IMMUNIZATION

Federal Bureau of Prisons

Clinical Guidance

December 2025

WHAT'S NEW IN THIS DOCUMENT

This guidance updates the Influenza and COVID-19 Vaccine modules in the December 2024 version and expands sources used in determining BOP clinical vaccine guidance. The following major changes were made to this guidance:

- Adult vaccination recommendations from professional medical organizations and BOP data were considered in addition to those of the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).
- Updated links to external resources to the most currently available publications.
- Influenza Vaccine Module: Afluria® and Fluad® vaccines are the 2025-2026 contract vaccines with highlights of prescribing information about both provided.
- COVID-19 Vaccine Module: The priority list for vaccine administration has been changed to better reflect BOP-specific risk factors.

ABOUT THIS DOCUMENT

The goal of this Clinical Guidance is to provide a comprehensive, user-friendly document containing 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 patients.

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 and 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 vaccines 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 VACCINES: 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 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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List of Abbreviations

PRINTING FROM THE PDF VERSION

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Click on any of the following links to go to that topic.

LIST OF ABBREVIATIONS

HAV	Hepatitis A virus
HBV	Hepatitis B virus
HepA	Hepatitis A vaccine
HepA-HepB	Combined hepatitis A and hepatitis B vaccine
HepB	Hepatitis B vaccine
HepB-CpG	Hepatitis B vaccine, CpG-adjuvanted
Hib	*Haemophilus influenzae* type b
HPV	Human papillomavirus
9vHPV	9-valent Human papillomavirus vaccine
IIV	Inactivated influenza vaccine
IIV3	Inactivated influenza vaccine, trivalent
ccIIV3	Cell-culture inactivated influenza vaccine, trivalent
HD-IIV3	High-dose, inactivated influenza vaccine, trivalent
aIIV	Adjuvanted inactivated influenza vaccine
aIIV3	Adjuvanted inactivated influenza vaccine, trivalent
LAIV	Live, attenuated influenza vaccine
LAIV4	Live, attenuated influenza vaccine, quadrivalent
MenACWY	Meningococcal conjugate vaccine, serogroup A, C, W, and Y
MenB	Meningococcal vaccine, serogroup B
MenABCWY	Meningococcal vaccine, serogroup A, B, C, W, and Y
MMR	Measles, mumps, and rubella
PCV7, 13, 15, 20, or 21	Pneumococcal conjugate vaccine, 7-valent, 13-valent, 15-valent, 20-valent, or 21-valent
PPSV23	Pneumococcal polysaccharide vaccine, 23-valent
RIV	Recombinant influenza vaccine
RIV3	Recombinant influenza vaccine, trivalent
RSV	Respiratory syncytial virus
RZV	Recombinant zoster vaccine
Td	Tetanus and diphtheria toxoid
Tdap	Tetanus and reduced diphtheria toxoid, and acellular pertussis
TIG	Tetanus immune globulin
VAR	Varicella vaccine
VIS	Vaccine Information Statement
ZVL	Zoster vaccine live

CHAPTER 1. OVERVIEW AND KEY PRINCIPLES

A. GOAL OF THE BOP IMMUNIZATION PROGRAM

The goal of the BOP immunization program is to decrease vaccine-preventable disease burden in the BOP by adhering to the following objectives:

- Screen patients for immunization indications, as defined in this Clinical Guidance.
- Administer vaccines in accordance with indications.
- Minimize adverse events through health care provider awareness of vaccine contraindications and precautions.
- Store and handle vaccines 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 patients 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 and Control Committee, annually determine priorities for vaccination in each facility.

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

- Schedule administration of preventive vaccines during clinic visits when the need for vaccination is noted (e.g., during the mandatory history and physical examination performed within 14 days of arrival at a facility or during preventive health and chronic care clinic visits).
- Develop a template to be used during clinic visits that summarizes a patient's vaccine administration history, for example:
  - Last tuberculin skin test (TST)
  - Last influenza
  - Last COVID-19
  - PCV15
  - PCV21
  - PPSV23
  - Tdap
  - MMR
  - HepA
  - HepB
  - HPV
  - 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 patients 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 assessing vaccine indications for adults with unknown vaccination histories. For inmates who received vaccinations elsewhere (i.e., not in the BOP):

- Enter vaccination information into BEMR as "History of" along with 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 and recommends single booster doses of MMR and Tdap. Regardless of vaccination history, a dose of Tdap is also recommended in the third trimester of each pregnancy.

3. Using Vaccine Procedure Modules

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

It is recommended that the institution Infection Prevention and 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 vaccines 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 protocol updates and updates to these vaccine procedure modules. The influenza vaccine module will be updated annually by the Health Services Division.

- ***Unless otherwise stated, 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 ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, the package inserts, and a local pharmacist.*

4. Health Care Provider Education

- It is recommended that health care workers who are responsible for administration of vaccinations be educated at an initial orientation and whenever vaccines or vaccine procedures change.
- The following chapters can be used for health care worker education:
  - *Chapter 3. Vaccine Procedure Modules* covers in detail the indications, contraindications, precautions, administration, reporting of adverse effects, and documentation procedures for specific vaccines.
  - *Chapter 4. Administering Vaccines: Dose, Route, Site, and Needle Size* is useful as a quick reference tool for vaccine administration.
- The **Skills Checklist for Vaccine Administration** is available as *Attachment 1*.
- Additional training resources can be found in this chapter, under *Section 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.

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*.
  - Translations of VISs into languages other than English are available from the Immunization Action Coalition at *https://immunize.org/*.
  - *If a VIS is not available, provide the Emergency Use Authorization Fact Sheet to patients each time a vaccine dose is administered.*

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. Persons administering vaccines should be familiar with identifying severe allergic reactions, including anaphylaxis, and be competent in responding to these events. Nurses and paramedics should refer to current protocols, available on *sallyport.bop.gov/co/hsd/nurse/Policyguidance.jsp*.

See Chapter 1, Section 4. Managing Adverse Reactions.

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. Multi-dose vials to be used for more than one patient should not be kept or accessed in the immediate patient treatment area. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment that could then lead to infections in subsequent patients.
- Prepare vaccines in a clean, designated medication area away from where the patient is being vaccinated and away from any potentially contaminated items. This is 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 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 (for example, with the contents of one multi-dose vial) may be considered with appropriate precautions:
        - Individually label prefilled syringes or place them in a labeled tray and store them at the proper temperature.
        - Doses should be administered 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.
- To 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/injection-safety/hcp/clinical-safety/?CDC_AAref_Val=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 processes 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

Health care providers must navigate several issues when vaccinating patients, including screening for contraindications and precautions, correctly timing each dose, determining 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* https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf.

1. Contraindications and Precautions

Contraindications and precautions generally dictate circumstances when vaccines should not be given. Some contraindications and most precautions are temporary, and the vaccine can be given at a later time.

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

Contraindications are conditions that increase the risk of 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 of a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity. In general, vaccination 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 uses, as well as the vaccines that contain each component, is available from the CDC: https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html. An allergen identified in a 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 can be accomplished with a few questions, depending on the potential precautions and contraindications for the vaccine being administered.

- *Routine physical examinations and procedures (e.g., measuring temperature) 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, any vaccine, or latex?
- Have you had a serious reaction to a vaccine in the past?
- Have you ever had a seizure, brain or nerve-related 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 undergone radiation 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 a vaccination in the past 4 weeks?
  - *A sample screening checklist is available at http://immunize.org/catg.d/p4065.pdf.*

1.B. Vaccination Contraindication Misconceptions

- 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 related to vaccination
- Multiple vaccines

1.C. Absolute 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, and 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 vaccines 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 2 or more weeks), HIV infection in patients who are severely immunocompromised (CD4+ T-cell count < 200 cells/mm^3). Live vaccine should be 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 with or without a fever.
- ***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*).

1.E. Egg Allergy

Most influenza vaccines today are produced using an egg-based manufacturing process and contain a small amount of egg protein—a potential cause of an allergic reaction. However, influenza vaccine studies in egg-allergic and non-egg-allergic persons have shown that severe allergic reactions in egg-allergic persons are unlikely. Therefore, additional safety measures (i.e., beyond those recommended for receipt of any vaccine) are no longer recommended for influenza vaccination of persons who are allergic to eggs, regardless of the severity of previous reaction to egg protein.

Irrespective of allergy history and the type of vaccine used, all vaccinations should be administered in a setting in which the personnel and equipment needed for rapid recognition and treatment of allergic reactions are available.

1.F. Latex Allergy

The rubber in vaccine vial stoppers or syringe plungers may be either dry natural rubber latex or synthetic rubber. Those made with latex pose a theoretical risk to latex-allergic patients as a result of liquid vaccine solution extracting latex allergens from the stopper by physical contact or by passing the needle through the stopper and retaining latex allergen in or on the needle.

- ***Contact allergy to latex:*** The most common type of latex hypersensitivity is a delayed type: allergic contact dermatitis. Patients with history of a contact allergy to latex products *can receive* vaccines supplied in vials or syringes that contain dry natural rubber latex or natural rubber latex.
- ***Anaphylactic allergy to latex:*** In general, if a person reports a severe anaphylactic allergy to latex, do not administer vaccines 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 history of allergic reactions to any added substances in vaccines. Additives used in the production of vaccines 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*** to help the vaccine's effectiveness, 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 (e.g., neomycin). Allergies to these substances are rare. Usually, neomycin hypersensitivity manifests as contact dermatitis.
    Example vaccines: Fluarix® (IIV3), 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 or 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® (IIV3, multi-dose)
  - ***Aluminum:*** Aluminum is sometimes added to vaccines to help stimulate a better or more persistent immune response.
    Example vaccines: Bexsero® and Trumenba® (MenB), Td, Tdap

2. Timing and Spacing of Vaccinations

2.A. Age

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

➔ *Age-specific immunization indications are noted in 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 intervals between vaccine doses.

➔ *See the CDC vaccine schedules at https://www.cdc.gov/vaccines/hcp/imz-schedules/?CDC_AAref_Val=https://www.cdc.gov/vaccines/schedules/hcp/index.html. For most patients, refer to the ACIP Adult Immunization Schedule, full version.*

- ***Vaccines should be administered as close as possible to the recommended dosing intervals.*** However, if a vaccine schedule lapses, longer intervals between doses of a multi-dose vaccine generally do 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 lapse in schedule is identified, simply complete the vaccine series.

  Example: If two hepatitis B vaccine doses were given a month apart 1 year ago, do not restart the series. Complete the third hepatitis B vaccine dose and, if indicated, obtain a titer for surface antibody 1 to 2 months later.

- ***In certain situations, it may be necessary to administer multi-dose vaccines at shorter intervals*** 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 guidance in the vaccine package insert.
- ***Vaccine doses administered at less than the recommended minimum interval (if not part of an intentionally 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. The one exception to this rule is as follows:

- *The pneumococcal conjugate disease vaccines (PCVs) and PPSV23 should not be administered simultaneously. See the Pneumococcal Vaccines module in Chapter 3 for guidance*.

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 risk of interference.

- When a live injectable vaccine (e.g., MMR or VAR) or a live attenuated influenza virus 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) vaccines for 3 or more months, depending on the product and dose. Providers should screen potential recipients of live vaccines for recent receipt of blood products.

- *See Tables 3-5 and 3-6 of the ACIP guidelines for recommended intervals: https://www.cdc.gov/vaccines/hcp/imz-best-practices/timing-spacing-immunobiologics.html*.

If a dose of an 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 or Other Assays and Live Vaccines

A tuberculin skin test (TST) may be administered on the same day as a live vaccine (e.g., MMR or VAR), or the TST should be deferred for 28 days after vaccination. These guidelines also apply to obtaining interferon-gamma release assays (IGRAs) such as T-Spot®.TB or QuantiFERON-TB Gold®.

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 because 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 caused by uninhibited growth of the attenuated live virus or bacteria. Vaccines also might be less effective during a period of altered immunocompetence.

Administration of non-live vaccines might best be deferred during a period of altered immunocompetence. In this circumstance, the concern is with vaccine effectiveness and not safety. Vaccination during chemotherapy or radiation treatment should generally be avoided ***EXCEPT for inactivated influenza vaccination.*** The reason for this is that the antibody response might be suboptimal. Patients vaccinated within 14 days 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. However, patients on chemotherapy with anti-B cell antibodies (e.g., rituximab) should wait at least 6 months after therapy before being vaccinated with non-live vaccines. Some experts recommended longer than 6 months for some anti-B cell antibodies.

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 or PCV21 alone), based on increased risk for disease. See the Pneumococcal Vaccines 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 Vaccines module in *Chapter 3* for guidance.

3.B. Antiviral Drugs

- Antiviral drugs used for prophylaxis or treatment of influenza virus infections have no effect on the immune response to inactivated influenza vaccines.
- Antiviral drug use in the setting of live, attenuated influenza (intranasal) vaccine has not been studied. However, antiviral drugs may interfere with the action of the vaccine, because it contains live influenza viruses. In the absence of supporting data, the following recommended intervals between antiviral drug cessation and vaccine administration are based on the half-life of each antiviral agent: 1) 48 hours for oseltamivir and zanamivir, 2) 5 days for peramivir, and 3) 17 days for baloxavir.
- 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 viral or bacterial vaccines or toxoid vaccines.

- ***HPV vaccine, an inactivated vaccine, is not recommended during pregnancy.*** Although HPV vaccines have not been linked to causing adverse pregnancy outcomes or adverse events to the developing fetus among inadvertently vaccinated pregnant women, HPV vaccines have not been studied in pregnant women in clinical trials.
- ***Live vaccines pose a theoretical risk to the fetus.*** Therefore, live attenuated virus and live bacterial vaccines (e.g., MMR, VAR) generally are contraindicated during pregnancy.
  - *Women should avoid conception for 12 months after VAR vaccination, according to the manufacturer, and for 4 weeks after vaccination with other live vaccines.*
- ***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, regardless of any previously received dose of Tdap. Vaccination of the mother generates antibodies that pass from the placenta 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 three-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*** can be generally administered during pregnancy, if indicated. However, the HEPLISAV-B® and PreHevbrio® vaccines are **NOT** recommended during pregnancy due to insufficient safety data.
- ***The HAV, pneumococcal, and meningococcal serogroup ACWY vaccines*** should be considered for pregnant women at increased risk for those infections. However, MenB and MenABCWY should be delayed until after pregnancy unless vaccination benefits outweigh potential risks.

3.D. Hematopoietic Stem Cell Transplantation

A hematopoietic stem cell transplant (HSTC) 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 for these patients is recommended as follows:***

- ***Inactivated influenza vaccine (IIV):*** At least 6 months post-transplant and annually thereafter.
- ***Tdap/Td, HepA, HepB, Hib, pneumococcal vaccines (PCVs and PPSV23), and, if indicated, meningococcal and HPV vaccines:*** At least 6 months post-transplant.
- ***MMR and VAR vaccines:*** At least 24 months post-transplant and only if immunocompetent and with no graft-versus-host disease.
- ***RZV vaccine****:* At least 6–12 months after allogeneic HSCT and at least 3–12 months after autologous HSCT, depending on the timing of discontinuation of prophylactic antiviral therapy (acyclovir, famciclovir, valacyclovir). Vaccination at least 2 months prior to discontinuation is preferred.

4. Managing Adverse Reactions

A vaccine ***adverse event*** is an untoward event that occurs after immunization and that might be caused by either 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 specific vaccines is available in the package insert for each vaccine and from the CDC at https://www.cdc.gov/vaccines/basics/possible-side-effects.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/vac-gen/side-effects.htm.*

➔ *A 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 of injury should they faint.
  - If syncope develops, patients should be assessed for injury and treated, or observed until the symptoms resolve.

4.C. Severe Allergic Reactions

Severe allergic reactions are a common area of 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 severe 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 anaphylaxis.
  - Epinephrine is available as an aqueous 1:1000 (i.e., 1 mg/mL) dilution in ampules, vials of solution, and 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: *https://vaers.hhs.gov/reportevent.html*.

In addition to the 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 two ways to report to VAERS:

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

D. RESOURCES FOR HEALTH CARE PROVIDER VACCINE EDUCATION

- **The CDC Vaccine Storage and 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 credits. Available at*: https://www.cdc.gov/immunization-training/hcp/you-call-the-shots/index.html*.
- **The CDC Immunization Education and Training:** *https://www.cdc.gov/immunization-training/hcp/index.html*.
- **The Immunize.org (formerly Immunization Action Coalition)** website provides information and educational materials for both patients and professionals: *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 *https://www.immunize.org/wp-content/uploads/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/immunization-training/hcp/pink-book-education-series/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

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Centers for Disease Control and Prevention. "Vaccine Storage & Handling Toolkit." Feb 2024: *https://www.cdc.gov/vaccines/hcp/storage-handling/?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html*.

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/pinkbook/hcp/table-of-contents/?CDC_AAref_Val=https://www.cdc.gov/vaccines/pubs/pinkbook/index.html*.

Kroger A., Bahta L., Hunter P. "Best Practices Guidance." *General Best Practice Guidelines for Immunization*. Available at: *https://www.cdc.gov/vaccines/hcp/imz-best-practices/?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html*. Accessed May 27, 2024.

The following may be of particular interest to providers:

- 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. Appendix A, ACIP Timing and Spacing Guidelines for Immunization: Timing and Spacing of Immunobiologics, Table 3-6. Recommended intervals between administration of antibody-containing products and measles- or varicella-containing vaccine, by product and indication for vaccination. Available at: *https://www.cdc.gov/vaccines/hcp/imz-best-practices/timing-spacing-immunobiologics.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html*. Accessed December 13, 2024.
- 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. Appendix A, ACIP Contraindications Guidelines for Immunizations: Contraindications and Precautions. Available at: *https://www.cdc.gov/vaccines/hcp/imz-best-practices/contraindications-precautions.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html*. Accessed December 13, 2024.
- Immunize.org. Quick Chart of Vaccine-Preventable Disease Terms in Multiple Languages. Available at: *https://www.immunize.org/wp-content/uploads/catg.d/p5122.pdf*. Accessed December 13, 2024.
- Centers for Disease Control and Prevention. *Vaccine by age.* Available at: *https://www.cdc.gov/vaccines/by-age/index.html*. Accessed December 13, 2024.
- Immunize.org. Vaccine Manufacturers: Contact and Product Information. Available at: https://www.immunize.org/clinical/external/manufacturers/. Accessed December 13, 2024.

CHAPTER 2. BOP IMMUNIZATION INDICATIONS

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

- ***For more information about the use of these vaccines in the BOP, see the vaccine procedure modules in CHAPTER 3. (The numbers above and in the chart correspond to the module numbers.)***
- ***Unless stated otherwise, 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 ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, package insert, and the local pharmacist.***
- ***For CDC vaccine recommendations based on age, see:*** *https://www.cdc.gov/vaccines/by-age/index.html*.

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER* * For persons aged 18 years or younger, consult the ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, pharmacist and package inserts.		
VACCINE	**INDICATION FOR VACCINE**	**KEY POINTS**
1. HEPATITIS A (HEPA)	**HepA is indicated for individuals with any of the following RISK FACTORS *and* no documented history of HepA or positive laboratory titer:** • Sexual exposure risk (i.e., men who have sex with men). • 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. **EXPOSURES:** See post-exposure information in **SECTION C** of Vaccine Procedure Module 1 (HepA).	**AT SCREENING VISIT:** Determine risk and immunity or vaccine history related to HAV. **NO DOCUMENTED OR KNOWN HISTORY OF VACCINE:** • Administer on a 2-single-dose schedule of 0 and 6 months. **DOCUMENTED HISTORY OR KNOWN HISTORY OF 1 DOSE:** • Administer 1 dose. **GENERAL:** • The two HAV vaccines (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 the Twinrix® vaccine. • Twinrix® vaccine is not recommended for outbreak or post-exposure vaccination to HAV. • 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. **FOREIGN-BORN INMATES:** • Consider pre-screening for HAV immunity prior to vaccination.
2. HEPATITIS B (HEPB)	**HepB is indicated for the following individuals unless they have a documented history of a HepB series or positive HBsAb or HBsAg laboratory titer:** • Age 19–59 years • Age ≥ 60 years, if incarcerated ★ **IMMUNOCOMPROMISED, FIRST SERIES NON-RESPONDERS:** See dialysis dosing schedule (Vaccine Procedure Module 2). HEPLISAV-B® can be considered for persons not responding with positive HBsAb after initial HepB series.	**AT SCREENING VISIT:** Determine vaccination history and whether individual has risk factors for HBV infection. **NO DOCUMENTED OR KNOWN HISTORY OF VACCINATION:** • Engerix-B®, Recombivax HB®, and PreHevbrio®: Administer on a 3-single-dose schedule of 0, 1, and 6 months. • HEPLISAV-B®: Administer on a 2-single-dose schedule of 0 and at least 1 month. **FOREIGN-BORN INMATESS:** • Consider pre-screening for positive HBsAg prior to vaccination. **GENERAL:** • Candidates for both HepA and HepB should utilize the Twinrix® vaccine. • Twinrix® vaccine is not recommended for outbreak or post-exposure vaccination to HAV. **CONTRAINDICATION:** • Pregnancy (only HEPLISAV-B® and PreHevbrio®)

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER* ** For persons aged 18 years or younger, consult the ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, pharmacist and package inserts.*		
VACCINE	**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 vaccination history and whether individual has risk conditions. **NO DOCUMENTED HISTORY OF VACCINATION:** • 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 vaccination 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 and 6 months. **IF PATIENT REPORTS PREVIOUS DOSE(S):** • See information on vaccine administration 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 the ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, pharmacist and package inserts.*		
VACCINE	**INDICATION FOR VACCINE**	**KEY POINTS**
5. INFLUENZA	**Influenza vaccine is indicated annually for all adults without known contraindications. First priority for vaccination are candidates with the following risk factors:** • Pregnancy or up to 2 weeks postpartum. • Chronic pulmonary disease, including asthma. • Cardiovascular disease (except isolated hypertension). • 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, such as medications (e.g., anti-alpha inhibitors or steroids), certain cancers (e.g., leukemia), and HIV infection. • Morbid obesity (BMI ≥ 40 kg/m^2). • American Indian/Alaska Native. • Housed in Nursing Care Center units. • Assigned to Health Services units. • 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., "Fluad®, prefilled, trivalent 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 the ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, pharmacist and package inserts.*		
VACCINE	**INDICATION FOR VACCINE**	**KEY POINTS**
6. MEASLES, MUMPS, AND 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. **MEASLES OR MUMPS OUTBREAKS:** See outbreak information in **SECTION B** of Vaccine Procedure Module 6 (Measles, Mumps, and Rubella). **HIV INFECTION WITH NO EVIDNECE OF IMMUNITY:** 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.	**AT SCREENING VISIT:** Determine whether patient is a candidate for the MMR vaccine. Administer 1 dose to those with no evidence of immunity, unless contraindicated. **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/mm^3. • **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. **PRECAUTIONS:** • Receipt of antibody-containing blood product within the last 11 months. • History of thrombocytopenia or thrombocytopenic purpura.

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER*

** For persons aged 18 years or younger, consult the ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, pharmacist and package inserts.*

VACCINE	INDICATION FOR VACCINE	KEY POINTS
7. MENINGOCOCCUS **MENINGOCOCCAL SEROGROUP B (MENB)** ***and*** **MENINGOCOCCAL SEROGROUP ACWY CONJUGATE (MENACWY)** ***and*** **MENINGOCOCCAL SEROGROUP ABCWY (MENABCWY)**	**MenB and MenACWY are two different vaccines protecting against different serogroups of meningococcal disease.** **MENABCWY is a combination vaccine that protects against the same meningococcal serogroups as the MenB and MenACWY vaccines.** **Meningococcal vaccines are indicated for persons with no documented history of vaccination 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 first dose of meningococcal vaccines at least 2 weeks ***prior*** *to* initiating medication. • **PREGNANCY:** Delay MenB and MenABCWY until after pregnancy, unless increased risk and vaccination benefits outweigh potential risks. **The MenACWY series and an *every*-5-year booster dose are indicated for persons with no documented history of MenACWY vaccination and who have:** • Any of the RISK FACTORS listed above *or* • HIV infection.	**AT SCREENING VISIT:** Determine vaccination history and risk factor indications for the vaccine. If at risk, administer as follows: **NOTE:** MenB and MenACWY vaccines may be given at the same time at different anatomic sites (e.g., different arms) *OR* alternatively, MenABCWY may be used in lieu of separate administration of MenB and MenACWY when both would be given on the same day. **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 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 1 additional dose every 5 years if risk factor remains. **IF DOCUMENTATION OF PRIMARY SERIES COMPLETION:** • Administer additional dose *every* 5 years if risk continues. **MENABCWY VACCINE:** • If used for dose 1 of MenB, Trumenba® should be administered for dose 2 of MenB. • May be used for additional MenACWY and MenB doses (including booster doses) ***IF*** both would be given on the same clinic day and at least 6 months have elapsed since most recent dose.

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER*

** For persons aged 18 years or younger, consult the ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, pharmacist and package inserts.*

VACCINE	INDICATION FOR VACCINE	KEY POINTS
8. PNEUMOCOCCUS **PNEUMOCOCCAL 15-, 20- AND 21-VALENT (PCV15, PCV20 & PCV21)** ***and*** **PNEUMOCOCCAL 23-VALENT (PPSV23)**	**PCV15, PCV20, or PCV21 is indicated for persons with the following AGE and RISK FACTORS who have not received these pneumococcal conjugate vaccines (PCVs) in the past**: • Age 50 years and older • Risk-factor based, age 19–49 years: ◆ Alcoholism ◆ Cerebrospinal fluid leak ◆ Chronic heart/liver/lung disease ◆ Chronic renal failure or nephrotic syndrome ◆ 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 **PCV21 considerations:** • PCV21 contains new pneumococcal serotypes not included in the other PCVs or PPSV23. However, it does not contain certain serotypes (e.g., serotype 4) included in the other pneumococcal vaccines. For **residents of the Navajo nation and those residing in the Western US (including Alaska) and Canada who have substance use disorder, experience homelessness, or have chronic lung disease**, PCV20 or both PCV15 and PPSV23 are expected to provide broader serotype coverage against locally circulating strains compared to PCV21.	**AT SCREENING VISIT:** Determine vaccination history *AND* whether individual meets the age and risk factor indications for PCV15, PCV20, or PCV21 vaccine. **CLINICAL GUIDANCE AND SCHEDULE:** • **IF VACCINATION HISTORY IS UNKNOWN OR ONLY PCV7 WAS RECEIVED IN THE PAST**, administer 1 dose of PCV15, PCV20, or PCV21. ◆ If PCV 15 is used, it should be followed by 1 dose of PPSV23 1 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 or PCV21 is used, PPSV23 is NOT indicated. • **IF ONLY PPSV23 WAS RECEIVED IN THE PAST**, 1 dose of PCV15, PCV20, or PCV21 should be administered at least 1 year after the most recent PPSV23. An additional dose of PPSV23 is NOT recommended. • **IF ONLY PCV13 WAS RECEIVED IN THE PAST,** administer 1 dose of PCV20 or 1 dose of PCV21 at least 1 year after the last PCV13 dose. • **PERSONS 50 YEARS OF AGE AND OLDER** ◆ **If both PCV13 and PPSV23 were received in the past *BUT* no PPSV23 was received at age 65 years or older**, administer 1 dose PCV20 or 1 dose PCV21 at least 5 years after the last pneumococcal vaccine dose. ◆ **If both PCV13 and PPSV23 were received in the past *AND* PPSV23 was received at age 65 years or older**, 1 dose of PCV20 or 1 dose of PCV21 at least 5 years after the last pneumococcal vaccine dose may be administered based on shared decision-making. • **PERSONS 19–49 YEARS OF AGE** ◆ **If PCV13 and PPSV23 were received in the past**, administer 1 dose PCV20 or 1 dose PCV21 at least 5 years after the last pneumococcal vaccine dose

PNEUMOCOCCUS INFORMATION CONTINUES ON THE FOLLOWING PAGE

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER* * *For persons aged 18 years or younger, consult the ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, pharmacist and package inserts.*		
VACCINE	**INDICATION FOR VACCINE**	**KEY POINTS**
8. PNEUMOCOCCUS (CONTINUED)		→ ***DO NOT GIVE PCVS AND PPSV23 DURING THE SAME VISIT.*** * **FOR MORE INFORMATION REGARDING WHEN PAST PCV13 AND PPSV23 VACCINATIONS WERE ADMINISTERED, SEE THE CDC DOCUMENT *PNEUMOCOCCAL VACCINE TIMING FOR ADULTS***
9. TETANUS, DIPHTHERIA, AND 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 10 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, and Pertussis Vaccines).	**AT SCREENING VISIT:** Determine vaccination 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 (VAR) *Non-Formulary*	**VAR is a live, non-formulary vaccine:** 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 the ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, pharmacist and package inserts.*		
VACCINE	**INDICATION FOR VACCINE**	**KEY POINTS**
11. RECOMBINANT ZOSTER VACCINE (RZV)	• Immunocompetent adults aged 50 years and older regardless of previous herpes zoster (shingles) or history of zoster vaccine live (ZVL, Zostavax®) vaccination. • 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 vaccination history and whether they meet indications and 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 second dose may be administered 1–2 months after the first dose for earlier benefit. ◆ Vaccinate before immunosuppression or when immune response is likely to be most robust. **IF HISTORY OF ZVL (ZOSTAVAX®) VACCINATION:** • Revaccinate with the 2-dose RZV series at least 2 months after ZVL.* **PRECAUTIONS (DEFER VACCINATION):** • **PREGNANCY AND LACTATION.** • **CURRENT HERPES ZOSTER INFECTION.** * As of July 2020, ZVL is no longer available in the United States.

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER*

** For persons aged 18 years or younger, consult the ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, pharmacist and package inserts.*

VACCINE	INDICATION FOR VACCINE	KEY POINTS
12. COVID-19 ***(2025–2026 formulation)***	**COVID-19 vaccine is indicated for all adults without known contraindications. First priority for vaccination are candidates with the following risk factors:** • Pregnancy and recent pregnancy • Cardiovascular disease limited to heart failure and myocardial infarction • Diabetes mellitus • Immunosuppression due to any cause (e.g., cancer treatment, solid organ or blood stem cell treatment, HIV infection, medications) • Age 65 years and older • Housed in Nursing Care Center units • Orderlies assigned to Health Service units **Adults who are moderately or severely immunocompromised may benefit from additional doses of COVID-19 vaccine.** • Active treatment for solid tumor and hematologic malignancies. • Hematologic malignancies associated with poor responses to COVID-19 vaccines, regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia). • Solid organ or islet transplant recipient and taking immunosuppressive therapy. • CAR T-cell therapy or hematopoietic cell transplant recipient (within 2 years of transplant or immunosuppressive therapy). • Moderate/severe primary immunodeficiency (e.g., DiGeorge syndrome, severe combined immunodeficiency, common variable immunodeficiency disease, Wiskott-Aldrich). • Advanced HIV infection (e.g., CD4 count < 200 cells/mm^3, history of AIDS-defining illness without immune reconstitution, symptomatic HIV infection) or untreated HIV infection. • Active treatment with high-dose steroids, alkylating agents, antimetabolites, transplant-related immunosuppressive agents, severely immunosuppressive cancer chemotherapeutic agents, TNF blockers, other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell-depleting agents).	**AT SCREENING VISIT:** Determine vaccination history and whether the individual is moderately or severely immunocompromised. **NOT IMMUNOCOMPROMISED:** • IF NO PRIOR COVID-19 VACCINES RECEIVED, ADMINISTER: • 1 mRNA dose, OR • 2 Novavax doses at 0, 3–8 weeks. • IF PREVIOUSLY VACCINATED WITH AN MRNA VACCINE OR AT LEAST 2 DOSES OF NOVAVAX VACCINE PRIOR TO THE UPDATED FORMULATION, ADMINISTER: • 1 mRNA or Novavax dose at least 8 weeks after the most recent dose. • IF PREVIOUSLY VACCINATED WITH THE JANSSEN VACCINE PRIOR TO THE UPDATED FORMULATION, ADMINISTER: • 1 mRNA or Novavax dose. • IF PREVIOUSLY VACCINATED WITH 1 NOVAVAX VACCINE DOSE PRIOR TO THE UPDATED FORMULATION, ADMINISTER: • 1 Novavax dose 3–8 weeks after most recent dose. • If > 8 weeks after most recent dose, administer 1 mRNA or Novavax dose. • IF AGE ≥ 65 YEARS • UNVACCINATED: follow unvaccinated guidance above ***AND*** administer dose 2 of the mRNA or Novavax dose 6 months later (minimum 2-month interval). • PREVIOUSLY VACCINATED: follow previously vaccinated guidance above ***AND*** administer dose 2 of the mRNA or Novavax dose 6 months later (minimum 2-month interval). **IF MODERATELY OR SEVERELY IMMUNOCOMPROMISED, <u>VACCINE DOSES FROM THE SAME MANUFACTURER SHOULD BE ADMINISTERED FOR THE INITIAL VACCINATION SERIES</u>:** • NO PRIOR COVID-19 VACCINES RECEIVED: • Administer a 3-dose (mRNA) or 2-dose (Novavax) initial vaccine series. • After initial series complete, administer 1 dose of any mRNA or Novavax vaccine 6 months later (2-month minimum interval).

COVID-19 information continues on the following page

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER*

** For persons aged 18 years or younger, consult the ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, pharmacist and package inserts.*

VACCINE	INDICATION FOR VACCINE	KEY POINTS
COVID-19 **(CONTINUED)**		• COVID-19 DOSE(S) RECEIVED PRIOR TO THE UPDATED FORMULATION *BUT* INITIAL VACCINE SERIES NOT COMPLETED: ◦ Complete the vaccine series using the same manufacturer for all vaccine doses. ◦ Administer 1 dose of any mRNA or Novavax vaccine 6 months later (2-month minimum interval). • COVID-19 DOSE(S) RECEIVED PRIOR TO THE UPDATED FORMULATION *AND* INITIAL VACCINE SERIES COMPLETED: ◦ Administer 2 doses of mRNA or Novavax vaccine 6 months apart (2-month minimum interval) using the same manufacturer. Administer dose 1 at least 8 weeks after the most recent dose. **In ALL cases, additional doses may be given at least 2 months after the last vaccine dose based on shared clinical decision-making**. **CONTRAINDICATIONS:** • **SEVERE ALLERGIC REACTION (E.G., ANAPHYLAXIS; PROGRESSIVE, LIFE-THREATENING REACTION) AFTER A PREVIOUS DOSE OF A SIMILAR COVID-19 VACCINE TYPE (E.G., MRNA) OR TO A COMPONENT OF THE COVID-19 VACCINE.** **PRECAUTIONS:** • **NON-SEVERE ALLERGY** to a component of the COVID-19 vaccine. • **NON-SEVERE, IMMEDIATE ONSET (WITHIN 4 HOURS) ALLERGIC REACTION** after a previous dose of a similar COVID-19 vaccine type (e.g., mRNA). • **HISTORY OF MULTISYSTEM INFLAMMATORY SYNDROME IN ADULTS (MIS-A) OR CHILDREN (MIS-C).** • **MYOCARDITIS OR PERICARDITIS** within 3 weeks after a dose of any COVID-19 vaccine.

BOP IMMUNIZATION INDICATIONS FOR ADULTS AGED 19 YEARS OR OLDER*

** For persons aged 18 years or younger, consult the ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, pharmacist and package inserts.*

VACCINE	INDICATION FOR VACCINE	KEY POINTS
13. RESPIRATORY SYNCYTIAL VIRUS (RSV)	• Pregnant women 32 weeks 0 days through 36 weeks 6 days gestation should receive 1 dose of maternal RSV vaccine before or during RSV season, which occurs September through January in most of the continental U.S. • Adults aged 75 years and older should receive 1 dose of vaccine. • Adults aged 60-74 years who are at increased risk for severe RSV disease should receive 1 dose of vaccine ideally late summer and early fall in most of the continental U.S, before RSV spread in communities. Associated underlying medical conditions and factors include: ◆ Chronic heart or lung disease, excluding isolated hypertension ◆ End stage renal disease, including hemodialysis dependence or other renal replacement therapy ◆ Chronic liver disease ◆ Chronic hematologic disorders ◆ Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness ◆ Diabetes mellitus complicated by end organ damage (e.g., neuropathy, retinopathy) or treated with insulin or SGLT2 inhibitors ◆ Moderate or severe immunocompromise ◆ Severe obesity (BMI ≥ 40 kg/m^2) ◆ Residence in nursing homes or other long-term care facilities ◆ Other chronic medical conditions or risk factors that a healthcare provider determines would increase the risk of severe disease	**FOR PREGNANT WOMEN:** • Abrysvo™ is the only approved RSV vaccine. • Administer vaccine regardless of previous RSV infection. • Either maternal vaccination or infant immunization with nirsevimab (an RSV monoclonal antibody) is recommended to prevent severe RSV disease in infants. **FOR ALL VACCINE RECIPIENTS:** • Only a single lifetime dose is recommended.

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 for the following vaccines. The modules are listed below as links:

VACCINE PROCEDURE MODULES 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 select institution health care personnel to administer vaccines utilizing 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 updates to other nursing protocols and/or updates to the vaccine procedure modules.

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

- *Unless stated otherwise, 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 ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, the package insert, and a local pharmacist.*

- *For CDC vaccine recommendations based on age, see: https://www.cdc.gov/vaccines/by-age/index.html.*

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 at this institution if checked (✓) below:	
	1. Hepatitis A vaccine (HepA)
	2. Hepatitis B vaccine (HepB)
	3. *Haemophilus influenzae* type B (Hib) vaccine
	4. Human papillomavirus (HPV) vaccine
	5. Influenza vaccine: ☐ inactivated, single-dose, trivalent (IIV3) ☐ inactivated, multi-dose, trivalent (IIV3) ☐ adjuvanted, inactivated, trivalent (HD-IIV3)
	6. Measles, mumps, and rubella (MMR) vaccine
	7. Meningococcal vaccine (MenB, MenACWY, and MenABCWY)
	8. Pneumococcal vaccine (PCV15, PCV20, PCV21, and PPSV23)
	9. Tetanus, diphtheria, and pertussis vaccine (Td and Tdap)
	10. Varicella vaccine (VAR)
	11. Recombinant zoster vaccine (RZV)
	12. COVID-19 vaccine
	13. Respiratory syncytial virus (RSV) vaccine

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, i.e., those who do not have evidence of immunity to HAV or a history of HepA and who have the following risk factors:***
   - Sexual exposure risk (e.g., 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 infection
   - ***During an HAV outbreak:*** Persons at risk for HAV infection should receive 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 previous 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 aged > 40 years depending on the provider's risk assessment, which should include consideration 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:** 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.
- **PREGNANT 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.
  - Have person administering the immunization sign and date 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 ACIP Child and Adolescent Immunization Schedule, American Academy of Pediatrics, package insert, and a local pharmacist.*

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

Patient Group	Vaqta® (Merck)			Havrix® (GSK)			Twinrix® HepA & HepB (GSK)			Considerations
	Dose	Volume (Route)	Schedule (2 doses)	Dose	Volume (Route)	Schedule (2 doses)	Dose	Volume (Route)	Schedule (3 doses)	
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** to neomycin and also yeast for Twinrix®. • **Severe allergy** to latex (see package insert).

- 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 two-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 HepA and HepB are recommended, administer the three-dose Twinrix® vaccine (combination HepA and HepB) at 0, 1, and 6 months.

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

- Record the vaccine administration location, 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 of age and appropriate dosing:***
   - Aged 19–59 years
   - Aged 60 years or older who are incarcerated
     - Starting in 2022, the CDC adult immunization schedule recommended all incarcerated persons ≥ 60 years of age receive HepB.
     - For hemodialysis/peritoneal dialysis recipients, use *dialysis dosing schedule*.
   - In the table below, 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 HepB:***
   - **CONTRAINDICATIONS:** 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®** and **PREHEVBRIO®.**

     ➔ *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html.*
   - **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.
     - Have person administering the immunization sign and date 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 (22–25 g, 1–1½" needle) in the deltoid; alternatively, the anterolateral thigh 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, 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 begins on the next page)

Vaccine	Dose/ Volume/ Schedule	Patient Group	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 years 5 mcg IM for age ≤ 19 years	N/A	**Contraindications:** • **Severe allergic response** to yeast (all HepB vaccines) or yeast and neomycin (TWINRIX®). • **Severe allergy** to latex (see package insert). • **Pregnancy** (Heplisav-B® and PreHevbrio® only).
	Volume	1 mL for age ≥ 20 years 0.5 mL for age ≤ 19 years	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 years 10 mcg IM for age ≤ 19 years	40 mcg (two separate 20 mcg doses)	
	Volume	1 mL for age ≥ 20 years 0.5 ml for age ≤ 19 years	Two 1 mL doses at same site, 1" apart	
	Schedule	0, 1, & 6 months	0, 1, 2, & 6 months	
Heplisav-B®[1,3] (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		
PreHevbrio®[4] (VBI) Approved for age 18 years and older	**Dose**	10 mcg	Safety and effectiveness of PreHevbrio® have not been established in adults on hemodialysis.	
	Volume	1 mL		
	Schedule	0, 1, & 6 months		
Twinrix® HepA & HepB (GSK)[1] Approved for age 18 years and older	**Dose**	**HepA:** 720 EL.U. **HepB:** 20 mcg	N/A	
	Volume	1 mL	N/A	
	Schedule	0, 1, & 6 months	N/A	

[1] Recombinant hepatitis B surface antigen proteins (monovalent), yeast derived.
[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®.
[4] Recombinant hepatitis B surface antigen proteins (trivalent), mammalian derived.

- ***Provide subsequent doses of HepB*** to complete each patient's dose schedule.
  - ***Observe the following dosing intervals (Engerix-B®, Recombivax HB®, and PreHevbrio®):*** 4 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®, Twinrix®)***, 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 HepA and HepB are recommended, administer the three-dose Twinrix® vaccine (combination of HepA and HepB) at 0, 1, and 6 months.
- ***For hemodialysis patients and as an alternative second series dosing schedule for HIV-positive adults:***
  - Recombivax® HB Dialysis Formulation: Administer three-dose series of 1 mL (40 mcg total) at 0, 1, and 6 months.

  or
  - Engerix-B®: Administer *four-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 (i.e., BEMR): Record the vaccine location, the manufacturer and lot number, dosage, 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.
   - 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 (Hib) vaccine.

1. ***Identify adults in need of the Hib vaccine, which is indicated for any of the following risk factors:***
   - Diagnosis of anatomic or functional asplenia (e.g., sickle cell disease) and no prior documented history of Hib vaccination.
   - Pending elective splenectomy and no prior documented history of Hib vaccination.
     - *Vaccine is recommended to be administered at least 14 days prior to splenectomy (see table under #4 below).*
   - Receipt of hematopoietic stem cell transplant (HSCT).
     - *Initiate series 6–12 months after successful transplant, regardless of Hib vaccination history (see table under #4 below).*

2. ***Screen all patients for contraindications and precautions to Hib vaccine:***
   - **CONTRAINDICATIONS:** 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 https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html.*
   - **PRECAUTIONS:** A moderate or severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks following receipt of 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	• Contraindication: Do NOT give if history of serious reaction or allergy to a component of the vaccine or a tetanus toxoid–containing vaccine. • Precaution: History of Guillain-Barré syndrome within 6 weeks following receipt of a previous tetanus vaccine. • Vaccine is reconstituted with accompanying saline diluent. • After reconstitution, administer Hib as soon as possible (must discard if not used within 24 hours).
Recipient of HSCT	0.5 mL (10 mcg)	**Three-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 (22–25 g, 1–1½" needle) in the deltoid; alternatively, the anterolateral thigh 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, 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 three-dose series to HSCT patients at 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, 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 no documented or self-reported history of receiving the complete vaccine series using appropriate time intervals between doses:***
   - ***HPV vaccination recommended for all adults through age 26 years:***
     - ***Age 15 years or older at initial vaccination:*** three-dose series at 0, 1–2, and 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 9–14 years at initial vaccination with receipt of 1 or 2 doses less than 5 months apart:*** administer 1 dose.
   - ***HPV vaccination recommended for adults aged 27–45 years*** based on shared clinical decision-making regarding future risk of HPV infection and transmission: two- or three-dose series, the latter administered as above. Two-dose series are administered at 0, and 6–12 months.
   - If valid vaccination series with any HPV vaccine has been completed, no additional doses are needed.
   - Special situations:
     - ***Pregnancy:*** HPV vaccination not recommended until after pregnancy; however, 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 those aged 27–45 years, the latter based on shared clinical decision-making; provide three-dose series.
2. ***Screen all patients for contraindications and precautions to HPV vaccine:***
   - **CONTRAINDICATIONS:** 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 to yeast is a contraindication to administration of the quadrivalent and 9-valent HPV vaccines.

→ *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html.*

- **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 (22–25 g, 1–1½" needle) in the deltoid; alternatively, the anterolateral thigh 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, 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 begins on the next page)

PATIENT GROUPS	9VHPV GARDASIL® (MERCK) NOTE: THIS GUIDANCE IS SPECIFIC TO 9-VALENT GARDASIL®.			
AGE ≤ 26 YEARS	**VOLUME**	**DOSE SCHEDULE**	**ROUTE**	**CONTRAINDICATIONS/PRECAUTIONS**
Initial vaccination at age 9–14 years and received 1 or 2 doses *LESS THAN* 5 months apart.	0.5 mL	Administer 1 dose.	IM	• Contraindication: History of a serious reaction (e.g., anaphylaxis) after a previous dose of HPV vaccine. • Contraindication: Severe allergy (e.g., anaphylaxis) to yeast. • Precaution: Pregnancy (delay until after pregnancy).
Initial vaccination at age ≥ 15 years.	0.5 mL	Administer a 3-dose series at 0, 1–2, and 6 months.	IM	
Immunocompromising conditions, including HIV infection.	0.5 mL	Administer a 3-dose series at 0, 1–2, and 6 months.	IM	
AGE 27–45 YEARS*				
Initial vaccination at age 9–14 years.	0.5 mL	Administer a 2-dose series at 0, and 6–12 months.	IM	
Initial vaccination at age ≥ 15 years.	0.5 mL	Administer a 3-dose series at 0, 1–2, and 6 months.	IM	
Immunocompromising conditions, including HIV infection.	0.5 mL	Administer a 3-dose series at 0, 1–2, and 6 months.	IM	

*Based on regarding future risk of HPV infection and transmission.

- Provide subsequent doses of vaccine to complete each patient's two- or three-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 three-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. For two-dose schedules, the second dose should be given at least 6 months after the first dose.

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

- Record the vaccine administration location, 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 VACCINE

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) and other professional medical organizations (e.g., American Academy of Family Physicians, American College of Obstetricians and Gynecologists).

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

Influenza Vaccine Abbreviations
➢ Inactivated influenza vaccine – **IIV**
➢ Inactivated influenza vaccine, trivalent – **IIV3**
➢ Inactivated influenza vaccine, trivalent, high-dose – **HD-IIV3**
➢ Adjuvanted inactivated influenza vaccine – **aIIV**
➢ Adjuvanted inactivated influenza vaccine, trivalent – **aIIV3**
➢ Cell-based inactivated influenza vaccine – **ccIIV** (egg-free)
➢ Recombinant influenza vaccine – **RIV** (egg-free)
➢ 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. Annual influenza vaccination is recommended for everyone 6 months of age and older. In the BOP, priority of vaccine administration will be directed by Central Office and the clinical director, based on influenza risk and vaccine availability.

➔ *This module will be updated annually based on a review of available medical recommendations and 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. Patients who are identified as priority candidates should be given priority for vaccination.***

   ➢ ***Priority candidates for vaccine administration*** *are those* with any of the following medical risk factors:

   - Pregnancy and up to 2 weeks postpartum
   - 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
- Housed in Nursing Care Center (long-term care) units
- Orderlies assigned to Health Services units
- Older than age 50 years

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

- **CONTRAINDICATIONS:** History of a serious reaction (e.g., anaphylaxis) to any component of the vaccine (e.g., 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* https://www.vaccinesafety.edu/components-excipients/**.**
- **PRECAUTIONS:**
  - If ***Guillain-Barré syndrome (GBS)*** has occurred within 6 weeks after a previous influenza vaccination, the decision to give influenza vaccine should be based on the potential benefits and risks.
  - If the individual has a ***moderate or severe acute illness*** with or without fever defer vaccination until resolution of illness.
  - Vaccination of persons with ***mild or asymptomatic COVID-19 illness or those in exposure quarantine*** should be guided by considerations of the individual's underlying risk of medical complications due to influenza, the degree of influenza circulation in the local community, and avoidance of confusing illness symptoms with vaccine reactions.
  - If the individual has an ***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.

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.
  - Have person administering the immunization sign and date 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 2025–26 BOP contract:

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

Influenza Vaccine by Type	Form	Total Strength	Dose	Route	Timing	Age Indications/Comments
Afluria® (Seqirus) **IIV3: Inactivated Influenza Vaccine** ***Trivalent***	Suspension **Multi-dose** vial (contains 10 0.5 mL doses)	45 mcg HA	0.5 mL	IM	One time annually	**6 months of age and older (*including ≥ 65 years*):** • Do not freeze and protect from light. • Shake the vial thoroughly before withdrawing each dose. The number of needle punctures should not exceed 20 per vial. • Contains thimerosal. • Latex-free. • Use syringe with safety device. • Disinfect top of vial before entering with sterile syringe. Once the stopper has been pierced, discard vial within 28 days. • Between uses, return vial to storage conditions at 2°C to 8°C (36°F to 46°F). Do not use after the expiration date shown on the label.
Fluad® (Seqirus) **AIIV3: Inactivated Influenza Vaccine** ***Trivalent, Adjuvanted***	Suspension **Single-dose**, prefilled syringes	45 mcg HA	0.5 mL	IM	One time annually	**An option for use *EITHER* for persons age ≥ 65 years *OR* for persons age < 65 years who are solid organ transplant recipients on immunosuppressive medications:** • Store refrigerated at 2°C to 8°C (36°F to 46°F). Do not use after expiration date shown on the label. • Do not freeze and protect from light. • Shake the syringe gently before use. • Preservative-free (thimerosal-free). • Latex-free. • Use appropriately sized safety needle.

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, and rubella.
   - Born in 1957 or later and without evidence of immunity★ to measles, mumps, or rubella.
   - HIV infection with CD4 percentage ≥ 15 and CD4 count ≥ 200 cells/mm^3 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 of MMR vaccine or have received ≤ 2 doses.
   - ***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 https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html.*
     - ***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 pregnancy status.*

(list of contraindications continues on next page)

- ***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 percentage < 15 and CD4 count < 200 cells/mm³.
  - *If HIV infection and CD4 percentage ≥ 15 or CD4 count ≥ 200 cells/mm^3 for least 6 months, can administer 1 dose.*

- Patients treated with certain steroids: see *vaccine package insert*.
- **PRECAUTIONS:**
  - Receipt of antibody-containing blood product within the last 11 months. 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.
  - Receipt of another live vaccine within the last 4 weeks, unless administered simultaneously.
  - 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.
  - Have person administering the immunization sign and date 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 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 (within 11 months) receipt of antibody-containing blood product (specific interval depends on product). • Precaution: history of thrombocytopenia or thrombocytopenic purpura. • Wait 4 weeks after administration of any other *live* vaccine (e.g., 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.
Born in 1957 or after, unless there is evidence of immunity	0.5 mL	1 dose	SQ	
HIV-infected with CD4 percentage ≥ 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 23–25 g, 5/8" needle in the posterolateral fat (triceps area) 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 two 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 vaccine.*** HOWEVER, if they are not given concurrently, do NOT give the TST until 28 days AFTER the MMR vaccine is administered, 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-TB Gold® or T-Spot®.TB) can be conducted concurrently with MMR vaccination or 28 days AFTER the MMR vaccine is given.

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 VACCINE

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 vaccines.

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

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

   INDICATIONS FOR SEROGROUP B MENINGOCOCCAL VACCINE (MENB):

   - 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 CONJUGATE VACCINE (MENACWY):

   - 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.

INDICATIONS FOR SEROGROUP A, B, C, W, Y MENINGOCOCCAL VACCINE (MENABCWY):

- Same as for MenB *and* MenACWY and may be used as an alternative to separate administration of MenB and MenACWY if both vaccines would be given on the same clinic day.

TABLE 1. INDICATIONS AND SCHEDULE FOR RECOMMENDED MENINGOCOCCAL VACCINES IN HIGH-RISK GROUPS

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

***** If MenABCWY is used for dose 1 MenB, Trumenba® should be administered for dose 2 MenB. MenABCWY may be used for additional MenACWY and MenB doses (including booster doses) ***IF*** both would be given on the same clinic day ***and*** at least 6 months have elapsed since most recent MenABCWY dose.

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

- **CONTRAINDICATIONS:** History of a serious reaction (e.g., anaphylaxis) after a previous dose of MenB, MenACWY, or MenABCWY vaccine or to a meningococcal vaccine component, including:
  - Diphtheria toxoid or CRM (a diphtheria toxin carrier protein): 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 https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html.*

- **PRECAUTIONS:**
  - A moderate or severe acute illness with or without fever.
  - Pregnancy: only for MenB vaccines (i.e., Bexsero® and Trumenba®) and MenABCWY (Penbraya®).
  - Latex sensitivity: avoid Bexero®.

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.
  - Have person administering the immunization sign and date 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 meningococcal vaccines:

- ***Storage (including only before reconstitution, if applicable):*** Store vials and pre-filled syringes in the refrigerator (36°F to 46°F; 2°C to 8°C).
  - ***DO NOT FREEZE.*** Discard if vials or syringes have been frozen***.***
  - ***Protect vials from light.***
- ***Before and after reconstitution: MenACWY (Menveo®) 2-vial presentation***
  - 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 in vial between 36°F and 77°F (2°C and 25°C) for up to 8 hours.
    - ***If stored, DO NOT FREEZE and shake well before using.***
    - ***Discard the reconstituted vaccine if it is not used within 8 hours.***
- ***Before and after reconstitution: MenABCWY (Penbraya®)***
  - Without removing the vial adapter from its packaging, peel off the top cover.
  - While keeping the vial adapter in the packaging, orient it vertically over the center of the lyophilized MenACWY-containing vial so that the adapter spike aligns with the center of the vial's rubber stopper. Connect the vial adapter to the vial with a straight downward push to lock it into place. Remove the vial adapter packaging.
  - Resuspend the MenB component by shaking the syringe vigorously to obtain a white homogenous suspension.
  - Remove the syringe cap and connect the syringe to the vial adapter.
  - Inject the entire contents of the syringe into the vial. Do not remove the empty syringe.
  - Gently swirl the vial in a circular motion until the powder is completely dissolved.
  - Invert the vial completely with the vial adapter and syringe still attached. Slowly withdraw the entire contents into the syringe to ensure an approximately 0.5 mL dose.
  - Disconnect the syringe from the vial adapter.
  - Attach a sterile needle suitable for intramuscular injection to the syringe.

(list continues on the next page)

- When reconstituted, the vaccine is a homogeneous white suspension. If the vaccine is not a homogenous suspension, shake to resuspend prior to administration.
- After reconstitution, administer vaccine intramuscularly immediately OR store between 36°F and 86°F (2°C and 30°C) for up to 4 hours.
  - ***If stored, DO NOT FREEZE.***
  - ***Discard the reconstituted vaccine if it is not used within 4 hours.***

- ***MenACWY-TT (MenQuadfi®), the single vial presentation of MenACWY-CRM (Menveo®), and MenB do not require reconstitution.***

5. ***Administer MenB, MenACWY, and MenABCWY vaccines to individuals meeting the indications described above and the age requirements, as shown in Table 2 below.***

   - *For more about contradictions and precautions, see 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 (22–25 g, 1–1½" needle) in the deltoid; alternatively, the anterolateral thigh 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, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

(Administration table begins on the next page)

TABLE 2. ADMINISTRATION OF MENINGOCOCCAL VACCINES[1]

MENINGOCOCCAL SEROGROUP B VACCINE (MENB)					
Type of Vaccine	***Age***	***Volume***	***Route***	***Schedule***	***Contraindications, Precautions***
Bexsero® (*GSK*)**:** MenB-4C	≥ 10 years	0.5 mL	IM	Two doses at 0 & 4 weeks (use same brand for entire series). One booster dose 1 year after primary series and 1 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:** Prefilled syringe tip caps may contain latex.
Trumenba® (*Pfizer*)**:** MenB-FHbp	≥ 10 years	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 1 booster dose every 2–3 years if risk remains.	
MENINGOCOCCAL SEROGROUP A, C, W, Y CONJUGATE VACCINE (MENACWY)					
Type of Vaccine	***Age***	***Volume***	***Route***	***Schedule***	***Contraindications, Precautions***
Menveo® (*GSK*)**:** MenACWY-CRM	≥ 2 months	0.5 mL *Reconstitute the 2-vial presentation and give immediately.*	IM	Two doses at 0 & 2 months. Booster every 5 years if risk remains.	**Contraindication:** Allergy to vaccine component, diphtheria toxoid, or CRM. **Precautions:** Pregnancy. **Menveo® diluent contains antigens C, W, and Y; do not use any other diluent.**
MenQuadfi® *(Sanofi)***:** MenACWY-TT	≥ 2 years	0.5 mL	IM	Two doses at 0 & 2 months. Booster every 5 years if risk remains.	**Contraindication:** Allergy to vaccine component or tetanus toxoid-containing vaccine.
MENINGOCOCCAL SEROGROUP A, B, C, W, Y VACCINE (MENABCWY)[2]					
Type of Vaccine	***Age***	***Volume***	***Route***	***Schedule***	***Contraindications, Precautions***
Penbraya® (P*fizer*)**:** MenABCWY	≥ 10 years	0.5 mL *Reconstitute and give immediately*	IM	Alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same day ***AND*** if used as a booster, at least 6 months have elapsed since most recent MenABCWY dose.	**Contraindication:** Allergy to any vaccine component or tetanus toxoid-containing vaccine. **Precaution:** Pregnancy. **If used for dose 1 MenB, Trumenba® should be administered for dose 2 MenB.**

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

- Provide subsequent doses of meningococcal vaccines to complete each patient's two- or three-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.
- ***If MenABCWY (Penbraya®) is used for dose 1 MenB, Trumenba® should be administered for dose 2 MenB.***
- MenB and MenACWY vaccines may be administered at the same time but at different anatomic sites (e.g., in different arms).

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

- Record the vaccine location, 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 VACCINE

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, PCV20, or PCV21 and PPSV23 at the same visit.** See table below for scheduling.*

TABLE 1. ADULTS AGED 19–49 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 ➢ 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:** History of a serious systemic reaction (e.g., anaphylaxis) after a previous dose of <u>any</u> pneumococcal vaccine or to a vaccine component, including diphtheria toxoid for PCV.
     - *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html.*
   - **PRECAUTIONS:** A moderate or severe acute illness with or without fever.
   - **PREGNANCY:** The CDC does not provide any recommendations for use of PCVs or PPSV23 during pregnancy due to limited data. For a summary of existing data on pneumococcal vaccination during pregnancy, see www.cdc.gov/mmwr/volumes/72/rr/rr7203a1.htm.
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.
     - Have person administering the immunization sign and date 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 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.
   - ***Administer PCV20*** (or PCV15 followed by PPSV23, if PCV20 is not available) ***to adults in the western United States (including Alaska) and the Navajo Nation who have substance use disorder, chronic lung disease, or experience homelessness rather than PCV21.*** Although PCV21 contains eight new pneumococcal serotypes, it does not contain serotype 4 which is included in the other pneumococcal vaccines and has caused high percentages of invasive pneumococcal disease in certain adult populations in these areas.
   - ***Do not give PCV and PPSV23 at the same visit.*** If PCV15 is used in adults whose vaccination history is unknown, were previously vaccinated with PCV7, or were not vaccinated with any pneumococcal vaccine, PCV15 is administered first, and PPSV23 is administered either 1 year later (routine) or 8 weeks later (for certain medical or at-risk conditions). If PPSV23 was given previously, administer PCV15, PCV20, or PCV21 ***at least*** 1 year after the most recent PPSV23 dose. See Tables 1 and 2.
   - Shake PCVs vigorously prior to administration.

- PCVs must be administered intramuscularly, preferably in the deltoid muscle of the arm. Use 22–25 g, 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, 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 22–25 g, 1–1½" needle. ***For SQ:*** Use 23–25 g, 5/8" needle.

TABLE 2. ADMINISTRATION OF PCV AND PPSV23 FOR ADULTS ≥ 50 YEARS OF AGE (ROUTINE) AND 19–49 YEARS OF AGE WITH RISK FACTORS

VACCINATION HISTORY	ROUTINE ADMINISTRATION OF PCV & PPSV23 [1,2]	VOLUME	ROUTE[3]	SCHEDULING CONCERNS
ALL AGE GROUPS None, unknown, or only PCV7 received previously.	• Administer 1 dose of PCV15, PCV20, or PCV21. If PCV15 used, administer 1 dose of PPSV23 ***at least*** 1 year later (8 weeks later if immunocompromised, cochlear implant, or CSF leak).	0.5 mL	**PCV:** IM only **PPSV23:** IM or SQ	Do not give PCVs and PPSV23 during same visit.
ALL AGE GROUPS Only PPSV23 received previously.	• Administer 1 dose of PCV15, PCV20, or PCV21 ***at least*** 1 year after the most recent PPSV23 dose. An additional dose of PPSV23 is NOT recommended.	0.5 mL		
ALL AGE GROUPS Only PCV13 received previously.	• Administer 1 dose of PCV20 or PCV21 ***at least*** 1 year after the last PCV13 dose.	0.5 mL		
19–49 YEARS OF AGE Both PCV13 and PPSV23 received previously.	• Administer 1 dose of PCV20 or 1 dose of PCV21 at least 5 years after the last pneumococcal vaccine dose.	0.5 mL		
≥ 50 YEARS OF AGE ◆ Both PCV13 and PPSV23 received previously *BUT* no PPSV23 received at age ≥ 65 years. --- ◆ Both PCV13 and PPSV23 received previously *AND* PPSV23 received at age ≥ 65 years.	• Administer 1 dose of PCV20 or 1 dose of PCV21 at least 5 years after the last pneumococcal vaccine dose. --- • Based on shared clinical decision-making, 1 dose of PCV20 or 1 dose of PCV21 may be administered at least 5 years after the last pneumococcal vaccine dose.	0.5 mL		

[1] *See CDC guidance for greater detail on pneumococcal vaccine schedules: Pneumococcal Vaccine Timing for Adults.*
[2] *To quickly and easily determine patient-specific pneumococcal vaccine guidance, see PneumoRecs VaxAdvisor App for Vaccine Providers | Pneumococcal | CDC.*
[3] **IM** = Intramuscular; **SQ** = Subcutaneous

5. ***Document patient vaccine administration information in the patient electronic health record:***
   - Record the vaccine location, 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 (PCV15, PCV20, PCV21, or PPSV23).
     - If vaccine was not given, record the reason(s) (e.g., medical contraindication, patient refusal).
6. ***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.
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 9. TETANUS, DIPHTHERIA, AND PERTUSSIS VACCINE

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 10 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 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.
3. ***Screen all patients for contraindications and precautions to Td or Tdap vaccine:***
   - **CONTRAINDICATIONS:** 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 receipt of pertussis-containing vaccines,*** not attributable to another identifiable cause.

  → *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/ or go to https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html.*

- **PRECAUTIONS:**
  - ***History of Guillain-Barré syndrome*** 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.
  - Have person administering the immunization sign and date 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 Guillain-Barré syndrome 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 years.	
Documented history of adult Tdap vaccine, no Td booster within last 10 years.	0.5 mL	IM	• Give 1 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, or 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 vaccines: 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 (22–25 g, 1–1½" needle) in the deltoid; alternatively, the anterolateral thigh 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, 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. Specialized pharmaceutical freezers are required to properly maintain this temperature range. Vaccine 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 the vaccine even if more than 5 days have passed since first exposure to the disease.
   - Obtain approval for administration through the non-formulary process.
2. ***Screen patients for contraindications and precautions.***
   - *VAR is a live attenuated varicella virus vaccine.*
   - **CONTRAINDICATIONS:** 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 women. (Vaccinate upon completion or termination of pregnancy.) In addition, pregnancy should be avoided for 3 months following vaccination.

(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., 2 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 https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html.*

➢ **PRECAUTIONS:**

- Receipt of antibody-containing blood product within the last 11 months. 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.
- Have person administering the immunization sign and date 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 count < 200 cells/mm^3, 2 weeks or more of 20 mg prednisone or equivalent); family history of altered immunocompetence, unless verified otherwise. • **Precautions:** Defer for 11 months after receipt of antibody-containing blood products (see vaccine insert); receipt of antiviral drugs against the herpes virus family 24 hours before vaccination (avoid use of these antiviral agents for 14 days after vaccination). • **Can administer same day** as MMR vaccine, TST, or IGRA *OR* wait 4 weeks to give MMR, TST, or IGRA. • **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. Administer at least 4 weeks after previous dose.	

- ***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 (23–25 g, 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 two-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; live attenuated viral vaccines, such as the varicella vaccine, can result in suppression of the TST or a false negative result. Similarly, interferon-gamma release assay (IGRA) testing (e.g., QuantiFERON-TB Gold® or T-Spot®.TB) 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 done 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, 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 zoster vaccine live (ZVL, Zostavax®) vaccination.
   - 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:** 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 https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html.*
   - **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.
  - Have person administering the immunization sign and date 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 6 hours (label appropriately).
  - ***DISCARD the reconstituted vaccine if it is not used WITHIN 6 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 (22–25 g, 1–1½" needle) in the deltoid muscle; alternatively, the anterolateral thigh 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, 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 for when immune response is likely to be most robust. • **REPEAT SECOND DOSE IF GIVEN TOO SOON.** • **RECONSTITUTE VACCINE** with accompanying adjuvant suspension. Use immediately or refrigerate up to 6 hours. ***Discard after 6 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. • Second dose may be given 1–2 months after first 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, 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.

MODULE 12. COVID-19 VACCINE

A. PURPOSE

The purpose of this guidance is to reduce morbidity and mortality from SARS-CoV-2, the virus that causes COVID-19 disease, 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) and other professional medical organizations (e.g., American Academy of Family Physicians, American College of Obstetricians and Gynecologists).

➔ *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 COVID-19 vaccine (2025–2026 formulation). In the BOP, priority of vaccine administration will be directed by the Central Office and the Clinical Director based on COVID-19 risk and BOP data.

➔ *This module will be updated annually based on a review of available vaccination recommendations, BOP data, and the BOP contract formulary COVID-19 vaccines available; it will need to be reprinted annually with updates.*

1. **One dose of the 2025-2026 COVID-19 vaccine is recommended for all adults**; however, some individuals may benefit from receipt of more than one dose as indicated in Table 1 below.

2. Patients who are identified as priority candidates should be offered vaccination first. For vaccination schedules, refer to Table 1.
   - ***Priority candidates for vaccine administration*** are those with any of the following risk factors:
     - Pregnancy and recent pregnancy
     - Cardiovascular disease limited to heart failure and myocardial infarction
     - Diabetes mellitus
     - Immunosuppression due to any cause (e.g., cancer treatment, solid organ or blood stem cell transplant, HIV infection, medications)
     - Age 65 years and older
     - Housed in Nursing Care Center units (long-term care)
     - Orderlies assigned to Health Service units
   - An inclusive list of all medical conditions associated with severe COVID-19 symptoms in the general population is provided by the CDC here: https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html?CDC_AAref_Val=https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html.

3. Screen all patients for contraindications and precautions to COVID-19 vaccine:

- **CONTRAINDICATIONS:**
  - History of a serious reaction (e.g., anaphylaxis) after a previous dose or to any component of the vaccine of a similar type (e.g., mRNA).

  → *For information on vaccine components, refer to the manufacturer's package insert at http://www.immunize.org/fda/.*

- **PRECAUTIONS:**
  - ***History of a non-severe allergy (e.g., urticaria beyond the injection site) to a component of the COVID-19 vaccine OR history of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of the COVID-19 vaccine.*** For these individuals, an alternative COVID-19 vaccine type should be considered. Vaccination with the same COVID-19 vaccine type should only be undertaken under the supervision of a healthcare provider experienced in the management of severe allergic reactions.
  - ***Moderate or severe acute illness with or without fever:*** defer vaccination until resolution of illness.
  - ***History of multisystem inflammatory syndrome in adults (MIS-A) or children (MIS-C) with SARS-CoV-2 infection.*** These are rare but severe conditions that include a dysregulated immune response to SARS-CoV-2 infection. Expert opinion favors vaccination (i.e., benefits outweigh theoretical risks) if clinical recovery has occurred, including return to baseline cardiac function, and it has been at least 90 days after the diagnosis of MIS-A or MIS-C. Decisions concerning administering subsequent COVID-19 vaccine doses depend on timing in relation to vaccination, clinical recovery from MIS-A, and epidemiologic considerations.
  - ***History of myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine.*** A subsequent dose of any COVID-19 vaccine should generally be avoided. However, if after a risk assessment, the decision is made to administer a subsequent COVID-19 dose, wait until at least after the episode of myocarditis or pericarditis has completely resolved. Individuals with a history of myocarditis or pericarditis unrelated to COVID-19 vaccination may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has resolved.

- **ADDITIONAL CONSIDERATIONS:**
  - ***Individuals who recently had SARS-CoV-2 infection*** may consider delaying a COVID-19 vaccine dose by 3 months from symptom onset or positive test result (if infection was asymptomatic).
  - ***Moderately to severely immunocompromised individuals on immunosuppressive therapies*** should ideally receive a COVID-19 vaccine at least 2 weeks before initiation or resumption of their therapies. For patients who receive B-cell-depleting therapies on a continuing basis, the COVID-19 vaccine should be administered approximately 4 weeks before the next scheduled therapy.

    → For a description of moderate and severe immunocompromising conditions and additional vaccination guidance, refer to *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised*.

- ***COVID-19 revaccination*** should be considered for recipients of HCT or CAR T-cell therapy who received one or more doses of COVID-19 vaccine prior to or during treatment. In addition, COVID-19 revaccination may be considered for those who received vaccine doses during treatment with B-cell-depleting therapies (e.g., rituximab) that were administered over a limited period. For additional information, refer to *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised*.
- For individuals who are recommended to receive an orthopoxvirus vaccine (i.e., JYNNEOS or ACAM2000) in addition to a COVID-19 vaccine, consider waiting 4 weeks between vaccinations because of the risk of myocarditis and pericarditis. The JYNNEOS vaccine is preferred to ACAM2000 when co-administering a COVID-19 vaccine.
- For information concerning individuals who received COVID-19 vaccine outside the United States, refer to *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html* .

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 the form.
  - Have person administering the immunization sign and date 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 the COVID-19 vaccine (2025–2026 formulation). The tables on the following pages provide information on vaccination schedules and the COVID-19 vaccines for the 2025–2026 BOP contract:

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

TABLE 1. COVID-19 VACCINE (2025–2026 FORMULATION) SCHEDULE FOR NON-IMMUNOCOMPROMISED ADULTS AND THOSE MODERATELY OR SEVERELY IMMUNOCOMPROMISED*

INDICATION FOR ADULTS	COVID-19 VACCINES	
	SCHEDULE	CONTRAINDICATIONS/NOTES
HISTORY – NON-IMMUNOCOMPROMISED: • No doses documented or none known. • Documented previous vaccination with any COVID-19 vaccine prior to the 2025-2026 formulation.	• **No doses documented or known**, administer 1 mRNA dose or 2 Novavax doses at 0, 3–8 weeks. • **Previously vaccinated with an mRNA vaccine or at least 2 doses of the Novavax vaccine**, administer 1 mRNA or Novavax dose at least 2 months after the most recent dose. • **Previously vaccinated with the Janssen vaccine**, administer 1 mRNA or Novavax dose. • **Previously vaccinated with 1 Novavax vaccine dose**, administer 1 Novavax dose 3–8 weeks after most recent dose. If > 8 weeks after most recent dose, administer 1 mRNA or Novavax dose. • **AGE ≥ 65 YEARS** • **UNVACCINATED:** follow unvaccinated guidance above ***AND*** administer dose 2 of the mRNA or Novavax vaccine 6 months later (minimum 2-month interval). • **PREVIOUSLY VACCINATED:** follow previously vaccinated guidance above ***AND*** administer dose 2 of the mRNA or Novavax vaccine 6 months later (minimum 2-month interval).	• **CONTRAINDICATIONS:** • History of serious reaction (e.g., anaphylaxis) to previous vaccine dose or vaccine components. • **PRECAUTIONS AND ADDITIONAL CONSIDERATIONS:** *See Section B2 for additional information.* • **CAN CO-ADMINISTER** with other vaccines if no contraindications ***except for*** orthopoxvirus vaccines. *See Section B2 for additional information.* • **4-DAY GRACE PERIOD:** Doses given up to 4 days before and any time after the recommended minimum interval are valid. If a dose is given before the 4-day grace period, see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-c.
HISTORY – IMMUNOCOMPROMISED: Vaccination not documented or unknown.	• **Administer a 3-dose (mRNA) or 2-dose (Novavax) initial vaccine series** from the same manufacturer. • **Moderna dose intervals:** • Doses 1 and 2: 4 weeks • Doses 2 and 3: at least 4 weeks • **Pfizer BioNTech dose intervals:** • Doses 1 and 2: 3 weeks • Doses 2 and 3: at least 4 weeks • **Novavax dose intervals:** • Doses 1 and 2: 3 weeks • **After initial series complete**, administer 1 dose of any mRNA or Novavax vaccine 6 months later (2-month minimum interval).	

Table continues on following page

HISTORY – IMMUNOCOMPROMISED: Received COVID-19 dose(s) prior to 2025-2026 formulation ***BUT*** initial vaccine series not completed.	• **Complete the initial vaccine series** using vaccine from the same manufacturer. • Use same manufacturer for all doses. • See above for dosing intervals by manufacturer. • **After initial series complete**, administer 1 dose of any mRNA or Novavax vaccine 6 months later (2-month minimum interval)**.**	
HISTORY – IMMUNOCOMPROMISED: Received COVID-19 doses prior to 2025-2026 formulation ***AND*** initial vaccine series completed.	• Administer 2 doses of mRNA or Novavax vaccine 6 months apart (2-month minimum interval) using the same manufacturer. • Administer dose 1 at least 2 months after the most recent dose.	
HISTORY – IMMUNOCOMPROMISED: Received all COVID-19 vaccine doses as indicated in the schedule, including one 2025-2026 vaccine.	• Additional vaccine doses may be administered at least 2 months after the last vaccine dose based on shared clinical decision-making.	

*For detailed immunocompromised schedules, including dose intervals, refer to *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02*.

(Administration table begins on the next page)

TABLE 2. COVID-19 VACCINE (2025–2026 FORMULATION) ADMINISTRATION

UPDATED MONOVALENT VACCINE BY TYPE	FORM	STRENGTH	DOSE	ROUTE	AGE INDICATIONS/INSTRUCTIONS
(Pfizer-BioNTech) ***mRNA***	Suspension **Single-dose** prefilled syringe	30 mcg	0.3 mL	IM	**For 12 years of age and older:** *DO NOT SHAKE prefilled syringes* • **Frozen prefilled syringes should be discarded** • **Preparation instructions** ○ Vaccine should appear as a white to off-white suspension with no visible particles. ○ Remove tip cap and attach a sterile needle. • **Vaccine timelines** ○ Use unrefrigerated (8°C to 25°C [46°F to 77°F]) prefilled syringes **within 12 hours**. ○ Prefilled syringes must be used **within 4 hours once a sterile needle has been attached**. • Egg, cell, latex, and preservative free. • Protect from light. • Contraindications and precautions: see *Section B2*, above. • 2025-2026 mRNA vaccine dose schedule: see *Chapter 2, Section 12*.

(Administration table continues on the following page)

UPDATED MONOVALENT VACCINE BY TYPE	FORM	STRENGTH	DOSE	ROUTE	AGE INDICATIONS/INSTRUCTIONS
(Moderna) ***mRNA***	Suspension **Single-dose** prefilled syringe	50 mcg	0.5 mL	IM	**For 12 years of age and older:** *DO NOT SHAKE syringes* • **Thawing instructions** ○ One prefilled syringe: ***In refrigerator*** 2°C to 8°C (36°F to 46°F) for 1 hour and 40 minutes. Alternatively, at room temperature 15°C to 25°C (59°F to 77°F) for 40 minutes. ○ Carton of 2 prefilled syringes: ***In refrigerator*** 2°C to 8°C (36°F to 46°F) for 1 hour and 40 minutes. Alternatively, at room temperature 15°C to 25°C (59°F to 77°F) for 40 minutes. ○ Carton of 10 prefilled syringes: ***In refrigerator*** 2°C to 8°C (36°F to 46°F) for 2 hours and 40 minutes. Alternatively, at room temperature 15°C to 25°C (59°F to 77°F) for 1 hour and 20 minutes. • After thawing, do not refreeze. • **Preparation instructions** ○ Vaccine should appear as a white to off-white suspension and may contain white or translucent product-related particulates. • **Vaccine timelines** ○ Use refrigerated prefilled syringes **within 60 days**, if expiration date is not exceeded. ○ Use unrefrigerated (8°C to 25°C [46°F to 77°F])d prefilled syringes **within 12 hours**. • Egg, cell, latex, and preservative free. • Protect from light during storage. • Contraindications and precautions: see *Section B2*, above. • 2025-2026 mRNA vaccine dose schedule: see *Chapter 2, Section 12*.
(Novavax) **Protein subunit**	Suspension **Single-dose** prefilled syringe	5 mcg + 50 mcg adjuvant	0.5 mL	IM	**For 12 years of age and older:** • Vaccine should appear as a is a colorless to slightly yellow, clear to mildly opalescent suspension. • Inspect vaccine visually for particulate matter and discoloration prior to administration. Do not use if either condition is present. • Store prefilled syringes in a refrigerator 2°C to 8°C (36°F to 46°F). • Do not freeze. • Protect from light. • Egg, latex, and preservative free.

6. ***Document the patient vaccine administration information in the patient electronic health record:***
   - Under COVID-19 Immunization (brand required), record the vaccine administration location, 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).***
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 13. RESPIRATORY SYNCYTIAL VIRUS VACCINE

A. PURPOSE

The purpose of this guidance is to reduce morbidity and mortality from RSV, the virus that causes RSV 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 RSV vaccine as recommended by the ACIP. Currently, RSV vaccination is recommended as a single lifetime dose.

1. ***Identify persons in need of vaccination:***
   - ***Pregnant women 32 weeks 0 days through 35 weeks 6 days of pregnancy*** should receive a one-time dose of the RSV vaccine. Vaccine should be administered immediately before or during RSV season (September through January in most of the continental U.S.) and regardless of previous RSV infection.
     - Abrysvo™ is the only RSV vaccine recommended during pregnancy.
     - Either maternal vaccination or infant immunization with nirsevimab (an RSV monoclonal antibody) is recommended to prevent severe RSV disease in infants.
   - **Adults 75 years of age and older** should receive a one-time dose of vaccine.
   - **Adults 60-74 years of age who are at increased risk for severe RSV disease** should receive a one-time dose of vaccine. Persons considered to be at increased risk for severe RSV disease include those with the following underlying chronic medical conditions:
     - Chronic heart disease (e.g., congestive heart failure, coronary artery disease), excluding isolated hypertension
     - Chronic lung disease (e.g., chronic obstructive pulmonary disease, asthma)
     - End stage kidney disease
     - Chronic liver disease
     - Chronic hematologic disorders
     - Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness
     - Diabetes mellitus complicated by end organ damage or requiring treatment with insulin or SGLT2 inhibitors
     - Moderate or severe immunocompromise (either attributable to a medical condition or receipt of immunosuppressive medications or treatment)

- Other factors associated with increased risk for severe RSV disease in those 60-74 years of age and older include:
  - Severe obesity
  - Residence in nursing homes or other long-term care facilities (such as a hospital unit at an MRC)
  - Other underlying conditions or factors that a provider determines might increase the risk for severe RSV disease
- **Administration timing**: Optimally, vaccination should occur before the onset of the fall and winter RSV season.

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

CONTRAINDICATIONS:

- History of a serious reaction (e.g., anaphylaxis) to any component of the vaccine.

→ *For information on vaccine components, refer to the manufacturer's package insert at* http://www.immunize.org/fda/ *or go to* https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html.

PRECAUTIONS:

- If the individual has a moderate or severe acute illness with or without fever defer vaccination until resolution of illness.

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.
  - Have person administering the immunization sign and date 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 RSV 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 (22–25 g, 1–1½" needle) in the deltoid.

  → *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, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

TABLE 1: ADMINISTER RSV VACCINE:

INDICATION FOR ADULTS	RSV VACCINE				
	VOLUME	ROUTE	SITE	SCHEDULE	CONTRAINDICATIONS/NOTES
Pregnant women: 32 weeks 0 day through 36 weeks 6 days gestation *Pfizer vaccine ONLY*	0.5 mL Reconstituted	IM	Deltoid	1 dose	• **DO NOT GIVE** if history of serious reaction (e.g., anaphylaxis) to vaccine components. • Abrysvo™ is the only RSV vaccine recommended during pregnancy. • May be given on the same day with other adult vaccines.
Age: • 60-74 years and older *AND* at increased risk for severe disease • 75 years and older	0.5 mL Reconstituted and not reconstituted	IM	Deltoid	1 dose	• ***DO NOT freeze*** Abrysvo™ (Pfizer) or Arexvy (GSK) RSV vaccines or their components. • Latex free **Abrysvo™ (Pfizer)** *Storage instructions*: • Before reconstitution, store components refrigerated at 2°C to 8°C (36°F to 46°F). • After reconstitution, ***DO NOT*** refrigerate or freeze. Store at room temperature at 15°C to 30°C (59°F to 86°F). *Preparation instructions:* • Reconstitute the lyophilized antigen (a sterile white powder) with the prefilled syringe containing sterile water diluent. • Gently swirl the vial in a circular motion until powder is completely dissolved (< 1 minute). **DO NOT shake**. • Vaccine should appear as a clear, colorless solution. *Vaccine timeline:* • Use within 4 hours. **Arexvy (GSK)** *Storage instructions:* • As for Abrysvo™. Also, protect from light. *Preparation instructions:* • Reconstitute the lyophilized antigen (a sterile white powder) with the adjuvant suspension (an opalescent, colorless to pale brownish sterile liquid). • Gently swirl the vial until powder is completely dissolved. **DO NOT shake vigorously.** • Vaccine should appear as an iridescent, colorless to pale brownish liquid. *Vaccine timeline:* • Administer immediately *OR* store refrigerated at 2°C to 8°C (36°F to 46°F) *OR* store at room temperature (up to 25°C [77°F]) for up to 4 hours prior to use.

(Administration table continues on the following page)

					MRESVIA (Moderna) *Thawing instructions for refrigerator temperatures (*2°C to 8°C [36°F to 46°F]): • **Carton of one prefilled syringe**: Thaw for 60 minutes. • **Carton of 10 prefilled syringes**: Thaw for 155 minutes. Let each prefilled syringe stand at room temperature between 10 and 20 minutes before administering the vaccine. *Thawing instructions for room temperatures (15°C to 25°C [59°F to 77°F]):* • **Carton of one prefilled syringe**: Thaw for 45 minutes. • **Carton of 10 prefilled syringes**: Thaw for 140 minutes. • After thawing, vaccine is ready to be administered. *Storage instructions:* • Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. • May be stored frozen -40°C to -15°C (-40°F to 5°F) prior to thawing. • Once thawed, do not refreeze and do not shake. *Vaccine timelines after thawing:* • Use refrigerated (2°C to 8°C [36°F to 46°F]) prefilled syringes within **30 days**. Use unrefrigerated (8°C to 25°C [46°F to 77°F]) prefilled syringes within **24 hours** of removal from refrigerated conditions. Do not return to the refrigerator.

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

- Under RSV Immunization (brand required), record the vaccine administration location, 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.

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

ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE (7 PAGES) AGE 19 YEARS AND OLDER – SEE PACKAGE INSERT FOR AGES 18 YEARS AND YOUNGER * VACCINATION PROVIDERS SHOULD CHECK FDA-APPROVED PRESCRIBING INFORMATION FOR THE MOST COMPLETE AND UPDATED INFORMATION. PACKAGE INSERTS FOR U.S.-LICENSED VACCINES ARE AVAILABLE AT HTTPS://WWW.FDA.GOV/VACCINES-BLOOD-BIOLOGICS/VACCINES/VACCINES-LICENSED-USE-UNITED-STATES				
VACCINE	**VOLUME**	**ROUTE**	**INJECTION SITE**	**KEY POINTS* – SEE MODULES FOR COMPLETE INFORMATION**
Diphtheria, Tetanus, and Pertussis **(Tdap**, **Td)**	0.5 mL	IM	Deltoid	• Tdap at each pregnancy unless contraindicated. • Wounds: Tdap preferred. • Tip caps of the prefilled syringes may contain latex (Tenivac® only).
Hepatitis A **(HepA)**	1 mL	IM	Deltoid	• *Contraindication*: Severe allergy to neomycin. • Vial stopper, syringe plunger stopper, and tip cap contain late (Vaqta® only).
Hepatitis B **(HepB)**	1 mL	IM	Deltoid	• *Contraindication*: Severe allergy to yeast; pregnancy (Heplisav-B® and PreHevbrio® only). • Vial stopper, syringe plunger stopper, and tip cap, contain latex (Recombivax® only). • Higher dosing for dialysis patients. • Alternative dosing schedule option for immunocompromised, first series non-responders (including HIV-infected persons).
HepA-HepB Combination **(Twinrix)**	1 mL	IM	Deltoid	• *Contraindications*: Severe allergy to yeast or neomycin. • Latex free.
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. • Latex free.
9-valent human papillomavirus **(9vHPV)**	0.5 mL	IM	Deltoid	• *Contraindication:* Severe allergy to yeast. • *Precaution:* Vaccination not recommended during pregnancy. • Latex free.
Influenza: inactivated trivalent (**IIV3**); adjuvanted inactivated trivalent (**aIIV3**); cell-based inactivated (**ccIIV**); high dose inactivated trivalent (**HD-IIV3**); recombinant **(RIV)**; live attenuated influenza vaccine (**LAIV**)	0.5 mL	IM	Deltoid	• High dose and adjuvant vaccines are *only* for persons age ≥ 65 years *and* for persons age < 65 years who are solid organ transplant recipients on immunosuppressive medications. • RIV and ccIIIV vaccines are the only influenza vaccines that are egg-free. • Adjuvanted vaccine is formulated with an ingredient (squalene) to create a stronger immune response. • Afluria® and Fluad® vaccines are latex free. For other vaccines, review the vaccine package inserts.

ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE (7 PAGES)

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

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VACCINE	VOLUME	ROUTE	INJECTION SITE	KEY POINTS* – SEE MODULES FOR COMPLETE INFORMATION
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. • The tip caps of the prefilled syringes contain latex (Priorix® only). • 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. • Latex free.
Meningococcal conjugate **(MenACWY** [Menveo® or MedQuadfi®]**)**	0.5 mL	IM	Deltoid	• **Menveo® only:** Prior to use, reconstitute the two-vial presentation with proper diluent containing CWY antigens. • ***Store vaccine and diluent vials in refrigerator***. • *Contraindications:* Severe allergy to diphtheria toxoid or CRM (a diphtheria toxin carrier protein applicable to Menveo® only) or to tetanus toxoid (MenQuadfi® only). • Booster doses: Administer booster dose every 5 years if risk remains. • Latex free.
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.
Meningococcal serogroup A, B, C, W, Y **(MenABCWY** [Penbraya®]**)**	0.5 mL	IM	Deltoid	• **Single dose alternative** to separate administration of MenACWY and MenB when both vaccines would be given on the same day. • **If used for dose 1 MenB, Trumenba® should be administered for dose 2 MenB.** • If used as a booster, wait at least 6 months since the most recent MenABCWY dose. • **Prior to use, reconstitute** the lyophilized MenACWY component with the MenB component. • *Contraindications:* Severe allergy to tetanus toxoid. • *Precautions*: Pregnancy.

ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE (7 PAGES)

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VACCINE	VOLUME	ROUTE	INJECTION SITE	KEY POINTS* – SEE MODULES FOR COMPLETE INFORMATION
Pneumococcal conjugate **(PCV15, PCV20, and PCV21)**	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 only PPSV23 received previously, administer PCV 15, PCV20, or PCV21 1 year later. ○ If only PCV13 received previously, administer PCV20 or PCV21 1 year later. ○ **If age 19–49 years and PPSV23 and PCV13 received in past**, administer PCV20 or PCV21 at least 5 years after last pneumococcal vaccine dose. ○ **If age ≥ 50 years and PPSV23 and PCV13 received in past** AND ○ ***NO* PPSV23 received at age ≥ 65 years**, administer PCV20 or PCV21 at least 5 years after last pneumococcal vaccine dose. ○ **PPSV23 received at age ≥ 65 years,** PCV20 or PCV21 may be administered at least 5 years after last pneumococcal vaccine dose based on shared clinical decision-making. • Adults living in the western United States (including Alaska) or the Navajo nation *and* who have substance use disorders, chronic lung disease, or experience homelessness **should NOT receive PCV21.** • Latex free.
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 not previously vaccinated with PCV13, PCV15, PCV20, or PCV21 and PCV15 is used, administer PPSV23 1 year later. • Latex free.

ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE (7 PAGES)

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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 of antibody products. • Latex free.
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. • Latex free.
COVID-19, mRNA vaccine *Pfizer-BioNTech*	0.3 mL	IM	Deltoid	• Prefilled syringes out of refrigeration must be used within 12 hours (storing up to 25°C [77°F]). • Prefilled syringes must be used within 4 hours after a sterile needle has been attached. • *Contraindications:* Serious allergic reaction (e.g., anaphylaxis) after a previous dose of vaccine or to any component of the vaccine. • *Precautions*: ○ Non-severe allergy (e.g., urticaria beyond the injection site) to a component of an mRNA COVID-19 vaccine ***OR*** history of a non-severe, immediate (onset < 4 hours) allergic reaction after a dose of an mRNA COVID-19 vaccine. ○ Myocarditis or pericarditis within 3 weeks after a dose of any COVID-***19 vaccine*** ○ ***MIS-A or MIS-C.*** • ***Latex free.*** • ***Additional considerations:*** ○ Adults receiving orthopoxvirus vaccine: Wait 4 weeks between vaccinations due to risk of myocarditis and pericarditis. Use of JYNNEOS vaccine preferred. ○ COVID-19 revaccination: Consider in recipients of HCT or CAR T-cell therapy who received ≥ 1 dose of vaccine before or during treatment. Also consider for those who received doses during treatment with B-cell-depleting therapies for a limited period of time. ○ Recent SARS-CoV-2 infection: May delay

ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE (7 PAGES)

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VACCINE	VOLUME	ROUTE	INJECTION SITE	KEY POINTS* – SEE MODULES FOR COMPLETE INFORMATION
				vaccination by 3 months from symptom onset or positive test result, if infection asymptomatic. ○ Moderately to severely immunocompromised persons on immunosuppressive therapies: Administer vaccine at least 2 weeks before initiation or resumption of therapy. For those receiving B-cell-depleting therapies on a continuing basis, administer vaccine ~4 weeks before the next scheduled therapy.
COVID-19, mRNA vaccine *Moderna*	0.5 mL	IM	Deltoid	• Refrigerated prefilled syringes must be used within 60 days. • Unrefrigerated (8°C to 25°C [46°F to 77°F]) prefilled syringes must be used within 12 hours. • *Contraindications, precautions, and additional considerations:* As for the 2025-2026 mRNA Pfizer-BioNTech COVID-19 vaccine, above. • Latex free.
COVID-19, protein subunit vaccine *Novavax*	0.5 mL	IM	Deltoid	• *Contraindications:* Serious allergic reaction (e.g., anaphylaxis) after a previous dose of the Novavax vaccine or to any component of the vaccine. • *Precautions*: ○ Non-severe allergy (e.g., urticaria beyond the injection site) to a component of the Novavax vaccine ***OR*** history of a non-severe, immediate (onset < 4 hours) allergic reaction after a previous dose of the Novavax vaccine. ○ Myocarditis or pericarditis within 3 weeks after a dose of any COVID-***19 vaccine.*** ○ ***MIS-A or MIS-C.*** • *Additional considerations:* As for the 2025-2026 mRNA Pfizer-BioNTech COVID-19 vaccine, above. • Latex free.

ADMINISTERING VACCINES: DOSE, ROUTE, SITE, AND NEEDLE SIZE (7 PAGES)

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VACCINE	VOLUME	ROUTE	INJECTION SITE	KEY POINTS* – SEE MODULES FOR COMPLETE INFORMATION
Respiratory syncytial virus **(RSV)**	0.5 mL	IM	Deltoid	• Abrysvo (Pfizer) is the only vaccine recommended during pregnancy. • For **Arexvy (GSK) and Abrysvo (Pfizer**) RSV vaccines: ○ Reconstitute prior to use (see RSV module for details). ○ ***DO NOT freeze*** the vaccines or their components. • Latex free. • **Arexvy (GSK): After reconstitution, either** ○ Administer immediately ***OR*** ○ Store refrigerated at 2°C and 8°C (36°F to 46°F) ***OR*** ○ Store at room temperature (up to 25°C [77°F]) for up to 4 hours prior to use. • **Abrysvo (Pfizer): After reconstitution, either** ○ Administer immediately ***OR*** ○ Store at room temperature at 15°C to 30°C (59°F to 86°F) and use within 4 hours. • **MRESVIA (Moderna)** ○ No reconstitution needed. ○ Refrigerated prefilled syringes must be used within 30 days. ○ Unrefrigerated (8°C to 25°C [46°F to 77°F]) prefilled syringes must be used within 24 hours.

<table>
<tr><th colspan="2">NEEDLE SIZE</th></tr>
<tr><th>FOR INTRAMUSCULAR (IM) INJECTIONS</th><th>FOR SUBCUTANEOUS (SQ) INJECTIONS</th></tr>
<tr>
<td>Administer IM injections in the deltoid muscle, with a 22–25-gauge needle. Choose needle length based on person's age and body mass:
<table>
<tr><td>< 130 lbs.</td><td>5/8*–1"</td></tr>
<tr><td>Female 130–152 lbs.</td><td>1"</td></tr>
<tr><td>Female 153–200 lbs.</td><td>1–1½"</td></tr>
<tr><td>Female 200+ lbs.</td><td>1½"</td></tr>
<tr><td>Male 130–152 lbs.</td><td>1"</td></tr>
<tr><td>Male 152-260 lbs.</td><td>1–1½"</td></tr>
<tr><td>Male 260+ lbs.</td><td>1½"</td></tr>
</table>
* 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.</td>
<td>Administer SQ (or subcutaneous) 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/.</td>
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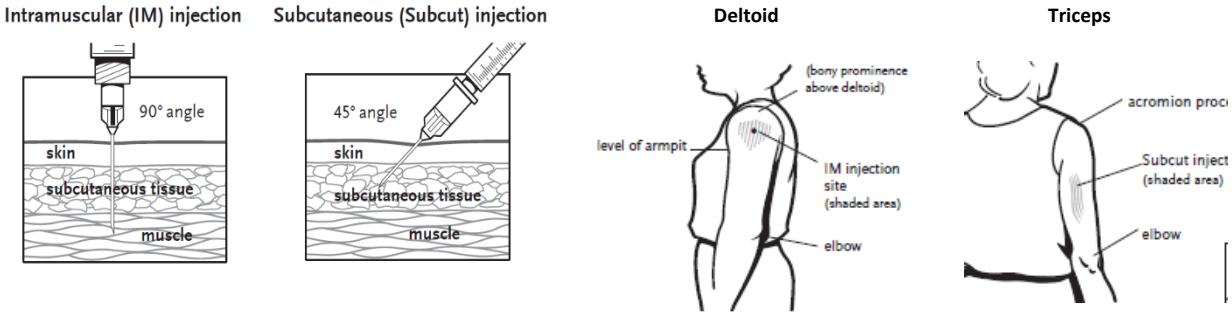

Image courtesy of *https://www.immunize.org/wp-content/uploads/catg.d/p2020a.pdf* (accessed 27 Dec. 2023).

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 the vaccine 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 manufacturing plant, extends to the transport and delivery of the vaccine, then to correct storage at the 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/storage-handling/?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html. *A PDF version of the toolkit is available on 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* https://www.immunize.org/wp-content/uploads/guide/pdfs/vacc-adults-entire.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 PROCESSES** to serve as a reference and training tool for proper vaccine management and after-hours 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 vaccines 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., VAR) should be stored at -58°F through 5°F (-50°C through -15°C) (ultra cold).*

The following is a summary of recommendations from the CDC regarding vaccine storage units:

For detailed information, see *https://www.cdc.gov/vaccines/hcp/admin/storage/index.html*.

1. ***The preferred type of vaccine storage** is a unit specifically designed to either refrigerate or freeze vaccines, sometimes referred to as a **PURPOSE-BUILT** or **PHARMACEUTICAL-GRADE** unit. These units can be either compact, under-the-counter-style, or large. 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 recovery from 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.
   - Use safeguards to ensure the doors of the unit remain closed (e.g., self-closing door hinges, door alarms, door locks).
   - ***Note:*** Many purpose-built refrigerators do not need water bottles to serve as thermal ballast. Consult the manufacturer's guidance.
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. VACCINE STORAGE BEST PRACTICES

1. **Use the BEMR Pharmacy Inventory Management System (PIMS) 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 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!***"
- 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 as ***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
- 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. ***The 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 as Attachment 4.*

E. RESPONDING TO TEMPERATURE EXCURSIONS

- *See the poster **Handling a Temperature Excursion in Your Vaccine Storage Unit**, available as 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/or 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 until further guidance is provided.*
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 other than vaccines (including water bottles)
     - Any problems with the storage unit and/or affected vaccines before the event
     - Other relevant information
4. Contact 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 vaccines as follows:
   - Utilize conditioned frozen water bottles to prevent vaccines from freezing.
     - To condition frozen water bottles, place them in lukewarm water until the ice 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 ADMINISTRATION

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

SKILLS CHECKLIST FOR VACCINE ADMINISTRATION (PAGE 1 OF 2)				
FACILITY:			EMPLOYEE:	
The following checklist (✓) can be used as an assessment tool for health care employees who administer vaccines.				
SELF-ASSESSMENT		SUPERVISOR/ PRECEPTOR REVIEW		SKILLS
Needs to Improve	Meets or Exceeds Expectations	Needs to Improve	Meets or Exceeds Expectations	
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				
				Double-checks vial label, contents, and expiration date 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 and storage to maintain the “cold chain.”
				Documents vaccine temperature monitoring appropriately.

SKILLS CHECKLIST FOR VACCINE ADMINISTRATION (PAGE 2 OF 2)				
SELF-ASSESSMENT		SUPERVISOR/ PRECEPTOR REVIEW		SKILLS
Needs to Improve	Meets or Exceeds Expectations	Needs to Improve	Meets or Exceeds Expectations	
ADMINISTERING VACCINES				
				Verifies prepared syringe with 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 is performed between patients.*
				Cleans the vaccine vial top with alcohol prior to withdrawing dose.
				Appropriately positions patient for vaccination.
ADMINISTERING VACCINES (CONTINUED)				
				Properly preps the injection site with an alcohol wipe and allows 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 years, trivalent 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 identify 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

EMPLOYEE CONTACT LIST FOR VACCINES		
NAME	**TITLE**	**TELEPHONE NUMBERS (OFFICE/CELL)**
	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 EMPLOYEE CONTACT LIST*		
NAME	**TITLE**	**TELEPHONE NUMBERS (OFFICE/CELL/PAGER)**
1.		
2.		
3.		
4.		
5.		
6.		

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: STORAGE UNIT IFU AND 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 manufacturer's package insert 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" 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 and reset. ◆ 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 the appropriate 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°F TO 46°F (2°C TO 8°C). OPTIMAL TEMPERATURE IS AROUND 40°F.**

➔ **IF TEMPERATURE IS OUT OF RANGE, CORRECTIVE ACTION MUST BE TAKEN.** For any out-of-range temperatures below, write in the number (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.