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 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 on the VAERS website, 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, and vaccine administration errors.

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*
- **The Immunize.org (formerly 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 Pink Book 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. April 2022: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
- Kroger A, Bahta L, Hunter P. 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 27, 2022.
- Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases.* Hall E., Wodi A.P., Hamborsky J., et al., eds. 14th ed. Washington D.C. Public Health Foundation, 2021. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/index.html.
- ***The following Appendices may be of particular interest to providers:***
  - Appendix A, p.23: Recommended intervals between administration of immune globulin preparations and MMR or VAR. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/recommended-intervals-between-administration.pdf
  - Appendix A, pp. 26-29: Guide to Contraindications and Precautions to Commonly Used Vaccines. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-a.pdf
  - Appendix B, pp. 13-14: Foreign Language Terms – Aids to translating foreign immunization records. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-b.pdf
  - Immunize.org. *Vaccine Manufacturers: Contact and Product Information*. Available at: Vaccine Product Information - Order Vaccines and Contact Manufacturers (immunize.org). Accessed on May 27, 2022. Vaccine Product Information - Order Vaccines and Contact Manufacturers (immunize.org)

CHAPTER 2. BOP IMMUNIZATION INDICATIONS

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

1. Hepatitis A (HepA) 2
2. Hepatitis B (HepB) 3
3. Haemophilus influenzae Type B (Hib) 4
4. Human Papillomavirus (HPV) 4
5. Influenza 5
6. Measles- Mumps-Rubella (MMR) 6
7. Meningococcal Vaccines 7
8. Pneumococcal Vaccines 8
9. Tetanus-Diphtheria-Pertussis (Tdap) and Tetanus-Diphtheria (Td) 9
10. Varicella Live Vaccine (VAR) 9
11. Recombinant Zoster Vaccine (RZV) 10

- ***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 aged 19 years or older. For patients aged 18 years or younger, consult the package insert and the local pharmacist.***

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER* ** For persons aged 18 years or younger consult pharmacist and package inserts.*		
VACCINE/POPULATION	**INDICATION FOR VACCINE**	**KEY POINTS**
1. HEPATITIS A (HEPA)	**HepA is indicated for individuals with the following RISK FACTORS *and* no documented history of HepA or positive laboratory titer:** • Men who have sex with men (MSM). • Injection or non-injection drug use. • Chronic liver disease or cirrhosis, including chronic hepatitis C (HCV RNA+) and hepatitis B (HBsAg+). • Homelessness prior to incarceration. • HIV infection. • Pregnancy, if at risk for infection or severe outcome from infection. • **OUTBREAKS:** Vaccinate Individuals at risk for infection during HAV outbreaks who have no documented immunity or positive laboratory 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-single dose schedule of 0 & 6 months. **DOCUMENTED HISTORY OR KNOWN HISTORY OF 1 DOSE:** • Administer 1 dose. **GENERAL:** • The two HepA (Vaqta® and Havrix®) can be used interchangeably; however, series completion with the same product is preferred. • For candidates who need both HepA and HepB, utilize Twinrix vaccine. • For states that CDC identifies as experiencing a current hepatitis A outbreak, enhanced screening and vaccination of "at risk" persons is advised per the Hepatitis A Clinical Guidance. • Twinrix vaccine is not recommended for outbreak or post exposure vaccination to hepatitis A.

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER* * For persons aged 18 years or younger consult pharmacist and package inserts.		
VACCINE/POPULATION	**INDICATION FOR VACCINE**	**KEY POINTS**
2. HEPATITIS B (HEPB)	***Vaccine is not indicated if there is a documented history of a HepB series or positive HBsAb or HBsAg laboratory titer.*** • Age 19-59 years • Age ≥60 years: ◆ ***The 2022 CDC adult immunization schedule recommends all incarcerated persons ≥60 years of age receive HepB vaccine.*** ◆ Sexual exposure risk (MSM, STD history or seeking STD evaluation, multiple sexual partners). ◆ Injection drug use. ◆ Chronic liver disease or cirrhosis, including hepatitis C (HCV RNA+). ◆ Adults in pre-dialysis care. ◆ Hemodialysis/peritoneal dialysis recipients. See dialysis dosing schedule under "Administer HepB" in Module 2 of **CHAPTER 3.** ◆ Diabetic adults. ◆ Inmate workers at risk for bloodborne pathogen exposure. ◆ HIV-infection (see below★). ◆ Want protection from hepatitis B infection. ◆ Post-exposure prophylaxis. ◆ Pregnancy, if at risk for infection or severe outcome from infection (Heplisav-B currently **NOT** recommended). ★ **IMMUNOCOMPROMISED, 1ST SERIES NON-RESPONDERS:** See dialysis dosing schedule (**MODULE 2**). Heplisav-B can be considered for persons 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 infection. **NO DOCUMENTED OR KNOWN HISTORY OF VACCINE:** • Engerix-B® or Recombivax HB®: Administer on a 3-single dose schedule of 0, 1, & 6 months. • Heplisav-B®: Administer on a 2-single dose schedule of 0 and at least 1 month. **FOREIGN-BORN INMATES:** • Consider pre-screening for positive HBsAg prior to vaccination. **GENERAL:** • Candidates for both HepA and HepB should utilize the Twinrix® vaccine. • **CONTRAINDICATION:** pregnancy

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER* * For persons aged 18 years or younger consult pharmacist and package inserts.		
VACCINE/POPULATION	**INDICATION FOR VACCINE**	**KEY POINTS**
3. *HAEMOPHILUS INFLUENZAE* TYPE B (HIB)	**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 4 weeks apart when immunocompetent (6–12 months after successful transplant).
4. HUMAN PAPILLOMAVIRUS (HPV)	**HPV vaccine is indicated for persons with no documented or *self-reported* history of vaccine *and* who meet the following AGE and RISK FACTORS:** • All adults through age 26 years. (*Do NOT vaccinate during PREGNANCY. Delay administration until after pregnancy.*) • Some adults aged 27- 45 years: Based on shared clinical decision-making. • Persons with immunocompromising conditions, including HIV infection: 3-dose series and as per age ranges above.	**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 HPV vaccine in Vaccine Procedure Module 4 (HPV) in **CHAPTER 3**. • **PREGNANCY:** For women of childbearing age, verbal denial of pregnancy should be documented.

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER* * *For persons aged 18 years or younger consult pharmacist and package inserts.*		
VACCINE/POPULATION	**INDICATION FOR VACCINE**	**KEY POINTS**
5. INFLUENZA	**Influenza vaccine is indicated annually for all adults without known contraindications. First priority for vaccination are the following candidates:** • Pregnancy or up to 2 weeks after delivery. • Chronic pulmonary disease, including asthma. • Cardiovascular disease (except isolated HTN). • Renal, hepatic, hematologic (e.g., sickle cell disease), and metabolic disorders (including diabetes) • Neurologic disorders and neurodevelopmental conditions (e.g., epilepsy, cerebral palsy, stroke, intellectual disability, muscular dystrophy, spinal cord injury). • Immunosuppression due to any cause (e.g., medications [e.g., anti-alpha inhibitors or steroids]; certain cancers [e.g., leukemia]; and HIV infection). • Morbid obesity (BMI $\geq$ 40). • American Indian/Alaska Native. • Inmates housed on Nursing Care Center Units. • Inmates working in Health Services Units (HSUs). • Inmates aged 50 years and older.	**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*., Afluria®, Pre-filled, quadrivalent flu vaccine administered*). **ALLERGIES:** • See information on contradictions and precautions in Vaccine Procedure Module 5 (Influenza) in **CHAPTER 3**.

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER* * For persons aged 18 years or younger consult pharmacist and package inserts.		
VACCINE/POPULATION	**INDICATION FOR VACCINE**	**KEY POINTS**
6. MEASLES- MUMPS-RUBELLA (MMR)	**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 1 dose* of MMR. • Laboratory evidence of immunity or disease. * For HIV Infection with CD4 percentage ≥15% and CD4 count ≥200 cells/mm^3 for at least 6 months, administer 2 doses at least 4 weeks apart. **MEASLES OR MUMPS OUTBREAKS:** See outbreak information in Section B 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 contraindicated. **MMR CONTRAINDICATIONS:** • **PREGNANCY:** For women of childbearing age, verbal denial of pregnancy should be documented. Pregnancy testing is recommended only if there is uncertainty about the pregnancy status of the woman. • **HIV INFECTION** with CD4 percentage <15% or CD4 count <200 cells/mm3. • **SEVERE IMMUNODEFICIENCY,** such as hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy. • **FAMILY HISTORY** of altered immunocompetence, unless verified as immunocompetent. **MMR PRECAUTION:** • Recent (within 11 months) receipt of antibody-containing blood product. • History of thrombocytopenia or thrombocytopenic purpura.

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER* * For persons aged 18 years or younger consult pharmacist and package inserts.		
VACCINE/POPULATION	**INDICATION FOR VACCINE**	**KEY POINTS**
7. MENINGOCOCCAL VACCINES **MENINGOCOCCAL B (MENB)** ***and*** **MENINGOCOCCAL ACWY (MENACWY)**	**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 or functional asplenia (including sickle cell disease). • Persistent complement component deficiency (e.g., inherited chronic deficiencies in C3, C5-C9, properdin, factor D, and factor H). • Complement inhibitor use (e.g., eculizumab [Soliris®], ravulizumab [Ultomiris®]): Administer 1st dose of meningococcal vaccines at least 2 weeks ***prior*** *to* initiating medication. • **PREGNANCY:** Delay MenB until after pregnancy, unless increased risk and vaccination benefits outweigh potential risks**.** **The MenACWY series and an *every* 5-year MenACWY booster dose are indicated for persons with no documented history of MenACWY vaccine and who have:** • Any of the RISK FACTORS listed above for MenB *or* • HIV infection.	**AT SCREENING VISIT:** Determine previous vaccine history and risk factor indications for MenB or MenACWY vaccines. If at risk, administer as follows: **NOTE:** MenB and MenACWY vaccines may be given at the same time, but in a different anatomic site (e.g., different arms). **MenB Vaccine:** • **IF NO DOCUMENTED DOSES:** Administer 2- or 3-dose series, dependent on vaccine brand.★ • **IF DOCUMENTATION OF PRIMARY SERIES COMPLETION:** Administer MenB booster 1 year after primary series and revaccinate every 2–3 years if risk remains using the 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 PRIMARY SERIES COMPLETION:** Administer additional dose *every* 5 years if risk continues.

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER*

** For persons aged 18 years or younger consult pharmacist and package inserts.*

VACCINE/POPULATION	INDICATION FOR VACCINE	KEY POINTS
8. PNEUMOCOCCAL VACCINES **PNEUMOCOCCAL 15 AND 20-VALENT (PCV15 & PCV20)** ***and*** **PNEUMOCOCCAL 23-VALENT (PPSV23)**	**PCV15 or PCV20 is indicated for persons with the following AGE and RISK FACTORS *and* who do not have documentation of history of adult pneumococcal conjugate vaccine (PCV)**: • **Age 65 years and older** • **Risk-factor based, age 19–64 years:** ◆ Alcoholism ◆ Cerebrospinal fluid leak ◆ Chronic heart/liver/lung disease ◆ Chronic renal failure or nephrotic syndrome (CKD) ◆ Cigarette smoking ◆ Cochlear implant ◆ Functional or anatomic asplenia (e.g., sickle cell disease or other hemoglobinopathies, or splenectomy) ◆ Iatrogenic immunosuppression (e.g., cancer chemotherapy, long-term systemic corticosteroids, cytokine inhibitors, tumor necrosis alpha factor inhibitors, and radiation therapy) ◆ Immunocompromising conditions (e.g., congenital or acquired immunodeficiency, HIV infection, leukemia, lymphoma, multiple myeloma, Hodgkin disease, generalized malignancy, or solid organ transplantation) ◆ Diabetes mellitus **PPSV23 is indicated when:** • No documented vaccination history is available and PCV15 is administered. In such situations, PPSV23 should be administered 1 year after the PCV15 dose. • Documented vaccination history shows PCV13 was administered in the past, but the recommended pneumococcal vaccination series was not completed.	**AT SCREENING VISIT:** Determine previous pneumococcal vaccine history *AND* whether individual meets the age and risk factor indications for PCV15 or PCV20 and PPSV23 vaccine. **CLINICAL GUIDANCE AND SCHEDULE:** • *If vaccination history is unknown*, administer 1 dose of PCV15 or PCV20. ◆ If PCV 15 is used, it should be followed by 1 dose of PPSV23 one year later. However, a minimum interval of 8 weeks can be considered in adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak. ◆ If PCV20 is used, PPSV23 is NOT indicated. • *If only PPSV23 was received in the past*, 1 dose of PCV15 or PCV20 should be administered at least 1 year after the most recent PPSV23. ◆ An additional dose of PPSV23 is NOT recommended. • *If PCV13 with or without PPSV23 was received in the past*, complete the PPSV23 series as previously recommended. * ◆ If the previously recommended PPSV23 series was not completed and PPSV23 is not available, 1 dose of PCV20 may be used. If PCV20 is used, the pneumococcal vaccination series is considered complete. ➔ ***Do NOT give PCV 15 and PPSV23 during the same visit.*** * ***For more information, see the algorithm for administering PCV13 and PPSV23 based on vaccination history in Vaccine Procedure MODULE 8 (Pneumococcal).***

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER* * For persons aged 18 years or younger consult pharmacist and package inserts.		
VACCINE/POPULATION	**INDICATION FOR VACCINE**	**KEY POINTS**
9. TETANUS-DIPHTHERIA-PERTUSSIS (TDAP) AND TETANUS-DIPHTHERIA (TD)	• Adults not previously vaccinated against tetanus, diphtheria, or pertussis. • Adults without documented Tdap vaccination history as an adolescent or as an adult. • Td or Tdap vaccine is indicated every ten years for adults with a complete prior vaccination series against tetanus, diphtheria, or pertussis. • 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 and/or Td vaccine. • **NO PRIOR VACCINATION SERIES AGAINST TETANUS, DIPHTHERIA, OR PERTUSSIS:** 1 dose Tdap followed by 1 dose Td or Tdap at least 4 weeks later, and another Td or Tdap dose 6-12 months after last dose (Tdap can be substituted for any Td dose but is preferred as the first dose); Td or Tdap booster every 10 years thereafter. • **NO DOCUMENTED HISTORY OF TDAP WITH COMPLETE PRIOR IMMUNIZATION AGAINST TETANUS AND DIPHTHERIA:** Administer a one-time Tdap dose. Thereafter, a Td or Tdap 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*).

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER* * For persons aged 18 years or younger consult pharmacist and package inserts.		
VACCINE/POPULATION	**INDICATION FOR VACCINE**	**KEY POINTS**
11. RECOMBINANT ZOSTER VACCINE (RZV)	• **IMMUNOCOMPETENT ADULTS AGED 50 YEARS AND OLDER** regardless of previous herpes zoster (shingles) episode or history of the live zoster vaccine (Zostavax, ZVL). • **ADULTS AGED 19 YEARS AND OLDER** who are or will be immunodeficient or immunosuppressed because of disease or therapy.	**AT SCREENING VISIT:** For persons aged 19 years and older, determine previous vaccine history and whether they meet indications or timing for RZV. **IF NO PREVIOUS VACCINE:** • **IMMUNOCOMPETENT ADULTS ≥ 50 YEARS OLD** Administer RZV 2-dose vaccine series 2-6 months apart (minimum interval 4 weeks). • **ADULTS ≥ 19 YEARS OLD WHO ARE/WILL BE IMMUNODEFICIENT OR IMMUNOSUPPRESSED** ◆ Administer RZV as per schedule above; however, the 2nd dose may be administered 1-2 months after the 1st dose for earlier benefit. ◆ Vaccinate before immunosuppression or when immune response likely most robust. **PRECAUTIONS (DEFER VACCINATION):** • **PREGNANCY AND LACTATION.** • **CURRENT HERPES ZOSTER INFECTION.** **PRIOR HISTORY OF ZOSTAVAX:** Persons with a prior history of live zoster vaccine (Zostavax, ZVL) should be revaccinated with the RZV series at least 2 months after ZVL. ***NOTE:*** As of July 2020, ZVL is no longer available in the United States.

CHAPTER 3. VACCINE PROCEDURE 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**:

MODULE 1. HEPATITIS A VACCINE
MODULE 2. HEPATITIS B VACCINE
MODULE 3. HAEMOPHILUS INFLUENZAE TYPE B VACCINE
MODULE 4. HUMAN PAPILLOMAVIRUS VACCINE
MODULE 5. INFLUENZA VACCINES
MODULE 6. MEASLES, MUMPS, AND RUBELLA VACCINE
MODULE 7. MENINGOCOCCAL DISEASE VACCINES
MODULE 8. PNEUMOCOCCAL VACCINES
MODULE 9. TETANUS, DIPHTHERIA, & PERTUSSIS VACCINES
MODULE 10. VARICELLA VACCINE
Module 11. HERPES ZOSTER VACCINE

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 health care 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 aged 19 years or older. For patients aged 18 years 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 health care 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. *Haemophilus influenzae* type B vaccine (Hib)
	4. Human papillomavirus vaccine (HPV)
	5. Influenza vaccines: ☐ inactivated single dose quadrivalent (IIV4), ☐ inactivated multi-dose quadrivalent (IIV4), and ☐ adjuvanted inactivated quadrivalent vaccine (aIIV4)
	6. Measles, mumps, rubella (MMR)
	7. Meningococcal vaccines (MenB and MenACWY)
	8. Pneumococcal vaccines (PCV15, PCV20, and PPSV23)
	9. Tetanus, diphtheria, pertussis vaccines (Td and Tdap)
	10. Varicella vaccine (VAR)
	11. Recombinant zoster vaccine (RZV) – Shingrix®

Signatures		
IP&C Coordinator (Last, First) – PRINT	*Signature*	*Date*
Health Services Administrator (Last, First) – PRINT	*Signature*	*Date*
Clinical Director (Last, First) – PRINT	*Signature*	*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 health care 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, who do not have evidence of immunity to HAV or a history of HepA and who have the following increased risks:***
   - Men who have sex with men
   - Injection or non-injection drug use
   - Chronic liver disease or cirrhosis, including chronic hepatitis C (HCV antibody positive, HCV RNA positive) and chronic hepatitis B (HBsAg positive)
   - History of homelessness
   - HIV-infected patients
   - ***During an HAV outbreak:*** Persons at risk for HAV infection. Administer one dose of HepA. A second dose may be considered, based on risk factors and status of outbreak, at 6–18 months after initial vaccination. During outbreak or exposure situations, the Twinrix® (combined hepatitis A/B) vaccine should NOT be used due to lower antigen content of the vaccine.
   - ***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 as soon as possible.
     ➔ *In addition to HepA, 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:***
   - **CONTRAINDICATIONS:** A history of a serious reaction (e.g., anaphylaxis) after a previous dose of HepA or to a HepA 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).

- **NEOMYCIN/YEAST ALLERGY:** Severe allergic reaction (e.g., anaphylaxis) to neomycin is a contraindication to administration of HepA (including the Twinrix® vaccine). Severe allergic reaction to yeast is an added contraindication to administration of the Twinrix® 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.
- **PREGNANCY OR NURSING:** Refer to primary provider.

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

- Review the vaccination information with the patient.
- 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.*

- ***BOP Immunization Consent Form (BP-A0808):***
  - Document the publication date of the VIS.
  - Have patient sign consent or declination and date the form.
  - The person administering the immunization signs and dates the form.
  - Scan the signed consent form (BP-A0808) for each administered or declined dose into the Document Manager of the patient electronic health record.

4. Administer HepA:

→ ***TWINRIX® is NOT interchangeable with VAQTA® or HAVRIX®: if the primary series is initiated with TWINRIX® it must be given for the other scheduled doses.***

→ *For patients aged 18 years 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 **Outbreak:** Do not use Twinrix in outbreak situation.	**Contraindications:** • **Severe allergy** or anaphylaxis to neomycin and also yeast for Twinrix. • **Severe allergy** to latex (see package insert).

- 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.*
  - 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 taut, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.
- ***To prevent syncope***, have patient sit or lie down for vaccination and consider observing the patient for 15 minutes after receipt of the vaccine.
- The two available single-antigen adult vaccines (Vaqta and Havrix) can be used interchangeably; however, series completion using the same product is preferred.
- Provide a subsequent dose of HepA to complete each patient's 2-dose schedule by observing a minimum interval of 6 months between the first and second doses.
  - Do not restart the vaccine series if the second dose is delayed beyond 6 months.
- For candidates for whom both the HepA and HepB 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 the patient electronic health record:***
   - Record the vaccine administration location, the manufacturer and lot number, dosage and route, dose number (if applicable), expiration date, and provider. Upon exiting, do not forget to save the immunization flow sheet data.
     - ***If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).***

6. ***Schedule additional doses of vaccine***
   - Schedule the subsequent vaccination in the electronic health record at the time of the initial vaccine dose.
   - Using BEMR scheduler is the preferred method to schedule subsequent vaccine doses.

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 (i.e., 1 mg/mL) dilution 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 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 health care 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 the following indications with consideration for age, chronic illnesses, and appropriate dosing:***
   - Aged 19-59 years
   - Aged 60 years or older with one of the following risk factors:
     - The 2022 CDC adult immunization schedule recommends all incarcerated persons ≥60 years of age receive HBV vaccine.
     - Sexual exposure risk (men who have sex with men [MSM], STD history or seeking STD evaluation, multiple sexual partners)
     - Injection drug use
     - Chronic liver disease or cirrhosis, including hepatitis C (HCV RNA+)
     - Adults in pre-dialysis care
     - Hemodialysis/peritoneal dialysis recipients (use dialysis dosing schedule in *table* under #4)
     - Diabetic patients
     - Inmate workers at risk for bloodborne pathogen exposure
     - HIV-infection
     - Post-exposure prophylaxis
   - In the table, there is an alternative dose option for immunocompromised (including HIV infected) patients who do not convert to HBsAb positive post-vaccination.
   - 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 or to a HepB component.
     - **LATEX ALLERGY:** Tip caps of some prefilled syringes contain natural rubber latex which may cause allergic reactions (see package insert).
     - **YEAST/NEOMYCIN ALLERGY:** Severe allergic reaction (e.g., anaphylaxis) to yeast is a contraindication to administration of all HepB. Also, a severe allergic reaction to neomycin is an added contraindication to administration of the Twinrix® vaccine.
     - **PREGNANCY:** only for **HEPLISAV-B®.**

     → *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.

3. ***Provide all patients with a copy of the most current Vaccine Information Statement (VIS) and obtain consent.***
   - Review the vaccination information with the patient.
   - 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.*
   - ***BOP Immunization Consent Form (BP-A0808):***
     - Document the publication date of the VIS.
     - Have patient sign consent or declination and date the form.
     - The person administering the immunization signs and dates the form.
     - Scan the signed consent form (BP-A0808) for each administered or declined dose into the Document Manager of the patient electronic health record.

4. ***Administer HepB:***

→ ***TWINRIX® is NOT interchangeable with VAQTA® or HAVRIX®: if the primary series is initiated with TWINRIX® it must be given for the other scheduled doses.***

   - 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.*
     - 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 taut, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.
   - ***To prevent syncope***, have patient sit or lie down for vaccination and consider observing the patient for 15 minutes after receipt of the vaccine.

Vaccine	Dose/ Volume/ Schedule	Most At-Risk Adults	Adults (≥ age 20 years) on Dialysis *and* Alternative Dose/Schedule for Immunocompromised Non-responders (including HIV Infection)[2]	Considerations
Recombivax® HB (Merck)[1]	**Dose**	10 mcg IM for age ≥20 yrs 5 mcg IM for age ≤19 yrs	N/A	**Contraindications:** • **Severe allergy** or anaphylaxis to yeast (all HepB vaccines) or yeast and neomycin (Twinrix). • **Severe allergy** to latex (see package insert). • **Pregnancy** (Heplisav-B only).
	Volume	1 mL for age ≥20 yrs 0.5 mL for age ≤19 yrs	N/A	
	Schedule	0, 1, & 6 months	N/A	
Recombivax HB (Merck)[1] Dialysis Formulation	**Dose**	N/A	40 mcg	
	Volume	N/A	1 mL	
	Schedule	N/A	0, 1, & 6 months	
Engerix-B® (GSK)[1] **Adult Dose**	**Dose**	20 mcg IM for age ≥20 yrs 10 mcg IM for age ≤19 yrs	40 mcg (two separate 20 mcg doses)	
	Volume	1 mL for age ≥20 yrs 0.5 ml for age ≤19 yrs	Two 1 mL doses at same site, 1" apart	
	Schedule	0, 1, & 6 months	0, 1, 2, & 6 months	
Heplisav-B®[3] (Dynavax) Approved for age 18 years 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)[1] Approved for age 18 yrs and older	**Dose**	**HepA:** 720 EL.units **HepB:** 20 mcg	N/A	
	Volume	1 mL	N/A	
	Schedule	0, 1, & 6 months	N/A	

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

- ***Provide subsequent doses of HepB*** 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.
  - ***Do not restart the vaccine series if a dose is given late in the sequence.*** If the series was interrupted after dose 1, give dose 2 as soon as possible. Doses 2 and 3 should be separated by a minimum interval of 8 weeks. If only dose 3 is delayed, it should be given as soon as possible.

- ***If an accelerated schedule is needed (Engerix-B® & Recombivax HB®)***, read package insert for dosing.
  - *The minimum dosing intervals are at least 1 week between doses 1 and 2; and at least 2 weeks between doses 2 and 3. Doses given at less than minimum intervals should not be counted and should be repeated.*

- For candidates for whom both the HepA and HepB 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 patient electronic health record:***
   - Patient Medical Record (BEMR): Record the vaccine location, the manufacturer and lot number, dosage and route, dose number, expiration date, and provider. Upon exiting, do not forget to save the immunization flow sheet data.
   - If the vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).

6. ***Schedule additional doses of vaccine***
   - Schedule the subsequent vaccinations in the electronic health record at the time of the initial vaccine dose.
   - Using BEMR scheduler is the preferred method to schedule subsequent vaccine doses.

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 (i.e., 1 mg/mL) dilution 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 3. *HAEMOPHILUS INFLUENZAE* TYPE B 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 health care 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 #5).*
   - Recipient of hematopoietic stem cell transplant (HSCT).
     ➔ *Initiate series 6–12 months after successful transplant, regardless of Hib vaccination history (see table under #5).*

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, a tetanus toxoid-containing 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 following a previous tetanus vaccine.

3. ***Provide all patients with a copy of the most current Vaccine Information Statement (VIS) and obtain consent.***
   - Review the vaccination information with the patient.

- 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.*
- ***BOP Immunization Consent Form (BP-A0808):***
  - Document the publication date of the VIS.
  - Have patient sign consent or declination and date form.
  - The person administering the immunization signs and dates form.
  - Scan the signed consent form (BP-A0808) for each administered or declined dose into the Document Manager of the patient electronic health record.

4. Safe handling and use of Haemophilus influenzae type b conjugate vaccine:

- ***Before reconstitution:*** Store both vials (lyophilized vaccine and saline diluent) in a refrigerator (36°F to 46°F; 2°C to 8°C).
  - ***DO NOT FREEZE.*** Discard if vials have been frozen.
  - ***Protect vials from light.***
- ***To reconstitute the vaccine***, first withdraw 0.6 mL of the provided saline diluent into a syringe (use only the diluent supplied).
  - Inject all the withdrawn saline diluent into the vial of lyophilized vaccine and shake well to mix thoroughly and dissolve completely.
  - When reconstituted, the vaccine is a clear and colorless solution.
- ***After reconstitution:*** Withdraw 0.5 mL (from the 0.6 mL solution) and administer vaccine intramuscularly immediately or store in refrigerator for up to 24 hours (label appropriately).
  - ***If the reconstituted vaccine is not administered immediately,*** shake the solution well again before administration.
  - ***Discard the reconstituted vaccine if it is not used within 24 hours.***
  - ***DO NOT FREEZE.*** Discard if the vaccine has been frozen***.***

5. Administer Hib 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:** *Administer at least 14 days prior to splenectomy.*	IM	• Do NOT give if history of serious reaction or allergy to a component of vaccine or a tetanus toxoid-containing vaccine. • Precaution: History of Guillain-Barré Syndrome within 6 weeks following a previous tetanus 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	

- 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.*
  - 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 taut, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.
- ***To prevent syncope***, have patient sit or lie down for vaccination, and consider observing the patient for 15 minutes after receipt of the vaccine.
- 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).

6. ***Document patient vaccine administration information in the patient electronic health record:***
   - Record the vaccine administration location the manufacturer and lot number, dosage and route, dose number (if applicable), expiration date, and provider. Upon exiting, do not forget to save the immunization flow sheet data.
     - ***If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).***

7. ***Scheduling additional doses of vaccine (if applicable)***
   - Schedule the subsequent vaccinations in the electronic health record at the time of the initial vaccine dose.
   - Using BEMR scheduler is the preferred method to schedule subsequent vaccine doses.

8. ***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 ***(i.e., 1 mg/mL)*** and respiratory support should be immediately available.

9. ***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 health care 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 if no documented or self-reported history of receiving the complete vaccine series:***
   - ***HPV vaccination recommended for all adults through age 26 years:*** 2- or 3-dose series depending on age at initial vaccination or condition:
     - ***Age 15 years or older at initial vaccination:*** 3-dose series at 0, 1–2, 6 months (minimum intervals: 4 weeks between doses 1 and 2, 12 weeks between doses 2 and 3, 5 months between doses 1 and 3; repeat dose if administered too soon)
     - ***Age 9 through 14 years at initial vaccination and received 1 dose or 2 doses less than 5 months apart:*** 1 dose
     - ***Age 9 through 14 years at initial vaccination and received 2 doses at least 5 months apart:*** HPV vaccination is complete; no additional dose needed.
   - ***Some adults aged 27-45 years*** based on shared clinical decision-making: 2- or 3-dose series as above.
   - ***If completed valid vaccination series with any HPV vaccine, no additional doses needed.***
   - ***Special situations***
     - ***Pregnancy:*** HPV vaccination not recommended until after pregnancy; no intervention needed if vaccinated while pregnant; pregnancy testing not needed before vaccination.
     - ***Immunocompromising conditions, including HIV infection:*** HPV vaccination recommended through age 26 years and for some age 27-45 years, the latter based on shared clinical decision-making; provide 3-dose series.
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 an HPV vaccine component.
     - **YEAST ALLERGY**: Severe allergic reaction (e.g., anaphylaxis) to yeast is a contraindication to administration of the quadrivalent and 9-valent HPV vaccines (i.e., Gardasil).

- *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
    - *Pregnancy testing is not required. Women of childbearing age should be asked about the possibility of being pregnant prior to vaccination and the answer documented in the medical record.*

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

- Review the vaccination information with the patient.
- 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.*

- ***BOP Immunization Consent Form (BP-A0808):***
  - Document the publication date of the VIS.
  - Have patient sign consent or declination and date form.
  - The person administering the immunization signs and dates form.
  - Scan the signed consent form (BP-A0808) for each administered or declined dose into the Document Manager of the patient electronic health record.

4. ***Administer HPV 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.*
  - 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 taut, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.
- ***To prevent syncope***, have patient sit or lie down for vaccination, and consider observing the patient for 15 minutes after receipt of the vaccine.

(Administration table on next page)

PATIENT GROUPS	9vHPV GARDASIL (MERCK) NOTE: THIS GUIDANCE IS SPECIFIC TO 9-VALENT GARDASIL.			
	VOLUME	DOSE SCHEDULE	ROUTE	CONTRAINDICATIONS/PRECAUTIONS
NO DOSES DOCUMENTED: • Age ≤26 years • Some adults age 27-45 years	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. • PRECAUTION: Pregnancy (delay until after pregnancy).
1–2 DOSES DOCUMENTED AS GIVEN AT AGE ≥15 YEARS OR UNKNOWN: • Age ≤26 years • Some adults aged 27-45 years	0.5 mL	Complete the 3-dose series as outlined above (with either one dose or two, as needed) with at least 4 weeks between the 1st and 2nd doses and at least 12 weeks between 2nd and 3rd doses.	IM	
1 DOSE DOCUMENTED AS GIVEN *BEFORE* AGE 15 YEARS: • Age ≤26 years • Some adults aged 27-45 years	0.5 mL	Give 1 additional dose.	IM	

- Provide subsequent doses of vaccine to complete each patient's 3-dose schedule by observing the recommended intervals.
  - Do not restart the vaccine series if longer than the suggested interval has elapsed between doses.
- ***Minimum intervals between doses:*** Complete each patient's 3-dose schedule by observing ***(1)*** a minimum interval of 4 weeks between the first and second doses, ***(2)*** 12 weeks between the second and third dose, and ***(3)*** at least 5 months between the first and third doses.

5. Document patient vaccine administration information in the patient electronic health record:

- Record the vaccine administration location, the manufacturer and lot number, dosage and route, dose number (if applicable), expiration date, and provider. Enter the next dose in the scheduler, if applicable. Upon exiting, do not forget to save the immunization flow sheet data.
  - ***If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).***

6. Scheduling additional doses of vaccine (if applicable).

- Schedule the subsequent vaccination in the electronic medical record at the time of the initial vaccine dose.
- Using BEMR scheduler is the preferred method to schedule subsequent vaccine doses.

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 (i.e., 1 mg/mL) dilution 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.
   - 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). Reducing the overall burden of respiratory illnesses is important to protect vulnerable populations at risk for severe illness, the healthcare system, and other critical infrastructure. Thus, health care providers should use every opportunity during the influenza vaccination season to administer influenza vaccines to all eligible persons

➔ *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, quadrivalent – **IIV4**
► Inactivated influenza vaccine, quadrivalent, high dose – **HD-IIV4**
► Adjuvanted inactivated influenza vaccine – **aIIV**
► Adjuvanted inactivated influenza vaccine, quadrivalent – **aIIV4**
► Cell-based inactivated influenza vaccine, quadrivalent – **ccIIV4** (egg-free vaccine)
► Recombinant influenza vaccine – **RIV** (egg-free vaccine)
► Live attenuated influenza vaccine - **LAIV**

B. PROCEDURE

Using this vaccine module, eligible health care 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 influenza vaccines available; it will need to be reprinted annually with updates.*

1. ***One dose of Influenza vaccine is indicated annually for all adults. Inmates who are identified as priority candidates should be given first priority for vaccination.***
   - ***Priority Candidates –*** Inmates with any of the following medical risk factors are first priority for vaccine administration:
     - Pregnancy and up to 2 weeks after delivery
     - Chronic pulmonary disease (including asthma)
     - Cardiovascular disease (except isolated hypertension)

(list continues on the following page)

- Renal, hepatic, hematologic (e.g., sickle cell disease), and metabolic disorders (including diabetes mellitus)
- Neurologic disorders and neurodevelopmental conditions (e.g., epilepsy, cerebral palsy, stroke, intellectual disability, muscular dystrophy, spinal cord injury)
- Immunosuppression due to any cause (e.g., medications, certain cancers, or HIV infection)
- Morbid obesity (BMI > 40)
- American Indian/Alaska Native
- Inmates housed on nursing care center (long-term care) units
- Inmates working in Health Services units
- Inmates older than age 50 years

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

- **CONTRAINDICATIONS:** A history of a serious reaction (e.g., anaphylaxis) to any component of the vaccine (e.g., 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:**
  - ***Clinical experience with influenza vaccination of persons with COVID-19 or recovering from COVID-19 is limited.*** Timing of vaccination for these individuals should be guided by considerations of the individual's underlying risk of medical complications due to influenza and the degree of influenza circulation in the local community. For those who have acute illness with suspected or laboratory-confirmed COVID-19 or for those who are in exposure quarantine, deferring influenza vaccination is recommended until the patients are no longer acutely ill or have met criteria for release from medical isolation or exposure quarantine status. A mechanism for tracking these cases for follow-up and offering the influenza vaccine is recommended.
  - 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® and Fluad® vaccines are 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.

(Egg allergy continues on next page)

- ***Anaphylactic allergy to eggs:*** Those with an egg allergy history involving symptoms other than hives (e.g., angioedema, respiratory distress) 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 the dose of flu vaccine.***

3. ***Provide all patients with a copy of the most current Vaccine Information Statement (VIS) and obtain consent.***
   - Review the vaccination information with the patient.
   - 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.*
   - ***BOP Immunization Consent Form (BP-A0808):***
     - Document the publication date of the VIS.
     - Have patient sign consent or declination and date the form.
     - The person administering the immunization signs and dates the form.
     - Scan the signed consent form (BP-A0808) for each administered or declined dose into the Document Manager of the patient electronic health record.

4. ***Administer influenza vaccine. The table on the following page provides information on influenza vaccines for the 2022–23 BOP contract:***
   - 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.*
     - 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 taut, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.
   - To prevent syncope, have patient sit or lie down for vaccination, and consider observing the patient for 15 minutes after receipt of the vaccine.

(Administration table on next page)

INFLUENZA VACCINE BY TYPE	FORM	STRENGTH	DOSE	ROUTE	TIMING	AGE INDICATIONS/COMMENTS
Afluria® (Seqirus) **IIV4: Inactivated Influenza Vaccine** ***Quadrivalent***	Suspension **Multi-dose** vial (contains ten 0.5 ml doses)	15 mcg HA	0.5 ml	IM	One time annually	**6 months 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® (Seqirus) **IIV4: Inactivated Influenza Vaccine** ***Quadrivalent***	Suspension **Single-dose**, pre-filled syringe	15 mcg HA	0.5 ml	IM	One time annually	**36 months of age and older (*including age 65 and older*):** • Shake the vial thoroughly before use. • Preservative-free. • Latex-free. • Thimerosal-free. • Use appropriate size safety needle. • Protect from light.
Fluad® (Seqirus) **aIIV4: Adjuvanted Inactivated Influenza Vaccine** ***Quadrivalent***	Suspension **Single-dose**, pre-filled syringes	15 mcg HA	0.5 ml	IM	One time annually	**An option for use *ONLY* for persons 65 years of age and older:** • Before administering, gently shake the prefilled syringe. • Thimerosal-free. • Latex-free. • Use needle with safety device. • Use appropriate size safety needle. • Protect from light.

5. ***Document the patient vaccine administration information in the patient electronic health record:***
   - Under Influenza Immunization (brand required), record the vaccine administration location, the manufacturer and lot number, dosage and route, expiration date, and provider. Upon exiting, do not forget to save the immunization flow sheet data.
     - ***If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).***

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 (i.e., 1 mg/mL) dilution 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 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 health care 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 and without evidence of immunity★ to measles, mumps, or rubella.
   - HIV infection with CD4 percentages ≥15% and CD4 count ≥200cells/mm3 for at least 6 months and no 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 who have received ≤ 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.

   ★ ***CDC EVIDENCE OF IMMUNITY:*** *Born before 1957, OR documentation of having received 1 dose 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., 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.*

(list of contraindications continues on next page)

- ***Pregnancy:*** Pregnant now or could become pregnant within 4 weeks.
  - *Pregnancy testing is not required. Women of childbearing age should be asked about the possibility of being pregnant prior to vaccination, with the answer documented in the medical record. Pregnancy testing is recommended only if there is uncertainty about the pregnancy status of a woman.*
- ***Immunodeficiency:*** Known severe immunodeficiency, such as hematologic or solid tumor, congenital immunodeficiency, receipt of chemotherapy, or receiving long-term immunosuppressive therapy or family history of altered immunocompetence (unless verified as immunocompetent). In particular:
  - HIV patient with (CD4 percentages <15% and CD4 count <200 cells/mm^3)
    - *If HIV Infection and CD4 percentages ≥15% or CD4 count ≥200 cells/mm^3 for least 6 months, can administer 1 dose.*
  - 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 package insert and/or Tables 3-5 and 3-6, 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 testing to determine status).
  - Moderate or severe acute illness with or without fever.
  - Recent receipt of another live vaccine unless administered simultaneously (i.e., defer vaccine administration for 4 weeks).
  - Personal or family history of seizures.

3. ***Provide all patients with a copy of the most current Vaccine Information Statement (VIS) and obtain consent.***
   - Review the vaccination information with the patient.
   - 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.*
   - ***BOP immunization Consent Form (BP-A0808):***
     - Document the publication date of the VIS.
     - Have patient sign consent or declination and date form.
     - The person administering the immunization signs and dates form.
     - Scan the signed consent form (BP-A0808) for each administered or declined dose into the Document Manager of the patient electronic health record.

4. ***Safe handling and use of the MMR vaccine:***

- ***Before reconstitution:***
  - ***Lyophilized (freeze-dried) vaccine:***
    - ***Refrigerate (36°F to 46°F; 2°C to 8°C) prior to reconstitution.***
    - Protect from light.
  - ***Diluent (sterile water):***
    - Store in a refrigerator (36°F to 46°F; 2°C to 8°C) or at room temperature (68°F to 77°F; 20°C to 25°C).
    - Do NOT freeze.
- ***To reconstitute the vaccine,*** first withdraw the total volume of provided sterile diluent into a syringe (use only the sterile diluent supplied with the vaccine)
  - Inject all the withdrawn diluent into the vial of lyophilized vaccine and agitate to mix thoroughly and dissolve completely.
  - When reconstituted, the vaccine is a clear, yellow liquid.
- ***After reconstitution,*** withdraw the entire amount of reconstituted vaccine into a syringe and administer the total volume subcutaneously or store in a refrigerator (36°F to 46°F; 2°C to 8°C) for up to 8 hours.
  - Protect from light.
  - ***Discard the reconstituted vaccine if it is not used within 8 hours.***
  - ***Do not freeze.***

5. ***Administer MMR vaccine:***

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 vaccine 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 or thrombocytopenic purpura. • Wait 4 weeks after administration of any other *live* vaccine (e.g., varicella [VAR]). • Check expiration date. • Protect vaccine from light. • **Reconstitute with proper diluent** (this will result in more than 0.5 mL, but dose is recorded as 0.5 mL 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 percentages ≥15% and CD4 count ≥200 cells/mm³ for 6 months or more if no evidence of immunity	0.5 mL	2 doses at least 4 weeks apart	SQ	
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	0.5 mL	1 dose	SQ	

- Give vaccine subcutaneously (SQ) with a 23–25g, 5/8" needle in the posterolateral fat (triceps) of the upper arm.
- ***To prevent syncope,*** have patient sit or lie down and consider observing the patient for 15 minutes after receipt of the vaccine.
- If 2 doses are required (e.g., certain HIV-infected patients), provide the subsequent dose while observing recommended intervals between the first and second doses.
- ***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 viral vaccines, such as measles vaccines (and possibly mumps, rubella and varicella vaccines), can result in suppression of the TST or a false negative result. Similarly, interferon gamma release assay (IGRA) testing (i.e., QuantiFERON-G® or T-Spot®) can be obtained concurrently with MMR vaccination or be obtained 28 days AFTER the MMR vaccine.

6. ***Document patient vaccine administration information in the patient electronic health record:***
   - Record the vaccine administration location, the manufacturer and lot number, the dosage and route, dose number (if applicable), expiration date, and provider. Upon exiting, do not forget to save the immunization flow sheet data.
     - ***If the vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).***

7. ***Scheduling additional doses of vaccine***
   - Schedule the subsequent vaccinations in the electronic health record at the time of the initial vaccine dose.
   - Using BEMR scheduler is the preferred method to schedule subsequent vaccine doses.

8. ***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 (i.e., 1 mg/mL) dilution and respiratory support should be immediately available.***

9. ***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 health care 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 .*

   INDICATIONS FOR MENINGOCOCCAL SEROGROUP B (MENB) VACCINE:

   - Anatomic or functional asplenia (including sickle cell disease).
   - Persistent complement component deficiency (e.g., inherited chronic deficiencies in C3, C5-C9, properdin, factor D, and factor H).
   - Complement inhibitor use (e.g.,eculizumab [Soliris®], ravulizumab [Ultomiris®])
     - Immunize patients with meningococcal vaccines *at least 2 weeks prior to* administering the first dose of a complement inhibitor.

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

   ➔ *Refer to the BOP National Formulary for list of current formulary vaccinations.*

   - Anatomic or functional asplenia (including sickle cell disease).
   - Persistent complement component deficiency (e.g., inherited chronic deficiencies in C3, C5-C9, properdin, factor D, and factor H).
   - Compliment inhibitor use (e.g.,eculizumab [Soliris®], ravulizumab [Ultomiris®])
     - Immunize patients with meningococcal vaccines *at least 2 weeks prior to* administering the first dose of a complement inhibitor.
   - HIV infection
   - 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.

TABLE 1. INDICATIONS FOR RECOMMENDED MENINGOCOCCAL VACCINES

MEDICAL INDICATION	MENB	MENB 1 YEAR BOOSTER	MENB 2–3 YEAR BOOSTER	MENACWY	MENACWY EVERY 5-YEAR BOOSTER
Anatomic or functional asplenia (including sickle cell disease)	X	X	X	X	X
Persistent complement component deficiency	X	X	X	X	X
HIV-infected persons				X	X
Two weeks prior to initiation of complement inhibitor (e.g., eculizumab [Soliris®] or ravulizumab [Ultomiris®])	X	X	X	X	X

2. ***Screen all patients for contraindications and precautions to meningococcal vaccine:***
   - **CONTRAINDICATIONS:** A history of a serious reaction (e.g., anaphylaxis) after a previous dose of MenB or MenACWY vaccine, or to a meningococcal vaccine component including:
     - Diphtheria toxoid or CRM (a diptheria toxin carrier protein): **MENACTRA® AND MENVEO®**.
     - Tetanus toxoid: **MENQUADFI®.**

     → *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
     - Previous diagnosis of Guillain-Barré syndrome (GBS): **MENECTRA®**.
     - Latex sensitivity: **BEXERO®**.
     - HIV infection and asplenia: MenACWY-D (Menactra®) and PCV15 or PCV20 should not be administered simultaneously; PCV15 or PCV20 should be administered first, and MenACWY-D (Menactra®) administered 4 weeks later. Note: this guidance does NOT apply to MenACWY-CRM (Menveo®).

3. ***Provide all patients with a copy of the most current Vaccine Information Statement (VIS) and obtain consent.***
   - Review the vaccination information with the patient.
   - 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.*

(Section continues on next page)

- ***BOP immunization Consent Form (BP-A0808):***
  - Document the publication date of the VIS.
  - Have patient sign consent or declination and date form.
  - The person administering the immunization signs and dates the form.
  - Scan the signed consent form (BP-A0808) for each administered or declined dose into the Document Manager of the patient electronic health record.

4. ***Safe handling and use of the MenACWY-CRM (Menveo®) vaccine:***
   - ***Before reconstitution:*** Store both vials (lyophilized vaccine and diluent with CWY antigens) in the refrigerator (36°F to 46°F; 2°C to 8°C).
     - ***DO NOT FREEZE.*** Discard if vials have been frozen***.***
     - ***Protect vials from light.***
   - ***To reconstitute the vaccine,*** first withdraw the total volume of provided diluent suspension into a syringe (use only the diluent suspension supplied)
     - Slowly inject all the withdrawn diluent suspension into the vial of lyophilized vaccine
     - Invert the vial and shake well until powder is completely dissolved.
     - When reconstituted, the vaccine is a clear, colorless solution.
   - ***After reconstitution:*** Withdraw 0.5 mL from the vial and administer vaccine intramuscularly immediately or store between 36°F and 77°F (2°C and 25°C) for up to eight hours (label appropriately).
     - ***If stored, shake well before using.***
     - ***Discard the reconstituted vaccine if it is not used within eight hours.***
     - ***DO NOT FREEZE.*** Discard if the vaccine has been frozen***.***

5. ***Administer MenB and MenACWY vaccines for individuals meeting the indications described above and the age requirements, as shown in Table 2.***
   - *For more about contradictions and precautions, see #2 on previous page.*
   - For both MenB vaccines, ***shake vaccine vigorously*** to form a homogenous 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.
   - 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.*
     - 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 taut, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

(Administration table on following page)

TABLE 2. ADMINISTRATION OF MENINGOCOCCAL VACCINES[1]

MENINGOCOCCAL SEROGROUP B VACCINE (MENB)[2]					
Type of Vaccine	***Age***	***Volume***	***Route***	***Schedule***	***Contraindications, Precautions***
Bexsero® (*GSK*)**:** MenB-4C	≥10 yrs	0.5 mL	IM	Two doses at 0 & 4 weeks later (use same brand for entire series). One booster dose 1 year after primary series and one booster dose every 2–3 years if risk remains.	**Contraindication:** Allergy to any 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	≥10 yrs	0.5 mL	IM	Three doses at 0, 2, & 6 months (use same brand for entire series). One booster dose 1 year after primary series and one booster dose every 2–3 years if risk remains.	
MENINGOCOCCAL SEROGROUP A, C,W,Y CONJUGATE VACCINE (MENACWY)[2]					
Type of Vaccine	***Age***	***Volume***	***Route***	***Schedule***	***Contraindications, Precautions***
Menactra® (*Sanofi Pasteur*)**:** MenACWY-D	NA	0.5 mL	IM	0 and 2 months. Booster every 5 years if risk remains.	**Contraindication:** Allergy to vaccine component, diphtheria toxoid or CRM. **Precautions:** History of GBS, pregnancy. **Do not administer MenACWY-D (Menactra®) and PCV15 or 20 simultaneously**—see *Precautions* above in the text. **Menveo® diluent contains antigens CWY; do not use any other diluent.**
Menveo® (*GSK*)**:** MenACWY-CRM	NA	0.5 mL *Reconstitute and give immediately.*	IM	0 and 2 months. Booster every 5 years if risk remains.	

[1] MenB and MenACWY may be given at the same time but in different anatomic sites (e.g., different arms).
[2] Refer to current BOP National Formulary for list of current formulary vaccinations.

- Provide subsequent doses of meningococcal vaccines to complete each patient's 2- or 3-dose schedule by observing recommended intervals between doses.
- ***The two available MenB vaccines, Bexsero® and Trumenba®, are not interchangeable*** and have different schedules of administration. Once initiated, subsequent doses must use the *same vaccine formulation*, observing the correct intervals between doses.
- MenB vaccine and MenACWY vaccines may be administered at the same time, but at different anatomic sites (e.g., different arms).

6. ***Document patient vaccine administration information in the patient electronic health record:***
   - Record the vaccine location, the manufacturer and lot number, the dosage and route, dose number (if applicable), expiration date, and provider. Upon exiting, do not forget to save the immunization flow sheet data.
     - ***If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).***

7. ***Scheduling additional doses of vaccine***
   - Schedule the subsequent vaccinations in the electronic health record at the time of the initial vaccine dose.
   - Using BEMR scheduler is the preferred method to schedule subsequent vaccine doses.

8. ***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 (i.e., 1 mg/mL) dilution and respiratory support should be immediately available.***

9. ***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 health care 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 2 and who have no documentation of a history of adult vaccine.

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

   ➔ ***Do not give PCV15 or PCV20 and PPSV23 at the same visit.*** *See table below for scheduling.*

TABLE 1. ADMINISTRATION OF PCV AND PPSV23 FOR ADULTS ≥ 65 YEARS OF AGE (ROUTINE) AND 19-64 YEARS OF AGE WITH RISK FACTORS

VACCINATION HISTORY	ROUTINE ADMINISTRATION OF PCV & PPSV23	VOLUME	ROUTE[1]	SCHEDULING CONCERNS
None or unknown.	• Administer 1 dose of PCV15 or PCV20. If PCV15 used, administer 1 dose of PPSV23 ***at least*** 1 year later (8 weeks later if immunocompromised).	0.5 mL	**PCV:** IM only **PPSV23:** IM or SQ	• Do not give PCV15 or PCV20 and PPSV23 during same visit. • Do not administer PCV15 or PCV20 simultaneously with MenACWY-D (Menactra®)—see PRECAUTIONS (after tables).
Only PPSV23 received in past.	• Administer 1 dose of PCV15 or PCV20 ***at least*** 1 year after the most recent PPSV23 dose. An additional dose of PPSV23 is NOT recommended.	0.5 mL		
PCV13 with or without PPSV23 received in past.	• Complete the PPSV23 series as previously recommended.[2] If PPSV23 not available, 1 dose of PCV20 may be used with the pneumococcal series then considered complete.	0.5 mL		

[1] **IM** = Intramuscular; **SQ** = Subcutaneous

[2] See *Algorithm for PCV13 and PPSV23 Vaccinations* later in this module.

TABLE 2. ADULTS AGED 19–64 YEARS: RISK-BASED INDICATIONS FOR PNEUMOCOCCAL VACCINATIONS

- Alcoholism
- Cerebrospinal fluid leak
- Chronic heart disease (excluding hypertension)
- Chronic liver disease, cirrhosis
- Chronic lung disease (including asthma)
- Chronic renal failure, nephrotic syndrome (CKD)
- Cigarette smoking
- Cochlear implant
- Congenital or acquired asplenia
- Congenital or acquired immunodeficiency[1]
- Diabetes mellitus
- Generalized malignancy
- HIV infection
- Hodgkin disease
- Iatrogenic immunosuppression[2]
- Leukemia
- Lymphoma
- Multiple myeloma
- Sickle cell disease, other hemoglobinopathy
- Solid organ transplant

[1] Including B- (humoral) or T-lymphocyte deficiency, complement deficiencies, and phagocytic disorder (excluding chronic granulomatous disease)

[2] Diseases requiring treatment with immuno-suppressive drugs, including cancer chemotherapy, long-term systemic corticosteroids, cytokine inhibitors, tumor necrosis alpha factor inhibitors, and radiation therapy

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 a vaccine component including
- Any diphtheria toxoid-containing vaccine: **PCV15 AND PCV20**.
  - *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-D (Menactra) and PCV15 or PCV20 should not be administered simultaneously; PCV15 or PCV20 should be administered first and MenACWY-D (Menactra) administered 4 weeks later. Note: this guidance does NOT apply to MenACWY-CRM (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) and obtain consent.***
   - Review the vaccination information with the patient.
   - 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.*
   - ***BOP Immunization Consent Form (BP-A0808):***
     - Document the publication date of the VIS.
     - Have the patient sign consent or declination and date form.
     - The person administering the immunization signs and dates the form.
     - Scan the signed consent form (BP-A0808) for each administered or declined dose into the Document Manager of the patient electronic health record.

5. ***Administer PCV and/or PPSV23 vaccine:***
   - ***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 PCV and PPSV23 at the same visit.*** If both the PCV15 and PPSV23 are recommended, the PCV15 is administered first, and the PPSV23 is administered either 1 year later (routine) or 8 weeks later (for certain medical or risk conditions). If PPSV23 was given previously, administer PCV15 (or PCV20) ***at least*** one year after the most recent PPSV23. See Table 1 above.
   - Shake PCV15 or PCV20 vigorously prior to administration.
   - PCV15 and PCV20 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.*
     - 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 taut, 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 patient vaccine administration information in the patient electronic health record:***
   - Record the vaccine location, the manufacturer and lot number, dosage and route, dose number (if applicable), expiration date, and provider. Upon exiting, do not forget to save the immunization flow sheet data.
     - Use comment section to clarify which pneumococcal vaccine is given (PCV or PPSV23).
     - If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).

7. Scheduling additional doses of vaccine

- Schedule the subsequent vaccinations in the electronic health record at the time of the initial vaccine dose.
- Using BEMR scheduler is the preferred method to schedule subsequent vaccine doses.

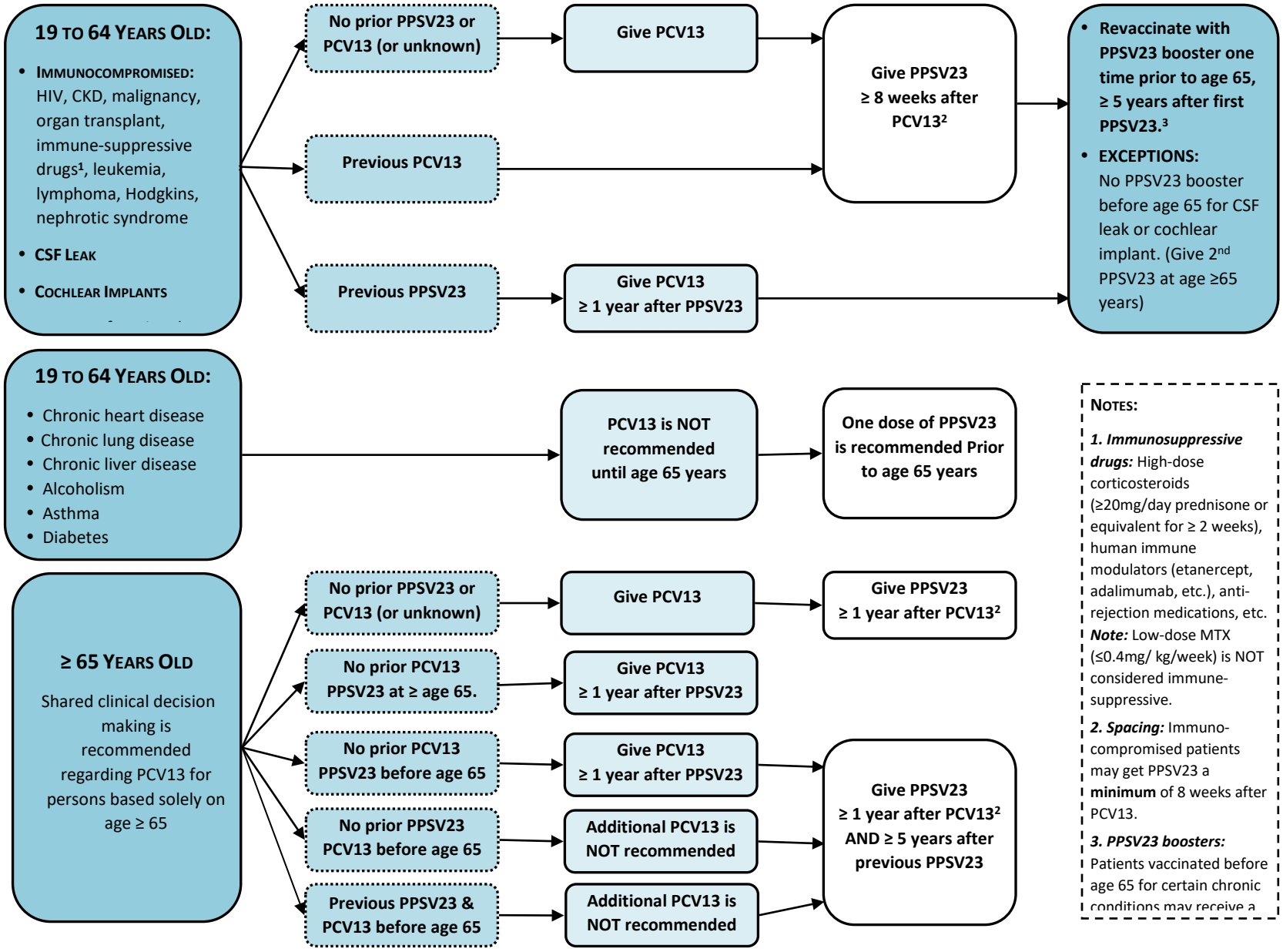
8. ***Medical Emergency or Anaphylaxis:*** Rash, difficulty breathing, itchy throat, bodily collapse, swollen tongue or throat.

- In the event of a medical emergency related to the administration of a vaccine, ***immediately call a medical emergency.***
- ***Epinephrine 1:1000 (i.e., 1 mg/mL) dilution and respiratory support should be immediately available.***

9. 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.

C. 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 health care 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:***
   - Adults who have not previously received a vaccination series for tetanus, diphtheria, or pertussis.
   - Lack of documentation or history of receipt of Tdap vaccine as an adult or adolescent with complete prior immunization against tetanus and diphtheria: Administer Tdap followed by a Td or Tdap 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:** A history of a serious systemic reaction (e.g., anaphylaxis) to a previous dose of any diphtheria toxoid-, tetanus toxoid-, or pertussis antigen-containing vaccine or to a vaccine component.
     - ***Do not give Tdap to a person who has experienced encephalopathy within 7 days following pertussis-containing vaccines,*** not attributable to another identifiable cause.
     - Tdap vaccines may contain **latex** in pre-filled syringe tip caps: **ADACEL® and BOOSTRIX®.**
       - *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:**
     - ***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 toxoid- or diphtheria toxoid-containing vaccine. In such cases, defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine.
     - ***A 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.
   - 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.*
   - ***BOP Immunization Consent Form (BP-A0808):***
     - Document the publication date of the VIS.
     - Have patient sign consent or declination and date form.
     - The person administering the immunization signs and dates the form.
     - Scan the signed consent form (BP-A0808) for each administered or declined dose into the Document Manager of the patient electronic health record.

5. Administer Tdap or Td vaccine[1]:

HISTORY/CONDITION	VOLUME	ROUTE	SCHEDULE	CONTRAINDICATIONS OR PRECAUTIONS
Not previously vaccinated against tetanus, diphtheria, or pertussis.	0.5 mL	IM	• Give 1 dose Tdap, then 1 dose Td or Tdap at least 4 weeks later, and another Td or Tdap dose 6-12 months after last dose. • Tdap can be substituted for any Td dose but is preferred for the first dose. • Give Td or Tdap booster every 10 years.	**CONTRAINDICATIONS:** • Severe allergy to any diphtheria toxoid-, tetanus toxoid-, or pertussis antigen-containing vaccine. • **Tdap only:** Previous encephalopathy post-vaccine. **PRECAUTIONS:** • History of GBS within 6 weeks of receipt of tetanus toxoid-containing vaccine. • Hypersensitivity. • Acute illness. • **Tdap only:** Unstable neurologic disorder, uncontrolled seizures, or progressive encephalopathy.
No adult or adolescent history of Tdap, either documented or self-reported.	0.5 mL	IM	• Give 1 dose Tdap, then Td or Tdap booster every 10 yrs.	
Documented history of adult Tdap vaccine, no Td booster within last 10 years.	0.5 mL	IM	• Give one dose Td or Tdap every 10 years.	
Each pregnancy, regardless of history.	0.5 mL	IM	• Give 1 dose Tdap **during each pregnancy**, preferably at 27–36 weeks of gestation.	
Clean, minor wound and no documented history of Td or Tdap in last 10 years.	0.5 mL	IM	• Give 1 dose, Tdap preferred.	
All other wounds with no documented history of Td or Tdap in last 5 years: *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. • Give 1 dose of tetanus immune globulin at same time as vaccination to persons who: • Are unvaccinated, • Have not received a primary series of tetanus toxoid-containing vaccines, or • Have HIV infection or severe immunodeficiency regardless of vaccination history.	

[1] **Tdap vaccines:** Adacel® (Sanofi)– Age 11–64 years; Boostrix® (GSK) all adults

Td: TdVax® (Grifols) all adults; TENIVAC® (Sanofi) 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.
- 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.*
  - 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 taut, 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 patient electronic health record:

- Record the vaccine administration location, the manufacturer and lot number, dosage and route, dose number (if applicable), expiration date, and provider. Upon exiting, do not forget to save the immunization flow sheet data.
  - If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).

7. Scheduling additional doses of vaccine

- Schedule the subsequent vaccinations in the electronic health record at the time of the initial vaccine dose.
- Using BEMR scheduler is the preferred method to schedule subsequent vaccine doses.

8. 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 (i.e., 1 mg/mL) dilution and respiratory support should be immediately available.***

9. 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 health care professionals, as defined by scope of duty, may vaccinate adults who meet the indications below for the varicella live vaccine (VAR).

➔ ***Vaccine must be approved through the non-formulary process prior to administration.*** *It is administered rarely, on a case-by-case basis and in varicella exposure situations but only after consultation with the Regional/Central Office.*

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

1. ***Identify persons in need of vaccination:*** The patient has been exposed to varicella, does not have evidence of varicella immunity, and a determination has been made in consultation with the Regional/Central Office that varicella vaccination is indicated.
   - Vaccine administered within 3 days of exposure to rash is most effective in preventing disease (≥90%); however, vaccine administered within 5 days of exposure to rash is approximately 70% effective in preventing disease and 100% effective in modifying disease.
   - To limit disease transmission during an outbreak and to provide protection against subsequent exposures, all persons without evidence of immunity to varicella should be offered vaccine even if more than 5 days have passed since first exposure to the disease
   - 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:** A history of a serious reaction (e.g., anaphylaxis) to a prior dose of the vaccine or to a vaccine component (e.g., neomycin or gelatin).
     - ***Pregnancy:*** 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).

(list continues on next page)

- ***Severe immunodeficiency***, including hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised [CD4 percentage ≥15% or CD4 count <200 cells/mm^3]).
- ***Individuals receiving high-dose systemic steroids*** (e.g., two weeks or more of daily receipt of ≥20 mg [or ≥2 mg/kg body weight] of prednisone or equivalent).
- ***Family history of altered immunocompetence*** unless verified clinically or by laboratory testing as immunocompetent.

➔ *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:**
  - Recent (within the past 11 months) receipt of antibody-containing blood product. For recommended intervals, see package insert and/or Tables 3-5 and 3-6 of the ACIP guidelines: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf
  - Administration of antiviral drugs against the herpesvirus family (e.g., acyclovir, famciclovir, or valacyclovir) may interfere with the vaccine – avoid vaccination within 24 hours of use; also, avoid use of these antiviral drugs for 14 days after vaccination.
  - 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.
- 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.*

- BOP Immunization Consent Form (BP-A0808):
  - Document the publication date of the VIS.
  - Have patient sign consent or declination and date form.
  - The person administering the immunization signs and dates the form.
  - Scan the signed consent form (BP-A0808) for each administered or declined dose into the Document Manger of the patient electronic health record.

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

- ***Before reconstitution:***
  - ***Lyophilized (freeze-dried) vaccine:***
    - ***Store in a freezer*** (−58°F to +5°F; −50°C to −15°C).
    - May be stored in a refrigerator (36°F to 46°F; 2°C to 8°C) for up to 72 continuous hours prior to reconstitution.

      ➔ *Discard if not used within 72 hours after removal from freezer.*
  - Protect from light.

- ***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. ***Do not freeze the diluent.***
- ***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 the withdrawn diluent into the vial of lyophilized vaccine, and gently agitate to mix thoroughly and dissolve completely.
- VARIVAX®, when reconstituted, is a clear, colorless to pale yellow liquid.
- ***After reconstitution:*** Withdraw the entire amount of reconstituted vaccine into a syringe and inject the total volume (approximately 0.5 mL) 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 upper outer triceps area.	2-dose series. Separate doses by at least 4 weeks.	• **Do not give** if history of serious reaction (e.g., anaphylaxis) to previous vaccine dose or vaccine components (neomycin, gelatin). • **Contraindications:** Pregnancy, severe immunodeficiency (e.g., chemotherapy, CD4 <200, 2 weeks or more of 20 mg prednisone or equivalent), family history of altered immunocompetence unless verified otherwise. • **Precautions:** Defer for 11 months after antibody-containing blood products (see vaccine insert), or receipt of antiviral drugs against the herpes virus family 24 hours before or 14 days after vaccination. • **Can administer same day** as MMR, TST, or IGRA *OR* wait 4 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 upper outer triceps area.	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.
- Give vaccine subcutaneously (23-25g, 5/8" needle) in the fatty tissue over triceps.

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

- Observe a minimum interval of at least 4 weeks between doses, if a 2-dose vaccine series is needed.
- Do not restart the vaccine series if the second dose is given more than 4 weeks later.
- ***Simultaneous vaccinations and procedures:***
  - ***A tuberculin skin test (TST) can be administered before or at the same time as the varicella vaccine.*** HOWEVER, if they are not given concurrently, do NOT give the TST until 4 weeks after the varicella vaccine as live attenuated viral vaccines, such as varicella vaccine, can result in suppression of the TST or a false negative result. Similarly, interferon gamma release assay (IGRA) testing (i.e., QuantiFERON-G® or T-Spot®) can be obtained concurrently with varicella vaccination or be obtained 28 days AFTER the varicella vaccine.
  - If needed, administration of two or more live vaccines (e.g., varicella and MMR) should either be given at the same visit or separated by at least 4 weeks.
  - Varicella vaccine may be administered simultaneously with other vaccines but at different anatomic sites and not combined in the same syringe.

6. Document patient vaccine administration information in the patient electronic health record:

- Record the vaccine administration location, the manufacturer and lot number, dosage and route, dose number (if applicable), expiration date, and provider. Upon exiting, do not forget to save the immunization flow sheet data.
  - ***If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).***

7. Scheduling additional doses of vaccine

- Schedule the subsequent vaccinations in the electronic health record at the time of the initial vaccine dose.
- Using BEMR scheduler is the preferred method to schedule subsequent vaccine doses.

8. 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 (i.e., 1 mg/mL) dilution and respiratory support should be immediately available.***

9. 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 health care professionals, as defined by scope of duty, may vaccinate adults who meet the indications below for **the recombinant zoster vaccine (RZV), Shingrix®.**

1. ***Assess adults for need of vaccination against the herpes zoster virus with RZV based on the following indications:***
   - Immunocompetent individuals 50 years and older, regardless of previous herpes zoster or history of vaccination with the live zoster vaccine (ZVL, Zostavax®).
   - Persons aged 19 years and older who are or will be immunodeficient or immunosuppressed because of disease or therapy.

2. ***Screen patients for contraindications and precautions.***
   - **CONTRAINDICATIONS:** A history of a serious reaction (e.g., anaphylaxis) after a previous dose of vaccine or to a 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:**
     - ***Pregnancy and lactation:*** Due to lack of data, delay vaccination during pregnancy and lactation.
     - Current herpes zoster infection.
     - A moderate or severe acute illness, with or without fever.

3. ***Provide all patients with a copy of the most current Vaccine Information Statement (VIS) and obtain consent.***
   - Review the vaccination information with the patient.
   - 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.*

- ***BOP Immunization Consent Form (BP-A0808):***
  - Document the publication date of the VIS.
  - Have the patient sign consent or declination and date form.
  - The person administering the immunization signs and dates the form.
  - Scan the signed consent form (BP-A0808) for each administered or declined dose into the Document Manager of the patient electronic health record.

4. ***Safe handling and use of RZV:***
   - ***Before reconstitution:*** Store both vials (lyophilized varicella zoster vaccine and adjuvant suspension) together in the refrigerator (36°F to 46°F; 2°C to 8°C).
     - *Adjuvant suspension has blue-green cap and red ring; antigen has brown cap and green ring and is a powder.*
     - **DO NOT FREEZE.** Discard if vials have been frozen**.**
     - **Protect vials from light.**
   - ***To reconstitute the vaccine***, first withdraw the total volume of provided adjuvant suspension into a syringe (use only the adjuvant suspension supplied)
     - Inject all the withdrawn adjuvant suspension into the vial of lyophilized vaccine, and gently swirl to mix thoroughly and dissolve completely. Do NOT shake vigorously.
     - When reconstituted, the vaccine is an opalescent, colorless to pale brownish liquid.
   - ***After reconstitution:*** Administer vaccine intramuscularly (0.5 mL) immediately or store in refrigerator for up to six hours (label appropriately).
     - ***DISCARD the reconstituted vaccine if it is not used WITHIN SIX HOURS.***
     - ***DO NOT FREEZE.*** Discard if the vaccine has been frozen***.***

5. ***Administer herpes zoster vaccine:***
   - ***To prevent syncope***, have patient sit or lie down for vaccination and consider observing the patient for 15 minutes after receipt of the 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.*
     - 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 taut, and the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

(Administration table on next page)

INDICATION	VOLUME	ROUTE	SCHEDULED	CONTRAINDICATIONS/NOTES
Immunocompetent adults ≥ 50 years old, regardless of previous herpes zoster or history of vaccination with ZVL.	0.5 mL	IM	2-dose series • Separate doses 2-6 months apart. • Minimum interval 4 weeks.	• **DO NOT GIVE** if history of serious reaction (e.g., anaphylaxis) to previous vaccine dose or vaccine components. • **PRECAUTIONS:** • **Pregnancy and lactation.** • **Current herpes zoster infection.** • Moderate/severe acute illness. • **VACCINATE BEFORE IMMUNOSUPPRESSION.** Otherwise, consider timing vaccination when immune response likely to be most robust. • **REPEAT 2ND DOSE IF GIVEN TOO SOON.** • **RECONSTITUTE VACCINE** with accompanying adjuvant suspension. Use immediately or refrigerate up to six hours. ***Discard after six hours.*** • **EXPECTED SIDE EFFECTS**: achiness, tiredness, shivering, fever, headache; local redness, swelling and pain.
Adults ≥ 19 years old who are/will be immunodeficient or immunosuppressed because of disease or therapy.	0.5 mL	IM	2-dose series • Separate doses 2-6 months apart. • 2nd dose may be given 1-2 months after 1st dose, if patient would benefit from a shorter vaccination schedule.	

- ► Provide a subsequent dose of RZV vaccine to complete each patient's 2-dose schedule by observing recommended intervals between the first and second doses.
- ► Do not restart the vaccine series if the second dose is delayed beyond 6 months.

6. Document the patient vaccine administration information in the patient electronic health record:

- ► Record the vaccine administration location, the manufacturer and lot number, dosage and route, dose number, expiration date, and provider. Upon exiting, do not forget to save the immunization flow sheet data.
  - ▪ If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).

7. Scheduling additional doses of vaccine

- ► Schedule the subsequent vaccinations in the electronic health record at the time of the initial vaccine dose.
- ► Using BEMR scheduler is the preferred method to schedule subsequent vaccine doses.

8. ***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 (i.e., 1 mg/mL) dilution and respiratory support should be immediately available.***

9. ***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 (3 PAGES) AGE 19 YEARS AND OLDER – SEE PACKAGE INSERT FOR AGES 18 YEARS AND YOUNGER				
VACCINE	**VOLUME**	**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, pregnancy (Heplisav-B only). • Higher dosing for dialysis patients. • Alternative dosing schedule option for immunocompromised, 1st series non-responders (including HIV infected persons).
HepA-HepB Combination **(Twinrix)**	1 mL	IM	Deltoid	• *Contraindications*: Severe allergy to yeast or neomycin. • Stopper cap may contain latex.
Haemophilus influenza type b **(Hib)**	0.5 mL	IM	Deltoid	• Reconstitute prior to use • ***Store vaccine and diluent vials in refrigerator***. • ActHIB® and Hiberix® are interchangeable.
9-valent Human Papillomavirus **(9vHPV)**	0.5 mL	IM	Deltoid	• *Contraindication:* Severe allergy to yeast. • *Precaution:* Vaccination not recommended during pregnancy.
Influenza: Inactivated quadrivalent (**IIV4**); adjuvanted inactivated quadrivalent (**aIIV4**); cell-based inactivated quadrivalent (**ccIIV4**); high dose inactivated quadrivalent (**HD-IIV4**); recombinant **(RIV)**; live attenuated influenza vaccine (**LAIV**)	0.5 mL	IM	Deltoid	• High dose and adjuvant vaccines are for age 65 years and older *only*. • RIV and ccIIIV4 vaccines are the only influenza vaccine that is egg-free. • Adjuvanted vaccine is formulated with an ingredient (squalene) to create a stronger immune response.
Measles, Mumps, Rubella; live **(MMR)**	0.5 mL	SQ	Triceps	• ***Live vaccine***; reconstitute prior to use. • ***Store vaccine in freezer or refrigerator (keep in refrigerator prior to reconstitution). Store diluent in refrigerator or keep at room temperature.*** • *Contraindications:* Pregnancy, immunodeficiency. • Can administer same day as TST or wait 4 weeks to administer TST. • Screen for receipt of blood products, and history of thrombocytopenia or seizures.

ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE (3 PAGES) AGE 19 YEARS AND OLDER – SEE PACKAGE INSERT FOR AGES 18 YEARS AND YOUNGER				
VACCINE	**VOLUME**	**ROUTE**	**INJECTION SITE**	**KEY POINTS – SEE MODULES FOR COMPLETE INFORMATION**
Meningococcal Conjugate **(MenACWY** [Menactra® or Menveo®]**)**	0.5 mL	IM	Deltoid	• **Menveo® only:** reconstitute prior to use with proper diluent containing CWY antigens. • ***Store vaccine and diluent vials in refrigerator***. • *Contraindications:* Severe allergies to diphtheria toxoid or CRM (a diphtheria toxin carrier protein applicable to Menveo® only) and to tetanus toxoid (MenQuadfi® only). • *Precautions:* Pregnancy, GBS (Menectra® only). • Booster doses: Administer booster dose every 5 years if risk remains. • **Menactra® only:** Do not administer with PCV15 or PCV20. Administer PCV first and Menactra® 4 weeks later.
Meningococcal serogroup B **(MenB** [Bexsero® or Trumenba®]**)**	0.5 mL	IM	Deltoid	• *Precautions*: Pregnancy, latex (Bexsero® only). • Bexsero® and Trumenba®: Brands are NOT interchangeable; start and finish MenB series with same brand. • Booster doses: Administer booster dose 1 year after primary series and every 2-3 years if risk remains.
Pneumococcal conjugate **(PCV15 and PCV20)**	0.5 mL	IM	Deltoid	• *Contraindication:* Severe allergy to diphtheria toxoid-containing vaccines • Scheduling concerns: • Do *NOT* administer PCV and PPSV23 at same visit. • If both PCV15 and PPSV23 are recommended, PCV15 is given first, followed by PPSV23 1 year later. • If only PPSV23 received previously, administer PCV 15 or PCV20 1 year later. • If PPSV23 and PCV13 received in past, complete previously recommended PPSV23 series **OR** administer PCV20. • Do *NOT* administer PCV and Menactra® (MenACWY-D) at same visit. Administer PCV first, followed by Menactra® 4 weeks later.
Pneumococcal polysaccharide **(PPSV23**)	0.5 mL	IM or SQ	Deltoid IM *or* Triceps SQ	• Scheduling concerns: • Do *NOT* administer PPSV23 and PCV at same visit. • If both PCV15 and PPSV23 are recommended, PCV15 is given first, followed by PPSV23 1 year later. • If PPSV23 and PCV13 received in past, complete previously recommended PPSV23 series **OR** administer PCV20.

ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE (3 PAGES)

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

VACCINE	VOLUME	ROUTE	INJECTION SITE	KEY POINTS – SEE MODULES FOR COMPLETE INFORMATION
Varicella, live **(VAR)**	0.5 mL	SQ	Triceps	• ***Live vaccine;*** reconstitute prior to use. • ***Store vaccine in freezer, diluent in refrigerator.*** • *Contraindications:* Severe allergy to neomycin or gelatin, severe immunodeficiency, pregnancy, family history of altered immunocompetence unless verified as immunocompetent • *Precautions:* History of recent antiviral use against the herpes virus family, recent use antibody products.
Recombinant Zoster **(RZV)**	0.5 mL	IM	Deltoid	• Reconstitute prior to use. • ***Store vaccine and diluent vials in refrigerator***. • *Precaution:* Pregnancy, breastfeeding, current herpes zoster infection. • 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 130–152 lbs.	1" length needle
Male 152-260 lbs.	1-1½" length needle
Male 260+ lbs.	1½" length needle

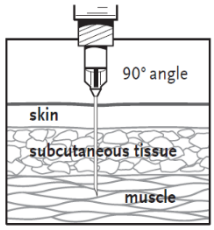
* A 5/8" needle may be used for patients who weigh less than 130 lbs (60 kg) for injection in the deltoid muscle, *only* if the skin over the deltoid is stretched taut, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

FOR SUBCUTANEOUS (SQ) INJECTIONS

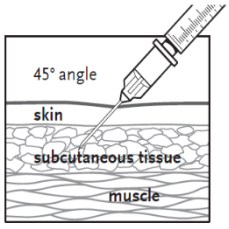
Administer SQ (or Subcut) injections in the fatty tissue overlying the triceps muscle, with a 23–25 gauge needle, 5/8" in length.

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 vaccine should be reviewed, as well. Access the ACIP recommendations at *http://www.immunize.org/acip/*.

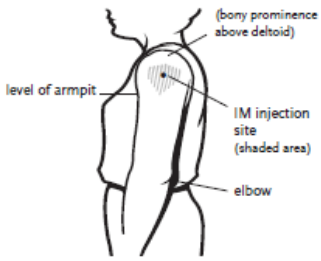
Intramuscular (IM) injection



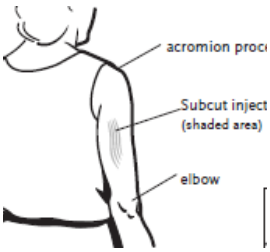
Subcutaneous (Subcut) injection



Deltoid



Triceps



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.

- *A single exposure to freezing temperatures (0° C [32° F] or colder) can destroy vaccine potency if it is not meant to be at freezing temperatures.*

Proper storage and handling begin with an effective vaccine cold chain.

A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. The cold chain begins with the cold storage unit at the manufacturing plant, extends to the transport and delivery of the vaccine, through to correct storage at the provider facility, and finally ends with administration of the vaccine to the patient.

- *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 proper 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** is a unit specifically designed to either refrigerate or freeze vaccines, sometimes referred to as **PURPOSE-BUILT** or **PHARMACEUTICAL-GRADE** unit. These units can be either compact, under-the-counter-style, or large units. These units often:*
   - Have microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistance temperature detector [RTD], or thermistor).
   - Have fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperatures.
   - Have built-in digital data loggers with electronic interfaces that allow tracking of continuous temperatures and/or provide min/max temperatures.
   - ***Note:*** Water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer's guidance.
   - Use safeguards to ensure the doors of the unit remain closed (e.g., self-closing door hinges, door alarms, door locks).

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, even when used for temporary storage.*
   - ***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 on the top shelf and 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).

C. USING VACCINE STORAGE BEST PRACTICES

1. **Use the pharmacy inventory management system to account for and document vaccine inventory.**
2. **Store vaccines in their original packaging, with lids closed to protect them from light.**
3. Whenever possible, store diluent with the corresponding refrigerated vaccine. **Never store any diluent in a freezer.**
4. Attach labels to shelves and containers to clearly identify where each type of vaccine and diluent is stored. 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).*
5. 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.
6. 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.*
7. Place vaccines and diluents with the earliest expiration dates in the front of those with later expiration dates in the storage unit.
   - *Vaccine stock should be rotated and checked for expiration dates weekly (document on Vaccine Refrigerator Temperature Log).*
8. Prevent refrigerator and freezer temperature fluctuations:
   - Plug in only one storage unit per electrical outlet.
   - 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!***"

(list continues on next page)

- Label all vaccine storage plugs: "***Do NOT unplug unit!"***
- Sample warning signs are available in the CDC's ***Vaccine Storage and Handling Toolkit***, at: *https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf*.

9. 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***.)

10. 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 (including each transport 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 2-3 years or according to the manufacturer's suggested timeline.

1. ***The CDC recommends that DDLs have the following characteristics***:

- 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. ***If not using a continuous temperature control monitor, 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 details 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 because of the excursion:
   - Chronology of what was done with the vaccines, including the time frame, and how long it took to act (e.g., *"Vaccine temperature alarm at 0800 and placed in pharmacy fridge at 0815."*).
   - Who 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 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 or freezer 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 are always equal amounts of vaccines and diluents for reconstitution. Follow the manufacturer's guidance for specific temperature requirements.
   - The total time for transport plus clinic workday should be a maximum of 8 hours, unless guidance from the manufacturer differs.

2. ***Key Points For emergency transport or storage:*** Hard-sided coolers or Styrofoam vaccine shipping containers can be used for transport of refrigerated vaccines. Do NOT use soft-sided collapsible 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 39°F to 41°F (4°C to 5°C) are available commercially and 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 ADMINISRATION

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 (2 PAGES)				
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.
SCREENING/PREPAREDNESS				
				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.
				Knows to use a new consent/declination form for each vaccine dose if series given.
				Can initiate CPR and maintain airway; locates epinephrine and knows how to administer.
				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 and Vaccine Procedure Module.
				Knowledgeable of the appropriate route, site, vaccine type and dose, and the type of syringe safety device being utilized (glide, snap or retraction device) for each vaccine.
				Washes or disinfects hands before and in-between patient encounters. *If gloves are worn, they are changed, and hand hygiene performed between patients.*
				Cleans the vaccine vial top with alcohol prior to withdrawing dose.
				Appropriately positions patient for vaccination.

SKILLS CHECKLIST FOR VACCINE ADMINISTRATION (2 PAGES)				
SELF-ASSESSMENT		SUPERVISOR/ PRECEPTOR REVIEW		SKILLS
Needs to Improve	Meets or Exceeds	Needs to Improve	Meets or Exceeds	
ADMINISTERING VACCINES (CONTINUED)				
				Properly preps the injection site with an alcohol wipe and allow to dry.
				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				
				Ensures the consent/declination form is signed, and the current VIS date is documented.
				Documents each vaccine dose in the appropriate place (BEMR, consent forms) including: date, lot number, manufacturer, site, VIS date, name/initials.
				Documents specific vaccine information in comments (e.g., age 65, quadrivalent flu vaccine, HepB #1 of 2 or 3 doses).
				Ensures any future appointments are added to the BEMR scheduler.
				Can properly document a vaccine adverse event (AE) in VAERS and identifies which health care personnel to notify in the case of an AE.

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)	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		
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**

VACCINE STORAGE UNIT INFORMATION*			
TYPE OF UNIT (REFRIGERATOR OR FREEZER)	**BRAND**	**MODEL NUMBER**	**SERIAL NUMBER**
1.			
2.			
3.			
4.			
5.			
* Keep this information 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
- **Dynavax**
  1-844-375-4728

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

If not using a continuous temperature control monitor, manually record refrigerator and freezer temperatures at least twice each workday. 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.

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.