PURPOSE FOR THIS GUIDE

The purpose of this guide is for general educational purposes only. Please discuss individual patient conditions with the patients’ physician(s) prior to administration of any vaccine or pharmaceutical. Also refer to the product package insert for the full prescribing information of any vaccine or pharmaceutical listed.

Acknowledgements

The majority of the information provided here is available publicly through various government websites that are referenced throughout this guide. Primarily, the Centers for Disease Control and Prevention (CDC), the Department of the U.S. Health and Human Service Department (HHS), the Immunization Action Coalition, and the Centers for Medicaid and Medicare Services (CMS) were instrumental in our information gathering. The nature of drug information is that it is constantly evolving because of ongoing research and clinical experience and is often subject to interpretation. While great care has been taken to ensure the accuracy of the information presented, the reader is advised that the authors, editors, reviewers, contributors and publishers cannot be responsible for the continued currency of the information. All readers are advised that decisions regarding drug therapy and treatment must be based on the independent judgment of treating clinicians, changing information about a drug (e.g., as reflected in literature and manufacturer’s most current product information), and changing medical practices. The editors are not responsible for any inaccuracy of quotations or for any false or misleading implication that may arise due to the text or formulas as used or due to the quotation of revisions no longer official. PharMerica Corporation does not represent or warrant the accuracy of the information provided in this manual and nothing in this manual is intended to replace the treatment by an established clinician. No official support or endorsement by any federal or state agency or pharmaceutical company is intended or inferred.
# TABLE OF CONTENTS

2  Purpose for this Guide
4  CMS Requires Flu/Pneumococcal Vaccinations for Nursing Homes
7  Insurance Coverage Information

8  **Seasonal Influenza**
9  2017-18 Vaccine Recommendation Updates
10  Consent for Influenza & Pneumonia Vaccines
12  VIS: Inactivated Influenza Vaccine
14  Standing Orders for Administering Seasonal Influenza to Adults
17  Declination of Influenza Vaccination
18  Interim Guidance for Influenza Outbreak Management in Long-Term Care Facilities

25  **Vaccine Info Statements**
26  VIS: Polysaccharide (Pneumovax/PPSV23)
28  VIS: Conjugate (Prevnar/PCV13)
30  VIS: MenACWY VIS
32  VIS: Men B VIS
34  VIS: Herpes Zoster (Shingles)
36  VIS: Tdap
38  VIS: Td

40  **Additional Info**
41  CDC Adult Vaccination Schedule
47  VAERS Form
51  Storage Best Practices for Refrigerated Vaccines
53  Temp Monitoring for Refrigerated Vaccines
55  Storage Best Practices for Frozen Vaccines
57  Temp Monitoring for Frozen Vaccines
Effective November 28th 2017, requirements for F-tag 334 Influenza and Pneumococcal Immunizations, pursuant to regulation §483.80(d), will now be found under F-tag 883.

The Centers for Medicare and Medicaid Services (CMS) requires nursing facilities participating in the Medicare and Medicaid programs to offer all residents influenza and pneumococcal vaccines and document the results. This information is to be reported in Section O of the CMS Minimum Data Set (MDS), which tracks nursing home health parameters. CMS uses this data in the Nursing Home Star Rating Program measuring the percent of both short-stay and long-stay residents assessed and given, appropriately, the seasonal influenza vaccine and the pneumococcal vaccine.

Surveyors will assess each facility’s vaccination policies and procedures for compliance during the annual survey. Key differences in F-tag 883 guidance to surveyors include:

1. New provisions have been added to document facility action during a national shortage OR when the facility has an inability to implement the influenza vaccine program. These standards require the facility to demonstrate:
   a. The vaccine is ordered and the facility received a confirmation of the order indicating that the vaccine has been shipped or that the product is not available but will be shipped when the supply is available
   b. Plans are developed on how and when the vaccines are to be administered
   c. Residents are screened to determine how many and which residents are eligible and wish to receive the vaccine; and
   d. Education regarding immunizations is implemented

2. New guidance requires that each resident is offered pneumococcal immunization, unless immunization is medically contraindicated or the resident has already been immunized. Provision of Immunizations; Pneumococcal Immunizations - the new guidance includes the statement:
   a. Facilities must follow the CDC and ACIP recommendations for vaccines

NOTE: As of the date of publication of this guidance, ACIP recommends that “both 23-valent pneumococcal polysaccharide vaccine (PPSV23) and 13-valent pneumococcal conjugate vaccine (PCV13) vaccines should be administered routinely in series to all adults aged > 65 years. “ ACIP explained that PPSV23 is effective in preventing invasive pneumococcal disease but the effectiveness of PPSV23 in preventing non-bacteremic pneumococcal pneumonia has been inconsistent. ACIP expects administration of both PCV13 and PPSV23 will provide optimal protection against pneumococcal infections. The recommendations for adults aged < 65 years are different than for those adults aged > 65 years so they should be vaccinated based on the ACIP recommendations for their age group.
CMS REQUIRES FLU/PNEUMOCOCCAL VACCINATIONS FOR NURSING HOMES – 2017 UPDATE

The full content of F-tag 883 can be viewed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes.html

The use of standing orders by nursing homes and skilled nursing facilities, hospitals, and home health agencies ensures that vaccination is offered. Generally, a standing orders program for influenza vaccinations would be conducted under the supervision of a licensed practitioner according to a physician-approved facility or agency policy by a Health Care Professional (HCP) trained to screen patients for contraindications to vaccination, administer vaccine, and monitor for adverse events. However, CMS has removed the physician signature requirement for the administration of influenza and pneumococcal vaccines to Medicare and Medicaid patients in hospitals, LTC facilities, and home health agencies. To the extent allowed by local and state law, these facilities and agencies may implement standing orders for influenza and pneumococcal vaccination of Medicare and Medicaid-eligible patients. In its collaborative effort to improve quality of care, CMS is also encouraging nursing facilities to provide influenza vaccine to their healthcare workers. Immunizing nursing staff has been shown to reduce mortality rates among residents of long-term care facilities.

The 5 Key Elements for Compliance with F-tag F883 are:

1. Develop, maintain, or follow policies and procedures for immunizations of residents against influenza and pneumococcal disease in accordance with national standards of practice
2. Vaccinate an eligible resident with the influenza and/or pneumococcal vaccine(s) unless the resident had previously received the vaccine, refused, or had a medical contraindication present
3. Allow a resident or a resident’s representative to refuse either the influenza and/or the pneumococcal vaccine(s)
4. Provide and/or document the provision of pertinent information regarding the immunizations to the resident or the resident’s representative such as the benefits and potential side effects of the influenza and, as applicable, the pneumococcal immunization(s)
5. Document that the resident either received the pneumococcal and influenza vaccine(s) or did not receive the vaccine(s) due to medical contraindications, previous vaccination, or refusal.

To verify your facility is in compliance, ensure your facility has a policy and procedure for influenza and pneumococcal administration that includes the following:

• Patients are provided education before administration of vaccine(s)
• Administration is in accordance with CDC & ACIP recommendations
• Residents (or their representatives) may refuse either the influenza and/or pneumococcal vaccine
  o requires documentation as to why the vaccine was not administered

The PharMerica 2017-2018 Immunization Guide provides the following documents to support your facility’s protocol:

• Vaccine Information Statement (VIS) for influenza and pneumococcal vaccines
• Standing Orders for administering seasonal influenza to adults
• Consent for Influenza and Pneumococcal Vaccines
• Declination of Influenza & Pneumococcal Vaccination form
# CDC Influenza and Pneumonia Recommendations & Schedule - IMMUNOCOMPETENT* patients > 65 years

The full CDC Adult Vaccination Schedule including recommendations for patients <65 years and for other vaccines is available in the "Additional Info" section of this guide.

<table>
<thead>
<tr>
<th>Influenza</th>
<th>Pneumonia</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommended every year as soon as it is available</strong></td>
<td>2 bacterial pneumonia vaccinations are available. ACIP expects administration of both PCV12 and PPSV23 will provide optimal protection against pneumococcal infections. The recommendations for adults aged &lt;65 years are different than for adults aged &gt;65 years so they should be vaccinated based on the ACIP recommendations for their age group. If pneumonia administration is unknown or incomplete, PCV13 and PPSV23 should be administered.</td>
</tr>
<tr>
<td>Admissions during late Flu Season (February &amp; March) are still recommended</td>
<td><strong>Pneumonia Vaccine Naïve Patients AND Patients with Unknown Immunization History</strong></td>
</tr>
<tr>
<td>Admissions outside of the flu season may be administered at the facility’s discretion</td>
<td><strong>Patients who have already received Prevnar</strong></td>
</tr>
<tr>
<td>Prevnar (PCV13)</td>
<td>Administer as soon as possible (before Pneumovax)</td>
</tr>
<tr>
<td>Pneumovax (PPSV23)</td>
<td>Administer at least 1 year after Prevnar</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Review the Special Populations section under Pneumococcal vaccination of the CDC Adult Vaccination Schedule Footnotes to determine if the patient qualifies as IMMUNOCOMPETENT.
## INSURANCE COVERAGE INFORMATION

### Medicare Coverage of Vaccinations

<table>
<thead>
<tr>
<th>Vaccine Preventable Disease</th>
<th>Products Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
<td>Trivalent, Quadrivalent, High Dose, Adjuvant</td>
</tr>
<tr>
<td>Pneumococcal</td>
<td>Pneumovax 23</td>
</tr>
<tr>
<td>Hepatitis B*</td>
<td>Energix-B, Recombivax HB</td>
</tr>
<tr>
<td>* Patients at Medium to High Risk for infection as designated by Medicare</td>
<td></td>
</tr>
</tbody>
</table>

### Part D

<table>
<thead>
<tr>
<th>Vaccine Preventable Disease</th>
<th>Products Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hep A/ Hep B</td>
<td>Twinrix</td>
</tr>
<tr>
<td>Herpes Zoster</td>
<td>Zostavax</td>
</tr>
<tr>
<td>HPV</td>
<td>Cervarix, Gardasil</td>
</tr>
<tr>
<td>Tdap</td>
<td>Adacel, Boostrix</td>
</tr>
<tr>
<td>Meningococcal</td>
<td>Menactra, Meneo, Menomune</td>
</tr>
<tr>
<td>Others</td>
<td>all commercially available vaccines not covered by Part B; co-pays may apply</td>
</tr>
</tbody>
</table>

### Part B with Clinical Review

<table>
<thead>
<tr>
<th>Vaccine Preventable Disease</th>
<th>Products Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabies</td>
<td>Imovax, RabAvert</td>
</tr>
<tr>
<td>Hep A</td>
<td>Havrix, VAQTA</td>
</tr>
<tr>
<td>Tetanus Toxoid</td>
<td>Tetanus Toxoid</td>
</tr>
<tr>
<td>Anthrax</td>
<td>BioThrax</td>
</tr>
</tbody>
</table>
In this section:

2017-18 Vaccine Recommendation Updates
Consent for Influenza & Pneumonia Vaccines
VIS: Inactivated Influenza Vaccine
Standing Orders for Administering Seasonal Influenza to Adults
Declination of Influenza Vaccination
Interim Guidance for Influenza Outbreak Management in Long-Term Care Facilities
2017-18 VACCINE RECOMMENDATION UPDATES

- Primary Updates and Notifications in the 2017-18 Recommendations
- For the 2017–18 season, quadrivalent and trivalent influenza vaccines will be available. Inactivated influenza vaccines (IIVs) will be available in trivalent (IIV3) and quadrivalent (IIV4) formulations. Recombinant influenza vaccine (RIV) will be available in trivalent (RIV3) and quadrivalent (RIV4) formulations.
- ACIP recommends that LAIV should not be used during the 2017-18 season.
- For persons aged > 65, any age-appropriate IIV formulation (standard-dose or high dose, trivalent or Quadrivalent, unadjuvanted or adjuvanted)
  - No preferential recommendation is made for any specific vaccine product. Vaccination should not be delayed if a specific product is not readily available
  - Fluzone HD® met prespecified criteria for superior efficacy to that of the SD-IIV3 in a randomized trial conducted over two seasons among 31,989 persons aged >65, and might provide better protection than SD-IIV3 for this age group.
  - Flublok Quadrivalent ® was more efficacious than SD-IIV4 in an exploratory analysis of data from a single-season randomized trial conducted among 8,604 adults aged > 50 years; however, no claim of superiority was approved for the package insert
  - Fluad® was more effective against laboratory-confirmed influenza than unadjuvanted SD-IIV3 among adults aged > 65 in an analysis from a small observation study
- All of the 2017-18 US – Licensed influenza vaccines will contain the following three strains: an A/Michigan/45/2015(H1N1)pdm09-like virus, an A/HongKong/4801/2014(H3N2)-like virus, and a B/Brisbane/60/2008-like(B/Victoria lineage) virus.
- Four-component (Quadrivalent) vaccines, which protect against a second lineage of B viruses, are recommended to be produced using the same viruses recommended for the trivalent vaccines, as well as B/Phuket/3073/2013-like (B/Yamagata lineage) virus.
- Severely egg-allergic patients should be made aware that an egg-free flu vaccine is available.
CONSENT FOR INFLUENZA & PNEUMONIA VACCINES

Resident: ___________________________________________ Birth Date: ____________________________

ID Number: ___________________________ Nursing Care Center: _____________________________________

Living Unit: ___________________________ Physician: ____________________________________________

INFORMATION:

It is not possible to estimate the risk of an individual getting the flu this year, but for the elderly and for people with diabetes or heart, lung or kidney diseases, flu may be especially serious. An injection of flu vaccine will not give you the flu, because the vaccine is made from killed viruses. The vaccine is made from viruses selected by the Office of Biologics, Food and Drug Administration and the Public Health Service. Side effects of influenza vaccine are generally mild in adults and occur at low frequency. These reactions consist of tenderness at the injection site, fever, chills, headaches, or muscular aches. These symptoms last up to 48 hours.

Gullian-Barre Syndrome (GBS) is typically characterized by a paralysis that begins in the hands or feet and then moves up the arms or legs or both. GBS is usually self-limiting, and most persons with GBS recover without permanent weakness. In approximately 5% of the cases a permanent or even fatal form of paralysis may occur. In 1976, GBS appeared with excess frequency among persons who had received the 1976 Swine Vaccine. For the ten weeks following vaccination, the risk of GBS was found to be approximately ten cases for every one million persons vaccinated. This represents a five to six times higher risk than in unvaccinated persons.

Data on the occurrence of GBS have been collected during three influenza seasons since the surveillance began in 1978. These data suggests that, in contrast to the 1976 situation, the risk of GBS in recipients of influenza vaccine was not significantly higher than that in non-vaccines. Nonetheless, persons who receive influenza vaccines should be aware of this possible risk as compared with the risk of influenza and its complications.

SPECIAL PRECAUTIONS:

• Children under three years of age and pregnant women should consult with their prescriber before receiving this vaccine.
• Persons who are allergic to eggs, chicken feather, or chicken dander should not receive this vaccine until they have consulted their prescriber.
• Persons with fever should not receive this vaccine. Persons who have received another type of vaccine within the past fourteen days should see their prescriber before receiving this vaccine.
• If you have a reaction, see your prescriber immediately. If you have any questions, please ask.

Has the person receiving the vaccine ever had a severe allergic (hypersensitivity) reaction to eggs, latex, or thimerosal?  
_____YES  _____NO  *Specify____________

Does the person receiving the vaccine have a history of Guillain-Barre syndrome or a persistent neurological illness?  
_____YES  _____NO
Has the person received a live vaccine within the past 30 days (i.e. MMR, Rotarix, Zostavax)

____YES  ____NO  If YES - recommended to space live vaccines by > 4 weeks for full efficacy

Is the person receiving the vaccine currently sick with a fever?

____YES  ____NO

Is the person receiving the vaccine currently receiving radiation, chemotherapy, or immunosuppressive therapy?

____YES  ____NO

I have read the above information and VIS for my requested vaccination and have had an opportunity to ask questions. I understand the benefits and risks of flu and pneumonia vaccinations as described. I request that the vaccine be given to me or to the person named below for whom I am authorized to sign.

____Influenza  ____PPSV23 (Pneumovax)  ____PCV13 (Prevnar)

Resident Name (please print)____________________________________ Date of birth_______________ Age______________

Address_____________________________ City____________________________ State_______ Zip Code________________

____________________________________________________________________________

Signature of person to receive vaccine (or authorized guardian)

FOR OFFICE USE ONLY----------------------------------------------------------------–––––––––––––––––––––––––––––––––––––––––---

Date/Time of Administration: __________________ Lot #:______________________________

Immunizer:_________________________________ Expiration Date: _____________________

Vaccine Name:_____________________

  o   Right arm
  o   Left arm
  o   Other:______________________
Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease that spreads around the United States every year, usually between October and May.

Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.

Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms vary by age, but can include:
- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Flu can also lead to pneumonia and blood infections, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

Flu is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk.

Each year thousands of people in the United States die from flu, and many more are hospitalized.

Flu vaccine can:
- keep you from getting flu,
- make flu less severe if you do get it, and
- keep you from spreading flu to your family and other people.

2 Inactivated and recombinant flu vaccines

A dose of flu vaccine is recommended every flu season. Children 6 months through 8 years of age may need two doses during the same flu season. Everyone else needs only one dose each flu season.

Some inactivated flu vaccines contain a very small amount of a mercury-based preservative called thimerosal. Studies have not shown thimerosal in vaccines to be harmful, but flu vaccines that do not contain thimerosal are available.

3 Some people should not get this vaccine

Tell the person who is giving you the vaccine:
- If you have any severe, life-threatening allergies. If you ever had a life-threatening allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Most, but not all, types of flu vaccine contain a small amount of egg protein.
- If you ever had Guillain-Barré Syndrome (also called GBS). Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.
- If you are not feeling well. It is usually okay to get flu vaccine when you have a mild illness, but you might be asked to come back when you feel better.

There is no live flu virus in flu shots. They cannot cause the flu.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against three or four viruses that are likely to cause disease in the upcoming flu season. But even when the vaccine doesn’t exactly match these viruses, it may still provide some protection.

Flu vaccine cannot prevent:
- flu that is caused by a virus not covered by the vaccine, or
- illnesses that look like flu but are not.

It takes about 2 weeks for protection to develop after vaccination, and protection lasts through the flu season.
4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible. Most people who get a flu shot do not have any problems with it.

Minor problems following a flu shot include:
• soreness, redness, or swelling where the shot was given
• hoarseness
• sore, red or itchy eyes
• cough
• fever
• aches
• headache
• itching
• fatigue

If these problems occur, they usually begin soon after the shot and last 1 or 2 days.

More serious problems following a flu shot can include the following:
• There may be a small increased risk of Guillain-Barré Syndrome (GBS) after inactivated flu vaccine. This risk has been estimated at 1 or 2 additional cases per million people vaccinated. This is much lower than the risk of severe complications from flu, which can be prevented by flu vaccine.
• Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Ask your doctor for more information. Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

Problems that could happen after any injected vaccine:
• People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
• Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
• Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5 What if there is a serious reaction?

What should I look for?
• Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?
• If you think it is a severe allergic reaction or other emergency that can’t wait, call 9-1-1 and get the person to the nearest hospital. Otherwise, call your doctor.
• Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7 How can I learn more?

• Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
• Call your local or state health department.
• Contact the Centers for Disease Control and Prevention (CDC):
   - Call 1-800-232-4636 (1-800-CDC-INFO) or
   - Visit CDC’s website at www.cdc.gov/flu

Vaccine Information Statement

Inactivated Influenza Vaccine

08/07/2015

42 U.S.C. § 300aa-26
STANDING ORDERS FOR ADMINISTERING SEASONAL INFLUENZA TO ADULTS

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.

Policy
Where allowed by state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure
1. Assess Adults for Need of Vaccination against influenza
   - All adults are recommended to receive influenza vaccination each year.
   - Pregnant women are recommended to receive influenza vaccination each year. Administer inactivated influenza vaccine (IIV) to pregnant women in any trimester.
   - People who do not recall whether they received influenza vaccine this year should be vaccinated.

2. Screen for Contraindications and Precautions
   **Contraindications for use of all influenza vaccines**
   Do not give influenza vaccine to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of the vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer’s package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.

   **Contraindications only for use of live attenuated influenza vaccine (LAIV; FluMist, nasal spray)**
   Do not give live attenuated influenza vaccine (LAIV4; nasal spray) to a person who:
   - is pregnant
   - has immunosuppression (including that caused by medications or HIV)
   - is age 50 years or older
   - received influenza antivirals (e.g., amantadine, rimantadine, zanamivir, or oseltamivir) within the previous 48 hours or will possibly receive them within 14 days after vaccination
   - provides care for a severely immunosuppressed person who requires a protective environment

   **Precautions for use of all influenza vaccines**
   - Moderate or severe acute illness with or without fever
   - History of Guillain-Barré syndrome within 6 weeks of a previous influenza vaccination

   **Precautions for use of LAIV only**
   - Asthma
   - Other chronic medical conditions (e.g., other chronic lung diseases, chronic cardiovascular disease [excluding isolated hypertension], chronic renal or hepatic disease, hematologic disease, neurologic disease, and metabolic disorders, including diabetes mellitus)

   **Note regarding patients with eggs allergy:** People with egg allergy of any severity can receive any licensed and recommended influenza vaccine (i.e., any IIV or RIV) that is otherwise appropriate for the patient’s age and

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**Technical content reviewed by the Centers for Disease Control and Prevention**

**PharMerica**

**Immunization Action Coalition**
Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org
www.immunize.org/catg.d/p3074.pdf • Item #P3074 (5/17)
Influenza & Adult Immunization Guide  |  2017-2018  

**STANDING ORDERS FOR ADMINISTERING SEASONAL INFLUENZA TO ADULTS**

Standing Orders for Administering Influenza Vaccine to Adults (continued)  

**3 Provide Vaccine Information Statements**

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled “Document Vaccination.”)

**4 Prepare to Administer Vaccine**

For vaccine that is to be administered intramuscularly, choose the needle gauge, needle length, and injection site according to the following chart:

<table>
<thead>
<tr>
<th>GENDER AND WEIGHT OF PATIENT</th>
<th>NEEDLE GAUGE</th>
<th>NEEDLE LENGTH</th>
<th>INJECTION SITE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female or male less than 130 lbs</td>
<td>22–25</td>
<td>5/8”–1”</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female or male 130–152 lbs</td>
<td>22–25</td>
<td>1”</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female 153–200 lbs</td>
<td>22–25</td>
<td>1–1½”</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Male 153–260 lbs</td>
<td>22–25</td>
<td>1–1½”</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female 200+ lbs</td>
<td>22–25</td>
<td>1½”</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Male 260+ lbs</td>
<td>22–25</td>
<td>1½”</td>
<td>Deltoid muscle of arm</td>
</tr>
</tbody>
</table>

* A 5⁄8” needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.

For vaccine that is to be administered intranasally or intradermally, prepare the vaccine according to directions in the package insert.

**5 Administer Influenza Vaccine** according to the criteria and guidance in the table below:

<table>
<thead>
<tr>
<th>TYPE OF VACCINE</th>
<th>AGE GROUP</th>
<th>DOSE</th>
<th>ROUTE</th>
<th>INSTRUCTIONS†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inactivated influ-</td>
<td>All ages</td>
<td>0.5 mL</td>
<td>Intramuscular (IM)</td>
<td>Administer vaccine in deltoid muscle.</td>
</tr>
<tr>
<td>enza vaccine (IIV)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IIV-intradermal</td>
<td>18 through 64 years</td>
<td>0.1 mL</td>
<td>Intradermal (ID)</td>
<td>Insert needle of the microinjection system at a 90 degree angle in the deltoid area.</td>
</tr>
<tr>
<td>IIV-high dose</td>
<td>65 years and older</td>
<td>0.5 mL</td>
<td>Intramuscular (IM)</td>
<td>Administer vaccine in deltoid muscle.</td>
</tr>
<tr>
<td>Adjuvanted inacti-</td>
<td>65 years and older</td>
<td>0.5 mL</td>
<td>Intramuscular (IM)</td>
<td>Administer vaccine in deltoid muscle.</td>
</tr>
<tr>
<td>vated influenza vaccine (aIIV)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cell culture-based</td>
<td>All ages</td>
<td>0.5 mL</td>
<td>Intramuscular (IM)</td>
<td>Administer vaccine in deltoid muscle.</td>
</tr>
<tr>
<td>IIV (ccIIV)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recombinant influ-</td>
<td>18 years and older</td>
<td>0.5 mL</td>
<td>Intramuscular (IM)</td>
<td>Administer vaccine in deltoid muscle.</td>
</tr>
<tr>
<td>enza vaccine (RIV)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Live attenuated influ-</td>
<td>Healthy, younger than age 50 years (except pregnant women)</td>
<td>0.2 mL (0.1 mL into each nostril)</td>
<td>Intranasal spray (NAS)</td>
<td>Spray half of vaccine into each nostril while the patient is in an upright position.</td>
</tr>
</tbody>
</table>

*For complete instructions on how to administer influenza vaccine, see “How to Administer Intramuscular, Intradermal, and Intranasal Influenza Vaccines” at www.immunize.org/catg.d/p2024.pdf.

Continued on the next page
6 Document Vaccination

Document each patient’s vaccine administration information and follow up in the following places:

**Medical record:** Document 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. You must also 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. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Reoffer this vaccine to the patient at the next visit.

**Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.

**Immunization Information System (IIS) or “registry”:** Report the vaccination to the appropriate state/local IIS, if available.

7 Be Prepared to Manage Medical Emergencies

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. For IAC’s “Medical Management of Vaccine Reactions in Adults,” go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8 Report All Adverse Events to VAERS

Report all adverse events following the administration of influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov. Forms are available on the website or by calling (800) 822-7967.

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the __________________________ effective __________ until rescinded or until __________. 

Medical Director ____________________________/ __________

NAME OF PRACTICE OR CLINIC
DECLINATION OF INFLUENZA OR PNEUMOCOCCAL VACCINATION

My health facility, _________________________, has recommended that I receive an influenza and/or pneumococcal vaccination to protect myself and other residents or employees in the facility.

I acknowledge that I am aware of the following facts:

Influenza

- Influenza is a serious respiratory disease that kills thousands of people in the US each year.
- Influenza vaccination is recommended for me to protect this facility's patients from influenza, its complications, and death.
- If I contract influenza, I can shed the virus for 24 hours before influenza symptoms appear.
- My shedding the virus can spread influenza to patients in this facility.
- If I become infected with influenza, even if my symptoms are mild or non-existent, I can spread it to others and they can become seriously ill.
- I understand that I cannot get influenza from the influenza vaccine.
- The consequences of my refusing to be vaccinated could have life-threatening consequences to my health and the health of those with whom I have contact.
- Influenza vaccination is recommended by the Centers for Disease Control and Prevention.

Pneumococcal

- Pneumococcal disease kills more people in the US each year than all other vaccine preventable diseases combined.
- Those >65 years, the very young, and people with special health problems (alcoholism, heart or lung disease, kidney failure, HIV, certain cancers) are at greater risk.
- Pneumococcal disease can lead to serious infections of the lungs (pneumonia), the blood (bacteremia), and the covering of the brain (meningitis).
- The bacteria causing pneumococcal disease have become more resistant to antibiotics used today, making prevention even more important.
- Pneumococcal vaccination is recommended by the Centers for Disease Control and Prevention.

I was offered a vaccination of (please circle)     Influenza Vaccine        Prevnar13           Pneumovax23

Despite these facts, I am choosing to decline vaccination right now for the following reasons:

______________________________________________________________________________________________________
______________________________________________________________________________________________________

I understand that I can change my mind at any time and accept this vaccination if it is still available.

I have read and fully understand the information on this declination form

Signature:_________________________________Date:_____________
Name (print):______________________________
Interim Guidance for Influenza Outbreak Management in Long-Term Care Facilities

The following guidance was created by the CDC for the 2016-2017 influenza season and was released in March 2017. Please visit www.cdc.gov for more information and/or updates from the CDC for up-to-date guidance for the latest information regarding recommended influenza vaccines. Please see Antiviral Drugs: Information for Health Care Professionals for the current summary of recommendations for clinical practice regarding the use of influenza antiviral medications.

Long-term care facilities may be defined as institutions, such as nursing homes and skilled nursing facilities that provide health care to people (including children) who are unable to manage independently in the community. This care may represent custodial or chronic care management or short-term rehabilitative services.

Influenza can be introduced into a long-term care facility by newly admitted residents, health care workers and by visitors. Spread of influenza can occur between and among residents, health care providers, and visitors. Residents of long-term care facilities can experience severe and fatal illness during influenza outbreaks.

Preventing transmission of influenza viruses and other infectious agents within health care settings, including in long-term care facilities, requires a multi-faceted approach that includes the following:

- Vaccination
- Testing
- Infection Control
- Antiviral Treatment
- Antiviral Chemoprophylaxis

Before an Outbreak Occurs

Influenza vaccination should be provided routinely to all residents and health care workers of long-term care facilities.

Residents

If possible, all residents should receive trivalent inactivated influenza vaccine (TIV) annually before influenza season. In the majority of seasons, TIV will become available to long-term care facilities beginning in September, and influenza vaccination should commence as soon as vaccine is available. Informed consent is required to implement a standing order for vaccination, but this does not necessarily mean a signed consent must be present.

In the event that a new patient or resident is admitted after the influenza vaccination program has concluded in the facility, the benefits of vaccination should be discussed, educational materials should be provided, and an opportunity for vaccination should be offered to the new resident as soon as possible after admission to the facility. Since October 2005, the Centers for Medicare and Medicaid Services (CMS) has required nursing homes participating in Medicare and Medicaid programs to offer all residents influenza and pneumococcal vaccines and to document the results. According to requirements, each resident is to be vaccinated unless contraindicated medically, the resident or legal representative refuses vaccination, or the vaccine is not available because of storage. This information is to be reported as part of the CMS Minimum Data Set, which tracks nursing home health parameters.

Health Care Personnel

CDC and the Advisory Committee on Immunization Practices (ACIP), recommend that all U.S. health care personnel get vaccinated annually against influenza.

- Health care personnel who get vaccinated help to reduce the following:
  - Transmission of influenza
  - Staff illness and absenteeism
  - Influenza-related illness and death, especially among people at increased risk for severe influenza illness
  - Higher vaccination levels among personnel have been associated with a lower risk of health care facility-associated influenza cases.
  - Influenza outbreaks in hospitals and long-term care facilities have been attributed to low influenza vaccination coverage among health care personnel.
  - Higher influenza vaccination levels among health care personnel can reduce influenza-related illness, and even deaths, in settings like nursing homes.
Surveillance
When there is influenza activity in the local community, active daily surveillance (defined below) for influenza illness should be conducted among all new and current residents, staff, and visitors of long-term care facilities, and continued until the end of influenza season. Ill residents, personnel, and visitors should be excluded from the facility until illness has resolved.

Testing
Even if it’s not influenza season, influenza testing should occur when any resident has signs and symptoms of influenza-like illness. More information about testing is included below.

When there is a confirmed or suspected influenza outbreak (2 or more ill residents)
If there is one laboratory-confirmed influenza positive case along with other cases of respiratory infection in a unit of a long-term care facility, an influenza outbreak might be occurring.

While unusual, an influenza outbreak can occur outside of the normal influenza season; therefore, testing for influenza should be added to testing for other respiratory pathogens during non-influenza season periods.

Even if it’s not influenza season, influenza testing should occur when any resident has signs and symptoms that could be due to influenza *, and especially when two residents or more develop respiratory illness within 72 hours of each other.

- Determine if influenza virus is the causative agent by performing influenza testing on respiratory specimens (i.e. nasal swabs, throat swabs, nasopharyngeal swab, or nasopharyngeal or nasal aspirates) of ill residents with recent onset of signs and symptoms suggestive of influenza.
- In order of priority, the following influenza tests are recommended: reverse transcription polymerase chain reaction (RT-PCR); immunofluorescence; rapid influenza diagnostic tests.
- Because of the possibility of false negative results during influenza season, if influenza is suspected and immunofluorescence or rapid influenza diagnostic test results are negative, perform confirmatory testing using RT-PCR or viral culture. Information on influenza diagnostic testing is available online or by contacting your state public health laboratory.
- Because of the possibility of false positive results, especially outside of influenza season, perform confirmatory testing using RT-PCR or viral culture if immunofluorescence or rapid influenza diagnostic test results are positive.
- Viral culture should be performed if additional information on influenza viruses, such as influenza A virus subtype, antigenic characterization to compare with vaccine strains, or antiviral resistance data, are needed. Additionally, viral culture can be used to confirm results from rapid diagnostic testing (as mentioned above)
- Determining influenza virus type or subtype of influenza A virus can help inform antiviral therapy decisions.
- Test for other respiratory pathogens as well if it’s not influenza season.
- Once an outbreak has been identified, outbreak prevention and control measures should be implemented immediately.

Implement daily active surveillance for respiratory illness among ill residents, health care personnel and visitors to the facility.

- During an outbreak, once a single laboratory-confirmed case of influenza has been identified, it is likely there are other cases among exposed persons.
- Conduct daily active surveillance until at least 1 week after the last confirmed influenza case occurred.
- Test for influenza in the following:
  - Ill persons who are in the affected unit as well as previously unaffected units in the facility
  - Persons who develop acute respiratory illness symptoms more than 72 hours after beginning antiviral chemoprophylaxis
  - Note that elderly persons and other long-term care residents, including those who are medically fragile and those with neurological or neurocognitive conditions, may manifest atypical signs and symptoms with influenza virus infection, and may not have fever.
  - Ensure that the laboratory performing the tests notifies the facility of tests results promptly.
• The local health and state health departments should be notified of every suspected or confirmed influenza outbreak in a long-term care facility, especially if a resident develops influenza while on or after receiving antiviral chemoprophylaxis.

Implement Standard and Droplet Precautions for all residents with suspected or confirmed influenza.

CDC’s guidance titled Prevention Strategies for Seasonal Influenza in Healthcare Settings contains details on the prevention strategies for all health care settings. Specific recommendations are highlighted below.

Standard Precautions are intended to be applied to the care of all patients in all health care settings, regardless of the suspected or confirmed presence of an infectious agent. Implementation of Standard Precautions constitutes the primary strategy for the prevention of healthcare-associated transmission of infectious agents among patients and health care personnel.

Examples of standard precautions include:
• Wearing gloves if hand contact with respiratory secretions or potentially contaminated surfaces is anticipated.
• Wearing a gown if soiling of clothes with a resident’s respiratory secretions is anticipated.
• Changing gloves and gowns after each resident encounter and performing hand hygiene
• Perform hand hygiene before and after touching the resident, after touching the resident’s environment, or after touching the resident’s respiratory secretions, whether or not gloves are worn. Gloves do not replace the need for performing hand hygiene.

Droplet Precautions are intended to prevent transmission of pathogens spread through close respiratory or mucous membrane contact with respiratory secretions. Droplet Precautions should be implemented for residents with suspected or confirmed influenza for 7 days after illness onset or until 24 hours after the resolution of fever and respiratory symptoms, whichever is longer, while a resident is in a health care facility.

Examples of Droplet Precautions include:
• Placing ill residents in a private room. If a private room is not available, place (cohort) residents suspected of having influenza residents with one another;
• Wear a facemask (e.g., surgical or procedure mask) upon entering the resident’s room. Remove the facemask when leaving the resident’s room and dispose of the facemask in a waste container.
• If resident movement or transport is necessary, have the resident wear a facemask (e.g., surgical or procedure mask), if possible.
• Communicate information about patients with suspected, probable, or confirmed influenza to appropriate personnel before transferring them to other departments.

These Precautions are part of the overall infection control strategy to protect against influenza in health care settings and should be used along with other infection control measures, such as isolation or cohorting of ill residents, screening employees and visitors for illness, furloughing ill health care personnel, and discouraging ill visitors from entering the facility.

In some cases, facilities may choose to apply Standard Precautions and Droplet Precautions for longer periods based on clinical judgment, such as in the case of young children or severely immunocompromised residents, who may shed influenza virus for longer periods of time.

Because residents with influenza may continue to shed influenza viruses while on antiviral treatment, infection control measures to reduce transmission, including following Standard and Droplet Precautions, should continue while the resident is taking antiviral therapy. This will also reduce transmission of viruses that may have become resistant to antiviral drugs during therapy.
Administer influenza antiviral treatment and chemoprophylaxis to residents and health care personnel according to current recommendations.

All long-term care facility residents who have confirmed or suspected influenza should receive antiviral treatment immediately.

Treatment should not wait for laboratory confirmation of influenza.

Antiviral treatment works best when started within the first 2 days of symptoms. However, these medications can still help when given after 48 hours to those that are very sick, such as those who are hospitalized, or those who have progressive illness.

Three influenza antiviral drugs approved by the U.S. Food and Drug Administration are recommended for use in the United States: oral oseltamivir (available as a generic version or under the trade name Tamiflu®), as a pill or suspension; zanamivir (trade name Relenza®), available as an inhaled powder using a disk inhaler device; and intravenous peramivir (trade name Rapivab®). It should be noted that some long-term care residents may have difficulty using the inhaler device for zanamivir.

Amantadine and rimantadine are **NOT** recommended for use because of high levels of antiviral resistance among circulating influenza A viruses.

The recommended dosing and duration of antiviral treatment is twice daily for 5 days. Longer treatment courses for patients who remain severely ill after 5 days of treatment can be considered. Dosage adjustment may be required for children and persons with certain underlying conditions. Clinicians should consult the manufacturers’ package insert for recommended drug dosing adjustments and contraindications.

Having preapproved orders from physicians or plans to obtain orders for antiviral medications on short notice can substantially expedite administration of antiviral medications.

For more information on the antiviral agents see **Recommended Dosage and Duration of Treatment or Chemoprophylaxis for Influenza Antiviral Medications**.

All eligible residents in the entire long-term care facility (not just currently impacted wards) should receive antiviral chemoprophylaxis as soon as an influenza outbreak is determined.

When at least 2 patients are ill within 72 hours of each other and at least one resident has laboratory-confirmed influenza, the facility should promptly initiate antiviral chemoprophylaxis to all non-ill residents, regardless of whether they received influenza vaccination during the previous fall. Priority should be given to residents living in the same unit or floor as an ill resident. However, since staff and residents may spread influenza to residents on other units, floors, or buildings of the same facility, all non-ill residents are recommended to receive antiviral chemoprophylaxis to control influenza outbreaks.

Antiviral chemoprophylaxis is recommended for all non-ill residents, regardless of their influenza vaccination status, in long-term care facilities that are experiencing outbreaks.

Antiviral chemoprophylaxis is meant for patients and residents who are not exhibiting influenza-like illness but who may be exposed or who may have been exposed to an ill person with influenza, to prevent transmission.

Use of antiviral drugs for chemoprophylaxis of influenza is a key component of influenza outbreak control in institutions that house residents at higher risk of influenza complications. While highly effective, antiviral chemoprophylaxis is not 100% effective in preventing influenza illness.

CDC recommends antiviral chemoprophylaxis for a minimum of 2 weeks, and continuing for at least 7 days after the last known case was identified.

Persons whose need for chemoprophylaxis is attributed to potential exposure to a person with laboratory-confirmed 2009 H1N1, influenza A (H3N2), or influenza B should receive oseltamivir or zanamivir. Zanamivir should be used when persons require chemoprophylaxis as a result of exposure to influenza virus strains that are suspected of being oseltamivir-resistant.

(For more information see **Recommended Dosage and Duration of Treatment or Chemoprophylaxis for Influenza Antiviral Medications** or the **IDSA guidelines**)

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Antiviral chemoprophylaxis can be considered or offered to unvaccinated personnel who provide care to persons at high risk of complications.

While CDC recommends judicious use of antiviral medications for chemoprophylaxis to reduce the possibility of development and spread of antiviral resistant influenza viruses, chemoprophylaxis may be considered for all employees, regardless of their influenza vaccination status, if the outbreak is caused by a strain of influenza virus that is not well matched by the vaccine.

Antiviral chemoprophylaxis should also be considered in personnel for whom influenza vaccine is contraindicated.

An emphasis on early treatment is an alternative to chemoprophylaxis in managing certain persons who have had a suspected exposure to influenza virus. Health care personnel who have occupational exposures can be counseled about the early signs and symptoms of influenza and advised to contact their health-care provider immediately for evaluation and possible early treatment if clinical signs or symptoms develop.

For newly vaccinated staff, antiviral chemoprophylaxis can be administered up to 2 weeks following influenza vaccination with TIV. Persons receiving antiviral chemoprophylaxis should not receive live attenuated influenza virus vaccine (LAIV), and persons receiving LAIV should not receive antiviral treatment or chemoprophylaxis until 14 days after LAIV administration.

The latest CDC antiviral recommendations are available on CDC’s influenza antiviral drugs page for health professionals.

Be Aware of the Possibility of a Drug-Resistant Virus

Residents receiving antiviral medications who do not respond to treatment or who become sick with influenza after starting chemoprophylaxis might have an infection with an antiviral-resistant influenza virus.

To limit the potential transmission of antiviral drug-resistant influenza virus, whether in chronic or acute-care settings or other closed settings, measures should be taken to reduce contact between ill persons taking antiviral drugs for treatment and other persons, including those receiving antiviral chemoprophylaxis.

Infection-control measures are especially important for patients who are immunocompromised to reduce the risk for transmission of oseltamivir-resistant viruses.

Notify the health department if a resident develops influenza while on or after receiving antiviral chemoprophylaxis.

Consider the following additional measures to reduce transmission among residents and health care personnel:

- Have symptomatic residents stay in their own rooms as much as possible, including restricting them from common activities, and have their meals served in their rooms when possible.
- Limit the number of large group activities in the facility and consider serving all meals in resident rooms if possible when the outbreak is widespread (involving multiple units of the facility).
- Avoid new admissions or transfers to wards with symptomatic residents.
- Limit visitation and exclude ill persons from visiting the facility via posted notices. Consider restricting visitation by children during community outbreaks of influenza.
- Monitor personnel absenteeism due to respiratory symptoms and exclude those with influenza-like symptoms from work until at least 24 hours after they no longer have a fever.
- Restrict personnel movement from areas of the facility having illness to areas not affected by the outbreak.
- Administer the current season’s influenza vaccine to unvaccinated residents and health care personnel as per current vaccination recommendations. For the latest information on influenza vaccination, see CDC’s seasonal influenza vaccination resources for health professionals page.

*Patients with illness associated with influenza virus infection often have fever or feverishness with cough, chills, headache, myalgias, sore throat, or runny nose. Some patients, such as the elderly, children with neuromuscular disorders, and young infants, may have atypical clinical presentations.
Resources

**Vaccine**
Seasonal Influenza Vaccination Resources for Health Professionals (https://www.cdc.gov/flu/professionals/vaccination/index.htm)
Prevention and Control of Influenza with Vaccines. Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010: Nursing Homes and Other Long-Term Care Facilities. MMWR 2010;59(RR08):1-62

**Antiviral Drugs**
Seasonal Influenza in Adults and Children—Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines of the Infectious Diseases Society of America
Recommendations of the Advisory Committee on Immunization Practices (ACIP): Antiviral Drug Information for Health Care Professionals: Control of Influenza Outbreaks in Institutions. MMWR 2011;60(RR01):1-24

**Testing**

**Infection Control**
Prevention Strategies for Seasonal Influenza in Healthcare Settings (https://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm)

**Reported Outbreaks in Long-Term Care Facilities**
CDC. Outbreaks of 2009 Pandemic Influenza A (H1N1) Among Long-Term Care Facility Residents --- Three States, 2009. MMWR 2010;59(03):74-77

**Additional References**


Influenza & Adult Immunization Guide  |  2017-2018

VACCINE INFO STATEMENTS

In this section:

- VIS: Polysaccharide (Pneumovax/PPSV23)
- VIS: Conjugate (Prevnar/PCV13)
- VIS: MenACWY VIS
- VIS: Men B VIS
- VIS: Herpes Zoster (Shingles)
- VIS: Tdap
- VIS: Td

Instead of updating the Vaccine Information Statement on an annual basis, the CDC provides updates when it is deemed necessary for the patient safety. All Vaccine Information Statements in this guide are current as of August 2017.
**Vaccine Information Statement**

### Pneumococcal Polysaccharide Vaccine

**What You Need to Know**

#### 1 Why get vaccinated?
Vaccination can protect older adults (and some children and younger adults) from pneumococcal disease.

Pneumococcal disease is caused by bacteria that can spread from person to person through close contact. It can cause ear infections, and it can also lead to more serious infections of the:
- Lungs (pneumonia),
- Blood (bacteremia), and
- Covering of the brain and spinal cord (meningitis).

Meningitis can cause deafness and brain damage, and it can be fatal.

Anyone can get pneumococcal disease, but children under 2 years of age, people with certain medical conditions, adults over 65 years of age, and cigarette smokers are at the highest risk.

About 18,000 older adults die each year from pneumococcal disease in the United States.

Treatment of pneumococcal infections with penicillin and other drugs used to be more effective. But some strains of the disease have become resistant to these drugs. This makes prevention of the disease, through vaccination, even more important.

#### 2 Pneumococcal polysaccharide vaccine (PPSV23)

Pneumococcal polysaccharide vaccine (PPSV23) protects against 23 types of pneumococcal bacteria. It will not prevent all pneumococcal disease.

PPSV23 is recommended for:
- All adults 65 years of age and older,
- Anyone 2 through 64 years of age with certain long-term health problems,
- Anyone 2 through 64 years of age with a weakened immune system,
- Adults 19 through 64 years of age who smoke cigarettes or have asthma.

Most people need only one dose of PPSV. A second dose is recommended for certain high-risk groups. People 65 and older should get a dose even if they have gotten one or more doses of the vaccine before they turned 65.

Your healthcare provider can give you more information about these recommendations.

Most healthy adults develop protection within 2 to 3 weeks of getting the shot.

#### 3 Some people should not get this vaccine

- Anyone who has had a life-threatening allergic reaction to PPSV should not get another dose.
- Anyone who has a severe allergy to any component of PPSV should not receive it. Tell your provider if you have any severe allergies.
- Anyone who is moderately or severely ill when the shot is scheduled may be asked to wait until they recover before getting the vaccine. Someone with a mild illness can usually be vaccinated.
- Children less than 2 years of age should not receive this vaccine.
- There is no evidence that PPSV is harmful to either a pregnant woman or to her fetus. However, as a precaution, women who need the vaccine should be vaccinated before becoming pregnant, if possible.
4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

About half of people who get PPSV have mild side effects, such as redness or pain where the shot is given, which go away within about two days.

Less than 1 out of 100 people develop a fever, muscle aches, or more severe local reactions.

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: [www.cdc.gov/vaccinesafety/](http://www.cdc.gov/vaccinesafety/)

5 What if there is a serious reaction?

What should I look for?

Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

If you think it is a severe allergic reaction or other emergency that can’t wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your doctor.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at [www.vaers.hhs.gov](http://www.vaers.hhs.gov), or by calling 1-800-822-7967.

*VAERS does not give medical advice.*

6 How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC’s website at [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)
VACCINE INFORMATION STATEMENT

PNEUMOCOCCAL CONJUGATE VACCINE (PCV13)

What You Need to Know

1 Why get vaccinated?

Vaccination can protect both children and adults from pneumococcal disease.

Pneumococcal disease is caused by bacteria that can spread from person to person through close contact. It can cause ear infections, and it can also lead to more serious infections of the:
- Lungs (pneumonia),
- Blood (bacteremia), and
- Covering of the brain and spinal cord (meningitis).

Pneumococcal pneumonia is most common among adults. Pneumococcal meningitis can cause deafness and brain damage, and it kills about 1 child in 10 who get it.

Anyone can get pneumococcal disease, but children under 2 years of age and adults 65 years and older, people with certain medical conditions, and cigarette smokers are at the highest risk.

Before there was a vaccine, the United States saw:
- more than 700 cases of meningitis,
- about 13,000 blood infections,
- about 5 million ear infections, and
- about 200 deaths in children under 5 each year from pneumococcal disease. Since vaccine became available, severe pneumococcal disease in these children has fallen by 88%.

About 18,000 older adults die of pneumococcal disease each year in the United States.

Treatment of pneumococcal infections with penicillin and other drugs is not as effective as it used to be, because some strains of the disease have become resistant to these drugs. This makes prevention of the disease, through vaccination, even more important.

2 PCV13 vaccine

Pneumococcal conjugate vaccine (called PCV13) protects against 13 types of pneumococcal bacteria.

PCV13 is routinely given to children at 2, 4, 6, and 12–15 months of age. It is also recommended for children and adults 2 to 64 years of age with certain health conditions, and for all adults 65 years of age and older. Your doctor can give you details.

3 Some people should not get this vaccine

Anyone who has ever had a life-threatening allergic reaction to a dose of this vaccine, to an earlier pneumococcal vaccine called PCV7, or to any vaccine containing diphtheria toxoid (for example, DTaP), should not get PCV13.

Anyone with a severe allergy to any component of PCV13 should not get the vaccine.

Tell your doctor if the person being vaccinated has any severe allergies.

If the person scheduled for vaccination is not feeling well, your healthcare provider might decide to reschedule the shot on another day.

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible.

Problems reported following PCV13 varied by age and dose in the series. The most common problems reported among children were:
- About half became drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given.
- About 1 out of 3 had swelling where the shot was given.
- About 1 out of 3 had a mild fever, and about 1 in 20 had a fever over 102.2°F.
- Up to about 8 out of 10 became fussy or irritable.

Adults have reported pain, redness, and swelling where the shot was given; also mild fever, fatigue, headache, chills, or muscle pain.

Young children who get PCV13 along with inactivated flu vaccine at the same time may be at increased risk for seizures caused by fever. Ask your doctor for more information.
Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some older children and adults get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very small chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: [www.cdc.gov/vaccinesafety](http://www.cdc.gov/vaccinesafety)

What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness—usually within a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can’t wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.

  Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at [www.vaers.hhs.gov](http://www.vaers.hhs.gov), or by calling 1-800-822-7967.

  [VAERS does not give medical advice.](http://www.vaers.hhs.gov)

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation). There is a time limit to file a claim for compensation.

How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC’s website at [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)

Vaccine Information Statement

PCV13 Vaccine

11/05/2015

42 U.S.C. § 300aa-26
Meningococcal ACWY Vaccines—MenACWY and MPSV4: What You Need to Know

**1 Why get vaccinated?**

Meningococcal disease is a serious illness caused by a type of bacteria called *Neisseria meningitidis*. It can lead to meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. Meningococcal disease often occurs without warning—even among people who are otherwise healthy.

Meningococcal disease can spread from person to person through close contact (coughing or kissing) or lengthy contact, especially among people living in the same household.

There are at least 12 types of *N. meningitidis*, called “serogroups.” Serogroups A, B, C, W, and Y cause most meningococcal disease.

Anyone can get meningococcal disease but certain people are at increased risk, including:

- Infants younger than one year old
- Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of *N. meningitidis*
- People at risk because of an outbreak in their community

Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, kidney damage, amputations, nervous system problems, or severe scars from skin grafts.

**Meningococcal ACWY** vaccines can help prevent meningococcal disease caused by serogroups A, C, W, and Y. A different meningococcal vaccine is available to help protect against serogroup B.

Two doses of MenACWY are routinely recommended for adolescents 11 through 18 years old: the first dose at 11 or 12 years old, with a booster dose at age 16. Some adolescents, including those with HIV, should get additional doses. Ask your health care provider for more information.

In addition to routine vaccination for adolescents, MenACWY vaccine is also recommended for certain groups of people:

- People at risk because of a serogroup A, C, W, or Y meningococcal disease outbreak
- Anyone whose spleen is damaged or has been removed
- Anyone with a rare immune system condition called “persistent complement component deficiency”
- Anyone taking a drug called eculizumab (also called Soliris®)
- Microbiologists who routinely work with isolates of *N. meningitidis*
- Anyone traveling to, or living in, a part of the world where meningococcal disease is common, such as parts of Africa
- College freshmen living in dormitories
- U.S. military recruits

Children between 2 and 23 months old, and people with certain medical conditions need multiple doses for adequate protection. Ask your health care provider about the number and timing of doses, and the need for booster doses.

**MenACWY** is the preferred vaccine for people in these groups who are 2 months through 55 years old, have received MenACWY previously, or anticipate requiring multiple doses.

**MPSV4** is recommended for adults older than 55 who anticipate requiring only a single dose (travelers, or during community outbreaks).
3 Some people should not get this vaccine

Tell the person who is giving you the vaccine:

• If you have any severe, life-threatening allergies.

If you have ever had a life-threatening allergic reaction after a previous dose of meningococcal ACWY vaccine, or if you have a severe allergy to any part of this vaccine, you should not get this vaccine. Your provider can tell you about the vaccine’s ingredients.

• If you are pregnant or breastfeeding.

There is not very much information about the potential risks of this vaccine for a pregnant woman or breastfeeding mother. It should be used during pregnancy only if clearly needed.

If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own within a few days, but serious reactions are also possible.

As many as half of the people who get meningococcal ACWY vaccine have mild problems following vaccination, such as redness or soreness where the shot was given. If these problems occur, they usually last for 1 or 2 days. They are more common after MenACWY than after MPSV4.

A small percentage of people who receive the vaccine develop a mild fever.

Problems that could happen after any injected vaccine:

• People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.

• Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.

• Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5 What if there is a serious reaction?

What should I look for?

• Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness—usually within a few minutes to a few hours after the vaccination.

What should I do?

• If you think it is a severe allergic reaction or other emergency that can’t wait, call 9-1-1 and get to the nearest hospital. Otherwise, call your doctor.

• Afterward, the reaction should be reported to the “Vaccine Adverse Event Reporting System” (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7 How can I learn more?

• Ask your health care provider. He or she can give you the vaccine package insert or suggest other sources of information.

• Call your local or state health department.

• Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC’s website at www.cdc.gov/vaccines

Vaccine Information Statement
Meningococcal ACWY Vaccines

03/31/2016

42 U.S.C. § 300aa-26
Serogroup B Meningococcal Vaccine (MenB): What You Need to Know

1 Why get vaccinated?

Meningococcal disease is a serious illness caused by a type of bacteria called Neisseria meningitidis. It can lead to meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. Meningococcal disease often occurs without warning—even among people who are otherwise healthy.

Meningococcal disease can spread from person to person through close contact (coughing or kissing) or lengthy contact, especially among people living in the same household.

There are at least 12 types of N. meningitidis, called “serogroups.” Serogroups A, B, C, W, and Y cause most meningococcal disease.

Anyone can get meningococcal disease but certain people are at increased risk, including:

- Infants younger than one year old
- Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of N. meningitidis
- People at risk because of an outbreak in their community

Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, kidney damage, amputations, nervous system problems, or severe scars from skin grafts.

Serogroup B meningococcal (MenB) vaccines can help prevent meningococcal disease caused by serogroup B. Other meningococcal vaccines are recommended to help protect against serogroups A, C, W, and Y.

2 Serogroup B Meningococcal Vaccines

Two serogroup B meningococcal vaccines — Bexsero® and Trumenba® — have been licensed by the Food and Drug Administration (FDA).

These vaccines are recommended routinely for people 10 years or older who are at increased risk for serogroup B meningococcal infections, including:

- People at risk because of a serogroup B meningococcal disease outbreak
- Anyone whose spleen is damaged or has been removed
- Anyone with a rare immune system condition called “persistent complement component deficiency”
- Anyone taking a drug called eculizumab (also called Soliris®)
- Microbiologists who routinely work with isolates of N. meningitidis

These vaccines may also be given to anyone 16 through 23 years old to provide short term protection against most strains of serogroup B meningococcal disease; 16 through 18 years are the preferred ages for vaccination.

For best protection, more than 1 dose of a serogroup B meningococcal vaccine is needed. The same vaccine must be used for all doses. Ask your health care provider about the number and timing of doses.

3 Some people should not get these vaccines

Tell the person who is giving you the vaccine:

- If you have any severe, life-threatening allergies.
  If you have ever had a life-threatening allergic reaction after a previous dose of serogroup B meningococcal vaccine, or if you have a severe allergy to any part of this vaccine, you should not get the vaccine. Tell your health care provider if you have any severe allergies that you know of, including a severe allergy to latex. He or she can tell you about the vaccine’s ingredients.

- If you are pregnant or breastfeeding.
  There is not very much information about the potential risks of this vaccine for a pregnant woman or breastfeeding mother. It should be used during pregnancy only if clearly needed.

If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.
Serogroup B Meningococcal Vaccine (MenB): What You Need to Know

1 Why get vaccinated?

Meningococcal disease is a serious illness caused by a type of bacteria called Neisseria meningitidis. It can lead to meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. Meningococcal disease often occurs without warning—even among people who are otherwise healthy.

Meningococcal disease can spread from person to person through close contact (coughing or kissing) or lengthy contact, especially among people living in the same household.

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Anyone can get meningococcal disease but certain people are at increased risk, including:
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- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of N. meningitidis
- People at risk because of an outbreak in their community

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Serogroup B meningococcal (MenB) vaccines can help prevent meningococcal disease caused by serogroup B. Other meningococcal vaccines are recommended to help protect against serogroups A, C, W, and Y.

2 Serogroup B Meningococcal Vaccines

Two serogroup B meningococcal vaccines—Bexsero® and Trumenba®—have been licensed by the Food and Drug Administration (FDA).

These vaccines are recommended routinely for people 10 years or older who are at increased risk for serogroup B meningococcal infections, including:
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- Anyone whose spleen is damaged or has been removed
- Anyone with a rare immune system condition called “persistent complement component deficiency”
- Anyone taking a drug called eculizumab (also called Soliris®)
- Microbiologists who routinely work with isolates of N. meningitidis

These vaccines may also be given to anyone 16 through 23 years old to provide short term protection against most strains of serogroup B meningococcal disease; 16 through 18 years are the preferred ages for vaccination.

For best protection, more than 1 dose of a serogroup B meningococcal vaccine is needed. The same vaccine must be used for all doses. Ask your health care provider about the number and timing of doses.

3 Some people should not get these vaccines

Tell the person who is giving you the vaccine:
- **If you have any severe, life-threatening allergies.** If you have ever had a life-threatening allergic reaction after a previous dose of serogroup B meningococcal vaccine, or if you have a severe allergy to any part of this vaccine, you should not get the vaccine. *Tell your health care provider if you have any severe allergies that you know of, including a severe allergy to latex.* He or she can tell you about the vaccine’s ingredients.

- **If you are pregnant or breastfeeding.** There is not very much information about the potential risks of this vaccine for a pregnant woman or breastfeeding mother. It should be used during pregnancy only if clearly needed.

If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.
VACCINE INFORMATION STATEMENT

Shingles Vaccine
What You Need to Know

1  What is shingles?

Shingles is a painful skin rash, often with blisters. It is also called Herpes Zoster, or just Zoster.

A shingles rash usually appears on one side of the face or body and lasts from 2 to 4 weeks. Its main symptom is pain, which can be quite severe. Other symptoms of shingles can include fever, headache, chills and upset stomach. Very rarely, a shingles infection can lead to pneumonia, hearing problems, blindness, brain inflammation (encephalitis) or death.

For about 1 person in 5, severe pain can continue even long after the rash clears up. This is called post-herpetic neuralgia.

Shingles is caused by the Varicella Zoster virus, the same virus that causes chickenpox.

Only someone who has had chickenpox—or, rarely, has gotten chickenpox vaccine—can get shingles. The virus stays in your body, and can cause shingles many years later.

You can’t catch shingles from another person with shingles. However, a person who has never had chickenpox (or chickenpox vaccine) could get chickenpox from someone with shingles. This is not very common.

Shingles is far more common in people 50 years of age and older than in younger people. It is also more common in people whose immune systems are weakened because of a disease such as cancer, or drugs such as steroids or chemotherapy.

At least 1 million people a year in the United States get shingles.

2  Shingles vaccine

A vaccine for shingles was licensed in 2006. In clinical trials, the vaccine reduced the risk of shingles by 50%. It can also reduce pain in people who still get shingles after being vaccinated.

A single dose of shingles vaccine is recommended for adults 60 years of age and older.

3  Some people should not get shingles vaccine or should wait.

A person should not get shingles vaccine who:

• has ever had a life-threatening allergic reaction to gelatin, the antibiotic neomycin, or any other component of shingles vaccine. Tell your doctor if you have any severe allergies.

• has a weakened immune system because of current:
  - AIDS or another disease that affects the immune system,
  - treatment with drugs that affect the immune system, such as prolonged use of high-dose steroids,
  - cancer treatment such as radiation or chemotherapy,
  - cancer affecting the bone marrow or lymphatic system, such as leukemia or lymphoma.

• is pregnant, or might be pregnant. Women should not become pregnant until at least 4 weeks after getting shingles vaccine.

Someone with a minor acute illness, such as a cold, may be vaccinated. But anyone with a moderate or severe acute illness should usually wait until they recover before getting the vaccine. This includes anyone with a temperature of 101.3°F or higher.
4 What are the risks from shingles vaccine?
A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. However, the risk of a vaccine causing serious harm, or death, is extremely small.
No serious problems have been identified with shingles vaccine.

Mild problems
• Redness, soreness, swelling, or itching at the site of the injection (about 1 person in 3).
• Headache (about 1 person in 70).

Like all vaccines, shingles vaccine is being closely monitored for unusual or severe problems.

5 What if there is a serious reaction?

What should I look for?
• Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?
• If you think it is a severe allergic reaction or other emergency that can’t wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
• Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS is only for reporting reactions. They do not give medical advice.

6 How can I learn more?
• Ask your doctor.
• Call your local or state health department.
• Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC’s website at www.cdc.gov/vaccines
VACCINE INFORMATION STATEMENT

Tdap Vaccine

What You Need to Know

1  Why get vaccinated?

Tetanus, diphtheria and pertussis are very serious diseases. Tdap vaccine can protect us from these diseases. And, Tdap vaccine given to pregnant women can protect newborn babies against pertussis.

TETANUS (Lockjaw) is rare in the United States today. It causes painful muscle tightening and stiffness, usually all over the body.

- It can lead to tightening of muscles in the head and neck so you can’t open your mouth, swallow, or sometimes even breathe. Tetanus kills about 1 out of 10 people who are infected even after receiving the best medical care.

DIPHTHERIA is also rare in the United States today. It can cause a thick coating to form in the back of the throat.

- It can lead to breathing problems, heart failure, paralysis, and death.

PERTUSSIS (Whooping Cough) causes severe coughing spells, which can cause difficulty breathing, vomiting and disturbed sleep.

- It can also lead to weight loss, incontinence, and rib fractures. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, which could include pneumonia or death.

These diseases are caused by bacteria. Diphtheria and pertussis are spread from person to person through secretions from coughing or sneezing. Tetanus enters the body through cuts, scratches, or wounds.

Before vaccines, as many as 200,000 cases of diphtheria, 200,000 cases of pertussis, and hundreds of cases of tetanus, were reported in the United States each year. Since vaccination began, reports of cases for tetanus and diphtheria have dropped by about 99% and for pertussis by about 80%.

2  Tdap vaccine

Tdap vaccine can protect adolescents and adults from tetanus, diphtheria, and pertussis. One dose of Tdap is routinely given at age 11 or 12. People who did not get Tdap at that age should get it as soon as possible.

Tdap is especially important for healthcare professionals and anyone having close contact with a baby younger than 12 months. Pregnant women should get a dose of Tdap during every pregnancy, to protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.

Another vaccine, called Td, protects against tetanus and diphtheria, but not pertussis. A Td booster should be given every 10 years. Tdap may be given as one of these boosters if you have never gotten Tdap before. Tdap may also be given after a severe cut or burn to prevent tetanus infection.

Your doctor or the person giving you the vaccine can give you more information.

Tdap may safely be given at the same time as other vaccines.

3  Some people should not get this vaccine

- A person who has ever had a life-threatening allergic reaction after a previous dose of any diphtheria, tetanus or pertussis containing vaccine, OR has a severe allergy to any part of this vaccine, should not get Tdap vaccine. Tell the person giving the vaccine about any severe allergies.

- Anyone who had coma or long repeated seizures within 7 days after a childhood dose of DTP or DTaP, or a previous dose of Tdap, should not get Tdap, unless a cause other than the vaccine was found. They can still get Td.

- Talk to your doctor if you:
  - have seizures or another nervous system problem,
  - had severe pain or swelling after any vaccine containing diphtheria, tetanus or pertussis,
  - ever had a condition called Guillain-Barré Syndrome (GBS),
  - aren’t feeling well on the day the shot is scheduled.
4  Risks
With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own. Serious reactions are also possible but are rare.

Most people who get Tdap vaccine do not have any problems with it.

Mild problems following Tdap
(Do not interfere with activities)
• Pain where the shot was given (about 3 in 4 adolescents or 2 in 3 adults)
• Redness or swelling where the shot was given (about 1 person in 5)
• Mild fever of at least 100.4°F (up to about 1 in 25 adolescents or 1 in 100 adults)
• Headache (about 3 or 4 people in 10)
• Tiredness (about 1 person in 3 or 4)
• Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents or 1 in 10 adults)
• Chills, sore joints (about 1 person in 10)
• Body aches (about 1 person in 3 or 4)
• Rash, swollen glands (uncommon)

Moderate problems following Tdap
(Interfered with activities, but did not require medical attention)
• Pain where the shot was given (up to 1 in 5 or 6)
• Redness or swelling where the shot was given (up to about 1 in 16 adolescents or 1 in 12 adults)
• Fever over 102°F (about 1 in 100 adolescents or 1 in 250 adults)
• Headache (about 1 in 7 adolescents or 1 in 10 adults)
• Nausea, vomiting, diarrhea, stomach ache (up to 1 or 3 people in 100)
• Swelling of the entire arm where the shot was given (up to about 1 in 500).

Severe problems following Tdap
(Unable to perform usual activities; required medical attention)
• Swelling, severe pain, bleeding and redness in the arm where the shot was given (rare).

Problems that could happen after any vaccine:
• People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
• Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
• Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5  What if there is a serious problem?

What should I look for?
• Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.
• Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?
• If you think it is a severe allergic reaction or other emergency that can’t wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
• Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.

6  The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

7  How can I learn more?

• Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
• Call your local or state health department.
• Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit CDC’s website at www.cdc.gov/vaccines

Vaccine Information Statement
Tdap Vaccine

2/24/2015
42 U.S.C. § 300aa-26
**VACCINE INFORMATION STATEMENT**

**Td Vaccine**

**What You Need to Know**

1. **Why get vaccinated?**

   Tetanus and diphtheria are very serious diseases. They are rare in the United States today, but people who do become infected often have severe complications. Td vaccine is used to protect adolescents and adults from both of these diseases.

   Both tetanus and diphtheria are infections caused by bacteria. Diphtheria spreads from person to person through coughing or sneezing. Tetanus-causing bacteria enter the body through cuts, scratches, or wounds.

   **TETANUS** (Lockjaw) causes painful muscle tightening and stiffness, usually all over the body.
   
   - It can lead to tightening of muscles in the head and neck so you can’t open your mouth, swallow, or sometimes even breathe. Tetanus kills about 1 out of every 10 people who are infected even after receiving the best medical care.

   **DIPHTHERIA** can cause a thick coating to form in the back of the throat.
   
   - It can lead to breathing problems, paralysis, heart failure, and death.

   Before vaccines, as many as 200,000 cases of diphtheria and hundreds of cases of tetanus were reported in the United States each year. Since vaccination began, reports of cases for both diseases have dropped by about 99%.

2. **Td vaccine**

   Td vaccine can protect adolescents and adults from tetanus and diphtheria. Td is usually given as a booster dose every 10 years but it can also be given earlier after a severe and dirty wound or burn.

   Another vaccine, called Tdap, which protects against pertussis in addition to tetanus and diphtheria, is sometimes recommended instead of Td vaccine.

   Your doctor or the person giving you the vaccine can give you more information.

   Td may safely be given at the same time as other vaccines.

3. **Some people should not get this vaccine**

   - A person who has ever had a life-threatening allergic reaction after a previous dose of any tetanus or diphtheria containing vaccine, OR has a severe allergy to any part of this vaccine, should not get Td vaccine. **Tell the person giving the vaccine about any severe allergies.**
   
   - Talk to your doctor if you:
     - had severe pain or swelling after any vaccine containing diphtheria or tetanus,
     - ever had a condition called Guillain Barré Syndrome (GBS),
     - aren’t feeling well on the day the shot is scheduled.

4. **Risks of a vaccine reaction**

   With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own. Serious reactions are also possible but are rare.

   Most people who get Td vaccine do not have any problems with it.

   **Mild Problems** following Td vaccine: *(Did not interfere with activities)*
   
   - Pain where the shot was given (about 8 people in 10)
   - Redness or swelling where the shot was given (about 1 person in 4)
   - Mild fever (rare)
   - Headache (about 1 person in 4)
   - Tiredness (about 1 person in 4)

   **Moderate Problems** following Td vaccine: *(Interfered with activities, but did not require medical attention)*
   
   - Fever over 102°F (rare)

   **Severe Problems** following Td vaccine: *(Unable to perform usual activities; required medical attention)*
   
   - Swelling, severe pain, bleeding and/or redness in the arm where the shot was given (rare).
Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: [www.cdc.gov/vaccinesafety/](http://www.cdc.gov/vaccinesafety/)

What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can’t wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at [www.vaers.hhs.gov](http://www.vaers.hhs.gov), or by calling 1-800-822-7967.

  *VAERS does not give medical advice.*

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation). There is a time limit to file a claim for compensation.

How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO)
  - Visit CDC’s website at [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)

Vaccine Information Statement

Td Vaccine

04/11/2017  42 U.S.C. § 300aa-26
In this section:

- CDC Adult Vaccination Schedule
- VAERS Form
- Storage Best Practices for Refrigerated Vaccines
- Temp Monitoring for Refrigerated Vaccines
- Storage Best Practices for Frozen Vaccines
- Temp Monitoring for Frozen Vaccines
Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States, 2017

In February 2017, the Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States, 2017 became effective, as recommended by the Advisory Committee on Immunization Practices (ACIP) and approved by the Centers for Disease Control and Prevention (CDC). The 2017 adult immunization schedule was also reviewed and approved by the following professional medical organizations:

- American College of Physicians (www.acponline.org)
- American Academy of Family Physicians (www.aafp.org)
- American College of Obstetricians and Gynecologists (www.acog.org)
- American College of Nurse-Midwives (www.midwife.org)

CDC announced the availability of the 2017 adult immunization schedule at www.cdc.gov/vaccines/schedules/hcp/index.html.1 The schedule is published in its entirety in the *Annals of Internal Medicine.*2

The adult immunization schedule describes the age groups and medical conditions and other indications for which licensed vaccines are recommended. The 2017 adult immunization schedule consists of:

- Figure 1. Recommended immunization schedule for adults by age group
- Figure 2. Recommended immunization schedule for adults by medical condition and other indications
- Footnotes that accompany each vaccine containing important general information and considerations for special populations
- Table. Contraindications and precautions for vaccines routinely recommended for adults

Consider the following information when reviewing the adult immunization schedule:

- The figures in the adult immunization schedule should be read with the footnotes that contain important general information and information about vaccination of special populations.
- When indicated, administer recommended vaccines to adults whose vaccination history is incomplete or unknown.
- Increased interval between doses of a multi-dose vaccine does not diminish vaccine effectiveness; therefore, it is not necessary to restart the vaccine series or add doses to the series because of an extended interval between doses.
- Adults with immunocompromising conditions should generally avoid live vaccines, e.g., measles, mumps, and rubella vaccine. Inactivated vaccines, e.g., pneumococcal or inactivated influenza vaccines, are generally acceptable.
- Combination vaccines may be used when any component of the combination is indicated and when the other components of the combination vaccine are not contraindicated.
- The use of trade names in the adult immunization schedule is for identification purposes only and does not imply endorsement by the ACIP or CDC.

Details on vaccines recommended for adults and complete ACIP statements are available at www.cdc.gov/vaccines/hcp/acip-recs/indexhtml. Additional CDC resources include:

- A summary of information on vaccination recommendations, vaccination of persons with immunodeficiencies, preventing and managing adverse reactions, vaccination contraindications and precautions, and other information can be found in *General Recommendations on Immunization* at www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm.

- Vaccine Information Statements that explain benefits and risks of vaccines are available at www.cdc.gov/vaccines/hcp/vis/index.html.
- Information and resources regarding vaccination of pregnant women are available at www.cdc.gov/vaccines/adults/rec-vac/pregnant.html.
- Information on travel vaccine requirements and recommendations is available at wwwnc.cdc.gov/travel/destinations/list.
- CDC Vaccine Schedules App for clinicians and other immunization service providers to download is available at www.cdc.gov/vaccines/schedules/hcp/schedule-app.html.
- Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger is available at www.cdc.gov/vaccines/schedules/hcp/index.html.
- Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States, 2017
- Report suspected cases of reportable vaccine-preventable diseases to the local or state health department.

Report all clinically significant post-vaccination reactions to the Vaccine Adverse Event Reporting System at www.vaers.hhs.gov or by telephone, 800-822-7967. All vaccines included in the 2017 adult immunization schedule except herpes zoster and 23-valent pneumococcal polysaccharide vaccines are covered by the Vaccine Injury Compensation Program. Information on how to file a vaccine injury claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382.

Submit questions and comments regarding the 2017 adult immunization schedule to CDC through www.cdc.gov/cdc-info or by telephone, 800-CDC-INFO (800-232-4636), in English and Spanish, 8:00am–8:00pm ET, Monday–Friday, excluding holidays.

The following acronyms are used for vaccines recommended for adults:

- HepA = hepatitis A vaccine
- HepA-HepB = hepatitis A and hepatitis B vaccines
- HepB = hepatitis B vaccine
- Hib = *Haemophilus influenzae* type b conjugate vaccine
- HPV vaccine = human papillomavirus vaccine
- HZV = herpes zoster vaccine
- IV = inactivated influenza vaccine
- LAIV = live attenuated influenza vaccine
- MenACWY = serogroups A, C, W, and Y meningococcal conjugate vaccine
- MenB = serogroup B meningococcal vaccine
- MMR = measles, mumps, and rubella vaccine
- MPSV4 = serogroups A, C, W, and Y meningococcal polysaccharide vaccine
- PCV13 = 13-valent pneumococcal conjugate vaccine
- PPSV23 = 23-valent pneumococcal polysaccharide vaccine
- RIV = recombinant influenza vaccine
- Td = tetanus and diphtheria toxoids
- Tdap = tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine
- VAR = varicella vaccine

1 MMWR Morb Mortal Wkly Rep. 2017;66(5). Available at www.cdc.gov/mmwr/volumes/66/wr/mm6605e2.htm?s_cid=mm6605e2_w.
Figures 1 and 2 should be read with the footnotes that contain important general information and considerations for special populations.

**Figure 1. Recommended immunization schedule for adults aged 19 years or older by age group, United States, 2017**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>19–21 years</th>
<th>22–26 years</th>
<th>27–59 years</th>
<th>60–64 years</th>
<th>≥ 65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza(^1)</td>
<td></td>
<td></td>
<td>1 dose annually</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Td/Tdap(^2)</td>
<td></td>
<td>Substitute Tdap for Td once, then Td booster every 10 yrs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMR(^3)</td>
<td></td>
<td></td>
<td>1 or 2 doses depending on indication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAR(^4)</td>
<td></td>
<td></td>
<td>2 doses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HZV(^5)</td>
<td></td>
<td></td>
<td></td>
<td>1 dose</td>
<td></td>
</tr>
<tr>
<td>HPV–Female(^6)</td>
<td></td>
<td></td>
<td>3 doses</td>
<td></td>
<td></td>
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<tr>
<td>HPV–Male(^6)</td>
<td></td>
<td></td>
<td>3 doses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCV13(^7)</td>
<td></td>
<td></td>
<td></td>
<td>1 dose</td>
<td></td>
</tr>
<tr>
<td>PPSV23(^7)</td>
<td></td>
<td></td>
<td>1 or 2 doses depending on indication</td>
<td>1 dose</td>
<td></td>
</tr>
<tr>
<td>HepA(^8)</td>
<td></td>
<td></td>
<td>2 or 3 doses depending on vaccine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HepB(^9)</td>
<td></td>
<td></td>
<td>3 doses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MenACWY or MPSV4(^10)</td>
<td></td>
<td></td>
<td>1 or more doses depending on indication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MenB(^10)</td>
<td></td>
<td></td>
<td>2 or 3 doses depending on vaccine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hib(^11)</td>
<td></td>
<td></td>
<td>1 or 3 doses depending on indication</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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*Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection.*

*Recommended for adults with additional medical conditions or other indications.*

*No recommendation.*
Figure 2. Recommended immunization schedule for adults aged 19 years or older by medical condition and other indications, United States, 2017

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Pregnancy</th>
<th>Immuno-compromised (excluding HIV infection)</th>
<th>HIV infection CD4+ count (cells/μL)</th>
<th>Asplenia, persistent complement deficiencies</th>
<th>Kidney failure, end-stage renal disease, on hemodialysis</th>
<th>Heart or lung disease, chronic alcoholism</th>
<th>Chronic liver disease</th>
<th>Diabetes</th>
<th>Healthcare personnel</th>
<th>Men who have sex with men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
<td></td>
<td></td>
<td>&lt; 200</td>
<td>≥ 200</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Tdap/Tdap</td>
<td>1 dose Tdap each pregnancy</td>
<td>Substitute Tdap for Td once, then Td booster every 10 yrs</td>
<td>1 or 2 doses depending on indication</td>
<td>Contraindicated</td>
<td>2 doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMR</td>
<td>Contraindicated</td>
<td>1 or 2 doses depending on indication</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAR</td>
<td>Contraindicated</td>
<td>2 doses</td>
<td></td>
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<tr>
<td>HZV</td>
<td>Contraindicated</td>
<td>1 dose</td>
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<tr>
<td>HPV–Female</td>
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<td>HPV–Male</td>
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<td>PCV13</td>
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<tr>
<td>PPSV23</td>
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<tr>
<td>HepA</td>
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<tr>
<td>HepB</td>
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<td></td>
<td></td>
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<tr>
<td>MenACWY or MPSV4</td>
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<tr>
<td>MenB</td>
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<tr>
<td>Hib</td>
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<td></td>
</tr>
</tbody>
</table>

Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection
Recommended for adults with additional medical conditions or other indications
Contraindicated
No recommendation

**Additional Info**

**Vaccine Info Statements**

**Influenza**
1. Influenza vaccination

General information

• All persons aged 6 months or older who do not have a contraindication should receive annual influenza vaccination with an age-appropriate formulation of inactivated influenza vaccine (IIV) or recombinant influenza vaccine (RIV).

• In addition to standard-dose RV, available options for adults in specific age groups include: high-dose or adjuvanted RV for adults aged 65 years or older, in trader RV for adults 18 through 64 years, and RV for adults aged 18 years or older.

• Notes: Live attenuated influenza vaccine (LAIV) should not be used during the 2016–2017 influenza season. A list of currently available influenza vaccines is available at www.cdc.gov/flu/professional/vaccine/vaccines.html.

Special populations

• Adults with a history of egg allergy who have only hives after exposure to egg should receive age-appropriate IIV or RIV.

• Adults with a history of egg allergy other than hives, e.g., angioedema, respiratory distress, lightheadedness, or recurrent emesis, or who required epinephrine or another emergency medical intervention, may receive age-appropriate IIV or RIV. The selected vaccine should be administered in an inpatient or outpatient medical setting and under the supervision of a healthcare provider who is able to recognize and manage severe allergic conditions.

• Pregnant women and women who might become pregnant in the upcoming influenza season should receive IIV.

2. Tetanus, diphtheria, and acellular pertussis vaccination

General information

• Adults who have not received tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap) or pertussis-containing vaccine (DTP) who are at risk for pertussis and whose pertussis vaccination status is unknown should receive 1 dose of Tdap followed by a tetanus and diphtheria toxoids (Td) booster every 10 years. Tdap should be administered regardless of when a tetanus or diphtheria toxoid-containing vaccine was last received.

• Adults with an unknown or incomplete history of a 3-dose primary series with tetanus and diphtheria toxoid-containing vaccines should complete the primary series that includes 1 dose of Tdap. Unvaccinated adults should receive the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second dose.

• Notes: Information on the use of Td or Tdap as tetanus prophylaxis in wound management is available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5517a1.htm.

Special populations

• Pregnant women should receive 1 dose of Tdap during each pregnancy, preferably during the early part of gestational weeks 27–36, regardless of prior history of receiving Tdap.

3. Measles, mumps, and rubella vaccination

General information

• Adults born in 1957 or later without acceptable evidence of immunity to measles, mumps, or rubella (defined below) should receive 1 dose of measles, mumps, and rubella vaccine (MMR) unless they have a medical contraindication to vaccination, e.g., pregnancy or severe immune deficiency.

• Notes: Acceptable evidence of immunity to measles, mumps, or rubella in adults is: born before 1957, documentation of receipt of MMR, or laboratory evidence of immunity to measles disease. Documentation of healthcare provider-diagnosed disease without laboratory confirmation is not acceptable evidence of immunity.

Special populations

• Pregnant women who do not have evidence of immunity to rubella should receive 1 dose of MMR upon completion of pregnancy and before discharge from the healthcare facility; non-pregnant women of childbearing age without evidence of rubella immunity should receive 1 dose of MMR.

• Adults with primary or acquired immunodeficiency including malignant conditions affecting the bone marrow or lymphatic system, systemic immunosuppressive therapy, or cellular immunodeficiency should not receive MMR.

• Adults with human immunodeficiency virus (HIV) infection and CD4+ T-lymphocyte count ≤200 cells/μl should not receive MMR.

• Adults who work in healthcare facilities should receive 2 doses of MMR at least 28 days apart; healthcare personnel considered to be at risk for the prevention of measles or mumps, or rubella immunity, or laboratory confirmation of disease should be considered for vaccination with 2 doses of MMR at least 28 days apart for measles or mumps, or 1 dose of MMR for rubella.

• Adults who are students in postsecondary educational institutions or plan to travel internationally should receive 2 doses of MMR at least 28 days apart.

• Adults who received inactivated (killed) measles vaccine or measles vaccine of unknown type during years 1963–1967 should be revaccinated with 1 or 2 doses of MMR.

• Adults who were vaccinated before 1979 with either inactivated mumps vaccine or mumps vaccine of unknown type who are at risk for mumps infection, e.g., work in a healthcare facility, should be considered for revaccination with 2 doses of MMR at least 28 days apart.

• Adults who received inactivated (killed) measles vaccine or measles vaccine of unknown type who are at risk for mumps infection, e.g., work in a healthcare facility, should be considered for revaccination with 2 doses of MMR at least 28 days apart.

4. Varicella vaccination

General information

• Adults without evidence of immunity to varicella (defined below) should receive 2 doses of single-antigen varicella vaccine (VAR) 4–8 weeks apart, or a second dose if they have received only 1 dose.

• Persons without evidence of immunity for whom VAR should be emphasized are: adults who have close contact with persons at high risk for serious complications, e.g., healthcare personnel and household contacts of immunocompromised persons; adults who live or work in an environment in which transmission of varicella zoster virus is likely, e.g., teachers, childcare workers, and residents and staff members of congregate institutions; and military personnel; non-pregnant women of childbearing age; adolescents and adults living in households with children; and international travelers.

• Notes: Evidence of immunity to varicella in adults is U.S.-born before 1980 (for pregnant women and healthcare personnel) or U.S.-born before 1990 (for nonpregnant women) not considered evidence of immunity; documentation of 2 doses of VAR at least 4 weeks apart; history of varicella or herpes zoster diagnosis or verification of varicella or herpes zoster by a healthcare provider; or laboratory evidence of immunity or disease.

Special populations

• Pregnant women should be assessed for evidence of varicella immunity. Pregnant women who do not have evidence of immunity should receive the first dose of VAR upon completion or termination of pregnancy and before discharge from the healthcare facility, and the second dose 4–8 weeks after the first dose.

• Adults with malignant conditions, including those that affect the bone marrow or lymphatic system or who receive systemic immunosuppressive therapy should be considered for receiving VAR.

5. Herpes zoster vaccination

General information

• Adults aged 60 years or older should receive 1 dose of herpes zoster vaccine (HZV), regardless of whether they had a prior episode of herpes zoster.

Special populations

• Adults aged 60 years or older with chronic medical conditions may receive HZV unless they have a medical contraindication, e.g., pregnancy or severe immunodeficiency.

• Adults with malignant conditions, including those that affect the bone marrow or lymphatic system or who receive systemic immunosuppressive therapy, should not receive HZV.

• Adults with human immunodeficiency virus (HIV) infection and CD4+ T-lymphocyte count ≤200 cells/μl should not receive HZV.

6. Human papillomavirus vaccination

General information

• Adult females through age 26 years and adult males through age 21 years who have not received any human papillomavirus (HPV) vaccine should receive a 3-dose series of HPV vaccine at 0, 1–2, and 6 months. Males aged 22 through 26 years may be vaccinated with a 3-dose series of HPV vaccine at 0, 1–2, and 6 months.

• Adult females through age 26 years and adult males through age 21 years (and males aged 22 through 26 years who may receive HPV vaccination) who initiated the HPV vaccination series before age 15 years and received 2 doses at least 5 months apart are considered adequately vaccinated and do not need an additional dose of HPV vaccine.

• Adult females through age 26 years and adult males through age 21 years (and males aged 22 through 26 years who may receive HPV vaccination) who initiated the HPV vaccination series before age 15 years and received only 1 dose, or 2 doses less than 5 months apart, are not considered adequately vaccinated and should receive 1 additional dose of HPV vaccine.

• Notes: HPV vaccination is routinely recommended for children at age 11 or 12 years. For adults who had initiated but did not complete the HPV vaccination series, consider the age at first HPV vaccination (discussed above) and other factors (described below) to determine if they have been adequately vaccinated.

Special populations

• Men who have sex with men through age 26 years who have not received any HPV vaccine should receive a 3-dose series of HPV vaccine at 0, 1–2, and 6 months.

• Adult males and females through age 26 years with immunocompromising conditions (described below), including those with human immunodeficiency virus (HIV) infection, should receive a 3-dose series of HPV vaccine at 0, 1–2, and 6 months.

• Pregnant women are not recommended to receive HPV vaccine, although there is evidence that the HPV vaccine is safe in pregnancy. However, a woman is found to be pregnant after initiating the HPV vaccination series, delay the remaining doses until after the pregnancy. No other intervention is needed. Pregnancy testing is not needed before administering HPV vaccine.

• Notes: Immunocompromising conditions for which a 3-dose series of HPV vaccine is indicated are primary or secondary immunocompromising conditions that affect cell-mediated immunity, e.g., B-lymphocyte antibody deficiencies, complete or partial T-lymphocyte defects, HIV infection, malignant neoplastic, transplantation, autoimmune disease, and immunosuppressive therapy.
7. Pneumococcal vaccination

Special populations
- Adults who have any of the following indications should receive a HepA series: have chronic liver disease, receive clotting factor concentrates, men who have sex with men, use injection or non-injection drugs, or work with Hepatitis A virus infected primates or in a hepatitis A research laboratory setting.
- Adults with cirrhosis in countries with high or intermediate levels of endemic hepatitis A infection or anticipate close person contact with an international adoptee, e.g., reside in the same household or regularly care for a country with high or intermediate level of endemic hepatitis A infection within the first 60 days of arrival in the United States should receive a HepA series.

9. Hepatitis B vaccination

Special populations
- Adults at risk for hepatitis B virus infection by percutaneous or mucosal exposure to blood should receive a HepB series. Adults and adolescents at high risk for occupational exposure to blood should receive a HepB series, including adults who are recent or current users of injectable drugs, household contacts of HBV-infected persons, residents and staff of facilities for pregnant women, residents of nursing homes, and public safety workers at risk for exposure to blood or blood-contaminated body fluids, younger than age 60 years with diabetes mellitus, and young adults with diabetes mellitus at the discretion of the treating clinician.
- Adults with chronic liver disease including, but not limited to, hepatitis C virus infection, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, and an alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal should receive a HepB series.
- Adults with end-stage renal disease including those on pre-dialysis care, hemodialysis, peritoneal dialysis, and home hemodialysis should receive a 3-dose series of 40 µg Recombivax HB at 0, 1, and 6 months or a 4-dose series of 40 µg Engerix-B at 0, 1, 2, and 6 months.
- Adults who have a hematopoietic stem cell transplant (HSCT) should receive a HepB series.
- Adults with a history of exposure to hepatitis A virus should receive a HepB series.

8. Hepatitis A vaccination

General information
- Adults who seek protection from hepatitis A virus infection may receive a 2-dose series of single antigen hepatitis A vaccine (HepA) at either 0 and 6 months or 0 and 12 months. Adults who have previously received 1 dose of HepA and 1 dose of HepB (Havrix) at 0 and 6 months may also receive a combined hepatitis A and hepatitis B vaccine (HepA-Heb) (Twisto) as a 3-dose series, at 0, 1, and 6 months. Acknowledgment of a specific risk factor by those who seek protection is not needed.

10. Meningococcal vaccination

Special populations
- Adults who have anatomical or functional asplenia or sickle cell disease or are undergoing elective splenectomy should receive 1 dose of Haemophilus influenzae type b conjugate vaccine (Hib) if they have not previously received Hib. Hib should be administered at least 14 days before splenectomy.
- Adults with a hematopoietic stem cell transplant (HSCT) should receive 3 doses of Hib at least 4 weeks intervals 6–12 months after transplant regardless of whether or not Hib history.
- Adults with a history of meningococcal disease or who are at high risk for meningococcal infection due to a meningococcal disease outbreak should receive 1 dose of MenB at least 1 month after the first dose. Adults with HIV infection are not routinely recommended to receive MenB because meningococcal disease in this population is caused primarily by serogroups C, W, and Y.

Microbiologists who are routinely exposed to single serogroup meningococcal disease should receive 1 dose of MenACWY and revaccinate every 5 years if the risk for infection remains, and either a 2-dose series of MenB-ACWY at least 1 month apart or a 3-dose series of MenB-FHbp at 0, 1, and 6 months.

Adults at risk because of a meningococcal disease outbreak should receive 1 dose of MenACWY if the outbreak is attributable to serogroups A, C, W, Y, or a 2-dose series of MenB-ACW-Y at least 1 month apart or a 3-dose series of MenB-FHbp at 0, 1, and 6 months if the outbreak is attributable to serogroup B.

Adults who travel to or live in countries with high or intermediate level of endemic meningococcal disease should receive 1 dose of MenACWY and revaccinate every 5 years if the risk for infection remains.

First-year college students aged 19 years or older who live in residence halls should receive 1 dose of MenACWY if they have not received MenACWY at age 16 years or older.

Adults aged 19 through 64 years who have not previously received MenACWY or anticipate receiving multiple doses of serogroups A, C, W, and Y meningococcal vaccine, MenACWY is preferred.

MenB-4C and MenB-FHbp are not interchangeable, i.e., the same vaccine should be used for all doses to complete a 2-dose series.

Notes: MenB-4C and MenB-FHbp are not interchangeable, i.e., the same vaccine should be used for all doses to complete a 2-dose series.
### Table. Contraindications and precautions for vaccines recommended for adults aged 19 years or older

The Advisory Committee on Immunization Practices (ACIP) recommendations and package inserts for vaccines provide information on contraindications and precautions related to vaccines. Contraindications are conditions that increase chances of a serious adverse reaction in vaccine recipients and the vaccine should not be administered when a contraindication is present. Precautions should be reviewed for potential risks and benefits for vaccine recipient. For a person with a severe allergy to latex, e.g., a naphthalene, vaccines supplied in vials or syringes that contain natural rubber latex should not be administered unless the benefit of vaccination clearly outweighs the risk for a potential allergic reaction. For latex allergies other than anaphylaxis, vaccines supplied in vials or syringes that contain dry, natural rubber or natural rubber latex may be administered.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Contraindications</th>
<th>Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV</td>
<td>- Severe reaction, e.g., anaphylaxis, after a previous dose or to a vaccine component</td>
<td>- History of Guillain–Barré Syndrome within 6 weeks after previous influenza vaccination</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Guillain–Barré Syndrome within 6 weeks after a previous dose of tetanus toxoid-containing vaccine</td>
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<tr>
<td>LAIV</td>
<td></td>
<td>- History of Guillain–Barré Syndrome within 6 weeks after previous influenza vaccination</td>
</tr>
<tr>
<td>Tdap/Td</td>
<td></td>
<td>- LAIV should not be used during 2016–2017 influenza season</td>
</tr>
<tr>
<td>MMR</td>
<td>- Severe immunodeficiency, e.g., hematologic and solid tumors, chemotherapy, congenital immunodeficiency or long-term immunosuppressive therapy, human immunodeficiency virus (HIV) infection with severe immunocompromise</td>
<td>- Recent (within 11 months) receipt of antibody-containing blood product (specific interval depends on product)</td>
</tr>
<tr>
<td></td>
<td>- Pregnancy</td>
<td>- History of thrombocytopenia or thrombocytopenic purpura</td>
</tr>
<tr>
<td>VAR</td>
<td>- Severe immunodeficiency, e.g., hematologic and solid tumors, chemotherapy, congenital immunodeficiency or long-term immunosuppressive therapy, HIV infection with severe immunocompromise</td>
<td>- Need for tuberculin skin testing</td>
</tr>
<tr>
<td></td>
<td>- Pregnancy</td>
<td>- Recent (within 11 months) receipt of antibody-containing blood product (specific interval depends on product)</td>
</tr>
<tr>
<td>HZV</td>
<td>- Severe immunodeficiency, e.g., hematologic and solid tumors, chemotherapy, congenital immunodeficiency or long-term immunosuppressive therapy, HIV infection with severe immunocompromise</td>
<td>- Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination</td>
</tr>
<tr>
<td></td>
<td>- Pregnancy</td>
<td>- Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination</td>
</tr>
<tr>
<td>HPV vaccine</td>
<td></td>
<td>- Pregnancy</td>
</tr>
<tr>
<td>PCV13</td>
<td>- Severe allergic reaction to any vaccine containing diphtheria toxoid</td>
<td>- Measles vaccination may temporarily suppress tuberculin reactivity. Measles-containing vaccine may be administered on the same day as tuberculin skin testing, or should be postponed for at least 4 weeks after vaccination.</td>
</tr>
</tbody>
</table>


MMR vaccine may be administered together with VAR or HZV on the same day. If not administered on the same day, separate live vaccines by at least 28 days.

Immune-suppressive steroid dose is considered to be daily receipt of 20 mg or more prednisone or equivalent for two or more weeks. Vaccination should be deferred for at least 1 month after discontinuation of immunosuppressive steroid therapy. Providers should consult ACIP recommendations for complete information on the use of specific live vaccines among persons on immune-suppressing medications or with immune suppression because of other reasons.

Vaccines should be deferred for the appropriate interval if replacement immune globulin products are being administered. See CDC. General recommendations for immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011;60(No. RR-2). Available at www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm.

Measles vaccination may temporarily suppress tuberculin reactivity. Measles-containing vaccine may be administered on the same day as tuberculin skin testing, or should be postponed for at least 4 weeks after vaccination.


<table>
<thead>
<tr>
<th>Acronyms of vaccines recommended for adults</th>
<th>LAIV</th>
<th>PCV13</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepA</td>
<td>live attenuated influenza vaccine</td>
<td>13-valent pneumococcal conjugate vaccine</td>
</tr>
<tr>
<td>HepA-HepB</td>
<td>serogroups A, C, W, and Y meningococcal conjugate vaccine</td>
<td>PPSV23</td>
</tr>
<tr>
<td>HepB</td>
<td>serogroups B meningococcal vaccine</td>
<td>23-valent pneumococcal polysaccharide vaccine</td>
</tr>
<tr>
<td>Hib</td>
<td>serogroups A, C, W, and Y meningococcal vaccine</td>
<td>RIV</td>
</tr>
<tr>
<td>HPV vaccine</td>
<td>varicella vaccine</td>
<td>tetrax and diphtheria toxoids</td>
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<td>varicella vaccine</td>
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<td>HPV vaccine</td>
<td>varicella vaccine</td>
<td>tetrax and diphtheria toxoids</td>
</tr>
</tbody>
</table>
Influenza & Adult Immunization Guide | 2017-2018

**INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE**

1. Patient name: (first) (last)
2. Date of birth: (mm/dd/yyyy)
3. Sex: □ Male □ Female □ Unknown
4. Date and time of vaccination: (mm/dd/yyyy)
   
   Time: hh:mm □ AM □ PM
5. Date and time adverse event started: (mm/dd/yyyy)
   
   Time: hh:mm □ AM □ PM
6. Age at vaccination: Years Months
7. Today's date: (mm/dd/yyyy)
8. Is the report about vaccine(s) given to a pregnant woman?: □ No □ Unknown □ Yes (If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18).
9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
10. Allergies to medications, food, or other products:
11. Other illnesses at the time of vaccination and up to one month prior:
12. Chronic or long-standing health conditions:
13. Form completed by: (name)
   - Relation to patient: □ Healthcare professional/staff □ Patient (yourself) □ Parent/guardian/caregiver □ Other:
   - Street address: □ Check if same as item 1.
   - City: □ Check if same as item 1.
   - Phone: ( ) □ Email: ( )
14. Best doctor/healthcare professional to contact about the adverse event: Name: ( ) □ Phone: ( ) □ Email: ( )
15. Facility/clinic name:
16. Type of facility: (Check one):
   - □ Doctor’s office or hospital
   - □ Pharmacy or drug store
   - □ Workplace clinic
   - □ Public health clinic
   - □ Nursing home or senior living facility
   - □ School/student health clinic
   - □ Other:
   - City:
   - ZIP code:
17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).
   - Vaccine (type and brand name) Manufacturer Lot number Route Body site
   - select □ select □ select □ select
   - select □ select □ select □ select
   - select □ select □ select □ select
   - select □ select □ select □ select
18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
   - □ Hospitalization: Number of days (if known)
   - □ Emergency room or emergency department visit
   - □ Prolongation of existing hospitalization (vaccine received during existing hospitalization)
   - □ Life threatening illness (immediate risk of death from the event)
   - □ Disability or permanent damage
   - □ Patient died: Date of death (mm/dd/yyyy)
   - □ Congenital anomaly or birth defect
   - □ None of the above
19. Medical tests and laboratory results related to the adverse event(s): (include dates)
20. Has the patient recovered from the adverse event(s)? □ Yes □ No □ Unknown
21. Result or outcome of adverse event(s): (Check all that apply):
   - □ Doctor or other healthcare professional office/clinic visit
   - □ Hospitalization: Number of days (if known)
   - □ Prolongation of existing hospitalization (vaccine received during existing hospitalization)
   - □ Life threatening illness (immediate risk of death from the event)
   - □ Disability or permanent damage
   - □ Patient died: Date of death (mm/dd/yyyy)
   - □ Congenital anomaly or birth defect
   - □ None of the above
22. Any other vaccines received within one month prior to the date listed in item 4:
   - Vaccine (type and brand name) Manufacturer Lot number Route Body site
   - select □ select □ select □ select
   - select □ select □ select □ select
   - select □ select □ select □ select
   - select □ select □ select □ select
23. Has the patient ever had an adverse event following any previous vaccine?: □ Yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name.
   - □ No □ Unknown □ Yes
24. Patient’s race: □ American Indian or Alaska Native □ Asian □ Black or African American □ Native Hawaiian or Other Pacific Islander
   - □ White □ Unknown □ Other:
25. Patient’s ethnicity: □ Hispanic or Latino □ Not Hispanic or Latino □ Unknown
26. Immuniz. proj. report no.: (Health Dept use only)

**INFORMATION ABOUT THE PERSON COMPLETING THIS FORM**

- Street address: □ Check if same as item 1.
- City: □ Check if same as item 1.
- Phone: ( ) □ Fax: ( )
- Name: ( ) □ Ext: ( )
- INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN
   - Facility/clinic name:
   - City:
   - ZIP code:
   - Type of facility: (Check one):
   - □ Doctor’s office or hospital
   - □ Pharmacy or drug store
   - □ Workplace clinic
   - □ Public health clinic
   - □ Nursing home or senior living facility
   - □ School/student health clinic
   - □ Other:

**ADDITIONAL INFORMATION**

- VINPAC ID: (Use continuation page if needed)
- Note: VAERS uses a free text entry system, so you can use any characters to enter responses. For specific terms, please refer to the VAERS website.

**COMPLET E ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS**

- Status at vaccination: □ Active duty □ Reserve □ National Guard □ Beneficiary □ Other:
- Vaccinated at Military/DoD site: □ Yes □ No

**FORM FDA VAERS-2.0 (6/17)**

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<table>
<thead>
<tr>
<th>Vaccine (type and brand name)</th>
<th>Manufacturer</th>
<th>Lot number</th>
<th>Route</th>
<th>Body site</th>
<th>Dose no. in series</th>
</tr>
</thead>
<tbody>
<tr>
<td>select</td>
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</table>

22. Any other vaccines received within one month prior to the date listed in item 4 (continued):

<table>
<thead>
<tr>
<th>Vaccine (type and brand name)</th>
<th>Manufacturer</th>
<th>Lot number</th>
<th>Route</th>
<th>Body site</th>
<th>Dose no. in series</th>
</tr>
</thead>
<tbody>
<tr>
<td>select</td>
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<td>select</td>
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</tbody>
</table>

Use the space below to provide any additional information (indicate Item number):
COMPLETING THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FORM

GENERAL INSTRUCTIONS
• Submit this form electronically using the Internet. For instructions, visit www.vaers.hhs.gov/uploadfile/.
• If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366.
• If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967, or send an email to info@vaers.org.
• Fill out the VAERS form as completely as possible and use the Continuation Page if needed. Use a separate VAERS form for each individual patient.
• If you do not know exact numbers, dates, or times, please provide your best guess. You may leave these spaces blank if you are not comfortable guessing.
• You can get specific information on the vaccine and vaccine lot number by contacting the facility or clinic where the vaccine was administered.
• Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.
• Healthcare professionals should refer to the VAERS Table of Reportable Events at www.vaers.hhs.gov/reportable.html for the list of adverse events that must be reported by law (42 USC 300aa-25).
• Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who administered the vaccine in order to exchange information and decide how best to complete and submit the VAERS form.

SPECIFIC INSTRUCTIONS
Items 2, 3, 4, 5, 6, 17, 18 and 21 are ESSENTIAL and should be completed.

• Items 4 and 5: Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the month and year even if you don’t know the day). If you do not know the exact time, but know it was in the morning (“AM”) or afternoon or evening (“PM”), please provide that information.

• Item 6: If you fill in the form by hand, provide age in years. If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, provide year and months (e.g., 1 year and 6 months). If a child is less than 1 month of age when vaccinated (e.g., a birth dose of hepatitis B vaccine) then answer 0 years and 0 months, but be sure to include the patient’s date of birth (Item 2) and date and time of vaccination (Item 4).

• Item 8: If the report is about a vaccine given to a pregnant woman, select “Yes” and describe the event, any pregnancy complications, and estimated due date if known in item 18. Otherwise, select “No” or “Unknown.”

• Item 9: List any prescriptions, over-the-counter medications, dietary supplements, herbal remedies, or other non-traditional/alternative medicines being taken by the patient when the vaccine(s) was given.

• Item 10: List any allergies the patient has to medications, foods, or other products.

• Item 11: List any short-term or acute illnesses the patient had on the date of vaccination AND up to one month prior to this date (e.g., cold, stomach flu, ear infection, etc.). This does NOT include the adverse event you are reporting.

• Item 12: List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).

• Item 13: List the name of the person who is completing the form. Select the “Check if same as item 1” box if you are the patient or if you live at the same address as the patient. The contact information you provided in item 1 will be automatically entered for you. Otherwise, please provide new contact information.

• Item 14: List the doctor or other healthcare professional who is the best person to contact to discuss the clinical details of the adverse event.

• Item 15: Select the “Check if same as item 13” box if the person completing the form works at the facility that administered the vaccine(s). The contact information provided in item 13 will be automatically entered for you. Otherwise, provide new contact information.

• Item 16: Select the option that best describes the type of facility where the vaccine(s) was given.
• **Item 17:** Include only vaccines given on the date provided in item 4. The vaccine route options include:
  - Injection/shot (intramuscular, subcutaneous, intradermal, jet injection, and unknown)
  - By mouth/oral
  - In nose/intranasal
  - Other (specify)
  - Unknown

  For body site, the options include:
  - Right arm
  - Left arm
  - Arm (side unknown)
  - Right thigh
  - Left thigh
  - Thigh (side unknown)
  - Nose
  - Mouth
  - Other (specify)
  - Unknown

  For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named “Dose no. in series.”

• **Item 18:** Describe the adverse event(s), treatment, and outcome(s). Include signs and symptoms, when the symptoms occurred, diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).

• **Item 19:** List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.

• **Item 20:** Select “Yes” if the patient’s health is the same as it was prior to the vaccination or “No” if the patient has not returned to the same state of health prior to the vaccination, and provide details in item 18. Select “Unknown” if the patient’s present condition is not known.

• **Item 21:** Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select “None of the above.” Prolongation of existing hospitalization means the patient received a vaccine during a hospital stay and an adverse event following vaccination occurred that resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this adverse event could have resulted in the death of the patient.

• **Item 22:** List any other vaccines the patient received within one month prior to the vaccination date listed in item 4.

• **Item 23:** Describe the adverse event(s) following any previous vaccine(s). Include patient age at vaccination, dates of vaccination, vaccine type, and brand name.

• **Item 24:** Check all races that apply.

• **Item 25:** Check the single best answer for ethnicity.

• **Item 26:** For health department use only.

• **Items 27 and 28:** Complete only for U.S. Military or Department of Defense related reports. In addition to active duty service members, Reserve and National Guard members, beneficiaries include: retirees, their families, survivors, certain former spouses, and others who are registered in the Defense Enrollment Eligibility Reporting System (DEERS).

**GENERAL INFORMATION**

- VAERS ([www.vaers.hhs.gov](http://www.vaers.hhs.gov)) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur during or after administration of vaccines licensed in the United States.

- VAERS protects patient identity and keeps patient identifying information confidential.

- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).

- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.

- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.

- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see [www.hrsa.gov/vaccinecompensation/index.html](http://www.hrsa.gov/vaccinecompensation/index.html)).

- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.
Storage Best Practices for Refrigerated Vaccines—Fahrenheit (F)

1. Unpack vaccines immediately
   1. Place the vaccines in trays or uncovered containers for proper air flow.
   2. Put vaccines that are first to expire in front.
   3. Keep vaccines in original boxes with lids closed to prevent exposure to light.
   4. Separate and label by vaccine type and public (VFC) or private vaccine.

2. Store vaccine at ideal temperature: 40°F
   - Never freeze refrigerated vaccine!
     Exception: MMR can be stored in refrigerator or freezer
   - Refrigerated Vaccine
     - Too Cold! Take Action!
     - Within Range
     - Too Warm! Take Action!
     - Report out-of-range temperatures immediately!

3. Use vaccine storage best practices
   - Refrigerator Only
     - 40°F ideal temp
     - DO
       - ✓ Do make sure the refrigerator door is closed!
       - ✓ Do replace crisper bins with water bottles to help maintain consistent temperature.
       - ✓ Do label water bottles “Do Not Drink.”
       - ✓ Do leave 2 to 3 inches between vaccine containers and refrigerator walls.
       - ✓ Do post “Do Not Unplug” signs on refrigerator and near electrical outlet.
     - DON’T
       - ☒ Don’t use dormitory-style refrigerator.
       - ☒ Don’t use top shelf for vaccine storage.
       - ☒ Don’t put food or beverages in refrigerator.
       - ☒ Don’t put vaccines on door shelves or on floor of refrigerator.
       - ☒ Don’t drink from or remove water bottles.
Test Your Knowledge

1. Can you find at least 8 things that are wrong with vaccine storage in this refrigerator?

2. When unpacking vaccine, why is it important to put the first to expire in the front?
   A. It reduces the risk that an expired vaccine will be given
   B. It saves money by reducing wastage
   C. It reduces time spent on returns
   D. All of the above
   E. None of the above—it’s really about organization

3. It is okay to drink from the water bottles as long as you replace them. True/False

4. One of the most common reasons that refrigerators are out of temperature range is:
   A. Power outage
   B. The thermometer is broken
   C. Staff doesn’t shut the refrigerator door
   D. The refrigerator thermostat is not working properly

5. Refrigerated vaccines should be stored between _____° F and _____° F, but the ideal temperature is _____° F.
Temperature Monitoring Best Practices for Refrigerated Vaccines—Fahrenheit (°F)

1. Store vaccine at ideal temperature: 40° F

   - Never freeze refrigerated vaccine!
   - Exception: MMR can be stored in refrigerator or freezer

Refrigerated Vaccine

   25° F 30° F 36° F 46° F 50° F

   Too Cold! Take Action!

   Within Range

   Too Warm! Take Action!

   Report out-of-range temperatures immediately!

2. Record daily temperatures

   3 steps, 2 times a day: Read and record temperatures first thing in the morning and before leaving at night.

   - Current temperature: The temperature in the refrigerator right now
   - Min/Max: The coldest and warmest temperatures in the refrigerator since you last reset the thermometer
   - Reset: The button you push after you have recorded the Min/Max temperatures

3. Take action if out of range!

   - Contact your state or local health department immediately. Or for private vaccine, call the manufacturer directly.
   - Tell them the total amount of time the refrigerator temperature was out of range.

   • Take your time. Read and record temperatures accurately.
   • Make your mark! Initial the log when recording temperatures.
   • Leave it blank. If a temperature was not recorded, leave the space blank!
**Test Your Knowledge**

Review the temperature readings below and select the correct answer.

1. "40° F 32° F 44° F"

A. Current temp and min/max are within range—no action necessary

B. Current temp is within range, min/max out of range—take action

C. Current temp is within range, min/max out of range—no action necessary

D. Current temp and min/max are out of range—take action

2. "38° F 36° F 45° F"

A. Current temp and min/max are within range—no action necessary

B. Current temp is within range, min/max out of range—take action

C. Current temp is within range, min/max out of range—no action necessary

D. Current temp and min/max are out of range—take action

3. "34° F 28° F 40° F"

A. Current temp and min/max are within range—no action necessary

B. Current temp is within range, min/max out of range—take action

C. Current temp is within range, min/max out of range—no action necessary

D. Current temp and min/max are out of range—take action

4. "44° F 44° F 48° F"

A. Current temp and min/max are within range—no action necessary

B. Current temp is within range, min/max out of range—take action

C. Current temp is within range, min/max out of range—no action necessary

D. Current temp and min/max are out of range—take action

5. "Take action" means (circle any that apply):

A. Remove all vaccines that are out of range and discard them.

B. Call the state/local VFC program (or manufacturer for private vaccine) for guidance.

C. Notify the practice’s vaccine coordinator to get the refrigerator temperature back in range.

D. Thaw any vaccines that were frozen for 45 minutes.

**Answers:** 1-B, 2-A, 3-D, 4-B, 5-B and C
Storage Best Practices for Frozen Vaccines—Fahrenheit (F)

1. **Unpack vaccines immediately**
   1. Place the vaccines in trays or uncovered containers for proper air flow.
   2. Put vaccines that are first to expire in front.
   3. Keep vaccines in original boxes with lids closed to prevent exposure to light.
   4. Separate and label vaccines by type and public (VFC) or private.

2. **Thermostat should be at the factory-set or midpoint temperature setting**

   - **Frozen Vaccine**
   - **Too Cold! Take Action!**
   - **Within Range**
   - **Too Warm! Take Action!**
   - **Report out-of-range temperatures immediately!**

3. **Use vaccine storage best practices**

   - **Freezer Only**
   - **temp range**
     - -58° F to 5° F
   - **don’t block vents**
   - **do not unplug**

   **DO**
   - ✓ Do make sure the freezer door is closed!
   - ✓ Do use water bottles to help maintain consistent temperature.
   - ✓ Do leave 2 to 3 inches between vaccine containers and freezer walls.
   - ✓ Do post “Do Not Unplug” signs on freezer and by electrical outlet.

   **DON’T**
   - ❌ Don’t use dormitory-style refrigerator/freezer.
   - ❌ Don’t use combo refrigerator/freezer unit.
   - ❌ Don’t put food in freezer.
   - ❌ Don’t store vaccines on shelves in freezer door.

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Visit [www.cdc.gov/vaccines/SandH](http://www.cdc.gov/vaccines/SandH) or contact your state health department for more information.

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**Test Your Knowledge**

1. Which of the following units is the best for storing frozen vaccine?
   - A. Full-size refrigerator/freezer (1 outside door/freezer is part of refrigerator)
   - B. Full-size refrigerator/freezer (2 outside doors, separate compartments)
   - C. “Stand-alone” freezer only unit
   - D. “Dormitory-style” or mini refrigerator (1 outside door/freezer is part of refrigerator)

2. Circle the TRUE statements:
   A. It is okay to remove vaccines from the original boxes as long as they are stored in the freezer.
   B. Water bottles in the freezer are important to help maintain consistent temperature.
   C. You can “eye test” frozen vaccines—if they look frozen, they are okay.
   D. Leave 2 to 3 inches between vaccine containers and freezer walls.

3. Circle the vaccines that MUST be stored in the freezer:
   - A. Varicella vaccine
   - B. MMR vaccine
   - C. Zoster vaccine
   - D. HPV vaccine

4. One of the most common reasons that freezers are out of temperature range is:
   - A. Staff doesn’t shut the freezer door
   - B. Power outage
   - C. The freezer thermostat is not working properly
   - D. The thermometer is broken

5. Frozen vaccines should be stored between _____° F and _____° F.

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1. **C—A stand-alone freezer is the best unit for storing frozen vaccines.**
   No vaccines—regardless of Frozen—should ever be stored in a dormitory-style unit (D).

2. **B and D are true statements.** All vaccines should stay in their original boxes. Proper temperature monitoring is very important and cannot be done by eye.

3. **Vaccines (A) and zoster (C) vaccines MUST be stored in the freezer.** MMR vaccine (B) can be stored in the refrigerator.

4. **A—Believe it or not, staff not shutting the freezer door is one of the most common reasons a freezer is out of temperature range!**

5. **Frozen vaccines should be stored between -58º F and 5º F.**

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**Test Your Knowledge**

1. Which of the following units is the best for storing frozen vaccine?
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   - B. Full-size refrigerator/freezer (2 outside doors, separate compartments)
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2. Circle the TRUE statements:
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4. One of the most common reasons that freezers are out of temperature range is:
   - A. Staff doesn’t shut the freezer door
   - B. Power outage
   - C. The freezer thermostat is not working properly
   - D. The thermometer is broken

5. Frozen vaccines should be stored between _____° F and _____° F.
**Temperature Monitoring Best Practices for Frozen Vaccines—Fahrenheit (°F)**

1. **Thermostat should be at the factory-set or midpoint temperature setting**

   - Too Cold! Take Action!
   - Within Range
   - Too Warm! Take Action!

   Report out-of-range temperatures immediately!

2. **Record daily temperatures**

   3 steps, 2 times a day: Read and record temperatures first thing in the morning and before leaving at night.

   - **Current temperature:** The temperature in the freezer right now
   - **Min/Max:** The coldest and warmest temperatures in the freezer since you last reset the thermometer
   - **Reset:** The button you push after you have recorded the Min/Max temperatures

3. **Take action if out of range!**

   - Contact your state or local health department immediately. Or for private vaccine, call the manufacturer directly.
   - Tell them the total amount of time the freezer temperature was out of range.

   **Best Practices**

   - **Take your time.** Read and record temperatures accurately.
   - **Make your mark!** Initial the log when recording temperatures.
   - **Leave it blank.** If a temperature was not recorded, leave the space blank!

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**CDC**

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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Visit [www.cdc.gov/vaccines/SandH](http://www.cdc.gov/vaccines/SandH) or contact your state health department for more information.
**Test Your Knowledge**

Review the temperature readings below and select the correct answer.

1. **A.** Current temp and min/max are within range—no action necessary  
   **B.** Current temp is within range, min/max out of range—take action  
   **C.** Current temp is within range, min/max out of range—no action necessary  
   **D.** Current temp and min/max are out of range—take action

2. **A.** Current temp and min/max are within range—no action necessary  
   **B.** Current temp is within range, min/max out of range—take action  
   **C.** Current temp is within range, min/max out of range—no action necessary  
   **D.** Current temp and min/max are out of range—take action

3. **A.** Current temp and min/max are within range—no action necessary  
   **B.** Current temp is within range, min/max out of range—take action  
   **C.** Current temp is within range, min/max out of range—no action necessary  
   **D.** Current temp and min/max are out of range—take action

4. **A.** Current temp and min/max are within range—no action necessary  
   **B.** Current temp is within range, min/max out of range—take action  
   **C.** Current temp is within range, min/max out of range—no action necessary  
   **D.** Current temp and min/max are out of range—take action

5. “Take action” means (circle any that apply)  
   **A.** Call the state/local VFC program (or manufacturer for private vaccine) for guidance.  
   **B.** Notify the practice’s vaccine coordinator to get the freezer temperature back in range.  
   **C.** Remove all vaccines that are out of range and discard them.  
   **D.** Discard any vaccine that does not look frozen.

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