

Pharmacy Immunization Protocol

Pharmacy Name

Authorizing Prescriber Statement for Vaccination

<Pharmacist, RPh> of the <Pharmacy>, and other licensed pharmacists employed by the <Pharmacy>, pharmacy students of the <Pharmacy>, acting as delegates for <Physician>, M.D. according to and in compliance with Article 3 of the Business and Professional Code 4052.(a).(4).(C) and B&P code 4052.(a).(5).(A).(iii) of the California Pharmacy Scope of Practice section, will independently determine the need for and administer vaccinations and epinephrine, on the premises of the USC Campus Pharmacies, or a suitable alternate location as authorized under Appendix A, and for a fee.

Qualifications of Persons Administering Vaccine

1. CPR certified (BLS) – American Red Cross or American Heart Association or equivalent
2. Certificate of completion of an appropriate immunization program (see Appendix B)

Vaccine(s) to be administered (see Appendix C) - check www.immunize.org/standingorders/orders_adult.asp

- Influenza (IM and Intranasal)
- Tetanus-diphtheria (Td)
- Tetanus-diphtheria-pertussis (Tdap)
- Pneumococcal (PPV23 adult)
- MMR (for adults)
- HPV
- Meningococcal (MCV4 and MPSV4)
- Varicella Zoster
- Herpes Zoster
- Hepatitis B

Policies

1. A standard form will be used to document immunizations and the pharmacy will maintain a patient record of administration, including, but not limited to, patient name, date, vaccine given (manufacturer, lot #, and expiration date), and signature of person administering vaccine (Appendix D)
2. The screening form contained in this protocol will be maintained as documentation (Appendix D)
3. The current Vaccine Information Statement for each vaccine will be discussed and given to each patient
4. Written informed consent will be obtained for each patient prior to vaccination (Appendix D)
5. The pharmacist will notify the patient's primary care provider of immunization when contact information is available (see Appendix E).
6. All supplies needed for vaccination and vaccine adverse event management as detailed in this protocol will be available and not expired.
7. Authorizing prescriber will be periodically notified of vaccinated patients

Emergencies

Authorize use of the Pharmacy Procedure and Standing Orders for Management of Allergic or Anaphylactic Reactions for emergencies (Appendix F)

Physician Authorization:

Physician Name: _____ *Physician, M.D.* _____ Affiliation (Clinic): _____

Phone: _____ Fax: _____ Pager/Mobile: _____

Physician CA license number: _____ Physician DEA number: _____

_____ Date

_____ <Physician>, MD

Principle Authorized Pharmacist

_____ Date

_____ <Pharmacist, RPh>

This authorization will be in effect for 2 years unless rescinded earlier in writing by either party. Any changes in the protocol must be agreed upon by both parties.

Pharmacy Immunization Protocol

APPENDIX A. Alternate Location Request for Vaccine Administration

The pharmacists and intern pharmacists authorized under this protocol may provide vaccination services at the following location in California for the time period specified. All provisions under the policy, procedure and protocol shall remain in effect. Cold chain for storage and subsequent administration of vaccines shall be maintained.

Location and/or Name of Event: _____

Address: _____

Date(s): _____

Signature:

<Physician> , M.D.

Date _____

APPENDIX B. Immunization Training

Certificate of completion of an appropriate immunization-training program that includes the *current guidelines and recommendations of the Advisory Committee on Immunization Practices* and uses the core curriculum of the CDC (Epidemiology and Prevention of Vaccine-Preventable Diseases). An appropriate training program shall include, at a minimum, instruction on how to:

- A. Identify persons eligible for vaccination based on current ACIP guidelines. (Factors taken into consideration will include age, vaccination status (e.g., persons previously unvaccinated or due for vaccination according to the recommended schedule), or the presence of a medical condition that puts them at high risk, etc.).
- B. Screen patients for contraindications and precautions to vaccination (e.g., severe illness, previous allergic reaction, egg allergy, etc.).
- C. Provide adequate information to patients or their guardians regarding the risks for and benefits of a vaccine and documenting the delivery of that information. (i.e. Distribution/discussion of Vaccination Information Statements as required by law).
- D. Administer vaccines.
- E. Monitor patients for adverse events.
- F. Manage anaphylactic reactions according to protocol
- G. Report adverse outcomes to the Vaccine Adverse Events Reporting System (VAERS).
- H. Record administration of a vaccine(s)
- I. Provide documentation of vaccine administration to patients and whenever possible, their primary-care providers.
- J. Follow Universal Precautions and Infection Control and pertinent OSHA regulations (i.e. for Blood Bourne Pathogens).

Appendix C. Criteria for Patients to Receive Vaccine

Hepatitis B Vaccine

Purpose: To reduce morbidity and mortality from hepatitis B virus (HBV) infection by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure:

1. Identify adults in need of hepatitis B vaccination based on the following criteria:
 - a. Persons less than 19 years of age who have not received the vaccine
 - b. Age 19 years or older meeting any of the following criteria:
 - having had more than one sex partner in the previous 6 months, a recently acquired sexually transmitted disease, or recent treatment for a sexually transmitted disease
 - male who has had sex with males
 - injection drug user
 - sex partner or household member of a person who is chronically infected with HBV (including an HBsAg-positive adopted child)
 - at occupational risk of infection through exposure to blood or blood-contaminated body fluid (e.g., health care worker, public safety worker, trainee in a health professional or allied health school)
 - client or staff of an institution for the developmentally disabled
 - hemodialysis patient or patient with early renal failure (who will become a dialysis patient)
 - receiving clotting-factor concentrate
 - planning to travel to or live in a high endemic area of the world for more than 6 months and will have close contact with the local population; also short-term travelers who are likely to have contact with blood (e.g., in a medical setting) or sexual contact with residents of areas with high or intermediate levels of endemic disease
 - housed in a long-term correctional facility
2. Screen all patients for contraindications and precautions to hepatitis B vaccine:
 - a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of hepatitis B vaccine or to a hepatitis B vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf
 - b. **Precautions:** a moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speakers with the VIS in their native language if available; these can be found at www.immunize.org/vis
4. For persons 20 years of age or older, administer 1.0 mL hepatitis B vaccine IM (22–25g, 1–1½" needle) in the deltoid muscle. For persons 19 years of age or younger, administer 0.5 mL hepatitis B vaccine IM (22–25g, 1–1½" needle) in the deltoid muscle.
5. Provide subsequent doses of hepatitis B vaccine to complete each patient's 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 8 weeks between the second and third doses, and at least 4 months between the first and third doses.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to hepatitis B vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or by calling (800) 822-7967. VAERS report forms are available at www.vaers.org

Varicella (Chickenpox) Vaccine to Adolescents/Adults

Purpose: To reduce morbidity and mortality from varicella (chickenpox) by vaccinating all people who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure

1. Identify adults in need of varicella (chickenpox) vaccination who (a) were born in the U.S. in 1980 or later or (b) are a healthcare worker or non-U.S.-born person, and who also meet any of the following criteria:
 - lack documentation of 2 doses of varicella vaccine
 - lack a history of varicella based on diagnosis or verification of varicella by a healthcare provider
 - lack a history of herpes zoster based on healthcare provider diagnosis
 - lack laboratory evidence of immunity or laboratory confirmation of disease
2. Screen all patients for contraindications and precautions to varicella vaccine:
 - a. **Contraindications:**
 - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of varicella vaccine or to a varicella vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf.
 - pregnant now or may become pregnant within 1 month (pregnant women should be vaccinated upon completion or termination of pregnancy)
 - substantial suppression of cellular immunity
 - b. **Precautions:**
 - recent (within the past 11 months) receipt of antibody-containing blood product (specific interval depends on product)
 - moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Administer 0.5 mL varicella vaccine subcutaneously (23–25g, 5/8" needle) in the posterolateral fat of the upper arm.
5. Administer a second dose 4–8 weeks after the first dose.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to varicella vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

Herpes Zoster (HZ Shingles) vaccine

Purpose: To reduce morbidity and mortality from herpes zoster shingles infection by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure:

1. Identify adults in need of herpes zoster shingle vaccination based on meeting the following criteria:
Any adult 60 years of age or older who has had a case of chicken-pox or received the chicken-pox vaccine previously
2. Screen all patients for contraindications and precautions to shingles vaccine:
 - a. **Contraindications:**
 - Are < 60 years of age
 - Serious life-threatening allergic reaction to gelatin, the antibiotic neomycin, or any other component of the HZ shingles vaccine. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf
 - Pregnant now, or may become pregnant with in three months of receiving the shingles vaccine
 - History of primary or acquired immune deficiency including HIV/AIDS, leukemia, lymphomas of any type, and other malignant neoplasms affecting the bone marrow or lymphatic system
 - Are on immune suppressive therapy including high dose corticosteroids
 - Have active untreated tuberculosis
 - b. **Possible adverse reactions:** redness, pain, swelling, itching, warmth, bruising at the injection site, and headache.
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record of office log, the publication date of the VIS and the date it was given to the patient. Provide on-English speakers with the VIS in their native language if available; these can be found at www.immunize.org/vis
4. Administer 0.65mL of Zostavax given SC (23-25g, 5/8-3/4" needle) for 1 dose only.
5. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal Immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
7. Report all adverse reactions to shingles vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or by calling (800) 822-7967. VAERS report forms are available at www.vaers.org

Updated 11/19/06

Human Papillomavirus Virus (HPV) Vaccine

Purpose: To reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure:

1. Identify adolescents and adults in need of HPV vaccination based on meeting any of the following criteria:
 - a. females 11-12 years of age (females 9 years of age may also be considered for the vaccine)
 - b. females 13-26 years of age who have not been vaccinated previously or who have not completed the full vaccine series
2. Screen all patients for contraindications and precautions to HPV vaccine:
 - a. **Contraindications:**
 - Serious life-threatening allergic reaction to yeast, or after receiving a previous dose of HPV vaccine, or any other component of HPV vaccine. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf
 - Avoid use in pregnancy
 - If a woman is found to be pregnant after the series is initiated, the remaining doses should be delayed until after completion of the pregnancy.
 - Merck maintains a Pregnancy Registry to monitor fetal outcomes of pregnant women exposed to Gardasil®. Patients and health care providers are encouraged to report any exposure to Gardasil® during pregnancy by calling 800-986-8999
 - Consider postponing vaccination in persons with moderate or severe illness, with or without fever, until recovery, to minimize potential adverse effects. Low-grade fever itself and mild upper respiratory infection are not generally contraindications to vaccination.
 - b. **Precautions:** moderate to severe fever and pain, redness, or tenderness at the injection site
3. Provide all patients with a copy of the most current federal Vaccine information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide on-English speakers with the VIS in their native language if available; these can be found at www.immunize.org/vis
4. For persons 9-26 years of age, administer 0.5mL per dose given IM (22-25g, 1-1 1/2" needle) in the deltoid region of the upper arm or higher anterolateral areas of the thigh.
5. Provide subsequent doses of HPV vaccine to complete each patient's 3 dose schedule by observing a minimum interval of 2 months for the second dose, and 6 months for the third dose.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal Immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or by calling (800) 822-7967. VAERS report forms are available at www.vaers.org

Updated 11/19/2006

Influenza Vaccine

Purpose: To reduce morbidity and mortality from influenza by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure:

1. Identify adults in need of influenza vaccination based on meeting any of the following criteria:
 - a. Age 50 years or older
 - b. Having any of the following conditions:
 - chronic disorder of the pulmonary or cardiovascular system, including asthma
 - chronic metabolic disease (e.g., diabetes), renal dysfunction, hemoglobinopathy, or immunosuppression (e.g., caused by medications, HIV) that has required regular medical follow-up or hospitalization during the preceding year)
 - any condition that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration (e.g., cognitive dysfunction, spinal cord injury, seizure disorder or other neuromuscular disorder)
 - will be pregnant during the influenza season
 - c. Residence in a nursing home or other chronic-care facility that houses persons of any age who have chronic medical conditions
 - d. In an occupation or living situation that puts one in proximity to persons at high risk, including
 - a healthcare worker, caregiver, or household member in contact with person(s) at high risk of developing complications from influenza
 - a household contact or out-of-home caretaker of a child age 0–59 months
 - e. Wish to reduce the likelihood of becoming ill with influenza
2. Screen all patients for contraindications and precautions to influenza vaccine:
 - a. **Contraindications:** serious reaction (e.g., anaphylaxis) after ingesting eggs or after receiving a previous dose of influenza vaccine or an influenza vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf. Do not give live attenuated influenza vaccine (LAIV) to pregnant women, immunosuppressed persons, or persons who have a history of Guillain-Barré syndrome. Use of inactivated influenza vaccine is preferred over LAIV for close contacts of severely immunosuppressed persons during periods when the immunocompromised person requires a protective environment.
 - b. **Precautions:** moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Administer 0.5 mL of injectable trivalent inactivated influenza vaccine (TIV) IM (22–25g, 1–1½" needle) in the deltoid muscle. Alternatively, healthy persons ages 5–49 years without contraindications may be given 0.5 mL of intranasal LAIV; 0.25 mL is sprayed into each nostril while the patient is in an upright position.
5. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
7. Report all adverse reactions to influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

Measles, Mumps, & Rubella Vaccine

Purpose: To reduce morbidity and mortality from measles, mumps, and rubella by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure

1. Identify adults in need of initial vaccination against measles, mumps, or rubella who were born in 1957 or later with no history of receipt of live, measles-, mumps-, and/or rubella-containing vaccine given at 12 months of age or older or other acceptable evidence of immunity (e.g., laboratory evidence). Combination MMR vaccine is recommended if one or more component is indicated.
2. Identify adults born in 1957 or later in need of a second dose of measles, mumps, and rubella (MMR) vaccine who are either planning to travel internationally, a student in a college, university, technical or vocational school, or a health care worker.
3. Screen all patients for contraindications and precautions to measles, mumps, and rubella (MMR) vaccine:
 - a. **Contraindications:**
 - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of MMR vaccine or to an MMR vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf
 - pregnant now or may become pregnant within 1 month
 - known severe immunodeficiency (e.g., hematologic and solid tumors; congenital immunodeficiency; long-term immunosuppressive therapy, or severely symptomatic HIV infection)
 - b. **Precautions:**
 - recent (<11 months) receipt of antibody-containing blood product (specific interval depends on product)
 - history of thrombocytopenia or thrombocytopenic purpura
 - moderate or severe acute illness with or without fever
4. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language; these can be found at www.immunize.org/vis
5. Administer 0.5 mL MMR vaccine SC (23–25g, 5/8–3/4" needle) in the posterolateral section of the upper arm.
6. For adults in need of second doses of MMR, observe a minimum interval of 4 weeks between the first and second doses.
7. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
8. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
9. Report all adverse reactions to MMR vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or (800) 822-7967. VAERS report forms are available at www.vaers.org

Meningococcal Vaccine

Purpose: To reduce morbidity and mortality from meningococcal disease by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices.

Procedure

1. Identify adults in need of vaccination against meningococcal disease based on any of the following criteria:
 - a. anticipated college enrollment, particularly anticipated residence in an on-campus dormitory
 - b. anticipated travel to a country in the “meningitis belt” of sub-Saharan Africa or other location of epidemic meningococcal disease, particularly if contact with the local population will be prolonged
 - c. anticipated travel to Mecca, Saudi Arabia, for the annual Hajj
 - d. diagnosis of a damaged spleen; splenectomy
 - e. diagnosis of terminal complement component deficiency (an immune system disorder)
 - f. employment as a microbiologist with routine exposure to isolates of *N. meningitidis*
 - g. military recruits
 - h. any other adult wishing to decrease their risk for meningococcal disease
 - i. age 55 years or younger with history of receiving **meningococcal polysaccharide vaccine (MPSV4)** at least 5 years earlier and with continued risk for infection (e.g., living in epidemic disease areas).
2. Screen all patients for contraindications and precautions to meningococcal vaccine:
 - a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of meningococcal vaccine or to a meningococcal vaccine component, including diphtheria toxoid for **meningococcal conjugate vaccine (MCV4)**. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf.
 - b. **Precautions:** moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Although not required by federal law, it is prudent to document in the patient’s medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. For adults ages 55 years and younger, administer 0.5 mL MCV4 via the intramuscular route (22–25g, 1–1½" needle) in the deltoid muscle. If MCV4 is unavailable, MPSV4 is an acceptable alternative, although it must be given subcutaneously. For adults older than age 55 years, administer 0.5 mL MPSV4 via the subcutaneous route (23–25g, 5⁄8" needle) in the posterolateral fat of the upper arm.
5. Document each patient’s vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
7. Report all adverse reactions to meningococcal vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

Pneumococcal Vaccine - Adults

Purpose: To reduce morbidity and mortality from pneumococcal disease by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure

1. Identify adults in need of vaccination with pneumococcal polysaccharide vaccine (PPV) based on the following criteria:
 - a. Age 65 years or older with no or unknown history of prior receipt of PPV
 - b. Age 18–64 years with no or unknown history of prior receipt of PPV and any of the following conditions:
 - i. chronic cardiovascular disease (e.g., congestive heart failure, cardiomyopathies)
 - ii. chronic pulmonary disease (e.g., emphysema or chronic obstructive pulmonary disease [not asthma])
 - iii. diabetes mellitus, alcoholism, chronic liver disease (cirrhosis), or cerebrospinal fluid leaks
 - iv. functional or anatomic asplenia (e.g., sickle cell disease, splenectomy)
 - v. immunosuppressive conditions (e.g., HIV infection, leukemia, congenital immunodeficiency, Hodgkin's disease, lymphoma, multiple myeloma, generalized malignancy)
 - vi. immunosuppressive chemotherapy (e.g., alkylating agents, antimetabolites, long-term systemic corticosteroids)
 - vii. organ or bone marrow transplantation
 - viii. chronic renal failure or nephrotic syndrome
 - ix. candidate for or recipient of cochlear implant
2. Identify adults in need of a second and final dose of PPV if five or more years have elapsed since the previous vaccination and the patient is:
 - a. Age 65 years or older and received prior PPV vaccination when less than age 65 years
 - b. At highest risk for serious pneumococcal infection and/or likely to have a rapid decline in pneumococcal antibody levels (i.e., categories iv.-viii. above)
3. Screen all patients for contraindications and precautions to PPV vaccine.
 - a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of PPV or to a vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf
 - b. **Precautions:** a moderate or severe acute illness with or without fever
4. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Although not required by federal law, it is prudent to document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available. These can be found at www.immunize.org/vis
5. Administer 0.5 mL PPV vaccine either IM (22–25g, 1–2" needle) or SC (23–25g, 5/8–3/4" needle).
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to PPV to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or by calling (800) 822-7967. VAERS report forms are available at www.vaers.org

Purpose: To reduce morbidity and mortality from tetanus, diphtheria, and (where indicated) pertussis by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure

1. Identify adults in need of vaccination against tetanus, diphtheria, and (where indicated) pertussis based on the following criteria:
 - a. lack of documentation of at least 3 doses of tetanus- and diphtheria-containing toxoids
 - b. younger than age 65 years with no history of pertussis-containing vaccine given since age 10 years
 - c. completion of a 3-dose primary series of tetanus- and diphtheria-containing toxoids with receipt of the last dose being 10 years ago or longer
 - d. recent deep and dirty wound (e.g., contaminated with dirt, feces, saliva) and lack of evidence of having received tetanus toxoid-containing vaccine in the previous 5 years
2. Screen all patients for contraindications and precautions to tetanus and diphtheria toxoids (Td) and, if applicable, pertussis vaccine (Tdap):
 - a. **Contraindications:**
 - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of Td or to a Td or Tdap component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf.
 - for Tdap only, a history of encephalopathy within 7 days following DTP/DTaP given before age 7 years
 - b. **Precautions:**
 - history of Guillain-Barré syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine
 - an unstable neurologic condition
 - moderate or severe acute illness with or without fever

Note: Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester.
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Administer 0.5 mL Td (or Tdap, if appropriate) vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle.
5. Provide subsequent doses of Td (a one-time dose of Tdap may be substituted for Td if younger than 65 years) to adults as follows:
 - a. to complete the primary 3-dose schedule: observe a minimum interval of 4 weeks between the first and second doses, and 6 months between the second and third doses.
 - b. to boost after primary schedule is complete: observe a 10-year interval since previous dose of Td/Tdap; if protection against pertussis is needed, an interval of 5 years is recommended and intervals as short as 2 years or less can be observed for parents and caregivers of infants younger than age 12 months, healthcare workers having direct patient contact, and adults in a pertussis outbreak setting.
 - c. In pregnancy, when indicated, give Td or Tdap in 2nd or 3rd trimester. If not administered during pregnancy, give Tdap in immediate postpartum period.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to Td and Tdap vaccines to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

Pharmacy Name
 Address 1
 Address 2
 Phone#

Patient Name: _____
 DOB: _____
 Today's Date: _____

VACCINE ADMINISTRATION RECORD, SCREENING and PATIENT CONSENT

	YES	NO
1. Have you ever had a severe reaction to any vaccine that required medical care? If yes, describe: _____	_____	_____
2. Do you have any allergies to food, medications, or vaccines?	_____	_____
3. Are you sick today?	_____	_____
4. Have you had Guillain-Barre Syndrome, seizure, brain, or nerve problems?	_____	_____
5. Are you pregnant or planning to become pregnant in the next 3 months?	_____	_____
6. Are you or anyone in your household being treated with chemotherapy or radiation for cancer, have HIV/AIDS or any immune deficiency disorder?	_____	_____
7. Do you or anyone in your household take oral prednisone (>20mg/day) or other oral steroids, or anticancer drugs?	_____	_____
8. Do you have a bleeding disorder or take "blood thinners" like coumadin or heparin?	_____	_____

The following questions will help determine any other indications or contraindications

1. What adult vaccinations has this patient received (vaccine and date)?

2. List all Rx and OTC medications this patient is currently taking

3. List all current medical conditions

INFORMATION ABOUT PERSON TO RECEIVE VACCINE (please print)

NAME last	first	middle initial	SOCIAL SECURITY NUMBER
ADDRESS	CITY	STATE/ZIP	PHONE#
BIRTHDATE	SEX	PHYSICIAN	PHYSICIAN PHONE OR FAX

Yes No I request to have this information sent to the physician's office specified above

DO NOT WRITE BELOW THIS LINE - For Pharmacy Use Only

VACCINE	LOT #	EXP DATE	MANUFACTURER	DOSE (mL)	ADMINISTRATOR	VIS DATE
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____

Please read the following statements and sign below on the signature line.

I have read or have had explained the information provided about the vaccine I am to receive. I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of vaccination and ask that the vaccine be given to me or to the person named above for whom I am authorized to make this request.

Medicare, I do hereby authorize the <Pharmacy> to release information and request payment. I certify that the information given by me in applying for payment under Medicare is correct. I authorize release of all records to act on this request. I request that payment of authorized benefits be made on my behalf.

X _____ DATE: _____
 Signature of person to receive vaccine or person authorized to make the request (parent or guardian)

Facsimile Transmittal

To:	Fax: () -
From:	Date: / /
Re: Patient Name	Pt. DOB:
CC:	Pages:

This fax has been sent to you with the consent of your patient to notify you that the patient named above received the following vaccination(s) at our pharmacy on the date that is listed below. Please make a note of this in the patient’s chart and feel free to call at the number above with any questions.

Administration Date	Product	Dose	Comments

Confidentiality Notice: This facsimile, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender and destroy all copies of the original message.

Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults

Supplies Needed

- | | |
|---|--|
| <input type="checkbox"/> Aqueous epinephrine 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen). If EpiPens are stocked, at least three adult EpiPens (0.30 mg) should be available. | <input type="checkbox"/> Adult airways (small, medium, and large) |
| <input type="checkbox"/> Diphenhydramine (Benadryl) injectable (50 mg/mL solution) and 25 mg or 50 mg capsules or tablets and syrup (12.5 mg/5 mL suspension) | <input type="checkbox"/> Sphygmomanometer (adult and extra-large cuffs) and stethoscope |
| <input type="checkbox"/> Syringes: 1–3 cc, 22–25g, 1", 1½", and 2" needles for epinephrine and diphenhydramine (Benadryl) | <input type="checkbox"/> Adult size pocket mask with one-way valve |
| <input type="checkbox"/> Wristwatch with second hand | <input type="checkbox"/> Alcohol swabs |
| | <input type="checkbox"/> Tourniquet |
| | <input type="checkbox"/> Tongue depressors |
| | <input type="checkbox"/> Flashlight with extra batteries (for examination of the mouth and throat) |
| | <input type="checkbox"/> Cell phone or access to an on-site phone |

Signs and Symptoms of Anaphylactic Reaction

Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.

Treatment in Adults

- If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.
- Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01 mL/kg/dose (adult dose ranges from 0.3 mL to 0.5 mL, with maximum single dose of 0.5 mL).
- In addition, for systemic anaphylaxis, administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1–2 mg/kg, up to 100 mg maximum single dose.
- Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
- If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 10–20 minutes for up to 3 doses, depending on patient's response.
- Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
- Notify the patient's primary care physician.

Sources: 1. American Academy of Pediatrics. Passive Immunization. In: Pickering LK, ed. *Red Book: 2006 Report of the Committee on Infectious Diseases*. 27th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006:64–66.
 2. American Pharmacists Association, Grabenstein, JD, *Pharmacy-Based Immunization Delivery*, 2002.
 3. *Got Your Shots? A Providers Guide to Immunizations in Minnesota*, Second Edition, Minnesota Department of Health, 2001:80-82.